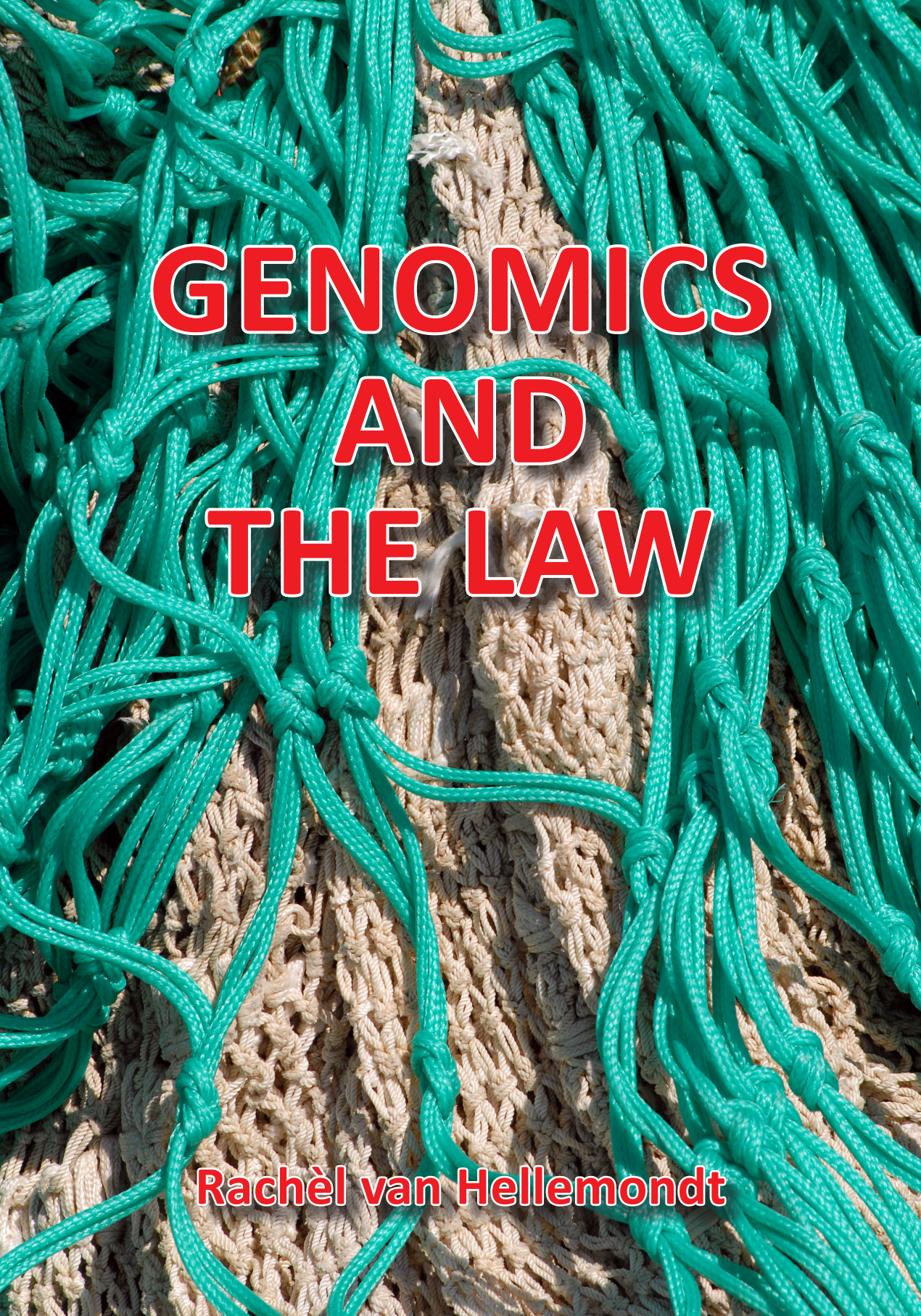
Genomics and the Law

Hellemondt, R.E. van


GENOMICS
AND
THE LAW
Rachèl van Hellemondt

GENOMICS AND THE LAW

ISBN: 978-94-90858-24-7
Author: Rachèl van Hellemondt
Lay out and printing: Drukkerij Mostert, Leiden, the Netherlands
Cover: D. Ketting
This thesis is the result of the research project: 'Large scale applications of genomics in the field of predictive medicine in the Netherlands: 'the role of the law' of the Centre for Society and the Life Sciences in The Netherlands, funded by the Netherlands Genomics Initiative and The Centre for Medical Systems Biology

GENOMICS AND THE LAW

Proefschrift

ter verkrijging van
de graad van Doctor aan de Universiteit Leiden,
op gezag van Rector Magnificus prof. mr. C.J.J.M. Stolker,
volgens besluit van het College voor Promoties
te verdedigen op donderdag 10 april 2014
klokke 15.00 uur

door
Rachèl Evelien van Hellemondt

geboren te Voorburg
in 1971

PROMOTIECOMMISSIE

Promotores:
Prof. dr. A.C. Hendriks
Prof. dr. M.H. Breuning

Overige leden:
Prof. dr. R.C. Tobler
Prof. dr. M.C. Cornel (Vrije Universiteit, Amsterdam)
Dr. E.C.A. Asscher (Erasmus MC, Rotterdam)

Voor Joas en Freeke

CONTENTS

Addendum

CHAPTER 1

GENERAL INTRODUCTION

1

1.1. INTRODUCTION

In today's world the common picture of screening is that there's no harm in trying. The leading concept in society is that screening is the best way to identify serious health threats at its most treatable stage. In some ways that is correct, but it is only half the truth. Screening involves not only opportunities and benefits but also serious health threats, risks and costs.

With the aim to promote health, the Netherlands – like many other European countries - introduced national programmes for neonatal screening, breast cancer screening and several others. These programmes were introduced after having decided that the benefits of screening outweigh the health risks and costs.

The worldwide highly respected principles of Wilson and Jungner are used as an instrument to assess the justification of screening programmes.[1] This ground breaking principles determine whether a condition potentially warrants screening efforts are also incorporated in the Dutch Act on population screening (in Dutch: 'Wet op het bevolkingsonderzoek' (WBO)).[2] This Act is the most important tool of the Dutch State to regulate screening which is classified as population screening.

Since the genetic background of many diseases has been partially elucidated, people are very eager to learn more about their genetic make-up. The provision of genetic screening directly to consumers via internet is a lucrative growth market for business. People believe genetic screening to be beneficial. They deem that genetic information contained in their DNA profile helps them to control their health and to live longer.

In the Netherlands – as in the rest of Europe - there is growing concern about the supply of a wide range of 'unregulated' genetic screening directly to consumers outside hospital care or the population screening programmes.[3] There seems to be a tendency to introduce new forms of screening like health checks, kits for 'self-testing' and direct-to-consumer (DTC) genetic tests, before they have been properly researched.[4]

With a DTC genetic test, which is an application of genetic screening, healthy individuals can acquire information concerning the presence of genetic risks and hereditary diseases. The DTC genetic tests, available via internet, have been criticised for their limited predictive value, the absence of medical supervision and the lack of adequate information regarding the characteristics of these tests.[5] Legal warrants similar to

---

1 Wilson & Jungner 1968. Wilson and Jungner have developed 10 criteria for judging screening. Screening programmes should meet these criteria before they are introduced to the public.

2 *Stb.* 1992, 611.

3 GR 2008; RVZ 2008; Brower 2010, p. 1611; See also *A Common Framework of Principles for direct-to-consumer genetic testing services* from the UK Human Genetic Commission. www.hgc.gov.UK; *Report on the Workshop Legal regulation for genetic testing*, ESHG-Conference in Gothenburg, June 14th 2010. The report can be find on the Internet:https://www.eshg.org/fileadmin/www.eshg.org/documents/Europe/LegalWS/ReportESHG-LegalWorkshop2010.pdf

4 GR 2008, p. 21.

5 EASAC & FEAM 2012.

national population screening programmes falling under the realm of the WBO are, at least in the Netherlands, often absent from the access to and the supply of DTC genetic tests.

The Dutch State is struggling to square the circle when it comes to the almost unrestricted availability of such forms of screening. On the one hand, States bound to human rights law have the duty to promote health and to protect citizens against serious health threats from unsound genetic screening. On the other hand it can be argued that the availability of DTC genetic screening without hurdles strengthens the individual's self-determination; one of the cornerstone of Dutch patients' rights legislation. Furthermore, free access to DTC genetic screening without barriers fits into a market-driven healthcare system. In such healthcare systems the concepts of own responsibility, self-management and freedom of choice are leading principles.

In other words, there is a need and an obligation for the Dutch State to find a proper balance between the duty to promote health and to protect individuals against health hazards and the obligation of the Dutch State to guarantee that their citizens can enjoy individual self-determination as recognised in national and international law.

This thesis focuses on the following central question: 'what are the normative criteria for the access to and supply of genetic screening from constitutional and European law perspectives?' As a corollary, I will explore what this means for the Dutch legal framework regulating genetic screening, particularly DTC genetic tests.

Finding a proper balance between self-determination of individuals and health protection is important since DTC genetic screening also affects the rights and freedoms of others. DTC genetic screenings have the capacity to reveal information about relatives and (potential) offspring. They have fundamental rights and freedoms too.

1.2. AIM AND SCOPE OF THE STUDY

The aim of this study is to define normative criteria that should govern the access to large scale applications of genetics (the study of heredity) and genomics (the study of genes and their function)[6] in the field of predictive medicine, notably DTC genetic tests. In doing so, the study primarily focuses on the Netherlands. In this thesis I will examine the role and the responsibilities of the Dutch State regarding the regulation of genetic screening and formulate normative criteria that should govern access to and supply of genetic screening, with DTC genetic tests as a case study. Formulating normative criteria according to genetic screening requires, first of all, the clarification of the responsibility of the State with respect to self-determination and health protection. In identifying the relevant normative criteria, the focus is not only confined to the existing

[6] WHO 2002, p. 203-204.

Dutch legal framework but attention is also paid to human rights and fundamental principles, European law (both legal instruments stemming from the Council of Europe and of the European Union) and legislation in other European countries.
In order to answer the central question, 'what are the normative criteria for the access to and supply of genetic screening from constitutional and European law perspectives', the following questions will be addressed:

1.2.1 Research questions:

1. What are, from a constitutional law perspective, the obligations of the Dutch State with respect to the access to and supply of genetic screening, particularly DTC genetic tests?
2. What normative criteria should, from a constitutional and European law perspective, apply to genetic population screening (programmes) in the Netherlands and, more specifically, to DTC genetic screening, particularly DTC genetic tests, with respect to self-determination of individuals?
3. What is the legal framework regarding the access to and supply of genetic screening in the Netherlands?
4. Is the Dutch legal framework regarding genetic screening in accordance with the legalisation of the Europe Union and the Council of Europe?

1.3. METHODS

This study thus encompasses four key research questions, subdivided into more specific questions which will be answered in the chapters of this thesis. The chapters have been published in several national and international, mostly legal journals. The method used is a review of the international literature to examine and to define the (legal) concept of self-determination and health protection, as well as the right to freedom of speech. I analysed Dutch law (legislation and case law) regarding genomics and genetics and issues related to screening, like patient's rights and confidentially. Furthermore, I examined the relevant law of the European Union (henceforth: EU) and the Council of Europe as well as the case law of the Court of Justice of the EU (henceforth: ECJ) and the European Court of Human Rights (henceforth: ECtHR) regulating genetic screening and thus DTC genetic tests. With respect to the ECtHR, the research is focused on the following provisions of the European Convention on Human Rights and Fundamental Freedoms (ECHR): Article 2 ECHR on the right to live, Article 3 ECHR on the prohibition of torture, Article 8 ECHR on the right to respect for private and family life and Article 10 ECHR on the freedom of expression. With respect to the ECJ the study is focused on the case law on the free movement of goods, the freedom of service and the freedom of establishment.

This study devotes great attention to the legal documents of the Council of Europe and the EU that apply to or are otherwise relevant to the access to and supply of genetic screening. The Council of Europe (box 1) and the EU (box 2) influence, both in their own specific ways, the freedom of the Netherlands to regulate access to and supply of genetic screening. The ECHR and the legislation of the EU are very important for the legal system of the Netherlands due to the fact that according to Articles 93 and 94 of the Dutch Constitution, legislation of both organisations in case of a conflict precede over Dutch law. Furthermore, Article 120 of the Dutch Constitution forbids national judges to consider the constitutionality of domestic laws. It also entails that our domestic law can be tested against (European) treaty norms and obligations before the national courts, and, secondly, before the ECtHR and the ECJ.

Box 1

Council of Europe

Organisation:
Inter-governmental
Established:
After the Second World War (1949)
Based in:
Strasbourg
Members:
47 States Parties & 5 Observer States and the Vatican
Aim:
Create a common democratic and legal area throughout the whole of the European Union, ensuring respect of human rights, democracy and the rule of law
How:
Member States cooperate on the basis of shared values and common political decisions
Decision making body:
Committee of Ministers
Most important achievement:
Adoption of the Convention for the Protection of Human Rights and Fundamental Freedoms (Adopted 1950, came in to force 1954)
Legal instruments:
Conventions, protocols & recommendations
Interpretation of the Convention for the Protection of Human Rights and Fundamental Freedoms:
European Court of Human Rights

Box 2

European Union

Organisation:
Supranational
Established:
After the Second World War (1951)
Based in:
Brussels & Luxembourg
Members:
28 Member States
Aim:
Focus on economic integration and created an Internal Market between the Member States
How:
Member States delegate sovereignty by handing over some powers to the Union for the benefit of the economic integration
Decision making body:
European Council & European Parliament
Operates on the basis of:
The Treaty on the European Union & the Treaty on the Functioning of the European Union
Legal instruments:
Regulations (binding as soon as it is passed) & Directives (have to be implemented in the national legislation
Interpretation of the treaties establishing the European Union:
European Court of Justice

Finally, I make some explanatory remarks with respect to the way in which I describe the law of the EU in the following chapters. The EU has developed and adopted specific legislation to harmonize the laws of its Member States in order to promote economic integration and achieve some other aims. The EU has not yet adopted a specific 'directive' or 'regulation' which covers primarily the access to or the supply of (DTC) genetic screening. This does not alter the fact that some directives also can or do apply to some aspects of genetic screening, depending on how people are invited to participate in a screening and in which way the screening is performed and supplied. The E-Commerce Directive (Directive 2000/31/EC) and the Distance Selling Directive (Directive 97/7/EC) for example cover only the access to and the supply of genetic screening through internet.

According to the *Tedeschi principle*[7] the first question with the respect to the applicable EU law is whether there is specific secondary law on a particular issues, in this case genetic screening. Only if there is no specific applicable secondary law, the question emerges whether there are relevant general rules of primary law of the EU, the Treaty on the Functioning of the European Union (TFEU) provisions on the free movement of people, goods, service and capital, apply to genetic screening. In the light of the *Tedeschi principle* it may be argued that we might have described in the separate chapters (published articles) consequently first the secondary law which covers genetic screening and secondly the primary law. We decided differently. However this does not affect the (final) conclusions of the thesis or the remarks in the last chapter.

1.4. LIMITATIONS AND EXTENSIONS

1.4.1. Study

This study focuses on the vertical relations between States and citizens and the legally binding instruments on national and European level which apply to genetic screening, like DTC genetic tests. Only limited attention is paid towards self-regulation instruments from professional groups and associations which set up quality criteria for the access to and supply of DTC genetic tests. The study is confined mostly to the Dutch and European legal framework regarding genetic screening but its outcomes may be considered relevant for the regulation of health services in general within Europe and genetic screening outside Europe.

Furthermore the study is largely confined to examining the legal framework applicable to genetic screening, more precisely genetic screening that is classified as health service, according to the present Dutch and EU legislation and case law. The regulation of health related goods in and outside the Netherlands is not a main subject of this thesis.

[7] Case C-5/77, *Tedeschi/ Denkavit* [1977] ECR 1555, para 35.

1.4.2. Thesis

This thesis consists of seven published articles published in different scientific (mostly legal) journals with different focus and primary target groups. Therefore the contents of the chapters are circumscribed by the main questions and the aims of the various articles. As a consequence the degree of accuracy and the opportunity of nuance vary from chapter to chapter. So certain subjects, matters and (legal) aspects of genetic screening have been tabled and described in more detail in one chapter than in another chapter(s).

1.5. OUTLINE OF THE THESIS

Part A of this thesis includes a study of the duties and responsibilities of the State regarding genetic screening, particularly towards screening initiatives, that emerge outside the healthcare sector as well as national population screening programmes. In this part I address the question to what extent the State is obliged to curtail this 'unregulated' access to genetic screening to protect individuals against serious health threats and to protect the rights and freedoms of others. The legislation in seven European countries and the laws from the EU and the Council of Europe regarding DTC genetic tests are the main subject of part B. In this part I formulate the normative criteria which should, from a constitutional and European law perspective, apply to genetic screening. The last chapter contains the most important findings of part A and part B and concluding remarks with respect to revising or drafting legislation at a National level.

PART A

SELF-DETERMINATION

&

PROTECTION

CHAPTER 2

FREEDOM, EQUALS HAPPINESS? THE REGULATION OF DNA DIAGNOSTICS IN HEALTH CARE FROM A HUMAN RIGHTS PERSPECTIVE

Abstract: *It is impossible to imagine our society without DNA tests. They play a large role as part of the evidence against those accused of criminal offences, in determining family relationships and in the fight against terrorism. DNA tests also feature prominently within healthcare. The (quality)guarantees that Dutch legislation and regulations aim to provide, not least to protect patients(rights), can however, be side-stepped relatively easily. There are numerous possibilities, via the internet and in other ways, to have one's own genetic material mapped. Thereby information is also provided which gives access to the hereditary traits of blood relatives. How must the greater availability of DNA tests and, in the future, of 'do-it-yourself tests' (DNA self-tests) be assessed from a human rights perspective: is it in line with the human right of self-determination or should the Dutch State take protective – read: restrictive – measures, also regarding the rights and freedoms of others?*

R.E. van Hellemondt, A.C. Hendriks & M.H. Breuning, 'Vrijheid, blijheid? Het reguleren van DNA-diagnostiek in de zorg vanuit mensenrechtelijk perspectief', *Nederlands Tijdschrift voor de Mensenrechten (NTM/NJCM-Bulletin)* 2010, p. 7-24.

2.1. INTRODUCTION

Thanks to the revolutionary developments in the field of human genetics and genomics it is known that many diseases and disorders have an inherited component. Via genetic testing, more specifically DNA testing,[8] it can be determined if someone is a carrier of a genetic mutation which predisposes to a particular disease or is associated with an increased risk of future (damage to) health problems.

Due to the specialised nature of DNA testing and the legal, ethical and social implications related to the provision of such testing, strict legally entrenched requirements apply. Contrary to these conditions individuals can at present, quite easily purchase DNA (self)tests via the internet or undergo genetic testing in our neighbouring countries, without any specific (quality)guarantees.[9]

The person concerned (the consumer), for reasons of his own, takes the initiative for testing. With these DNA tests all sorts of information concerning the consumer's (future) health can come to light. The quality, safety, reliability and user-friendliness of these forms of predictive testing can be called into question.[10] Furthermore, there are concerns about the way in which providers inform the (potential) consumers regarding the benefits and risks of these tests and also about the way in which the results are communicated.[11]

The increased possibilities of undergoing DNA testing affect the rights and freedoms of others. The results of DNA tests also often provide information about the genetic constitution of the blood relatives of the person concerned. Blood relatives could in such situations, without any counselling or giving consent, be confronted with (future) health information that they were unaware of – and that they perhaps also would have liked to remain.

The fact that people resort to the internet and other 'alternative' providers of DNA testing, has led in 2008 to advisory reports[12] from the Dutch Health Council[13] and the Dutch Council for Public Health and Care.[14] These advisory councils examined the role and the responsibility of the Dutch State in relation to preventive testing. In the same year also the Healthcare Inspectorate[15] published a report about health checks, medical check-ups, total body scans and other forms of undirected preventive medical testing.[16] The question, which arises – also as a result of these publications – is: (to what extent)

---

[8] DNA represents Deoxyribonucleic acid.

[9] For example http://www.quoak.nl; http://www.verilabs.nl/; http//www.store.genelex.com; htpp//www.delphitesv.com/content/GeneticAnalysis/html; http//www.23andme.com/; http://www.prescan.nl/

[10] Wasson 2008, p. 16-18.

[11] Bunnik et al. 2009, p.23-25; Timmermans 2009.

[12] GR 2008 & RVZ 2008.

[13] De Gezondheidsraad.

[14] Raad voor de Volksgezondheid.

[15] Inspectie voor de Gezondheidzorg.

[16] IGZ 2008.

is the State obliged to curtail this 'unregulated' access to and supply of DNA (self)tests, in which the initiative originates from the consumer, to prevent individual damage to health and to protect the rights and freedoms of others? The answer to this question partly depends on the value that is accorded to autonomy and protection, important human rights and health law principles.

For a clear understanding of the matter, this contribution opens with an explanation of the way in which DNA (self)diagnostics can play a part in the identification of carriership or (latent) present diseases which can benefit the people concerned (2.2). This is followed by a description of the values(s) of the principles of autonomy and protection in the academic literature (2.3.1), in the Convention for the protection on Human Rights and fundamental freedoms (henceforth: ECHR) and the case law of the European Court of Human Rights (henceforth: ECtHR) (section 2.3.2). Then, we provide an overview of the relevant legislation in the Netherlands and the consequences of this for DNA (self)tests (section 2.4). Lastly we formulate an answer on the question: 'whether, from the human rights point of view, the access to and supply of DNA (self) tests should (not) or must be regulated' (section 2.5) followed by conclusions (section 2.6).

2.2. DNA (SELF)DIAGNOSTICS

2.2.1. Genetics and DNA (self)diagnostics

The human body consists of more than 10.000 billion cells. The genome is the total genetic material of a body cell. A body cell consists of 46 chromosomes. The genetic material in the chromosomes is called DNA. Apart from identical twins, the composition of the DNA between individuals is different in a great many places. On average one in 1000 nucleotides, the building blocks of DNA, has a variant. Most of these variants have no effect on the health of the person concerned. However, some variants do.

DNA diagnostics provides knowledge about variants that have an influence on (the chance of) developing a particular disease or disorder. By typing these variants it is possible to identify if someone has a higher or lower risk for a disease. In this respect it is important to make a distinction between presymptomatic diagnostic genetic tests and susceptibility genetic tests. Presymptomatic diagnostic genetic tests are mostly aimed at discovering a monogenetic disease. Monogenetic diseases are caused by mutations in one gene. Examples of this are familial hypercholesterolemia (genetically determined high cholesterol) and Huntington's disease (hereditary brain disorder in which the nerve cells in certain parts of the brain gradually die off). In monogenetic hereditary disease and disorders, which incidentally are relatively rare, symptoms of the disease nearly always appear after a period of time, when the mutation in question is identified. Hence via DNA diagnostics it can be determined to a very high degree whether or not the person concerned gets the disease or disorder.

Multifactorial genetic diseases are associated with the effects of multiple genes in combination with the environment and the lifestyle. The influence of one or more genes, the environment and the lifestyle play a role in the development of a multifactorial genetic disease. Most multifactorial genetic diseases manifest themselves later in life, such as various types of cancer, neurodegenerative disorders (dementia) and cardiovascular diseases. The moment and the way that the disease manifests itself is partly dependent on other factors than the genetic constitution of the person concerned.

Some genetic mutations are associated with an increased risk of a disease and other DNA variants reduce the risk of developing a disorder. Most people have a combination of favourable and unfavourable variants, so that they come out at an average. DNA diagnostics for multifactorial diseases – which are increasingly available[17] – give the person concerned much less certainty about future health than testing for monogenetic disorders. DNA diagnostics only gives information about the risk of a particular disorder. If it actually manifests also dependents on factors such as 'favourable' DNA variants, lifestyle and environmental factors.[18]

2.2.2. DNA (self)tests: advantages and disadvantages

Rapid technological developments have made it possible at a relatively low cost to identify large numbers of DNA variants via blood samples, saliva or other body material. The business world sees an interesting market for DNA (self)tests, in other words diagnostic testing on body material.[19]

DNA diagnostics offers opportunities, such as detecting the presence of latent diseases at an early stage. Through preventive measures/treatment and adjustment of lifestyle and environmental factors, it is sometimes possible to reduce the risk of expression of the disease, such as the preventive amputation of the breast(s) by hereditary forms of breast cancer. The results of DNA diagnostics can also play a role in reproductive choices. Thus DNA diagnostics, including DNA (self)tests, provide individuals possibilities of better organising their life as they see fit (autonomy).

The possibility of (self)testing also has drawbacks. The risk of false positive or false negative results, and therefore of unjustified reassurance or concern is present. This risk is probably larger when the consumer, 'unhampered by any knowledge', interprets the test results himself. For the average consumer it is not easy to put the results – mostly given in percentages – about the risk of getting multifactorial genetic disease into the right perspective. As Timmermans aptly stated in her inaugural lecture, for many patients the concept '15%-chance is less clear than when you say 'of every

[17] Calsbeek et al. 2009, p. 493.
[18] Van de Pol 2003; Hendriks & Gevers 2004, p.1114-1130.
[19] Van der Weijden et al. 2007, p. 9.

hundred people there are fifteen who become ill'.[20] The reliability of the test results depends furthermore on the number of individuals which are tested and the number of mutations which are found. It is highly debatable if the consumers realise the limited value of a DNA (self)test at the moment that they give their consent.

The psychological consequences of testing for the risk of certain forms of cancer, unlike the testing for monogenetic hereditary diseases – such as Huntington's disease – are less well known.[21] However, it is evident from research addressing the effect of DNA diagnostics on the quality of life of women from breast cancer families that after the diagnostics, regardless of the results of the test, the feelings of anxiety lessen. Untested women appeared to be more depressed than tested women.[22] In DNA diagnostics, positive test results (i.e. the risk factor is present) of hereditary, untreatable diseases can have social and psychological implications. Research shows that individuals who test positive to Huntington's disease have a higher risk of getting depressed and committing suicide. Also people who test negative to this disease (i.e. the risk factor is not present) have a higher risk of psychological complaints as a consequence of the stress of testing.[23] For these reasons, informed consent before testing and good counselling during the testing process is of great importance. Furthermore, DNA diagnostics can lead to misuse, such as discrimination on the labour and insurance market.[24] The consumer will need to be duly aware of these risks.

The possibility of DNA (self)tests can not only lead to avoidable health damage to the consumer, but can also cause unwanted side effects for society and affect the interests of others. Health costs can increase through the demand for reappraisal of test results in the 'mainstream circuit' and through follow-up tests and overtreatment as a result of this.

Furthermore, DNA testing differs from a 'conventional medical examination', in that the test results also provide information of the genetic constitution of blood relatives. This implies that the application of DNA diagnostics within and outside healthcare raises human rights questions as well. A positive test result for Huntington's disease entails that not only the person concerned is affected, but that also (at least) one of the parents of the tested carries the same genetic mutation. For a child who tests positive for Cystic Fibrosis it means that both parents and at least two of the grandparents are carriers of this disease. There is a strong possibility that the parents and grandparents are unaware of this, and that they would also actually prefer to remain so. Thereby the availability of the results of DNA (self)tests leads to tough normative questions about dealing with this with regard to blood relatives.

---

[20] Timmermans 2009.
[21] Calsbeek et al. 2009, p. 493.
[22] Grann & Jacobson 2002, p. 346.
[23] Asscher & Koops 2009, p. 27-35.
[24] RVZ 2008, p. 23; Wasson 2008, p.18.

For the time being the possible benefits of DNA (self)tests do not seem to outweigh the cost. This raises the question whether or not we need to offer protection, by restricting free access to DNA (self)tests. We will cover this in more depth in section 2.3.

2.3. AUTONOMY AND PROTECTION

2.3.1. Academic literature

Autonomy and protection are important human rights and health law principles.[25] There is a lively debate amongst scholars and society in general about the exact meaning of these principles, also in connection with each other.[26]

In our society, which is strongly oriented toward individuality, independency and freedom of choice, the principle of protection is not always viewed in a favourable light. Protection evokes memories of paternalism and other types of (external) intervention and dependence.[27] However, the principle of protection reflects that we must try to prevent injury to ourselves and others as much as possible. The provision of such protection is also recognised as a precondition for individual self-determination. Autonomy, considered in this way, is closely linked with the principle of protection.

In the literature there is a difference of opinion about the exact meaning of autonomy.[28] Autonomy is traditionally associated with individual self-determination.[29] Individual self-determination is above all associated with negative freedom: the right to organise one's own life without intervention by others. At the same time this implies positive freedom, the possibility to shape life to our own wishes.[30]

Following on from this, criticism of the individualistic autonomy concept is possible. Autonomy can after all also be regarded as a relational concept, in which individuals – as social beings – in interaction with others, experience their life as their own. The role of the other is important in this, because an individual in contact with others discovers who he is and what he wants.[31] The guarantee of positive freedom, such as through the principle of protection, clashes with the view that autonomy especially or exclusively includes a right to be left alone, because that indicates that 'negative freedom' without 'positive freedom' is possible.[32]

The fact that we are by no means finished with discussing the meaning of the concept autonomy and protection, or their importance and of their mutual relationship is well

[25] Hendriks 2006.
[26] Sinding Aasen et al. 2009.
[27] Jonkers 2006, p. 57-67; Schmitz & Reinacher 2006, p. 497-498.
[28] McGregor 2008, p. 9-10; Buijsen 2004, p. 425-429.
[29] Leenen et al. 2007, p. 37-40.
[30] Bauduin 2000, p. 40-52.
[31] More detailed Hendriks et al. 2008, p. 4-6.
[32] Hendriks et al. 2008, p. 4-6.

illustrated by the lively discussion at and as a result of the Dutch Lawyers Association[33] members meeting 2009. The theme of this meeting was human biotechnology and rights. The meaning of the right to autonomy and the role and the responsibility of the State regarding the use of human biotechnological applications was addressed as the central question in the pre-advisory report.[34] Pre-advisor Van Beers took the standpoint that the right to autonomy does not by definition provide us with a free pass 'to reap the fruits' of the possibilities within genetics. The restriction of autonomy is justified by 'the poisonous fruits' that can cause harm.[35] In contrast pre-advisor Bovenberg, with a call for autonomy, made a strong appeal for the recognition of the right to gather knowledge about our own health.[36] At the voting on the statements on this matter there was likewise a great difference of opinion.

It can be concluded that in the academic literature no communis opinion exists about the intrinsic meaning of autonomy and protection, nor about the relationship between both principles. The intrinsic meaning of the concept autonomy defines the scope of the principle of protection. It is necessary to objectify the mutual relationship between both principles to answer the question, whether the Dutch State is obliged to regulate the access to and supply of DNA (self)tests.

2.3.2. Autonomy and protection in the case law of the ECtHR

It is not surprising that the principle of protection, especially in relation to health, takes an important place within human rights charters. Article 11 of the European Social Charter (ESC) requires States Parties to take appropriate steps to warrant 'the right to health protection'. This right is also firmly embedded in other human rights instruments and our Constitution (Article 22 (1) Dutch Constitution). That the ECHR lacks a counterpart does not mean that the principle of protection in this convention is of secondary importance. The title of this convention immediately makes this clear: 'The Convention for the protection of Human Rights and Fundamental Freedoms'. Partly in view of this, the ECHR-provisions include, according to established case law of the ECtHR, both negative as positive obligations for contracted States of the ECHR. State authorities for example have the negative obligation in principle not to make use of a medical treatment in order to get criminal evidence.[37] The positive duty of States Parties includes, for instance, taking effective measures to prevent disease.[38]

Seemingly in contrast with the solid legal basis of the principle of protection is the recent recognition by the ECtHR of the right to autonomy[39] (remarkably this happened

[33] Nederlandse Juristen-Vereniging (NJV).
[34] Somsen et al. 2009.
[35] Somsen et al. 2009, p. 103.
[36] Somsen et al. 2009, p. 96.
[37] ECtHR 11 July 2006, *Jalloh/ Germany* (GC) no. 54810/00, para. 71.
[38] ECtHR 26 November 2002, *E. et al./ the UK,* no. 33218/96.
[39] ECtHR 20 March 2007, *Tysiąc/ Poland*, no. 5410/03, para. 107.

after the ECtHR a short time before explicitly rejected the existence of a 'right to self-determination').[40] Also the rights which are protected by the Convention on the Rights of Persons with Disabilities [41] are based not just on 'protection', but also on 'personal autonomy'. Nevertheless, this recognition of the independent importance of autonomy is not as clearly visible in all conventions. In the ESC there is not any reference to autonomy, just like in various other international conventions.

In the case law of the ECtHR, the mutual relationship between the principle of protection and the principle of autonomy is often central to this. According to the case law of the ECtHR, States Parties have a requirement to make due effort to protect individuals who live on their territory from (health)damage.[42] This 'duty to protect' – which is potentially also of importance for the regulation of DNA (self)tests – has manifested itself in the case law of the ECtHR, in particular in law cases in relation to Article 2 (Right to life), Article 3 (Prohibition of torture) and Article 8 (Right to respect private and family life).

The right to life, according to the ECtHR covers, among other things, the State's (positive) obligation to protect life,[43] including the life of people who receive or need (health)care. The State must in principle ensure the quality and safety of goods and services offered.[44] This obligation extends to preventive healthcare.[45] In the *Pretty case* the ECtHR noted that this duty forms a justification for the restriction of personal autonomy.[46] The State must also make every effort to prevent individuals from taking their own life because of their disease or because of the pressure from others.[47] Also in other ways States Parties have the obligation to prevent individuals dying prematurely?[48] From the admissibility decision in the *Bône* case it is evident that the right to life does not guarantee an absolute level of safety to every person. Risks are a part of life. The extent to which the person himself creates risks plays a part in the assessment.[49]

Just as the right to life, the ban on torture provides States with (positive) obligations to protect, including the duty to offer medical care.[50] The judicial review of both norms is identical: *'Nonetheless, where allegations are made under Articles 2 and 3 of the*

---

[40] ECtHR 29 April 2002, *Pretty/ the UK*, no. 2346/02, para. 61.

[41] *Trb.* 2007, 169 (Verdrag inzake de rechten van personen met een handicap).

[42] ECtHR 14 November 2002, *Mouisel/ France*, no. 67263/01; ECtHR 27 January 2009, *Tatar/ Romania*, no. 67021/01.

[43] ECtHR 9 June 1998, *L.C.B./ the UK*, no. 23413/94, para. 36; ECtHR 28 October 1998, *Osman/ the UK* (GC), no. 23452/94, para. 115.

[44] ECtHR 1 December 2009, *G.N. et al./ Italy*, no. 43134/05; ECtHR 15 December 2009, *Kalender/ Turkey*, no. 4314/02.

[45] ECtHR 22 September 2005, *Gheorghe/ Romania*, (admissibility decision), no. 19215/04.

[46] ECtHR 29 April 2002, *Pretty/ the UK*, no. 2346/02, para. 39.

[47] ECtHR 3 April 2001, *Keenan/ the UK,* no. 27229/95; ECtHR 15 December 2009, *Abdulhadi Yildrim/ Turkey*, no. 13694/04.

[48] ECtHR 5 April 2005, *Nevmerzhitsky/ Ukraine*, no. 54825/00; ECtHR 23 May 2006, *Taïs/ France* (GC), no. 39922/03.

[49] ECtHR 1 March 2005, *Bône/ France*, no. 69869/01.

[50] ECtHR 28 January1994, *Hurtado/ Switzerland*, no. 17549/90, para. 79.

Convention, the ECtHR must apply a particularly thorough scrutiny.'[51] When applying Article 3 ECHR the ECtHR takes into consideration all the circumstances of the case.[52] In some cases, it takes into account the importance of gender, age and health status of the victim.[53]

Medical care should also preclude any inhuman or humiliating treatment – namely physical or mental suffering (Article 3 ECHR).[54] The basic assumption is that the person concerned voluntarily gives consent to the offered care, based on sufficient and understandable information.[55] Informed consent is a condition of the right to personal autonomy.[56]

It is however a misconception to think that only care – and hence protection – may be provided after the person concerned has agreed to it. If a protective measure meets the requirement of *'therapeutic necessity from the point of view of established principles of medicine'* there is, according to established case law of the ECtHR, in principle no question of inhuman and humiliating treatment.[57] In situations like these the provision of protection prevails over the (negative) autonomy, also for mentally competent people. Individuals can under Article 8 ECHR likewise derive a proviso claim to remain free of damage to health, and the right to (an effective and accessible procedure to obtain access to) information in the event of possible health risks.[58] Also in relation to this right, a medically necessary treatment, imposed without informed consent of the person concerned, does not automatically result in a violation of autonomy and thereby the right to private life.[59] The protection of the health of the individual concerned or the rights and freedoms of others can be a justification for treatment without informed consent.

The under Article 8 underlying right to (negative) autonomy is thus not absolute. The way in which individuals give direction to their life is not just restricted by the rights and freedoms of others, but must also be compatible with the dignity of the people concerned. In according to the ECtHR decisions about the sadomasochistic activities of a group of English men and a Belgian couple, mutual consent to harmful behaviour that affect the dignity of the people concerned, does not alter this fact.[60]

---

[51] ECtHR 26 july 2005, Şimşek *et al./ Turkey*, no. 35072/97 & 37194/97, para. 102.
[52] ECtHR 15 January 2004, *Matencio/ France*, no. 58749/00.
[53] ECtHR 18 January1978, *Ireland/ the UK*, no. 5310/71, para.162.
[54] ECtHR 27 June 2000, *Ilhan/ Turkey* (GC), no. 22277/93, para. 87.
[55] ECtHR 9 March 2004, *Glass/ the UK*, no. 61827/00; ECtHR 2 June 2009, *Codarcea/ Romania*, no. 31675/04.
[56] ECtHR 20 March 2007, *Tysiąc/ Poland*, no. 5410/03, para. 107; ECtHR 10 April 2007, *Evans/ the UK* (GC), no. 6339/05, para.71.
[57] ECtHR 24 September 1992, *Herczegfalvy/ Austria*, no. 10533/83, para. 82; ECtHR 10 February 2004, *Gennadi Naoumenko/ Ukraine*, no. 42023/98, para. 112; ECtHR 7 October 2008, *Bogumil/ Portugal*, no. 35228/03.
[58] ECtHR 9 December 1994, *López Ostra/ Spain*, no. 16798/90.
[59] ECtHR7 October 2008, *Bogumil/ Portugal*, no. 35228/03.
[60] ECtHR 19 February 1997, *Laskey, Jaggard & Brown/ the UK*, no. 21627/93; 21826/93 & 21974/93.

The ECtHR examines alleged violations of positive obligation inherent in Article 8 via the so-called *fair balance-test*, which is a weighing up between the conflicting interests.[61] The aspect of private life concerned in the infringement and all the other circumstances determine the extent of the *margin of appreciation* of States Parties.
Generally, the less consensus there exists between States Parties about a certain subject, the greater the freedom for policy making, for example in relation to individuals' access to the data on the identity of their biological parents.[62] The more this data affects the identity of the person concerned, the smaller the *margin of appreciation* of the State.
Although the ECHR at first sight is primarily directed to the guarantees of personal autonomy in the sense of 'freedom of', it is apparent from the case law outline above that this image needs some adjustment. The provision of protection against the breach of dignity of individuals as well as infringements of the rights and freedoms of others is according to the ECtHR an integral part of the norms and values inherent in the ECHR. This duty to protect can, because of the 'freedom to shape life to our own wishes', make it necessary to restrict the 'freedom to be left alone' including the autonomy to undergo certain activities.

2.3.3. Normative criteria of DNA (self)tests

Because of the autonomy of individuals, the State is obliged to respect the integrity and identity of individuals as much as possible.[63] This also implies the duty to respect the person's ability to make decisions that can, in principle, be damaging to the welfare and health of the person concerned. So as long as a person decides to do this based on adequate information, he may decide to have his DNA tested by means of a (self)test of which the benefits, the quality and the user-friendliness are questionable. This is different when no informed consent is obtained, a norm which creates an obligation for the other party than the consumer.[64] Accordingly we must ask ourselves, in making use of DNA (self)tests outside the regulated access, if there is a question of legally obtained valid consent. As mentioned before, many consumers will have great difficulty with the interpretation of the test results, the reliability of which is often questionable. In the most favourable case, the consumer often remains with unanswered questions. From the protection principle, which is included in all ECHR-rights, there are thus good reasons for the State to bind strict rules to the access to and use of such (self)tests.
As stated in section 2.3.2 information about the own health and identity is at the heart of private life protected by Article 8 ECHR.[65] This also applies to fingerprints, DNA

[61] Barkhuysen 2004, p. 40-41.
[62] ECtHR 13 February 2003, *Odièvre/ France* (GC), no. 42326/98, para. 42-47; ECtHR 7 February 2002, *Mikulić/ Croatia,* no. 53176/99, para. 53-54 & 64.
[63] ECtHR 13 February 2003, *Odièvre/ France* (GC), no. 42326/98, para.42-47.
[64] ECtHR 2 June 2009, *Codarcea/ Romania*, no. 31675/04.
[65] ECtHR 25 February 1997, *Z./ Finland*, no. 22009/93, para. 95; ECtHR 10 October 2006, *L.L./ France*, no. 7508/02, para. 44; ECtHR 7 February 2002, *Mikulic/ Croatia,* no. 53176/99.

profiles and tissue material.[66] In accordance to the ECtHR case law the State should ensure that individuals can have access to the recorded data about them.[67]

The question of whether a right to self diagnostics exists must be answered in the negative in the light of the current case law of the ECtHR. The right to autonomy, interpreted as self-determination, offers no claim to access to DNA (self)tests. Via DNA (self)tests information is also gained about blood relatives. They too have the right to protection of their privacy. But can others perhaps be obliged to agree to cooperate with DNA testing? It is apparent from case law regarding the determining of the identity of biological parents that in certain situations that can be so.[68] There is nevertheless a *fair balance-test* beforehand, in which particular importance is accorded to the interests of the child and all this in the knowledge that the information goes no further than to ascertain or disprove parenthood. DNA diagnostics directed to ascertain if the predisposition or the carriership of a hereditary disease nevertheless make (even) greater interference into the privacy of others. It is not plausible that 'the right to be left alone' of 'the other' must yield to the 'claim right' of the consumer. Also this argues in favour of regulation of the access to DNA (self) tests to prevent the undermining of the other's right to protection.

2.3.4. Preliminary conclusion

Where is the border between autonomy and protection, between unrestricted access to DNA (self)tests and regulation? The case law (and academic literature) provides no clear grip on this. The same is true of the concept 'human dignity' that in the DNA era creates obligations for the State for both not interfering (negative obligation) as well as taking measures (positive obligation).[69]

It must be concluded that, in both the academic literature and the case law of the ECtHR, autonomy and the duty to protect against (health)damage play a central role. Neither of these values have an absolute meaning. The restriction of autonomy in the interests of the principle of protection and the rights and freedoms of others is under conditions permissible and sometimes required. This need seems to be present in DNA (self)tests, because in many situations informed consent seems to be absent and the test results can also have far-reaching implications for the rights and freedoms of others.

---

[66] ECtHR 4 December 2008, *S. & Marper/ the UK* (GC), no. 30562/04 & 30566/04.
[67] ECtHR 7 July 1989, *Gaskin/ the UK*, no. 10454/83.
[68] ECtHR13 February 2003, *Odièvre/ France* (GC), no. 42326/98; ECtHR 17 July 2007, *Jevremović/ Serbia*, no. 3150/05; ECtHR 7 May 2009, *Kalacheva/ Russia*, no. 3451/05.
[69] Van Beers 2009; The contributions of Ach and Taureck 2009.

2.4. THE NETHERLANDS

2.4.1. Legal framework

The principles of autonomy and protection play an important role in the legislation and regulations pertaining to the use of DNA diagnostics. This is reflected in the laws (1) to promote health and to prevent diseases (prevention) and (2) to safeguard the rights of the patient (incl. autonomy) and to prevent damage to the patient as a result of the (poor) quality of professional practice, provision of services or goods. We discuss both elements separately below.

2.4.2. Prevention

Under the previously mentioned right to health, the State has a great responsibility to promote health and to protect against diseases, which is clearly expressed via the laws in the field of preventive health. The most important of these – also for the subject of this chapter– are the 'Act on Public Health', [70] the 'Act on population screening' (henceforth: WBO), the National Programme Population Screening[71] (henceforth: NPPS) and the National Immunisation Programme.[72]

With the exception of the WBO these (public law) legislation assume an offer of or on behalf of the State. Genetic screening, meaning: 'the systematic early detection or exclusion of a hereditary disease, the hereditary predisposition for a disorder or the carriership of a hereditary disease (which in the offspring can lead to a hereditary disease)',[73] is part of the programmes that are carried out within the framework of these laws. Screenings can not only be offered by or on behalf of the State, but also by private organisations and companies.

The WBO regulates the access to and supply of screenings in the Netherlands, which are classified as 'population screening'. The WBO defines this term as 'a medical examination which is carried out to an offer made to the entire population or to a section thereof and to detect of diseases of a certain kind or certain risk indicators, either wholly or partly for the benefit of the persons examined'. The WBO seeks to protect individuals against screenings that in terms of execution can be harmful to the physical and mental health of the people being screened. The means used to accomplish this is a licensing system.[74] At present three categories of population screenings require a licence: screening which uses ionising radiation, such as a CT-scan, screening for (risk-indicators for) cancer and screening for (risk-indicators for) untreatable diseases [75](Article 2 WBO). The Minister of Health Welfare and Sports under Article 7 (1) WBO

[70] *Stb.* 2008, 460 (Wet publieke gezondheid).
[71] Nationaal Programma Bevolkingsonderzoek.
[72] Het Rijksvaccinatieprogramma.
[73] Bijlsma et al. 2005, p. 375.
[74] Van der Maas et al. 2000, p. 7.
[75] Untreatable: now treatment or prevention is possible.

does not issue a licence if the screening is scientifically unsound or the screening is not in accordance with the professional medical practice standard of if the expected benefits do not offset the risks. The basic assumption is that screening can only be responsibly offered if it is established that the advantages for the participants outweigh the disadvantages.[76]

2.4.3. Quality safeguards and patient rights

Quality legislation applies to DNA diagnostics carried out by a healthcare professional or in a care institution. According to these laws, healthcare professionals and care institutions are obliged to provide 'good care' (Article 40 Individual Healthcare Professions Act[77] and Article 3 Act on Quality[78]). The Health Care Inspectorate oversees the compliance of these norms; the Minister of Health, Welfare and Sports and the (disciplinary)judge can enforce them when appropriate.

Furthermore, a health care worker always needs informed consent of the patient in order to perform DNA diagnostics (Article 7:448 BW[79] in conjunction with Article 7:450 BW). The self-determined patient can also decide that he wishes to be spared certain information or the results (Article 7:449 BW). Patient legislation thereby, on the one side, safeguards the autonomy of the patient (whether or not to have DNA testing, whether or not to know) and offers at the same time protection (adequate information; moreover a health care worker must act as a 'good health care worker' (Article. 7:453 BW).

The WBO sets up – as already stated – quality guarantees for DNA screening, as far as the screening can be defined as population screening. In experimental and medical-scientific screening research, the provider will have to satisfy the requirements of Medical Research Involving Human Subjects Act.[80] This act, unlike the WBO, is not based on a licensing system but an approval of the research protocol by a Medical Research Ethics Committee before the research concerned is carried out. This committee evaluates risks and objections of the testing for the human subjects and the scientific soundness. Administrative appeal is open against a negative decision of such a committee.

The Act Exceptional Medical Procedures regulates, for effectiveness and quality reasons, the supply of 'exceptional medical procedures'. The Minister can, for social, legal or ethical aspects, (completely) forbid such procedures or, for important interests, subject them to a licensing system. This last regime applies to individual DNA testing in the framework of treatment. The Clinical genetics departments of the University

[76] GR 2008, p. 15.
[77] *Stb.* 1993, 655 (Wet op de Beroepen Individuele Gezondheidszorg).
[78] *Stb.* 1996, 80 (Kwaliteitswet zorginstellingen).
[79] Medical Treatment Contracts Act as part of the Dutch Civil Code.
[80] *Stb.* 1998, 161 (de Wet medisch- wetenschappelijk onderzoek met mensen).

Medical Centres have licences based on the Act Exceptional Medical Procedures and its accompanying 'Decree identified medical procedures 2007'[81] for giving genetic inheritance advice and for performing genome analysis. The clinical genetic advice practice extends to nearly all the branches of medicine.

For quality reasons there are also quality requirements in the Netherlands for 'do-it-yourself-tests' in which body material can be examined, for instance the pregnancy test. These tests come under the scope of the Directive regarding in vitro diagnostics (98/79/EC), implemented in The Netherlands via the Decree in vitro diagnostics. These tests are not bound to a licensing system, but are freely available if provided with the so-called CE marking. Incidentally, such a marking as a quality requirement has little meaning, because aspects such as diagnostic value and clinical utility are not evaluated.[82]

2.4.4. Significance for DNA (self)tests

That DNA diagnostics, for quality reasons, can best be performed by medical specialists (clinical geneticists) is generally accepted in the Netherlands. This is for example expressed in the way in which the Dutch State has regulated the access to and supply of screening and individual genetic diagnostics. This legislation barely covers DNA (self)tests, that is to say DNA diagnostics which are carried out on the initiative of a 'consumer' and which are not incorporated in a (regular) screening programme or take place on the basis of a medical indication. This loophole is current, now that companies via websites, magazines and newspapers call on individuals to have their DNA tested, without intervention of a doctor associated with a Clinical Genetics Department. The one time it is a case of directed testing (on one or more genetic risk factors indicated beforehand), the other time there is undirected testing (the outcome is uncertain, dependent on what the researchers 'come across'). In the framework of such testing it can be that the consumer, the person who is tested, must check in with a (health) professional or laboratory, or that the provider sends a toolkit to the address of the person concerned. In the last situation the consumer takes a sample (saliva, hair or blood) and sends it back to the test provider for a risk analysis. DNA self-tests are at present not yet available; samples of blood, saliva or tissue will always have to be analysed by another. For these reason the meaning of the existing legislation and regulations as regulatory instruments for DNA diagnostics as a service is the most pressing.

According to the Health Care Inspectorate the concept 'offer' should be broadly interpreted in the WBO.[83] 'Offering' is not just actively inviting, but also the passive 'seduction' of individuals via adverts on websites, in magazines and newspapers

[81] *Stb.* 2007, 238.
[82] Leenen et al. 2008, p. 168-170.
[83] IGZ 2008, p. 14.

for DNA (self)testing. According to the WBO a licence is required for offering DNA diagnostics for some forms of cancer, because it is screening - 'population screening'- (Article 2 (1)). In 'unaimed' DNA diagnostics it is not clear what diseases the screening is focused on and if a licence is required.[84] From the standpoint of patient legislation it is not clear if there is informed consent because it is groping in the dark about the possible outcomes and implications of the testing.

The WBO is difficult to enforce because a license is required for offering and performing population screening (Article 1). However the Act only prohibits *performing* of population screening without a licence and makes it punishable (Article 3 (1) juncto Article 13). It seems that providers are not always affected by this. In practice a provider can freely offer DNA diagnostics in the Netherlands if the analysis of the DNA sample ('the performing') takes place outside the Netherlands.[85]

A Dutch provider or performer of DNA (self)tests obtains a licence, after advice of the Dutch Health Council, from the Minister of Health, Welfare and Sports if the testing services meets the requirements of scientific soundness, the testing is in accordance with the professional medical practice standard and the benefits of the tests outweigh the risks. So far as we know the Minister has yet not issued a licence to a (private) company that provides DNA (self)tests. It is not (very) likely that the Minister will issue a licence to a company to put DNA (self)tests on the Dutch market because of the strict legislation regarding the access to DNA (self)tests and the criticism of the reliability and the benefits of these tests.

Dutch consumers who want to have their DNA mapped outside regular healthcare have to turn to internet providers from the United States and the United Kingdom because of the strict requirements in the Netherlands.[86] The Netherlands has no jurisdiction over foreign internet providers that offer their DNA (self)tests in the Netherlands. Consequently, the protection and quality guarantees from the current legislation are not applicable. At the moment two companies offer DNA (self)tests in the Netherlands.[87] These companies make use of the lack of clarity and the enforcement problems of the WBO. These companies for example invite (potential) consumers via websites to make up their genetic profile and perform DNA (self)tests without a licence abroad.[88]

2.4.5. Preliminary conclusion

In the Netherlands there are strict rules for the access to and supply of DNA diagnostics within the framework of healthcare. The emphasis of them is on the protection of participants of such testing against the possible risks and dangers, including the

[84] GR 2009, p. 13.
[85] IGZ 2008, p. 6.
[86] Borry & Howard 2008, p. 14-16.
[87] http://www.quoak.nl, http://www.verilabs.nl/
[88] http://www.quoak.nl

inadequacy of the testing and the consequences of an 'unfavourable' result. Such restrictions are in line with the rights of the patient. This protective regime can relatively easily be circumvented by consumers who, whether or not they fall for promising invitations from/via businesses operating abroad, decide to have their DNA tested. From the protection perspective, this 'profit' for personal autonomy raises concerns and reservations.

2.5. IS THE STATE OBLIGED TO REGULATE THE ACCESS AND SUPPLY OF DNA (SELF)TESTS?

The current legislation and regulations, clearly based on the provision of protection with respect for the autonomy of the patient/consumer, have shortcomings. The guarantees for responsible prevention activities, good quality and patient rights can thus be circumvented by both providers and patients/consumers. It can be argued that these shortcomings imply a strengthening of the right to autonomy, in the sense of individual self-determination; DNA (self)tests are, in an indirect way, quite freely available. It is evident from section 2.2 that the use of DNA (self)tests also has a downside and that, for the time being, the benefits do not offset the cost.

As we pointed out in section 2.3.1 autonomy implies alongside negative freedom also positive freedom, the possibility to organise life to our own wishes. It is generally acknowledged that the State can take restrictive measures to protect individuals and their dignity (2.3.2). The provision of protection against (health)damage is part of this duty.[89] Freedom restricting measures to prevent damage to health are, under strict conditions, accepted to prevent damage to others and the person concerned.[90] This calls for measures for the sake of positive freedom and thus to safeguard autonomy.

Assuming that DNA (self)tests can cause damage, an obligation to protect rests on State Parties, according to the case law of the ECtHR. Moreover, attaching conditions to DNA diagnostics for health reasons is in agreement with the Protocol on 'genetic testing for health purposes' (2008) in the Biomedicine Convention.[91] For the sake of everyone's 'dignity, identity, integrity and other rights and freedoms' (Article 1) this protocol stipulates that:

'Parties shall take the necessary measures to ensure that genetic services are of appropriate quality. In particular, they shall see to it that:

a genetic tests meet generally accepted criteria of scientific validity and clinical validity;

[89] Boom & Giessen 2001, p. 1676.
[90] Brug et al. 2005, p. 116.
[91] *Trb*. 1997, 113; *Trb*. 1999, 58.

b a quality assurance programme is implemented in each laboratory and that laboratories are subject to regular monitoring;
c persons providing genetic services have appropriate qualifications to enable them to perform their role in accordance with professional obligations and standards.' (Article 5)

Given that the ECtHR has explicitly been assigned a role in the clarification and application of this convention, the Biomedicine Convention and the accompanying protocols are also of significance for the Netherlands and other countries that have not yet ratified the Convention.[92] Consequently the obligation rests on the State to take the necessary measures that guarantee the quality, reliability, validity, safety and the benefits of DNA (self)tests. Furthermore the State should promote that prior to DNA diagnostics individuals give well-informed consent, that the right not-to-know is respected, that misuse of health information is counteracted and that the privacy of others than the patient/consumer does not come under pressure through DNA diagnostics.

As pointed out before, it is evident from the Biomedicine Convention and the accompanying protocols and case law of the ECtHR that the State has freedom of policy in the choice of a regulatory and enforcement system, on the condition that the measures offer effective and appropriate protection to the rights and freedoms in question. The latter seem to be under disproportionate pressure from the increased possibilities of DNA diagnostics outside the 'normal' supply. All in all, there is no obligation to implement legislation; however, it should be noted that in self-regulation the State remains fully accountable for violations of fundamental rights and freedoms. Given the fact that many advantages and disadvantages are not specific to the DNA (self)tests but also apply to screening, population screening and individual diagnostics, for the time being it is hard to see why in practice different quality requirements and patient rights apply, depending on the type of testing and the person who takes the initiative to do this. From the standpoint of autonomy, protection and the judicial system there are good arguments for advocating specific quality requirements for screenings, both population screening, and individual diagnostics.

It requires further investigation which form of regulation offers the most appropriate and effective protection against damage to health and safeguards the quality and patient rights. One can think in terms of, for instance, streamlining existing legislation and regulations and/or stimulating self-regulation. Whichever form is chosen, it is important that the regulator takes various factors into account. It is not entirely clear for some diseases and disorders whether they are treatable or untreatable) for instance HIV, familial hypercholesterolemia and certain types of cancer).[93] Yet the criterion of

[92] Lawson 2009, p. 23-36.
[93] GR 2001.

'treatability' for the licence obligation for the offering and performing of DNA testing for untreatable disorders, according to the current legislation and regulations, is an important distinction. First and foremost, from the standpoint of the protection of privacy and the fight against discrimination, the 'sensitivity' of the information must be considered; the greater the risk of misuse and discrimination, the more quality guarantees should be considered.

Consideration of the benefits and risks of DNA diagnostics, can call into question if a balancing of interests should take place between the risk and the public benefits or between the risks and the individual benefits. DNA diagnostics that do not directly have public benefits can have a considerable number of personal benefits which justify its acceptance.[94]

The risk of developing damage to health relates to the disorders and diseases for which the testing is or can be done. For example, the likelihood of damage to health (psychological and social problems) is greater in testing for Huntington's disease than for Alzheimer's disease and hereditary forms of breast cancer (section 2.2).
The arguments mentioned above plead in favour of regulating DNA diagnostics, making a distinction between the intrusiveness from the quality requirements at the one hand, and the seriousness and risk of resulting health damage and the implications of unfavourable test results at the other hand. In choosing regulation, particular attention should be paid to the consequences for new developments and applications of genetics. Likewise, attention should be paid to the restriction of the administrative burden for both mainstream and 'alternative' providers.
The State is obliged to take measures to combat without proviso access to and supply of DNA (self)tests, not just to prevent damage to health, but also to protect the rights and freedoms of others.
On the one hand the lack of validity, benefits and reliability of the DNA (self)tests offered in the Netherlands does not necessarily mean damage to health. The actual material and immaterial damage in the Netherlands as a result of DNA (self)tests for the risk of cancer is unknown. The same is true regarding the number of Dutch or European people who make use of DNA (self)tests.[95] But on the other hand, from a human rights perspective, the restriction of autonomy (negative freedom), is justified by the protection of the interests of others. Autonomy implies that the human person is a social animal and has a responsibility towards others and society. Measures to promote protection and quality requirements are necessary to protect the rights of others. DNA (self)tests can divulge information about others. It is not inconceivable that

[94] Grann & Jacobson 2002, p. 346.
[95] Borry & Howard 2008, p. 14-16.

with non-regulation the cost for healthcare can increase through unnecessary follow-up tests or not strictly medically necessary treatment.[96] Even though two Dutch studies[97] tone down the argument of the rising costs, healthcare remains a scarce commodity. Escalating costs through DNA (self)tests undermine the accessibility and the availability of healthcare. Measures that provide effective protection against possible damage to health from DNA (self)tests contribute to the strengthening of autonomy as a positive freedom, and do not detract from it.[98]Given the cross-border problem of DNA (self) tests the adoption of measures will not just have to be at national level, but also at a European level and/or worldwide.

2.6. CONCLUSION

Owing to the increasing expertise in the field of genetics, the knowledge and application of techniques for the detection of the carriership of (latent) present diseases and disorders continues to expand. Due to the specialised nature of DNA testing and the legal, ethical and social implications, strict requirements apply to the provision of it. At the same time, it is quite simple to order a test for an analysis of DNA via the internet or to undergo testing in a neighbouring country. The legislation – also at European and international level – has loopholes.

DNA (self)tests bring with them advantages and disadvantages for the people concerned and for society as a whole. The quality, safety, reliability and user-friendliness of the tests are debatable, as well as the conditions in which providers inform the (potential) consumers about the benefits and the risks.

In making DNA (self)tests freely available, the fundamental principles of autonomy and protection conflict with each other. These principles are closely bound to fundamental human rights and freedoms. They are inalienable rights aimed at safeguarding human dignity. Neither of these principles is given the absolute value that they are entitled to. To what extent is the State obliged to curb the access to and supply of DNA (self)tests, in which the initiative comes from the consumer? As argued above, from a human rights standpoint there are good arguments to set strict (quality)requirements for the access to and supply of DNA (self)tests. Not only it can be questioned if there is always informed consent from the consumer; also DNA diagnostics can – unlike conventional medical testing – infringe on the rights and freedoms of others. Moreover, there is the risk of false concern (or reassurance) and rising health costs as a result of such testing not always being reliable. In short, many reasons to resort to regulation of the access.

[96] Van der Weijden et al. 2007, p. 73.
[97] Van der Weijden et al. 2007, p. 83 & Nielen et al. 2009, p. 381.
[98] Hendriks 2008, p. 9.

Which form of regulation safeguards the quality and patient rights most effectively, requires further investigation. This contribution argues in favour of regulation in which a differentiation of quality requirements is introduced for the risk of manifestation, the seriousness of damage to health and the implications of unfavourable test results. For screening and individual diagnostics the same minimum quality requirements should apply. Furthermore, in our view in choosing regulation, attention should be paid to the consequences of it for new developments in genetics and the application of them.

CHAPTER 3

PRENATAL SCREENING IN THE LIGHT OF SELF-DETERMINATION

Abstract: *Information is of great importance for exercising self-determination in prenatal screening. The Dutch Health Council, the Dutch Government and Parliament attach great importance to standardised information and a non-directive attitude of those who supervise the pregnant woman within the scope of the national prenatal screening programme. However, to ensure the self-determination of the pregnant woman it is important that the provision of information about prenatal screening is perceived as a social-dialogic process that goes further than just providing factual information. Furthermore, it is imperative to dispense with the age limit for the reimbursement of the combined test, so that the pregnant women actually have freedom of choice in decisions surrounding prenatal screening for Down syndrome.*

Rachèl van Hellemondt, Carla van Os, Aart Hendriks & Martijn Breuning, 'Prenatale screening in het licht van zelfbeschikking', *Tijdschrift voor Gezondheidsrecht* 2012, p. 463-474.

3.1. INTRODUCTION

Prenatal screening can provide the pregnant woman[99] with information about (the risk of) abnormalities in their unborn child. Based on the results, they can decide if they want to continue the pregnancy or not.

Providing access to such information, and thereby to these diagnostics and screening methods, is not a 'free-standing' obligation. According to the settled case law of the European Court of the Human Rights (henceforth: ECtHR) the State is obliged to inform citizens adequately of serious (health) threats.[100] Parents not infrequently experience having a child with serious anomalies, such as the syndrome of Down (trisomy 21, henceforth: Down syndrome), as a threat, about which they wish to be informed in good time.

In accordance with the case law of the ECtHR, but also of the Dutch Supreme Court,[101] the pregnant woman must have timely access to relevant information on which she can decide if she wants to continue with the pregnancy or not.[102] At the same time individuals have the right to be spared information that they do not appreciate. Both rights, to know and not-to-know, are part of self-determination, a notion which underpins all human and patient rights.[103] Individual self-determination assumes that individuals are able to make free choices. This imposes requirements on the information which they (can) have access to and to the decision-making process.[104]

In the decision-making process of the pregnant woman about participating in prenatal screening programmes various dimensions of self-determination play a role; self-determination as the right 'to be left alone', self-determination 'as freedom to choice' and as a 'claim to self-development'.[105] In order to make use of all these dimensions of self-determination, adequate information is of essential importance. Furthermore, the way in which the screening programme is implemented must be critically examined.[106]

In this chapter we examine the guarantees for self-determination within the scope of the national programme of prenatal screening for Down syndrome. Down syndrome is a congenital disorder which is associated with intellectual disability as well as medical problems and physical characteristics. The prevalence of this disorder among all

---

[99] We mean by the term 'pregnant woman' also the (possible) partner.

[100] More detailed Hendriks 2010, p. 57-68; see also ECtHR 28 February 2012, *Kolyadenko et al./ Russia*, no. 17423/05.

[101] Hoge Raad der Nederlanden.

[102] ECtHR 26 may 2011, *R.R./ Poland*, no. 27617/04; HR 18 March 2005, *NJ* 2006, 606; HR 23 November 2003, *NJ* 2002, 386/387.

[103] Hendriks 2008, p. 2-18.

[104] Stirrat & Gill 2005, p. 127-130; Van Os & Hendriks 2010, p. 180-186.

[105] R.E. van Hellemondt, A.C. Hendriks & M.H. Breuning, 'Vrijheid, blijheid? Het reguleren van DNA-diagnostiek in de zorg vanuit mensenrechtelijk perspectief', *Nederlands Tijdschrift voor de Mensenrechten (NTM/NJCM-Bulletin)* 2010, p. 7-24.

[106] Leenen et al. 2007, p. 189-190.

pregnancies with a gestation period of more than twenty weeks in the Netherlands is 15.7 per 10,000 births. Furthermore, it should be noted that 42% of the children with Down syndrome are detected prenatally and in three-quarters of these cases it is decided to terminate the pregnancy.

In our research for the safeguarding of self-determination, we examine not just the case law of the ECtHR and the relevant national legislation, but also the (legal) conditions and basic assumptions which according to the Dutch Health Council, the Government and Parliament apply to the provision of information to pregnant woman regarding prenatal screening for Down syndrome. Particular attention is given to the age limit applied, that means the minimum age of the pregnant woman for having the prenatal screening costs reimbursement by a Health Insurance Company.

The structure of this chapter is as follows. After a short description of prenatal screening and the relevant legal framework, we examine, in section 3.3. The right of the pregnant woman to self-determination from a constitutional perspective. In section 3.4. we analyse the significance that the Dutch Health Council and the Government attach to self-determination within the scope of prenatal screening for Down syndrome. In section 3.5. we analyse the justification for erecting a financial threshold on the basis of age regarding the national prenatal screening programme. In section 3.6. we discuss the implementation of the current national prenatal screening programme in relation to self-determination and we offer a few recommendations for improvement. We end this chapter in section 3.7. with conclusions.

In this contribution we do not pay attention to the application of (new) technique(s) in which (cell-free) fetal DNA in the maternal blood can be examined for Down syndrome. The (future) use of non-invasive prenatal screening and diagnostics in which fetal DNA is examined for Down syndrome or other diseases and disorders, raises different legal issues than prenatal screening and diagnostics by means of the combined test, amniocentesis and the chorionic villus testing.[107]

3.2. THE FRAMEWORK OF THE DUTCH PRENATAL SCREENING PROGRAMME

3.2.1. Prenatal screening

The possibilities for the pregnant woman to seek advice about possible handicaps and diseases in the child before the delivery have increased considerably. The most well-known and used tests are prenatal screening for Down syndrome and the prenatal screening for physical defects (the anomaly scan). Both are part of the national programme for prenatal screening. Midwives, gynaecologists and general practitioners

[107] Herderschee 2011; Van Osselen 2011; Verweij et al. 2012; De Jong et al. 2011, p. 657-663.

draw the attention of all pregnant women in respectively the first and second trimester of the pregnancy to the possibility of these forms of screening. Prenatal screening in the Netherlands is seen as providing good care as part of the general provision of information to the pregnant woman.[108] The aim of these screenings is to inform the pregnant woman concerning possible anomalies in the unborn child, also with a view to making a decision about continuing or terminating the pregnancy.

The combined risk assessment test is used for prenatal screening for Down syndrome in week 9-14 of the pregnancy. It is possibly preceded by a family history and an ultrasound (in week 9-12). This non-invasive test consists of a blood test of the pregnant woman and measurement of the skin fold in the foetus neck. This is conducted with an ultrasound scan. The risk of having a child with Down syndrome can be calculated with the results of these tests, in combination with the age of the pregnant woman and the length of the pregnancy.[109] The percentage of the pregnant women that take part in this form of screening is 25-30%.

In prenatal screening for physical anomalies in the form of a structural ultrasound scan (US), better known as the 20-week scan,[110] the structure and development of the organs[111] of the foetus is checked, plus the size of the unborn child and whether there is sufficient amniotic fluid. The participation percentage in this examination is approximately 80%.

The structural US is included in the basic health insurance package of the Health Insurance Act (Article 10)[112] and is reimbursed to all pregnant women. However, to participate in prenatal screening for Down syndrome there is a financial threshold. Women younger than 36 years do not get this screening reimbursed via their health insurance, as opposed to the pregnant woman of 36 years and older, (Article 2.4 (1a) Decree Health Care).[113] This is different when from the (family)history of the pregnant woman, younger than 36 years, it emerges that there is an increased risk of having a child with a (genetic) disorder. In such situations the combined test is reimbursed due to the existence of a medical indication.

3.2.2. Prenatal diagnostics

Prenatal screening is sometimes confused with prenatal diagnostics. Prenatal diagnostics, unlike prenatal screening, takes place as a result of specific indications of

[108] Kamerstukken II 2003/04, 29 323, no. 1; Kamerstukken II 2003/04, 29 323, no. 3; Centraal Orgaan and RIVM 2011, p. 23.

[109] The combined test also gives information regarding the risk of having a child with the Patausyndroom (trisomy 13) or Edward's syndrome (trisomy 18). If the pregnant woman will remain of this information she has to state this prior to the screening.

[110] An ultrasound scan sends high-frequency sound waves that are reflected by tissues and organs. The reflected sound waves are made visible on a screen.

[111] The foetus is examined for various physical defects, among other things, the heart, the skull, lungs, kidneys and bones, and also characteristics of Down syndrome.

[112] *Stb.* 2005,358 (Zorgverzekeringswet).

[113] *Stb.* 2005, 389 (Besluit zorgverzekering).

an increased risk of the (possible) presence of a (genetic) disorder.[114] If it is determined there is an increased risk of Down syndrome, prenatal diagnostics is often offered in the form of a chorionic villus testing or amniocentesis. For these invasive tests a puncture is necessary. This puncture, as opposed to the combined test and the structural US, can interfere with the pregnancy, and can lead to a miscarriage.[115]
The human rights relevance of the difference between screening and diagnostics lies in the fact that the screening is offered to all individuals of the section of the population group concerned (in this case pregnant women) without having a medical indication for it. This makes specific demands on the safe-guarding of self-determination in whether or not to participate in the screening.

3.2.3. Legal framework

The Dutch Act on population screening (WBO) lays down quality criteria for the offer and practicing of (prenatal) screening. The permit system of the WBO applies to offer and performing prenatal screening for Down syndrome, because it is a population screening for the risk of a disorder for which no treatment or prevention is available.[116] According to the WBO the Minister of Health, Welfare and Sports grants a licence when the population screening is scientifically sound, the screening is in accordance with the professional medical practice standard and the expected benefits offset the risks.[117]Moreover, the decision regarding granting a licences is open to objection and appeal (Article 7:1 General Administrative Law Act),[118] in which when failing to give a timely decision and after a declaration in breach the applicant could claim a penalty payment (Article 4:17 et seq Awb).
The aim of the WBO can be deduced from the balance between benefit and risk and the definition of population screening: promoting public health and gaining health benefits.[119] In the case of prenatal screening the question can be asked what needs to be protected, the health of the pregnant woman, the unborn child or both the pregnant women and the foetus.[120] The fact is that with the WBO the screening of unborn life has acquired a place in a law which is meant to protect the health of those who have been born already.[121]
Before granting a licence the Minister is advised by the Dutch Health Council.[122] The Dutch Health Council has advised the Minister a number of times regarding the

[114] > 0.5 by the combined test.
[115] 0,3 tot 0,5%. of the pregnancy ended in a miscarriage after an invasive tests. Downsyndroom. Prenatale Screening (version 2011), RIVM March 2011; www.rivm.nl/pns/Images/Down%20folder%20NED%20%28mrt%202011%29_tcm95-57264.pdf
[116] Art. 2(1) WBO.
[117] Art. 7(1) WBO.
[118] *Stb.* 1992, 315 (Algemene wet bestuursrecht).
[119] Art. 1(c); Art. 7(1c) WBO; Aartsen 1996, p. 71-84.
[120] Van Os & Hendriks 2010.
[121] Olsthoorn-Heim 1996, p. 57.
[122] Art. 6 WBO.

national programme for prenatal screening.[123] We examine this in more detail in the next section.

To summarize, under the WBO a licence is required for offering and performing prenatal screening. A risk indicated test – combined test - for Down syndrome is offered to all pregnant women within the framework of the national prenatal screening programme. This takes place in week 9-14 of the pregnancy. The pregnant woman of 36 years and older and the pregnant woman with a medical indication have the choice between the combined test or to immediately undergo prenatal diagnostics – chorionic villus testing or amniocentesis.[124] The combined test, unlike the structural ultrasound scan (US), in principle is not reimbursed by the health insurance to the pregnant woman younger than 36 years (Article 2.4 (1a) Decree Health Insurance).

3.3. CONSTITUTIONAL FRAMEWORK

According to the ECtHR Self-determination – commonly referred as 'personal autonomy' – is an important aspect of the private life of individuals.[125] Self-determination, or individual autonomy, is *'an essential corollary of the individual's freedom of choice',*[126] a view which denotes self-determination as 'freedom of choice'. In this respect, self-determination also includes the right to respect decisions about whether or not to become pregnant[127] and the right to choose the circumstances to have children.[128]

The notion of self-determination 'as a right to be left alone', in other words the right to organise one's own life without intervention by others,[129] also means the freedom of pregnant women to decide for themselves about participating in prenatal screening. The self-determination of the pregnant woman thereby also encompasses 'the right to freedom of choice' and a 'claim right', namely the desire for information and help for 'self-development' about whether or not to continue the pregnancy. These freedoms presume, according to the ECtHR in the *R.R.* case, that if required, the pregnant woman is to be given access to comprehensive, reliable and timely information, including information about the health of the foetus.[130] This 'freedom to choice', as a separate dimension of self-determination in addition to 'the right to be left alone' and 'right

[123] GR 2007a; GR 2006a; GR 2004; GR 2001b.
[124] KNOV, Standpunt prenatale diagnostiek, Bilthoven: KNOV 2005.
[125] ECtHR 29 April 2002, *Pretty/ the UK*, no. 2346/02; ECtHR 11 July 2002, *Christine Goodwin/ the UK* (GC), no. 28957/95.
[126] ECtHR 29 April 2002, *Pretty/ the UK*, no. 2346/02, para. 61; ECtHR 28 November 1984, *Rasmussen/ Denmark*, no. 8777/79, para. 54.
[127] ECtHR 10 April 2007, *Evans/ the UK* (GC), no. 6339/05, para. 71.
[128] ECtHR 14 December 2010, *Ternovszky/ Hungary*, no. 67545/09, para. 22.
[129] There are various designations of this dimension of self-determination, see for example Dupuis 2004, p. 56-58; Beers 2009, p. 29.
[130] ECtHR 26 May 2011, no. 27617/04, *R.R./ Poland*, para. 197-199.

to self-development', provide specific responsibilities for the doctor regarding the counselling of the patient in making choices which fit in with him or her.[131] However, it cannot be concluded from above that the right to personal autonomy is absolute.[132] In the case *Ternovzky* the ECtHR considered that *'the mother is entitled to a legal and institutional environment that enables her choice, except where other rights render necessary the restriction thereof.'*[133] In other words, the being able to exercise self-determination by pregnant women, in particular for their self-development, should be legally and socially guaranteed, but can be restricted as far as this is necessary for safeguarding other rights and interests.

At a national level this view of self-determination underpins Article 11 Dutch Constitution.[134] It is also elaborated in the Medical Treatment Contract Act.[135] In this view the possibility of rejecting an offer of treatment and/or care is an expression of self-determination. The Dutch Supreme Court ruled that not fulfilling the information obligation by a healthcare worker to the pregnant woman entails the risk that the patient cannot make use of her self-determination in the way she wishes, 'and consequently entails the risk that the patient makes a choice which (s)he would not have made if (s)he was well-informed.'[136]

3.4. GUARANTEEING SELF-DETERMINATION AND PRENATAL SCREENING

3.4.1. The Dutch health council and informed consent

Consent

In the opinion of the Dutch Health Council, the offer of prenatal screening for Down syndrome should be presented in such a way that the pregnant woman could make a decision based on 'informed consent' in order to realise self-determination. In its advisory reports the Dutch Health Council emphasizes that due to the unsolicited offer – 'uninvited force into someone's life' – the offer of prenatal screening for Down syndrome requires strict quality norms for the provision of information and the consent procedure.[137] The offer of prenatal screening for Down syndrome demands explicit consent for receiving objective information. The consent requirement does not just look at the performing of the screening, but also at the information given about the prenatal screening – a combination of the right to information (Article 7:448 BW) and the right of not-to-know (Article 7:449 BW).

---

[131] MacLean 2006, p. 321-338.
[132] ECtHR 16 December 2010, A.,B. & C./ Ireland., no 25579/05.
[133] ECtHR 14 December 2010, *Ternovszky/ Hungary*, no. 67545/09, para. 24.
[134] Kamerstukken II 1978/79, 15 463, no. 1-2, p. 5.
[135] Art. 7:448; 7:450 BW.
[136] HR 23 November 2001, *NJ* 2002, 386/387, para. 5.3; HR 18 March 2005, *NJ* 2006, 606.
[137] GR 2004, p. 138.

Phased information

The Dutch Health Council stipulates that making a well-considered choice about prenatal screening for Down syndrome requires time for consideration. Accordingly, and to prevent an information overload, the Dutch Health Council pleads, just like Government and Parliament, for a phased, uniform and standardised approach[138] of 'informed consent' concerning the decision-making process around prenatal screening.[139] This process consists of three phases, namely a) the phase in which the pregnant woman is asked if she wants to receive information about prenatal screening; b) the phase in which providing information has the aim to give the pregnant woman a choice between whether or not to make use of prenatal screening for Down syndrome; c) the phase after establishing a higher risk of Down syndrome; the information from the health care worker will then concern possible follow-up diagnostic tests.[140] During this decision-making process the health care worker should continually check if the pregnant woman is sufficiently informed to prevent her from making a choice which is not in accordance with her norms and values.[141] This notes self-determination as a form of freedom of choice, which calls for counselling and protecting.

Guideline

In 2008 the then Minister Klink (CDA) of Health, Welfare and Sports informed Parliament about a guideline of quality requirements for the counselling of pregnant women. This guideline was established as a result of the call from the Parliament to inform expectant parents about prenatal screening in a standardised and non-directive way. The National Institute for Public Health and the Environment (RIVM) published a brochure and developed a choice-indicator (www.ikkiesbeter.nl) for pregnant women which should help them to choose whether or not to take part in the prenatal screening programme. According to the Minister, the most important objective of the prenatal screening – the informed choice of expectant parents – is guaranteed by these measures.[142]

3.4.2. Analysis

In prenatal screening for Down syndrome, the Dutch Health Council, as well as the Government and Parliament, emphasize the realisation of an informed choice. To safeguard the self-determination of the pregnant woman in the decision-making process surrounding prenatal screening he argues for a phased and standardised 'informed consent'-approach. The Dutch Health Council argued for standardised and non-directive attitude of those who inform the pregnant woman about prenatal screening and throughout the counselling.

[138] GR 2006a, p. 12-13.
[139] GR 2001b, p. 27.
[140] GR 2006a, p. 11-13; GR 2001b, p. 29.
[141] GR 2004, p. 59.
[142] Kamerstukken II 2007/08, 29 323 and 22 894, no. 49.

This approach offers good opportunities to establish quality requirements in the decision-making process and so promote the self-determination of the pregnant woman. A possible disadvantage of standardisation is that the health care worker does not feel free to tune the information to the individual and does not check enough if the way of informing also fits in with the person who has to process the information. Not everyone will find that (the same) factual, objective information sufficient to be able to make a choice. Standardisation that is too strict can therefore clash with the legal requirement that the health care worker should be guided by that which the patient in that specific case in all reasonableness should know (Article 7:448 (1) BW) and with the requirements of good health care worker practices (Article 7:453 BW). Consequently an important responsibility rests with the health care worker to check if the information is understood by the person concerned and if this information forms a good basis for making an informed decision. Important indications for the necessity for differentiation can also be found in a recent study by Erasmus University Rotterdam. Factors such as the level of education, cultural background and religion distinguish determine the extent to which women with 'informed consent' take part in prenatal screening.[143]

3.5. SELF-DETERMINATION AND AGE LIMITS

3.5.1. Justification age limit

In 2003 the then Secretary of State for Health, Welfare and Sports Ross-van Dorp (CDA) argued for restraint regarding the offer of prenatal screening, on the one hand to prevent medicalization and on the other hand 'not proceed further down the road of a misleading idealised image, namely human enhancement.'[144] She therefore made a distinction between the offer of prenatal screening for Down syndrome reimbursed by the insurance company and providing information about the combined test to all the pregnant women. Pregnant women, younger than 36, would have to pay for the prenatal screening themselves.[145] Ross-van Dorp underpinned this distinction between information and offer with a reference to the research report *'Opgelucht maar ook aangedaan'*.[146] This, while the researchers raised the question if it is realistic to expect that good information about the possibility of prenatal screening for Down syndrome can compensate the infringement of autonomy. The financial threshold on the basis of age is a restriction of the access to prenatal screening which affects the self-determination of pregnant women.

[143] Van Agt et al. 2012, p. 4.
[144] Kamerstukken II 2003/04, 29 323, no. 1, p. 8.
[145] Kamerstukken II 2003/04, 29 323, no. 3, p. 2.
[146] Geelen et al. 2004.

3.5.2. Age limit dispute

The age limit regarding the offer and the reimbursement of the combined test is medically and socially controversial. Although the risk of having a child with Down syndrome increases in with years of age, the Dutch Health Council advised, already in 2001, not to apply an age limit to prenatal screening.[147] The combined test without an age limit gives the most favourable combination of false positive/false negative test results and detection-miscarriage ratio. Furthermore, most of the pregnant women are younger than 36 years, the combined test during the first trimester of the pregnancy will thus reduce the number of pregnant women that have to undergo an invasive test at a later stage of the pregnancy, for example as a result of the structural US.

3.5.3. Quiet introduction ultrasound at 20 weeks

The final cabinet standpoint that pregnant women must be informed about the possibility of prenatal screening for Down syndrome, but that for the reimbursement of this screening an age limit will apply, was announced to the Parliament in a letter dated 15 September 2005.[148] A month later a letter followed in which it was announced that the structural US for all pregnant women would be reimbursed.[149]

While there were many and frequent discussions about the introduction of a national screening programme for Down syndrome, and the age limit associated with reimbursing, the reimbursement of the structural US for all pregnant women was quietly accepted. That is remarkable, given the fact that the decision-making process surrounding the structural US is complex due to the nature of the test. The decision-making process of prenatal screening for Down syndrome is compared to the structural US more transparent because yet one anomaly is screened.[150] Moreover, in the structural US the pregnant woman is put under greater pressure of time because in accordance with the Termination of Pregnancy Act it is no longer permitted to terminate the pregnancy later than a few weeks after the structural US.

3.5.4. Analysis

Yet, in contrast to the structural US, an age limit applies to the reimbursement of prenatal screening for Down syndrome. A clear and unequivocal justification for the age limit is absent. The question must be asked whether an age limit for prenatal screening conflicts with the constitutional notion of self-determination in relation with

[147] GR 2001b, p. 13-15.

[148] Kamerstukken II 2004/05, 29 323, no. 15.

[149] Kamerstukken II 2005/06, 29 323, no. 17.

[150] The combined test also gives information regarding the risk of having a child with the Patausyndroom (trisomy 13) or Edward's syndrome (trisomy 18). If the pregnant woman will remain of this information she has to state this prior to the screening. See about the complexity of the decision making process ; Dondorp et al. 2010; vorige.nrc.nl/opinie/article2484612.ece/Echo_zorgt_voor_onverwachte_dilemma_s; De Kort 2008, p. 36-37; Oepkes 2008, p. 38-40.

the principle of non-discrimination due to the financial threshold for access to 'health information'. If women younger than 36 years (have to) waive the prenatal screening with the combined test for financial reasons, also because they can be informed 'free' about it in the twentieth week of the pregnancy, it restricts their self-determination without good justification and in a seemingly discriminatory way.

3.6. IS IT ENOUGH?

3.6.1. Self-determination and standardised information

As we saw in the previous sections the information given to pregnant women about prenatal screening is standardised. Furthermore, Government, Parliament and professional associations set great store by the principle of non-directivity. Standardised information guarantees minimum quality requirements of the information for prenatal screening and is in accordance with the procedural norm of Article 8 ECHR. Nevertheless, a quarter of the women that participate in prenatal screening appear not to do this on the basis of an informed choice.[151] In practice it was found that pregnant women do not only need to have information so that they can make an informed decision about rejecting (information about) prenatal screening for Down syndrome (self-determination as 'right to be left alone'). The pregnant women say that they also want to receive information that is related to the implications of prenatal screening, namely the consequences of the test results and the choices arising from that about the continuation or termination of the pregnancy (self-determinations as freedom 'to choice' and as 'self-development').[152] Illustrative are the experiences of parents of a child who has Down syndrome that took part in prenatal screening. In a survey only 32% of these parents stated that they remembered having received information regarding Down syndrome. Moreover, a quarter of this group found that the information was insufficient. The parents mostly had the feeling of being alone in the decisions about screening and about whether or not to continue the pregnancy.[153] We emphatically note, however, that these figures are based on the experiences and memories of the parents.

Moreover (expectant) parents stated that they would also like to know more about the experiences of living with a child with Down syndrome, the psychosocial aspects of it.[154] In addition to factual information the pregnant women also want support in taking decisions regarding the period after the combined test based on the interpretation of the test results. Furthermore, they expect the experts to state their opinion about

[151] Van Agt et al. 2012, p. 3.
[152] Geelen 2004.
[153] De Graaf et al. 2010, p. 37-48.
[154] De Graaf et al. 2010, p. 37-48.

the seriousness of the situation, and the health care worker to advise the pregnant woman from his professional experience with regard to further diagnostics and the continuation or termination of the pregnancy.[155]

From the above it can be concluded that a standardised 'informed consent' approach as transfer of knowledge and information does not give an absolute guarantee of the pregnant woman being able to exercise self-determination and the freedom to choose with regard to prenatal screening. Should not be given more attention to individualised information tailored to the pregnant woman (Article 7:448 (1) BW)? After all, not every pregnant woman needs the same assistance to make the choices concerning prenatal screening. Furthermore, the need for information of those involved is strongly influenced by factors as knowledge and education, previous pregnancies, the circumstances in which the family lives, the presence of other children and the phase in the decision-making process of the screening. It seems advisable that the health care worker, who cares for the pregnant woman in the first trimester of the pregnancy, first and foremost finds out if the information regarding prenatal screening is understood by the pregnant woman, in order that this information actually helps her to make choices.[156] Furthermore, the health care worker could be guided by the question which information, tailored to her individual needs, the pregnant woman needs in order to be able to make a decision and the purpose of the information. This implies a concept of professional responsibility from midwives, gynaecologists and general practitioners that goes beyond non-directivity. The safeguarding of self-determination via giving information and offering support is more than the provision of information about facts.[157] There must be the opportunity to exchange feelings, ideas, doubts and dilemmas between the pregnant woman and those who supervise the pregnancy as professionals. Communication perceived as a social-dialogical process guarantees the material norm of self-determination better than a standardised and non-directive form of provision of information.[158]

3.6.2. Self-determination and the age limit

In view of self-determination it is important for the pregnant woman to receive information about the health of her unborn child as early as possible in the pregnancy. The sooner the risk of a (genetic) abnormality is detected the more time the pregnant woman is given for making choices after screening. It can be assumed that the barrier to participate in prenatal screening is higher if the pregnant woman has to pay for it, also because not reimbursing screening from the basic health insurance package of the Health Insurance Act seems to suggest that it is not necessary.[159]

[155] Slagboom 2011, p. 21-22.
[156] Coggon & Miola 2011, p. 523-547.
[157] Van der Stouwe 2008, p. 43.
[158] Geelen 2004, p. 52; Van der Stouwe 2008, p. 43.
[159] Zeeman 2008, p. 40.

If strict requirements apply to the information about screening due to the unsolicited offer, and having time for reflection is an important condition for being able to take a well-considered choice, then it seems that not reimbursing screening for Down syndrome to pregnant women younger than 36 years is an unnecessary restriction of self-determination, in terms of 'freedom to choice and self-development'.
The procedural norm concerning self-determination of the pregnant woman as a 'right to be left alone' is adequately safeguarded with the current screenings policy. In contrast, the material norm does not appear to be sufficiently safeguarded. Prenatal screening for Down syndrome and the structural US are part of the provision of information and good care for pregnant women. Not reimbursing prenatal screening for Down syndrome to pregnant women aged less than 36 years seems to be inconsistent policy, which is at odds with Article 8 ECHR. In our view the pregnant women under 36 years have just as much right as pregnant women of 36 years and older to adequate and sound information given in good time about the risk that their foetus is affected with syndrome of Down. The decision of the Minister of Health, Welfare and Sports regarding reimbursement of the structural US shows that this can be arranged with a single letter to the Parliament. From a health and human rights standpoint this benefits the self-determination of all pregnant women in the dimension of 'freedom to choice and freedom of development'.

3.7. CONCLUSION

Pregnant women have the right to self-determination and thereby have the right to make their own choice regarding their pregnancy and to undergo prenatal screening. Information is of great importance for exercising self-determination in prenatal screening. This information, according to the ECtHR, must be complete, reliable and timely accessible. In the advisory reports of the Dutch Health Council regarding prenatal screening for Down syndrome, self-determination in the dimension of providing possibilities for making informed choices predominates. Besides factual information it seems that in practice pregnant women especially have needs for professional counselling by health care workers in applying the information to their own situation. In respect of self-determination the professional groups and implementing agencies should reformulate the principle of non-directivity regarding the provision of information about prenatal screening. It should be formulated in such a way that it (better) expresses that informing pregnant women about prenatal screening is a social-dialogical process that goes beyond just giving factual information. Furthermore, it is important that the Minister of Health, Welfare and Sports reconsiders the age limit for the reimbursement of prenatal screening for Down syndrome from the primary health care package, so that not just the procedural norm of Article 8 ECHR is guaranteed –

the access to prenatal screening and receiving information about it – but that also the material norm for all pregnant women is guaranteed: actually having and experiencing freedom of choice.

CHAPTER 4

THE RESTRICTION OF FREEDOM OF EXPRESSION FOR HEALTH SERVICES VIEWED FROM AN EU AND CONSTITUTIONAL LAW PERSPECTIVE

Abstract: *In this chapter the authors analyse advertising for health services (regardless of whether via the internet) and the permissibility of the restriction of this form of expression from an EU and constitutional law perspective. Using a case study regarding direct-to-consumer (DTC) genetic testing, the authors examine EU and constitutional law provisions imposing restrictions on advertising for health services. The authors note that licensing or forbidding advertising for health services on health protection grounds will not easily be regarded as an unjustified infringement owing to the wide margin of appreciation granted to states.*

From the case study it appears that EU law with regard to 'pure' cross-border advertising for health services provides more effective protection against infringements of freedom of expression than the ECHR. Furthermore, according to EU law there are fewer conditions attached to advertising bans than to systems of prior consent.

It specifically applies to DTC genetic testing that the proportionality between an advertising ban or a licensing system for such testing and the desired objective can be called into question. Conceivable goals for the restriction of advertising such testing can be achieved with measures that encroach less on the rights and freedoms of consumers and providers.

Moreover a laissez-faire attitude fits in with regard to advertising health services within the dominant free-market oriented view of healthcare, where unfortunately, freedom of choice and own responsibility are too often used as synonyms for self-determination.

R.E. van Hellemondt, A.C. Hendriks & M.H. Breuning, 'Het beperken van de vrijheid van meningsuiting voor gezondheidsdiensten bezien vanuit EU- en grondrechtelijk perspectief', *Tijdschrift voor Constitutioneel Recht* 2013, p. 184-204.

4.1. INTRODUCTION

A variety of health services and goods can be purchased via the worldwide virtual shopping centre on the web. Internet users can obtain information regarding all sorts of matters, ask specific health questions and buy all sorts of medicines and medical devices, including services that are not available in their own country.
Via the internet, services can be acquired such as the screening of individual health. By using such services, citizens are not only able to obtain information regarding their current state of health, but also about future health risks. This knowledge is indispensable for a healthy and longer life. At least that is what the providers of screening that directly focus on citizens via the internet would have you believe. However, these companies are less generous when it comes to the provision of information about the value and the risks of such tests.[160]

The question must be asked whether citizens should be protected from incomplete and possibly misleading information concerning internet health services, in particular about direct-to-consumer (DTC) screening.[161] This protection could be achieved through the introduction of compulsory licensing for advertising these health services.[162] This legal concept is in keeping with the existing legislation and regulations in the Netherlands for the offer and execution of risky screening.[163]
Answering this question raises various EU and constitutional law dilemmas. On the one hand, the State has a particular responsibility according to Article 2(1) Dutch Constitution and Article 8 ECHR with regard to the protection of health.[164] According to the case law of the European Court of Human Rights, this responsibility involves the positive obligation to safeguard the quality and safety of healthcare, to provide a system of supervision and to warn citizens in case of health risks (obligation to provide information).[165]
The combination of a licence obligation for providing – and advertising – certain health services, such as screening, can be regarded as a curtailment of freedom of expression, as protected by Article 7(1), Dutch Constitution and Article 10 ECHR. Advertising[166] health services is considered to be an expression of an opinion.[167] An advertising ban

---

[160] Bunnik 2009, p. 23-25; Singleton 2012, p. 435-436.
[161] Goldsmith et al. 2012, p. 811-816.
[162] DTC genetic test is a service; R.E. van Hellemondt, A.C. Hendriks & M.H. Breuning, 'Wet bevolkingsonderzoek op gespannen voet met EU recht', *Nederlands Tijdschrift voor Europees Recht* 2010, p. 245-251.
[163] De Wert 2004.
[164] Hendriks 2012a, p. 23-50; R.E. van Hellemondt, A.C. Hendriks & M.H. Breuning, 'Vrijheid, blijheid? Het reguleren van DNA-diagnostiek in de zorg vanuit mensenrechtelijk perspectief', *Nederlands Tijdschrift voor de Mensenrechten (NTM/NJCM-Bulletin)* 2010, p. 7-24.
[165] More detailed Hendriks 2012b, p. 101-123; Hendriks 2010, p. 57-68.
[166] Advertising is communication characterized by payment, publicity and promotion of goods and services, Kabel 2003, p. 175-191, www.ivir.nl / staff / cable.html. Last visited on March 21, 2013. Kabel mentions another feature, the influence of the channel on the spread of the message.
[167] HR 15 January 1999, *NJ* 1999, 665.

without prior authorisation (i.e., licence) can moreover impede the free movement of health services. This can be at odds with the free movement of services, one of the pillars of EU law. The restriction of access to health services, by means of a licensing system, can also be regarded as a restriction of the rights of a citizen searching for information about his health and life perspectives to self-determination. Individual self-determination or personal autonomy forms an important EU and constitutional value, which entails various negative and positive obligations for the State.[168]

In this chapter, we examine EU and constitutional law provisions with regard to the restriction (i.e., impediment) of advertising health services via a licensing system or ban. We do this using a case study regarding the restriction of advertising DTC genetic screening. The focus will be on the case law of the European Court of Human Rights (ECtHR) and the European Court of Justice (ECJ).

We open with a short description of DTC genetic screening and the relevant Dutch constitutional framework (Section 4.2). Subsequently in Section 4.3, we examine the meaning of the principles of protection and self-determination with regard to the access to DTC genetic screening. In Sections 4.4 and 4.5 we analyse the ban of advertising (without prior authorisation) in relation to the right to the freedom of expression and the free movement regime. This chapter is concluded with a few remarks.

4.2. THE FRAMEWORK

4.2.1. DTC genetic screening

Consumers can quite easily and without the intervention of a doctor, order tests for the mapping of (a part of) their genetic profile via the internet. Such a test – a DTC genetic test – is an application of genetic screening.

Genetic screening is a (medical) examination that is aimed at uncovering hereditary disorders, genetic predisposition for diseases or risk factors that increase the risk of (hereditary) disease in people without health problems.[169]

A few days after placing an order over the internet the consumer receives a toolkit. This comprises a tube to collect the DNA sample, mostly through saliva. A few weeks after sending the sample, the individual receives the test results, often also via the internet. The 'commercial' decoding of genes using a DTC genetic test in practice means the examination of a part of the genome – the complete set of genetic material of a cell – for certain variations and mutations which are associated with hereditary diseases. It is important to distinguish between monogenetic and multifactorial genetic disorders. In genetic mutations that correspond to monogenetic disorders, it can be determined

[168] Koffeman 2010.
[169] GR 2008, p. 13.

with great certainty whether someone has a hereditary disorder and is going to develop symptoms of the disease in the future.[170] In multifactorial genetic diseases, however, there is only a possibility of obtaining certain hereditary diseases.
Using a DTC genetic test, fragments of the genome are often simultaneously screened for more than a hundred, mostly multifactorial genetic disorders. Strong statements concerning the chance of getting certain multifactorial genetic diseases can mostly not be made as there is (still) too little known about the morbific genetic disorders in the genome and the precise interaction between genetic and environmental factors.
It is debatable whether consumers sufficiently realise the limited benefits and predictive value of DTC genetic testing, and the associated risks of false positive and false negative results. Furthermore, the interpretation of the test results, for a layman with little knowledge of genetics and statistics, is not an easy task. The use of DTC genetic tests can not only lead to avoidable damage (including psychological damage) to those tested, but can also cause unwanted side effects for society. Healthcare costs can increase due to the need to interpret or re-interpret the test results by general practitioners and clinical geneticists, follow-up tests (often times unnecessary) and over-treatment.[171] In addition, the interests of blood relatives can also be at stake, as DNA tests for hereditary disorders can also give an insight into the possibility that blood relatives are carriers of the same genetic mutation(s).
Due to the (potential) health risks strict conditions are attached to marketing (genetic) screening in the Netherlands in accordance with the Dutch Act on population screening (In Dutch: 'Wet op het bevolkingsonderzoek' (WBO)).

4.2.2. The Dutch Act on population screening

The WBO is a public law regulation that seeks to protect individuals from certain types of (potentially) harmful screening. A 'population screening' according to the WBO is 'a medical examination which is carried out in response to an offer made to the entire population or to a section thereof and to detect diseases of a certain kind or certain risk indicators, either wholly or partly for the benefit of the persons to be examined'.[172] This examination is not conducted because there is a concrete request for help from those involved (medically 'indicated' examination), but is directed towards individuals who in principle have no symptoms. This is the reason why strict due diligence requirements apply to the offer and execution of population screening.[173]
In the legal definition of population screening, the term 'offer' should be interpreted broadly.[174] It does not just mean the active invitation to individuals to have themselves tested, for example a personal written invitation to take part in the population screening

[170] Maassen 2006, p. 772-773.
[171] Bloss et al. 2013, p. 5.
[172] GR 1994, p. 18; art. 1(c) WBO.
[173] Drewes et al. 2009, p. 1660-1664.
[174] GR 2007b; IGZ 2008, p. 14.

for breast cancer, but also the passive 'seduction' of consumers to buy a service or a good via advertising on websites, magazines and newspapers. For the offering and performing of (potentially damaging) population screening a licence is required.[175] At the moment, there are three categories of population screening indicated in the WBO as potentially harmful, namely (a) population screening using ionising radiation, (b) for cancer and (c) for untreatable disorders.[176] For other types of population screening no licence is required.

The Minister of Health, Welfare and Sports (VWS) issues a licence for the offer and execution of population screening if it is scientifically sound, is in accordance with the professional medical practice standards and the expected benefits offset the risks.[177] The Act does not contain any specific licensing criteria with regard to the offer – including the advertising – of population screening.

Given the strict requirements which apply to the offer and execution of population screening and the oft-heard criticism of the limited predictive value and the benefits of DTC genetic tests,[178] there is little likelihood of the Minister issuing a licence to a company in the Netherlands for the marketing of DTC genetic tests in which consumers are screened for (risk-indicators for) certain types of cancer or untreatable disorders.[179]

4.2.3. Interim reflections

DTC genetic tests in the Netherlands fall within the scope of the WBO. Generally for the offer and execution of DTC genetic testing a licence is required under the WBO, because most of the time such a test provides information concerning the risk of contracting more than a hundred diseases, including certain types of cancer and untreatable disorders.

As a rule in screening outside the mainstream circuit,[180] also known as commercial screening, the concept of advertising is brought within the concept of 'offer'. A distinction is rarely drawn between the concepts of offer, invitation and advertising in commercial screening, because public sales promotion texts on paid websites or advertising messages in newspapers and magazines screening are offered directly to consumers. This way consumers are invited to buy a health care service - screening. The licence obligation, which applies to screening for types of cancer and untreatable disorders, should in this way also protect the consumer from these types of advertising.

[175] Art. 3(1) WBO.
[176] Art. 2 WBO.
[177] Art. 7(1) WBO.
[178] Report EASAC & FEAM 2012.
[179] To our knowledge the Minister has not yet issued a licence to a company which provides and/or carries out DTC genetic tests.
[180] Screening which is not a part of the Dutch National Population Screening Programme or performed as a national screening programme.

This raises the question of whether erecting barriers to advertising encounters EU or constitutional objections, especially the right to freedom of expression and the concept of self-determination.

4.3. PROTECTION AND SELF-DETERMINATION

4.3.1. The principles protection and the notion of self-determination

The State is bound to provide its citizens with optimum protection from risks and dangers to life, welfare and health. This 'duty to protect'[181] is not only conveyed in social economic fundamental rights, but also in the positive obligations of classic fundamental rights. It is also evident from the case law of the ECtHR. According to the ECHR, States Parties have a 'best endeavours' duty to protect people who live within their territory from damage, including damage to their health.[182]

This duty of protection – which is also potentially important for the regulation of health services, such as DTC genetic tests – has manifested itself in the case law of the ECtHR particularly in matters with regard to Article 2 (right to life), Article 3 (ban on torture) and Article 8 ECHR (right to privacy).[183] For the subject matter of this chapter, the positive obligations that the ECHR has interpolated in Article 8 ECHR that concern protection from health damage and the access to information on one's health, are of particular interest.

Individuals derive from Article 8 ECHR a proviso that the State ensure that they remain free of damage to health, as well as have the right to an effective and accessible procedure to obtain access to information in the event of possible health risks.[184] According to the ECtHR, the States Parties do not have to wait until the damaging effect is indisputably clear before standardizing the potentially harmful events and informing the population with regard to the health risks.[185] Furthermore, it can be expected from the State that it take action against people who wilfully disseminate information that is damaging or at least potentially damaging to the health of people.[186] Article 8 ECHR in principle thereby creates far-reaching positive obligations, although the ECHR always allows the States Party a certain extent of policy freedom to elaborate on this obligation at their own discretion.

---

[181] See Shue 1980. The typology of obligations ('to respect, to protect and to fulfil') became better known after the Special Reporter Eide 1987 was published. See also San Giorgi 2012, p. 42 and further.

[182] ECtHR 14 November 2002, *Mouisel/ France*, no. 67263/01; ECtHR 27 January 2009, *Tatar/ Romania*, no. 67021/01.

[183] San Giorgi 2012, p. 103-109.

[184] ECtHR 19 February 1998, *Guerra et al./ Italy*, no. 14967/89; ECtHR 19 October 2005, *Roche/ the UK* no. 32555/96, para. 167; ECtHR 26 July 2011, *George & Georgeta Stoicescu/ Romania,* no. 9718/03.

[185] ECtHR 27 January 2009, *Tatar/ Romania*, no. 67021/01.

[186] ECtHR 6 November 2009, *Leela Forderkreis et al./ Germany*, no. 58911/00.

The rapidly increasing offer of health checks, DTC genetic tests and other types of screening fits in well in healthcare determined by a free-market, with the emphasis on freedom of choice and personal responsibility as expressions of self-determination.[187] With regard to the access to such health services, it is the question whether individuals under Article 8 ECHR should not only have access to collected and recorded information related to them,[188] but also if they should be entitled to access as yet unknown information via a so-called 'right to screening'. In the light of existing case law of the ECtHR, the question whether a general right to health screening exists must be answered negatively.

At the same time it follows from case law of the ECtHR that the State should respect decisions made competently, even if they are possibly damaging to the welfare and the health of the person concerned. The restriction of access to DTC genetic tests with a limited predictive value, which result in possible damage, including health damage, is consequently at odds with the freedom of individuals to allow themselves to be screened for future health risks and to receive information with regard to these risks without State interference. This freedom of choice is also protected by Article 8 ECHR.[189] However, when no informed consent is provided, the situation is very different.

According to the ECHR, the requirement of informed consent for medical treatment is an essential safeguard of the right to respect for private life (Article 8 ECHR) and the self-determination of the individual.[190] It expresses the principle that consent based on adequate information is a condition for carrying out a medical procedure. This implies, for example, that State Parties have the positive obligation to safeguard that individuals are informed about the foreseeable consequences of a contemplated medical treatment in good time, sufficiently and understandably.[191] Accordingly, the case law ECtHR has recognised a general right to information regarding choice.[192] However, in the case of people using DTC genetic testing, we must ask ourselves if there is valid consent as information about the limited benefits and predictive value is not provided.

4.3.2. Interim reflections

The right to self-determination, as recognised in the context of Article 8 ECHR, does not entail a right to claim access to health services such as DTC genetic testing. However, the State has a positive obligation to impose quality requirements on the access to, the information regarding and the use of such health services.

---

[187] GR 2008, p. 13.

[188] ECtHR 7 July 1989, *Gaskin/ the UK,* no. 10454/831990; ECtHR 13 February 2003, *Odièvre/ France*, no. 42326/98 (GC); ECtHR 25 September 2012, *Godelli/ Italy*, no. 33783/09.

[189] ECtHR 13 November 2012, no. 47039/11 & 358/12, *Hristizov et al./ Bulgaria*, para. 117.

[190] ECtHR 9 March 2004, *Glass/ the UK*, no. 61827/00, ECHR 20 March 2007, *Tysiqc/ Poland,* no. 5410/03, para. 107; ECtHR 10 April 2007, *Evans/ the UK (GC),* no. 6339/05, para. 71; ECtHR 26 May 2011, *R.R./ Poland*, no. 27617/04.

[191] ECtHR 5 October 2006, *Trocellier/ France,* (admissibility decision), no. 75725/01 & no. 75725/01; ECtHR 2 June 2009, *Codarcea v. Romania*, no. 31675/04, para. 105.

[192] ECtHR 26 May 2011, *R.R./ Poland,* no. 27617/04; ECtHR 28 August 2012, Costa & Pavan/ Italy, nr 54270/10.

Imposing quality requirements on the offer and the execution of DTC (genetic) screening is in our view permissible and desirable, also regarding the possible (consequences of) test results for the fundamental rights and freedoms of others. Such quality requirements may, however, not conflict with EU and constitutional law. In this chapter, we focus specifically on the advertising of DTC genetic tests as little mention is made of this aspect of the testing in academic literature; a situation that contrasts starkly with the EU and constitutional objections regarding the use of and procedure for such health services.[193]

4.4. ADVERTISING VIEWED FROM THE PERSPECTIVE OF FREEDOM OF EXPRESSION

4.4.1. Introduction

With the advent of internet, the possibility has been created for companies to simply and quickly inform large groups of people about certain health services.[194] At the same time individuals are able to obtain a wealth of information via the internet. The so-called 'freedom of communication' safeguards not just from State intervention with regard to the content of the communication, but also from impeding communication.[195] Freedom of communication thus affects the self-determination of the individual in question to choose if and the way in which he or she wishes to express his opinion or wants to receive an opinion.[196]

Advertising DTC genetic tests entails commercial communication about a specific health care service. Advertising is defined as any form of communication intended for the direct or indirect promotion of goods, services or the image of a business, organisation or person that exercises an industrial or craft activity or a regulated profession.[197] Advertising is an expression of an opinion.[198] In the following section, we examine the restriction of advertising DTC genetic tests in the context of the Dutch Constitution and Article 10 ECHR.

[193] Kaye 2008, p. 180-183; Soini 2012, p. 143-153; Roscam Abbbing 2010, p. 11-22; DTC genetic test is a service; R.E. van Hellemondt, A.C. Hendriks & M.H. Breuning, 'Wet bevolkingsonderzoek op gespannen voet met EU recht', *Nederlands Tijdschrift voor Europees Recht* 2010, p. 245-251; R.E. Hellemondt, A.C. Hendriks & M.H. Breuning, 'Regulating the use of genetic tests:is Dutch law an example for other countries with regard to DTC genetic testing?', *Amsterdam Law Forum* 2011, p.13-24.

[194] Heerma van Voss & Zwaan 2010, p. 207.

[195] Dommering et al. 2000, p. 48.

[196] Asscher 2002, p. 6.

[197] Directive 2000/31/EC.

[198] HR 1 April 1997, *LJN* ZD 0677; ECtHR 24 February 1994, Casado Coca/ Spain, no. 15450/89.

4.4.2. Advertising and the Dutch Constitution

Article 7 Dutch Constitution safeguards the freedom of public communication:

'1. Nobody requires prior permission to publish thoughts or feelings through the press, without prejudice to the responsibility of everyone under the law.
2. The law lays down rules concerning radio and television. There is no prior supervision of the content of a radio or television broadcast.
3. Apart from everyone's responsibility under the law no one requires prior permission to publish thoughts or feelings through other means than those mentioned in the previous sections because of its content. The law can regulate the access to holding performances to people below the age of sixteen years to protect good morals.
4. The previous sections are not applicable to commercial advertising.'

According to Article 7(4) Dutch Constitution, commercial advertising is excluded from the scope of constitutional protection. This means that other types of (commercial) communication regarding goods and services, such as communication relating to ideals or informative communication, do enjoy the protection of Article 7 Dutch Constitution. Idealistic expressions, irrespective of whether they are related to advertising, are expressions in which the commercial interest is not the main issue, but rather the ideal, or the social or political interest is.[199] Think of the 'Loesje posters', posters for political parties and the former 'Postbus 51' (translated as 'PO Box 51') advertising. The hallmark of informative expressions is the lack of a clear commercial message. Examples of informative expressions are the announcements on an annual fair billboard, a market or a sports event.

By excluding commercial advertising from the scope of constitutional protection, the legislature has created the possibility of imposing restrictions by means of secondary legislation on commercial advertising in order to protect, for example, public health. As a result, some types of commercial advertising, such as medicine advertising can be subject to prior supervision.[200]

The classification of communication based on the nature of the expression – ideals or purely commercial – proves to be difficult in practice. Partly as a result of this, the National Commission on the Constitution recommended in 2010 to lift the exclusion of commercial advertising from constitutional protection.[201] Restricting or forbidding commercial advertising would still be possible due to the dissemination jurisprudence.[202] However, this proposal from the National Commission was not taken up by the cabinet of that time.[203]

---

[199] HR 25 October 2005, *LJN* AU2030; HR 1 April 1997, *LJN* ZD 0677.
[200] Dommering et al. 2000, p. 61.
[201] Staatscommissie 2010, p. 75; Commissie Franken 2000, p. 99-101, 107 & 111-112.
[202] HR 28 November 1950, *NJ* 1951, 137; Staatscommissie 2010, p. 75.
[203] Kamerstukken II 2011/12, 31 570, p. 7-8.

4.4.3. The significance of Article 7 Dutch Constitution for DTC genetic testing

In its rulings the Dutch Supreme Court has never really determined what should be understood by commercial advertising. The highest court (always) dexterously avoided defining the concept of commercial advertising in its rulings.[204] According to Advocate-Generals *Machielse and Knigge*, commercial advertising is any form of public extolling of goods and services for commercial purposes.[205] This implies that advertisements for DTC genetic tests in newspapers, magazines and websites and promotional texts on the internet should be classified as commercial advertising, at least, as long as these tests are offered commercially, in other words with a financial contribution in return.

With their advertisements and promotional texts, providers of DTC genetic tests primarily intend to seduce consumers to buy their services. Some providers also explicitly mention this on their website by stating that their services are a form of amusement and pleasure and do not entail medical services. Such providers endeavour to achieve financial gain with a service that predicts the risk of disease. It should also be assumed that providers, who offer DTC genetic testing outside the 'mainstream circuit' and advertise such services, do not enjoy the protection of Article 7 Dutch Constitution. This does not mean that the freedom to advertise commercially lacks constitutional protection. The Dutch Supreme Court introduced advertising in the field of freedom of expression via Article 10 ECHR.[206]

4.4.4. Advertising and Article 10 ECHR

The freedom of expression is also laid down in Article 10 ECHR. This freedom is defined in the first paragraph of this provision as:

'1. Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers. This Article shall not prevent States from requiring the licensing of broadcasting, television or cinema enterprises.'

Informing others and holding an opinion, as well as the freedom to receive and pass on information and ideas without hindrance, are independent rights.[207] However, the right to receive information does not go beyond the freedom to gather already available and accessible information. In contrast to Article 8 ECHR, Article 10 ECHR contains no positive obligation for the State to safeguard the access to information, including health information.[208]

---

[204] HR 25 October 2005, *LJN*: AU3030; HR 1 April 1997, *NJ* 1997, 457.
[205] Conclusion by HR 25 October 2005, *LJN*: AU3030; HR 1 April 1997, *NJ* 1997, 457.
[206] HR 13 February 1987, *NJ* 1987, 899.
[207] ECtHR 26 April 1979, Sunday *Times/ the UK*, no. 6538/74, para. 65; ECtHR 20 November 1989, *Markt Intern/ Germany (GC),* no. 10572/83.
[208] ECtHR 19 February 1998, *Guerra et al./ Italy*, no. 14967/89; ECtHR 10 July 2006, *Sdružení Jihočeské Matky/ Czech Republic,* no. 19101/03. This case is covered public sector information, which cannot be equated in line with health information of individuals.

According to the ECtHR, advertising is 'a means of discovering the characteristics of services and goods' and, therefore, falls within the scope of the freedom of expression.[209] For the protection of the freedom of expression – as opposed to the constitutional protection under Article 7 Dutch Constitution – the nature of the expression (i.e., whether commercial, informative, ideal or a mixture) is not relevant.[210]

Article 10 ECHR safeguards not just the content of announcements, including advertising announcements, but also the form in which they are delivered. Restrictive measures, such as a ban or a licence obligation for advertising, are permissible if such an infringement is justified by general interest objectives. One such interest is the protection of health. The scope of the *margin of appreciation* that States Parties are entitled to in taking measures that infringe the freedom of expression depends on the pursuit of a legitimate purpose, the relationship between the information and democratic society, and the existence of shared principles between State Parties.[211] The *margin of appreciation* granted to State Parties in advertising – i.e., commercial speech – is wider than expressions that are regarded as the core of the freedom of expression.[212]

This explains why as a rule the ECtHR deems permissible infringements of the expression of advertising messages more readily than expressions that are important for the social debate, provided that these restrictions are proportional and proportionate to the desired objective.[213] State Parties consequently have a relatively wide authority to impose restrictions on 'pure' advertising messages. From case law, it is evident that such restrictions imposed by the ECtHR are not readily regarded as unjustified, certainly if it these relate to unfair commercial practices with respect to citizens (see also section 4.5.3.).

4.4.5. Interim reflections

Promotional texts on websites, newspapers and magazines for health services, such as DTC genetic tests, are types of commercial advertising that do not enjoy constitutional protection in accordance with Article 7 Dutch Constitution. The classification of

[209] ECtHR 18 October 2002, *Stambuk/ Germany*, no. 37928/97, para. 39.

[210] ECtHR 29 October 1992, *Open Door and Dublin Well Woman/ Ireland*, no. 14235/88, *para.* 53- 55; ECtHR 24 February 1994, *Casado Coca/ Spain,* no. 15450/89, *para.* 35; ECtHR 16 December 2008, Frankowicz/ Poland, no. 53025/99, *para. 39.*

[211] Compare with each other for example ECtHR 7 December 1976, *Handyside/ the UK,* no. 5493/72 a case about common decency and sexual morality and ECtHR 26 April 1979, *Sunday Times/ the UK*, no. 6538/74 criticism regarding the operation of the justice system. See also ECtHR 17 Oktober 2002, *Stambuk/ Germany*, no. 37928/97.

[212] ECtHR 17 October 2002, *Stambuk/ Germany*, no. 37928/97, para. 29-30; ECtHR 29 January 2008, Villnow/ Belgium, (admissibility decision), no. 16938/05; ECtHR 5 March 2009, *Hachette Filipacchi Presse Automobile & Dupuy/ France*, no. 13353/05; *Société de Conception de Presse et d'Edition & Ponson/ France*, no. 26935/05; A.J. Nieuwenhuis 2012, p. 153.

[213] Boukema & Drijber 2004, p. 70; ECtHR 21 March 2000, *Wabl/ Austria*, no. 24773/94; ECtHR 20 November 1989, *Markt Intern/ Germany*, no. 10572/83.

commercial advertising appears difficult in practice. The Dutch Supreme Court has not provided a decisive answer on this issue, any more than the case law of the ECtHR about advertising. Probably this is not deemed very necessary, because all types of advertising are protected by Article 10 ECHR.

The freedom of expression is not absolute. Advertising, however, enjoys limited protection under Article 10 ECHR due to the fact that such types of communication do not belong to the core of freedom of expression. In connection with this, the State has a wide *margin of appreciation* with regard to taking restrictive measures for commercial advertising. The ECtHR has only rarely decided that forbidding or requiring prior administrative consent procedures (i.e., licensing systems) with regard to advertising is contrary to Article 10 ECHR.
Yet, how do such bans and consent procedures interact with EU law, in particular the free movement of services?

4.5. FREE MOVEMENT REGIME AND ADVERTISING

4.5.1. Charter of Fundamental rights of the European Union

The Charter of Fundamental Rights of the European Union (hereinafter: EU Charter) has a provision that obliges EU and the Member States to safeguard the protection of human health during the determining and implementation of EU policy (Article 35 TFEU).[214] The protection principle (Article 35 EU Charter) is confirmed by Article 168 (1) TFEU (distribution of authority between the EU and the Member States with regard to health policy) and put into practice in Article 52 TFEU (health exception).[215]
Besides the protection principle for the free movement of health services, such as DTC genetic tests, important fundamental freedoms of expression (Article 11 EU Charter) and entrepreneurship (Article EU Charter) are laid down in the EU Charter. In a similar vein to Article 10 ECHR, Article 11 EU Charter should be explained extensively. It does not simply contain just the expressing of an opinion, but also the freedom to receive information.[216] In the *Damgaard*[217] case, the ECJ confirmed the case law of the ECtHR in that Member States are granted a certain *margin of appreciation*, depending on the activity, with regard to the restriction of advertising.[218] In situations where the freedom

[214] C-544/10, C-544/10, Deutsche Weintor/ Land Rheinland- Pfalz [2012] ECR I-000 (not published yet), para 53.
[215] C-570/07 & C571/07, *Blanco Pérez & Chao Gómez* [2010] ECR I-04629, para. 65; C-84/11, *Marja-Liisa Susisalo, Olli Tuomaala & Merja Ritala* [2012], not published yet, para. 37.
[216] Case C-70/10, *Scarlet Extended SA/ Société belge des auteurs, compositeurs et éditeurs SCRL (SABAM)* [2011] ECR I-11959, para 50.
[217] C-421/07, *Damgaard* [2009] ECR I-2629.
[218] C-421/07, *Damgaard* [2009] ECR I-2629, para. 26-27; C-71/02 Herbert Karner Industrie-Auktionen GmbH [2005] ECR I-3025, para 50-51.

Article 51 EU Charter of Fundamental Rights:
'1. The provisions of this Charter are addressed to the Institutions, bodies and agencies of the Union with due regard for the principle of subsidiarity and to the Member States only when they are implementing Union law. They shall therefore respect the rights, observe the principles and promote the application thereof in accordance with their respective powers and respecting the limits of the powers of the Union as conferred on it in the other Parts of the Constitution.
2. This Charter does not extend the field of application of Union law beyond the powers of the Union or establish any new power or task for the Union, or modify powers and tasks defined in the other Parts of the Constitution.'

The interpretation of Article 51 EU Charter of Fundamental Rights:
The Charter of the Fundamental rights of the European Union does not, contrary to the ECHR, provide 'free-standing rights'. The EU Chapter is only applicable in all situations where organisations and Member States of the EU explore activities governed by European Law or they otherwise implement or determent EU law or EU policy (Case C-617/10, Åkerberg Fransson [2013], not yet reported, para. 17 et seq).

The EU charter of Fundamental Rights has different functions:
- It is a constitutional framework to check the legality of EU secondary law.
- An aid to interpretation of other EU law.
- A tool to fill caps.

of expression contributes to a debate of general interest, the ECJ (only) marginally tests whether the interference is reasonable and proportional.
Advertising in the field of free movement is known by the term commercial communication. Commercial communication is classified as any form of communication intended for the direct or indirect promotion of goods, services or the image of a business, organisation or person who pursues a commercial, industrial or craft activity or a regulated profession. Goods and services can be extolled on the internet (i.e., online advertising), but also in newspapers, magazines and on television (i.e., offline advertising). A ban or a licensing system for advertising DTC genetic tests is a restriction of the free movement of services. It denies residents of EU Member State information and deprives them of the possibility of purchasing the services.
In the Netherlands, however, Article 11 EU Charter is not of great interest for the restriction of advertising (genetic) screening from health considerations by the WBO, since this does not concern the implementation or determining of EU policy (Article 51 EU Charter, box 1).[219] This does not alter the fact that in cross-border situations – for example when a provider from another Member State wishes to establish in the Netherlands or desires to offer and exercise its services here – the ECJ weighs up the compatibility of an advertising ban or a licence obligation for the expression of business messages against the freedom of expression and the right to protection of human health and the freedom of entrepreneurship (Article 16 EU Charter).[220]

[219] However, see also C-617/10, Åkerberg *Fransson* [2013]. In this case the scope of the EU-Charter seems to be stretched.
[220] C-544/10, Deutsche Weintor/ Land Rheinland- Pfalz [2012] ECR I-000 (not published yet), para. 44-46.

The ECJ compares the compatibility of an advertising ban or a licence obligation for the expression of business messages with the freedom of expression and the right to protection of human health and the freedom of entrepreneurship (Article 16 EU Charter).[221] In such an evaluation, none of these fundamental rights have absolute validity. The fundamental rights involved should be reconciled with each other in the sense that a proper balance should be found.[222] This can also lead to the freedom of entrepreneurship being subject to restrictions for purposes of general interest. The condition is, however, imposed that the restriction must be proportionate to the pursued goal and furthermore may not affect the core fundamental rights.[223] Consequently under the EU Charter the offer (i.e., the advertising) of DTC genetic tests can in principle be restricted for health purposes by institutions and Member States of the EU.

4.5.2. Free movement of advertising services

The offer of DTC genetic tests is subject to the regulation of free movement for services.[224] Directive 2000/31/EG regarding certain legal aspects of information society services, also known as the E-Commerce Directive, is applicable to online advertising.[225] The E-Commerce Directive leaves room for restrictive measures with regard to online advertising to safeguard public health, provided that the barrier of the free movement of information society services is proportionate to the desired objective.[226] In addition the E-Commerce Directive does not obstruct licensing systems that do not specifically and exclusively concern information society services.[227] Measures that Member States take to regulate online advertising services must however be submitted to the European Commission.[228]

In the absence of community harmonisation measures, the provisions of the treaty with regard to the free movement of services are applicable to offline-advertising for DTC genetic tests (Articles 56-62 TFEU). Compelling reasons of general interest – in this case public health – can justify barriers to free movement for services, including advertising services.[229] Established case law concerning the exception of public health is meant to guarantee accessible healthcare for all, to achieve a high level of health

[221] C-544/10, Deutsche Weintor/ Land Rheinland- Pfalz [2012] ECR I-000 (not published yet), para. 44-46.
[222] C-544/10, Deutsche Weintor/ Land Rheinland- Pfalz [2012] ECR I-000 (not published yet), para. 47.
[223] C-544/10, Deutsche Weintor/ Land Rheinland- Pfalz [2012] ECR I-000 (not published yet), para. 52-55.
[224] C-171/07 and C-172/07, *Apothekerkammer des Saarlandes et al.* [2009] ECR I-4171, para. 22-23; C-531/06, *Commissiion/ Italy* [2009] ECR I-4103, para. 43-44; C-169/07, Hartlauer Handelsgesellschaft mbH/ Wiener Landesregierung, Oberösterreichische Landesregierung [2009] ECR I-1721, para. 33-36.
[225] *OJ* 2000, L 178/16.
[226] Art. 3 Directive 2000/31/EC; C-108/09, *Ker-Optika* [2010] ECR I-12113, para. 76.
[227] Art. 4(2) Directive 2000/31.
[228] Art. 3(4) (b) Directive 2000/31.
[229] C-500/06, *Corporación Dermoestética SA/ To Me Group Advertising Media* [2008] ECR I-578, para. 35; C-531/06 *Commission/ Italy* [2009] ECR I-4103, para. 49; C-169/07, *Hartlauer Handelsgesellschaft mbH / Wiener Landesregierung, Oberösterreichische Landesregierung* [2009] ECR I-1721; Maasdam & Sluijs 2009, p. 214-219.

protection and to maintain the financial balance to prevent serious damage to the social security system.[230]

According to established case law of the ECJ, a justifiable barrier must meet the requirements of non-discrimination and proportionality.[231] To meet the second criterion, the proportionality requirement, the restriction of advertising DTC genetic tests may not go any further than the realisation of the desired objective.[232] Moreover, national legislation should be suitable for both the realisation of the pursued objectives, as well as their coherent and systematic implementation.[233] The regulation of prior consent may not be used to justify discretionary action by national authorities. To prevent this, a system of prior authorisation must contain objectively discernible criteria.

4.5.3. Misleading advertising

The content of advertisements is regulated by EU law concerning the protection of (public)health and consumers rights.[234] The ban on unfair commercial practices, including misleading advertising originates from the EU Directive 2005/29/EG concerning unfair commercial practices. Directive 2005/29/EU[235] has been implemented in the Netherlands in Book 6 of the Dutch Civil Code and for the most part adopted into a system of self-regulation in the form of the Dutch Advertising Code. The implementation Act 'Unfair Commercial Practices Act' came into force on 15 October 2008.[236] The judge and the Advertising Code Commission have repeatedly concluded that advertising messages are misleading, for example either because a rosy picture is painted or health risks are not sufficiently stated.[237]

EU Directive 2005/29/EG is applicable to communication (including advertising) from traders or providers that have a direct connection with influencing the decisions of individuals about the purchase of products.[238] The Directive sets information-requirements for advertising health services, such as DTC genetic tests. For a number

[230] C-169/07, *Hartlauer Handelsgesellschaft mbH/ Wiener Landesregierung, Oberösterreichische Landesregierung* [2009] ECR I 1721, para. 46-49; C-444/05, *Aikaterini Stamatelaki/ NPDD Organismos Asfaliseos Eleftheron Epagelmation* [2007] ECR I-3185, para. 31; C-372/04, *Watts* [2006] ECR I-4325, para. 108-109; C-385/99 Müller-Fauré & Van Riet [2003] ECR I-4509, para. 80; C-157/99, *Smits & Peerbooms* [2001] ECR I-5473, para. 76-80.

[231] C-444/05, *Aikaterini Stamatelaki/ NPDD Organismos Asfaliseos Eleftheron Epagelmation* [2007] ECR I-3185, para. 34; C-385/99, *Müller-Fauré & Van Riet* [2003] ECR I-4509, para. 68.

[232] C-531/06, *Commissission/ Italy* [2009] ECR I-4103, para. 82; C-500/06, *Corporación Dermoestética SA/ To Me Group Advertising Media*[2008], para. 36 - 41; C-444/05, Aikaterini Stamatelaki/ NPDD Organismos Asfaliseos Eleftheron Epagelmation [2007] ECR I-3185, para. 35; C-385/99, Müller-Fauré & Van Riet [2003], ECR I-4509, para. 68.

[233] C-531/06, *Commission/ Italy* [2009] ECR I-4103, para. 66.

[234] Staatscommissie Grondwet 2010, p. 75-76.

[235] *OJ* 2005, L 149/22.

[236] *Stb.* 2008, 397 (De implementatie wet: 'Wet oneerlijke handelspraktijken').

[237] https://www.reclamecode.nl/; Reclame Code Commissie 30 July 2007, no. 2007/07.0343; Reclame Code Commissie 27 September 2010, no. 2011/ 00874; Reclame Code Commissie 6 July 2011, no. 2011/00489; College van Beroep Stichting Reclame Code 7 November 2011, no. 2011/00727.

[238] Preamble Directive 2005/29/EG, para. 7.

of commercial practices it is assumed that they always obstruct the average consumer from making an informed choice; they are, therefore, always regarded as unfair.[239] Accordingly, a so-called black list of unfair commercial practices has been developed, which includes deceptive claims that a product, i.e., a good or a service can cure diseases, deficiencies or deformities,[240] as well as factually false statements concerning the nature and the extent of the danger that would threaten the personal safety of the consumer if the consumer does not buy the product.[241]

Advertising is not only classified as misleading due to the single fact that an expression is false, incomplete or unclear. A commercial practice is unfair, and can be classified as misleading advertising, if it is at variance with the requirements of professional dedication and the commercial practice limits, or if it can limit the consumer in making an informed decision, causing the average consumer to purchase a good of a service that he otherwise would not have done.[242] The average consumer is 'a reasonably informed, prudent and perceptive consumer'.[243] Professional dedication is the normal level of special skill and meticulousness that can reasonably be expected of traders.[244]

Examples of misleading advertising are: the provision of false information, half-truths, as well as factually correct information, which through the way of presenting leads the average consumer 'up the garden path'.[245] A misleading omission under the Directive includes holding back or concealing essential information or ambiguous presentation of the information because of which the consumer is not able to make an informed choice.[246] The EU Directive 2005/29/EG only safeguards the economic interests of consumers and no other interests such as health. Through this, the Directive, despite the fact that the basic assumption of this Directive has maximum harmonisation, provides Member States with the possibility to uphold restrictions – licensing systems – and advertising bans to protect the health and safety of consumers.[247] The Member States have a wide freedom policy with regard to choosing appropriate instruments for the way in which the norms from the Directive are upheld, and in which way 'unfair traders' are sanctioned. This must, however, be in accordance with the principles of effectiveness and proportionality, and the chosen system should have a preventive effect.[248]

The Netherlands has chosen a reasonably complicated system of enforcement when it comes to combating unfair commercial practices. It is outside the scope of this chapter

[239] Annex I of Directive 2005/29/EG.
[240] Item 17, Annex I, Directive 2005/29/EC.
[241] Item 12, Annex I, Directive 2005/29/EC.
[242] Art.5; Art. 2(e) Directive 2005/29/EC; Art. 6: 193a BW and further.
[243] Kamerstukken II 2006/07, 30928, no. 3, p. 14; Preamble Directive 2005/29/EC, para.18; C-210/96, *Gut Springenheide* [1998] ECR 1-04657, para. 37.
[244] Art. 6:193a (1)(f) BW.
[245] Art. 6 Directive 2005/29/EC ; Art. 6:193c; Art. 6:193 d BW.
[246] Art.7 Directive 2005/29/EC.
[247] Preamble Directive2005/29/EC, para 9; Art. 3(3) Directive2005/29/EC; Van Dam 2009, p. 3.
[248] Art. 11(1) Directive 2005/29/EC.

to thoroughly address this matter. It suffices to observe that besides the individual enforcement by the consumer, a system of public law enforcement has also been created in the framework of Regulation 2006/2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws.[249] The Consumer Protection Act 2006[250] placed public law enforcement in the hands of the Authority for Consumers and Markets.

4.5.4. Interim reflections

In principle, the EU Charter and the free movement regime for services also offer sufficient space to Member States to limit advertising with regard to health services by means of an advertising ban or licensing system, but only in the framework of the protection of public health. Hence, the restriction or barrier to free movement should be proportionate to the pursued goal and to the requirement of non-discrimination. The fight to protect the consumer against unfair commercial practices has been harmonised at the European level. The Directive Unfair Commercial Practices is also applicable to health services and seeks to guarantee informed choice, and with this also self-determination, of the average consumer in the purchase of such a service.

4.6. CONCLUDING REMARKS

As a result of examining the EU law and Dutch constitutional legal framework with regard to the restriction of advertising DTC genetic tests, a few general conclusions can be drawn regarding advertising health services. Advertising a health care service is an expression of an opinion and fall within the scope of Article 10 ECHR. The introduction of a licensing system for advertising or an advertising ban with regard to health services is an infringement of the freedom of expression. However, as a result of the *wide margin of appreciation* that applies as a result of the ECtHRs case law to the regulation of advertising the licensing or banning of advertising health services tests on health protection grounds will not quickly be regarded as an unjustified infringement.

It is notable that EU law for advertising health services, which is primarily directed at harmonising and securing free movement, provides a more effective protection against infringements of the freedom of expression than the ECHR. The ECJ employs a stricter test than the ECtHR at least for restrictions such as administrative consent. It is also remarkable that evidently under EU law fewer conditions are attached to banning advertising, despite the fact that such measures more deeply encroach on the free movement regime for services, including health services, than on systems of

[249] *OJ* 2004, L 364/1.
[250] *Stb.* 2006, 591 (Wet handhaving consumentenbescherming 2006), amended several times since then.

prior consent, including administrative consent. Through this, advertising bans less frequently conflict with the rules for the free movement of services than licensing systems that do not forbid but attach certain conditions to the access and use of health services.

In concluding, we would like to draw attention to some specific issues regarding the case study on the EU law and constitutional framework for advertising with regard to health services. In our opinion, citizens as consumers should be protected from incomplete and possibly misleading information emanating from providers of screening in general and in particular genetic screening.

In the Netherlands a licence under the WBO is necessary for the offer and performing of certain types of screening. In practice the health protecting measure of the WBO wards off DTC (genetic) screening from the 'screening market', thus depriving individuals of access to (predictive) health information. Moreover, for the offer and performing of DTC genetic tests a licence is normally required, because providers of such testing generally screen (fragments of) the genome for more than 100 diseases. They often also look for mutations and variations that are associated with certain types of cancer and untreatable diseases.

In our view imposing quality requirements on the use of DTC genetic tests and advertising is easily defensible from an EU and constitutional law perspective. Potential risks, including health risks, that can cause damage adhere to the use of DTC genetic tests. The information concerning the testing leaves much to be desired.[251] Accordingly individuals are not able to make an informed choice.[252] This is not just a condition for being able to exercise self-determination, but it is also an important criterion for conducting a 'good commercial practice' and 'fair advertising'. Other important reasons for the regulation of the access to DTC genetic tests are the potential risks of avoidable health damage and – which is not unimportant in today's society – the probability of rising costs of healthcare due to unnecessary follow-up diagnostics and over-treatment as a result of drawing up the genetic profile 'commercially'.

However, questions need to be asked about the proportionality of a ban (without prior administrative authorisation) for DTC genetic tests and the desired objective. Conceivable goals for the restriction of advertising DTC genetic tests are or can also be achieved with measures that encroach to a much lesser extent on the fundamental rights and freedoms at stake of individuals and providers of such tests.

The licensing system of the WBO sets quality requirements on the procedure of DTC genetic tests to protect individuals from (potentially) risky screening, which can cause health damage. The question can be asked whether a restriction of advertising DTC genetic tests by means of a ban or a licensing system adds something to the already

[251] Eindsiedel & Geransar 2009; Singleton et al. 2012.
[252] HR 12 March 2013, *LJN* BY4876.

offered protection of health. Why should a provider that has been granted a licence under the WBO not be allowed to invite individuals for services, or for services for which no licence is required under the WBO? Why should these individuals not be allowed to have at their disposal advertising regarding approved or permitted tests? In addition the Minister of Health Welfare and Sports issues a licence under the WBO if the procedure of DTC genetic tests takes place in accordance with current legislation for medical treatment. This also means that there are sufficient safeguards that meet the informed consent requirement during the execution of the screening. Moreover the Dutch Civil Code and the Advertising Code also impose requirements on the content of advertising, both for DTC genetic tests that require a licence, as well as for the less common tests not requiring a licence. In the past this was sometimes more effective with regard to the protection of the consumer in a dubious offer of cross-border preventive healthcare, than the licence obligation for the offer under the WBO.[253]

To conclude, *a laissez-faire* attitude complements the advertisement of health services within the dominant free-market oriented view of healthcare, where freedom of choice and personal responsibility unfortunately are too often used as synonyms for self-determination.

[253] College van Beroep Stichting Reclame Code 7 November 2011, no. 2011/00727.

PART B

EUROPEAN LEGAL FRAMEWORK

CHAPTER 5

LEGISLATION ON DIRECT-TO-CONSUMER GENETIC TESTING IN SEVEN EUROPEAN COUNTRIES

Abstract: *An increasing number of private companies is now offering direct-to-consumer (DTC) genetic testing services. Although a lot of attention has been devoted to the regulatory framework of DTC genetic testing services in the USA, only limited information about the regulatory framework in Europe is available. We will report on the situation with regard to the national legislation on DTC genetic testing in seven European countries (Belgium, the Netherlands, Switzerland, Portugal, France, Germany, and the United Kingdom). This chapter will address whether these countries have legislation that specifically address the issue of DTC genetic testing or have relevant laws that is pertinent to the regulatory control of these services in their countries. The findings show that France, Germany, Portugal and Switzerland have specific legislation that defines that genetic tests can only be carried out by a medical doctor after the provision of sufficient information concerning the nature, meaning and consequences of the genetic test and after the consent of the person concerned. In the Netherlands, some DTC genetic tests could fall under legislation that provides the Minister the right to refuse to provide a license to operate if a test is scientifically unsound, not in accordance with the professional medical practice standards or if the expected benefit is not in balance with the (potential) health risks. Belgium and the United Kingdom allow without restrictions the provision of DTC genetic tests.*

Pascal Borry, Rachèl E van Hellemondt, Dominique Sprumont, Camilla Fittipaldi Duarte Jales, Emmanuelle Rial-Sebbag, Tade Matthias Spranger, Liam Curren, Jane Kaye, Herman Nys and Heidi Howard. 'Legislation on direct-to-consumer genetic testing in seven European countries', *European Journal of Human Genetics 2012*, p. 715-721.

5.1. INTRODUCTION

A wide variety of genetic tests are currently being offered directly to consumers by private companies that are located within the USA, Europe and elsewhere. The type of tests being offered to the public are diagnostic tests, (preconception) carrier tests, tests indicating a predisposition to common disorders, tests profiling a risk to addiction, nutrigenomic tests, pharmacogenomics tests and ancestry tests. According to the companies selling these tests, individuals have a fundamental right to access information about themselves, including genetic information.[254] Companies market their tests to consumers on the basis that they will be able to use the test results in their daily life, particularly, in monitoring or improving their health conditions.[255] Moreover, companies maintain that ordering a genetic test outside the traditional healthcare system will result in a better guarantee of privacy, at least with respect to insurance companies and employers. Autonomy, empowerment, prevention, convenience and privacy are usually the keywords in the marketing of these direct-to-consumer (DTC) genetic tests.[256]

There have also been a number of criticisms made about the services that these companies provide to consumers. Although a few companies are currently involving physicians in the provision of their services,[257] the majority of companies operate without the involvement of a healthcare professional. Indeed, in some cases, a health-care professional may have been hired by the company to 'formally' sign off on orders to circumvent legal issues,[258] most companies do not require consumers to ever interact directly with a health-care professional in order to obtain a genetic test. This is contrary to the way that genetic tests have been provided within most healthcare frameworks. The DTC provision model of genetic tests has been criticized for its absence of individualized medical supervision,[259] the absence and/or dubious quality of pre- and post-test information provision and genetic counselling,[260] and the inappropriate genetic testing of minors.[261] This adds to the concerns regarding the limited predictive value, clinical validity and utility of various DTC genetic tests presently on offer.[262] Further concerns include the way that DTC genetic testing companies carry out research,[263] the (lack of) respect for privacy and the potential burden on public health-care resources.[264]

[254] Ledley 2002, p 767.
[255] Foster et al. 2006, p. 635-638.
[256] Howard & Borry 2009, p. 11-13.
[257] Howard & Borry 2011.
[258] Mitchell et al. 2010, p. 829-846; Wadman 2008, p. 1148-1149.
[259] Hogarth et al. 2008, p. 161-182.
[260] Wade & Wilfond 2006, p. 284-292.
[261] Borry et al. 2009a; Borry et al. 2009b, p. 51-59.
[262] Janssens et al. 2008, p. 593–599; Misheascu et al. 2009, p. 588-594; Foster et al. 2009, p. 570-574.
[263] Borry et al. 2009a; Howard et al. 2010, p. 579-582.
[264] McGuire et al. 2009, p. 3-10.

In light of these concerns, various professional organisations and governmental agencies have published statements to inform, educate and/or warn consumers about DTC genetic testing.[265] Along these lines, the European Society of Human Genetics' statement set a bench mark that included recommendations to ensure the quality of the testing services, the provision of pre-test information and genetic counselling, and individualized medical supervision.[266] Furthermore, most statements have urged for closer regulatory oversight of this market. Recently, the US Food and Drug Administration (FDA) has decided to investigate more closely the market activities of DTC genetic testing companies; this may impact on the future regulatory oversight of the DTC genetic testing market both in the US and elsewhere.[267]

Although various publications have focused on the regulation of DTC genetic testing activities in the US7,[268]only a limited attention has been devoted to the regulation of these activities in the Europe.[269] Therefore, the aim of this article is to analyse whether specific European countries have national legislation that specifically addresses DTC genetic testing or that have other legislation that may impact on the regulatory control of these genetic testing services. This publication discusses national initiatives from different European countries and does not focus on the European Union legal framework. However, it is important to stress that various European legislations are binding for companies offering DTC genetic testing in the European Union. Specifically, the Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data; the Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the internal market; the Medical Devices Directives; the Directive 97/7/EC on the protection of consumers in respect of distance contracts; Consumer legislation and the

[265] American College of Obstetricians and Gynaecologists 2008, p. 1493-1494; Federal Trade Commission: FTC Facts for Consumers. At-Home Genetic Tests: a Healthy Dose of Skepticism may be the Best Prescription 2009, http://www.ftc.gov/bcp/edu/pubs/consumer/health/hea02.shtm (accessed 26 April 2011); Human Genetics Commission: A Common Framework of Principles for Direct-to-Consumer Genetic Testing Services 2010, http://www.hgc.gov.uk/Client/document.asp?DocId=280&CAtegoryId=10 (accessed 2 May 2011); United States Government Accountability Office: Nutrigenetic Testing: Tests Purchased from four Websites Mislead Consumers. Washington: US GAO, 2006; United States Government Accountability Office: Direct-to-Consumer Genetic Tests Misleading Test Results are Further Complicated by Deceptive Marketing and Other Questionable Practices 2010, http://democrats.energycommerce.house.gov/documents/20100722/Kutz.Testimony.07.22.2010.pdf (accessed 17 January 2011); Nuffield Council on Bioethics: Medical Profiling and Online Medicine: the Ethics of 'Personalised Healthcare' in a Consumer Age. Oxfordshire: Nuffield Press, 2010.

[266] European Society of Human Genetics Statement of the ESHG on direct-to-consumer genetic testing for health-related purposes, *European Journal Human Genetic* 2010, p. 1271–1273.

[267] Allison 2010, p. 633; Genetics and Public Policy Center, 2008, http://www.dnapolicy.org/resources/DTCcompanieslist.pdf.

[268] Hogarth et al. 2008; Tamir 2010, p. 213; Solberg 2009, p. 711-1141; Gniady 2007, p. 2429; Novy 2010, p. 157-239; Bernstein 2010, p. 283-295; Wagner 2010, p. 451-456; Robertson 2009, p. 213.

[269] R.E. Hellemondt, A.C. Hendriks & M.H. Breuning, 'Regulating the use of genetic tests:is Dutch law an example for other countries with regard to DTC genetic testing?', *Amsterdam Law Forum* 2011, p.13-24; p. 13-24; Bonneau et al. 2010, p. 396-401; Kaye 2008, p. 180–183; Borry 2008, p. 736–737

Directive 2006/114/EC concerning misleading and comparative advertising; and the Directive 2005/29/EC concerning unfair business-to-consumer commercial practices and Competition Law.

5.2. METHODS

Experts in Health Law (all co-authors of this paper) from seven European countries (Belgium, Germany, France, the Netherlands, Portugal, Switzerland and the United Kingdom) were contacted by PB and HCH to describe the regulatory frameworks that apply to DTC genetic testing activities in their countries. In answering this question, they were asked first, whether their country had legislation that specifically addressed the issue of DTC genetic testing, and second, whether there was legislation that regulated genetic testing services in general. These countries were selected on the basis of the willingness of experts to participate and on the basis of previous involvement in debates on this subject. The United Kingdom has been the most active European country in this area. Since 1997, the Advisory Committee on Genetic Testing[270] and subsequently the Human Genetics Commission (HGC) has published various documents specifically addressing the issue of DTC genetic testing.[271] In Belgium, the National Advisory Committee on Bioethics prepared a document on this issue in 2004[272] and the Superior Health Council is at this moment debating whether more regulatory control for DTC genetic testing is necessary. In France and Portugal, the National Consultative Ethics Committee for Health and Life Sciences[273] and the National Council for Ethics in the Life Sciences, respectively, issued statements on the direct marketing of genetic tests in 2008.[274] In the Netherlands, the Health Council[275] and the Council for Public Health and Health Care[276] both published a report on self-testing, discussing DTC genetic testing as well. In Switzerland, the Swiss Society of Medical Genetics had published a statement

[270] Advisory Committee on Genetic Testing: Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public. London: Health Departments of the United Kingdom, 1997.

[271] Human Genetics Commission: A Common Framework of Principles for Direct-to-Consumer Genetic Testing Services 2010, http://www.hgc.gov.uk/Client/ document.asp?DocId=280&CAtegoryId=10 (accessed 2 May 2011); Human Genetics Commission: Genes direct. Ensuring the Effective Oversight of Genetic Tests Supplied Directly to the Public 2003, http://www.hgc.gov.uk; Human Genetics Commission: More Genes Direct. A Report on Developments in the Availability, Marketing and Regulation of Genetic Tests Supplied Directly to the Public 2007, http://www.hgc.gov.uk.

[272] Belgian Advisory Committee on Bioethics: Opinion no. 32 of 5 July 2004 on the free availability of genetic tests, 2004, http://www.health.fgov.be/bioeth.

[273] National Consultative Ethics Committee for Health and Life Sciences: Opinion no. 86. Problems connected to marketing self-kits for HIV screening and diagnosis of genetic disease, 2004, http://www.ccne-ethique.fr.

[274] National Council for Ethics in the Life Sciences: Opinion no. 56 on direct marketing of genetic tests to the public 2008, http://www.cnecv.pt/admin/files/data/docs/ 1273504469_56CNECV2008_EN.pdf.

[275] Gezondheidsraad 2007.

[276] Raad voor de volksgezondheid 1999.

on DTC genetic testing.[277] In Germany, DTC genetic testing has been discussed in relation to new legislation[278] and in a report elaborated by German National Academy of Sciences.[279] This demonstrates that this is a key issue across Europe, and there has been considerable debate around the best way to regulate this area.

5.3. RESULTS

Belgium

In Belgium, no specific legislation forbids or regulates the provision of DTC genetic tests. A Royal Decree of 14 December 1987 (published in the Belgian Official Journal of 25 December 1987) lays down the rules for the provision of genetic testing in the Centres for Human Genetics in Belgium. Genetic examinations are only reimbursed by statutory health insurance if they are carried out at one of the eight recognized Centres for Human Genetics. No information is provided about the potential provision of genetic testing outside this context. The only legal basis applying to DTC genetic tests could be found in Article 2 of the Law on the practice of health-care professions (Royal decree n°178 (B.S. 14.11.1967)), which stipulates that a physician should be involved in the practice of medicine. Hence, if a DTC genetic test falls under the practice of medicine, as a consequence, a physician should be involved and the law on patient rights would apply. In this respect, it is important to determine whether a DTC genetic test could be considered the 'practice of medicine'. As we know, most DTC companies write in their 'terms of services' that they are not practicing medicine, and that their tests should not be considered medical information, but only serve 'informational purposes'. Whether or not this statement would stand further legal or judicial scrutiny has yet to be proven.

France

In France, genetic tests are well described and framed in the context of health, and this legislation could apply to the DTC context. According to the French Law (Article 16–1 Civil Code) genetic tests can only be performed for an individual for 'medical or scientific research purposes'. When accomplished in a medical context, the genetic analysis should fulfil one of the following elements: (a) to give, confirm or refute the diagnosis of genetic disease for an individual; (b) to detect characteristics of one or more genes, which may be the cause of developing a disease by a person or family members potentially affected; or (c) to adapt the medical care of a person according to its genetic characteristics (Article R1131-1 Public Health Code). As a consequence, there

[277] Swiss Society of Medical Genetics Tests 2011.
[278] Katz & Schweitzer 2010, p. 90-197.
[279] German National Academy of Sciences: Predictive Genetic Diagnostics as an Instrument of Disease Prevention. Halle: German National Academy of Sciences, 2010.

is no possibility in France to access a genetic test for another aim, for example, just to obtain information. Moreover, the Public Health Code provides some complementary provisions with regard to (a) the quality of laboratories and training of scientists and (b) the respect of the medical relationship. First, in order to perform genetic tests in France, laboratories need to get a specific authorization delivered for 5 years, by the Head of the Regional Agency for Health after consultation of the Biomedicine Agency (Article R1131-14, Public Health Code). In the same way, geneticists must conform to specific requirements to perform genetic tests. They must be specifically trained to be able to verify the results of a genetic analysis (Articles R1131-6 and R1131-7, Public Health Code). Second, the use of genetic tests in the clinical context means that the relationship between the user (patient) and the provider (medical doctor) should be defined as a 'medical relationship'. Any other use outside of this context is outlawed and cannot be covered by the following provisions. The French Law gives details on the respect of various duties regarding the terms of the patients (or their family) information, the test prescription and the announcement of the results (Articles R1131-4 and following). The law is also strict on the requirements for consent, which must be obtained in writing after the patient has been informed of the nature and the purposes of the test. This regulation insists on the importance of the quality of the information delivered by a medical doctor or explained by a genetics counsellor.

During the revision process of the French Bioethics Law (Law 2004–800 of 6 August 2004 on Bioethics, JO 182 of 7 August 2004 adapting the Law 94–653 of 29 July 1994 on respect for the human body and the Law 94–654 of 29 July 1994 on the gift and use of parts and products of the human body, for medical assistance to procreation and prenatal diagnosis), some of the preparatory reports underlined the necessity to elaborate specific provisions with regard to DTC genetic testing. Considering that DTC tests are being offered internationally and that anticipating the scope of the consumer demand in France will be very difficult, these reports have encouraged the legislator to adopt two kinds of provisions. The conclusions of the reports proposed that, first, prohibition for individuals to use the results of these tests in France should be enshrined in law, and, second, that the Biomedicine Agency should be charged to watch the websites offering these tests to ensure their quality and validity (Parliamentary Office on Scientific and Technological Choices (evaluation of the application of the Law of 6 August 2004 on Bioethics, 20 November 2008), Biomedicine Agency (the evaluation of the Law of 6 August 2004 on Bioethics, 2008), information mission on the revision of the Bioethics Law (Information Report n° 2235, deposited on 20 January 2010)).

Finally, the new Bioethics Law that entered into force on 7 July 2011 (Law n°2011-814 of 7 July 2011, published JORF n°0157 8 July 2011, page 11826) has implemented most of these proposals. The most significant of these is that from the persons' rights perspective, for the first time the French Public Health code prohibits a person from requesting a genetic test for herself or for a third person, or for identification through

her DNA profile, outside the conditions laid by the law (Article L.1133-4-1). This action is punishable under the Article 226-28-1 of the criminal code by a fine of 3.750 Euro. Second, from the institutional perspective, the French Bioethics Law reinforces the conditions to be fulfilled by the laboratories, which perform genetic tests. In particular, the new Article L. 1131-2-1 (Public Health Code) specifies that the study of the genetic characteristics of a person or the identification of a person through his DNA profile can only be performed by authorized and accredited laboratories (which excludes companies that are not considered as laboratories). Finally, the Biomedicine Agency is unlikely to be in charge of website surveillance due to the difficulty of such a management. Nevertheless the new law added a new mission for the Agency to 'make information about the uses of direct to consumer genetic tests available to the public and to elaborate a benchmark for the evaluation of their quality' (Article L. 1418-1 paragraph 9, Public Health Code). The modalities to implement this measure are not given by the law. It will be up to the Biomedicine Agency to act as an independent body and to choose the best way to ensure and fulfil this mission.

Germany

In Germany, there is no legislation that specifically addresses the issue of DTC genetic testing. However, on 24 April 2009 the German Bundestag passed the Human Genetic Examination Act (The Genetic Diagnosis Act, GenDG),[280] which covers some aspects of these genetic testing services. A prior aim of this law, which came into effect on the 1 February 2010 (sec. 27 para. 1; for divergences, see sec. 27 para. 2 to 4), is on one hand the strengthening of the right to informational self-determination concerning the execution of diagnostic or predictive genetic tests, and on the other hand the protection against abusive use of the information originating from genetic testing and screening. The Act, however, focuses on tests carried out under specific circumstances. As sec. 2 para. 1 points out, the Act only applies to genetic examinations and genetic analyses conducted within the framework of genetic examinations involving born natural persons, as well as embryos and foetuses during pregnancy and the handling of genetic data and genetic samples gained thereby for medical purposes, for purposes of determining descent as well as in the insurance and employment sectors. This Act does not apply to genetic analyses or the handling of genetic samples or genetic data conducted for research purposes or on the basis of applicable regulations relating to criminal procedures or the Infection Protection Act.

According to sec. 7 para. 1 of the Act, a diagnostic genetic examination may only be undertaken by physicians and a predictive genetic examination may only be undertaken by medical specialists in the field of human genetics or other physicians who have

[280] Bundesrat Gesetz über genetische Untersuchungen bei Menschen (Gendiagnostikgesetz-GenDG) [Human Genetic Examination Act (The Genetic Diagnostis Act)] 2009, http://www.gfhev.de/de/startseite_news/2009_GenDG_mit_freundl_genehmg_Baz_ Verlag.pdf (accessed 19 April 2011).

qualified themselves via the acquisition of some specialist designation for genetic examination within their specialist area. Para. 2 states that the genetic analysis of a biological sample may only be carried out within the scope of a genetic examination and by the medical person in charge or by person or institution commissioned by the responsible medical doctor. Para. 3 finally declares that genetic counselling according to sec. 10 may only be undertaken by physicians named in para. 1 and who are qualified to provide genetic counselling.

Furthermore, a precondition for valid informed consent is the clarification presented in sec. 9 para. 1–3: 'Before obtaining consent, the medical person in charge must inform the person concerned on the nature, meaning and consequences of the genetic examination. After being informed the person concerned must receive sufficient time for consideration before deciding to provide consent. The clarification covers in particular: (1) the purpose, type, scope and significance of the genetic examination including the results attainable in the course of the purpose of the examination and with the designated means of examination; the foregoing also includes any genetic characteristics which are to be examined and which are significant in terms of avoiding, preventing or treating any illness or health condition; (2) the health risks for the person concerned which are connected to the knowledge of the results of the genetic examination and the procurement of the necessary biological sample (…); (3) the intended use of any sample as well as the results of any genetic examination or analysis; (4) the right of the person concerned to revoke his or her consent at any time; (5) the right of the concerned person to not have to know results (….)'.

Under this legislation, the DTC provision of genetic tests in Germany is clearly restricted. Genetic tests can only be carried out by a medical doctor after the provision of sufficient information concerning the nature, meaning and consequences of the genetic test, and after the consent of the person concerned. The German Law described in this article does not regulate tests for research purposes, but companies cannot just avoid this legislation by suggesting that their tests are for research and educational purposes only. However, the mere sale of test kits and the application of DTC GT outside the areas described are not prohibited *per se*, and individuals purchasing tests from abroad will not be penalized. Finally, it must also be noted that the legal discussion of the DTC problem has just begun and therefore many questions are still open. In particular, the relevance of self-determination as a legal concept and the degree to which German Law requires protection of the person concerned from their own decisions remains to be clarified.

The Netherlands

The Netherlands has no legislation that specifically addresses DTC genetic testing.[281] In principle, companies are allowed to offer DTC genetic tests to the public. However, the Dutch Act on population screening (henceforth Act),[282] by way of a permit system, seeks to protect individuals against screening programmes that may be a threat to health. This legal framework was introduced to establish and guarantee a fair balance between the right of self-determination individuals and the need to protect them against (potentially) harmful screening programmes.[283] Hence, although the Dutch Act on population screening was not developed to regulate the access and the use of DTC genetic tests specifically, it does apply to certain of these tests.

In this Act, population screening is defined as 'a medical examination which is carried out in response to an offer made to the entire population or to a section thereof and to detect diseases of a certain kind or certain risk indicators, either wholly or partly for the benefit of the persons examined'.[284] The key word in the definition is 'offer'. DTC genetic tests that predict diseases on the basis of risk indicators fit within this definition due to the fact that companies advertise and offer their genetic tests directly to the public in magazines, newspapers and through the Internet. The fact that individuals visit the website or the web shop of 'test companies' on their own initiative makes no difference when classifying DTC genetic tests as population screening.

According to the Act, some forms of DTC genetic tests can only be carried out with a permit issued by the Dutch Minister of Welfare and Sports. Offering and practicing DTC genetic tests for detecting (risk factors of) cancer and (risk factors of) 'incurable' diseases – which can neither be treated nor prevented – without a licence is against the law in the Netherlands. Moreover, performing these tests without permission is a punishable offence (Article 3 (1) and Article 13).[285] Based on Article 7, the responsible Dutch Minister can refuse to provide a licence if a test is scientifically unsound, is not in accordance with the professional medical practice standards or if the expected benefit is not in balance with the (potential) health risks. The Act does not set up quality norms for the information to be provided to consumers of DTC genetic tests nor for consent to use samples and counselling to be provided. Nevertheless, DTC genetic testing companies wishing to sell genetic tests for detecting (risk factors of) cancer and (risk factors of) 'incurable' diseases have to comply with the professional medical practice

[281] R.E. Hellemondt, A.C. Hendriks & M.H. Breuning, 'Regulating the use of genetic tests:is Dutch law an example for other countries with regard to DTC genetic testing?', *Amsterdam Law Forum* 2011, p.13-24; p. 13-24; Bonneau et al. 2010, p. 396-401; Kaye 2008, p. 180–183; Borry 2008, p. 736–737.

[282] Wet op het bevolkingsonderzoek [Dutch Act on population screening], http://wetten.overheid.nl/BWBR0005699/geldigheidsdatum_09-02-2010 (accessed 19 April 2011).

[283] Van der Maas et al. 2000.

[284] Wet op het bevolkingsonderzoek [Dutch Act on population screening], http://wetten.overheid.nl/BWBR0005699/geldigheidsdatum_09-02-2010 (accessed 19 April 2011).

[285] Wet op het bevolkingsonderzoek [Dutch Act on population screening], http://wetten.overheid.nl/BWBR0005699/geldigheidsdatum_09-02-2010 (accessed 19 April 2011).

standards, which entail the main rights of patients laid down in the Dutch Civil Code. Furthermore, the Dutch 'Medical Treatment Contracts Act', as part of the Dutch Civil Code, applies to all contracts whereby a health-care provider undertakes to provide medical services. The main purpose of this 'Act' is to clarify and strengthen the legal position of the patient. It lays down the rights and obligations of care providers and the patient. Among other rights, it sets up quality norms for the information to be provided, for obtaining consent and how to deal with confidential patient data. According to the 'Medical Treatment Contracts Act', health-care providers have to give information about the indication, the proposed treatment, alternatives, prognoses, risks and possible side effects before starting with a medical intervention.

The Dutch permit system guarantees normative criteria for DTC genetic tests aimed at detecting (risk indicators of) cancer and (risk indicators of) 'incurable' diseases. This legal framework effectively prevents individuals from getting access to some DTC genetic tests, with a questionable validity and clinical utility in the Netherlands.

However, from the beginning there was confusion about the scope of the Act, and thus uncertainty about the requirement of obtaining a licence. The Health Council – a scientific advisory body – has been allotted the task of advising the Minister on the provision of a licence to applicants under the Act (Article 6). The Dutch Health Council has written several reports to clarify the scope of the Act. Despite these helpful reports certain uncertainties remain that are probably inherent to the use of terms like 'population screening', 'offer' and incurable'. In the light of these difficulties, already more than 10 years ago there was a call to revise the Act in order to enhance its effectiveness.[286]

Portugal

In Portugal, the Law n°12/2005 of 26 January 2005[287] defines the concept of health information and genetic information, and sets forth rules for the collection and preservation of biological products for genetic testing for clinical or research purposes. In Article 10 of this law, different genetic tests are categorized based on use: tests to be used for the detection of carriers of recessive disorders; pre-symptomatic tests for monogenic diseases; predictive tests allowing the detection of susceptibility genes; pharmacogenetic tests; prenatal tests and tests used for screening. According to Article 9.2 of the Law n°12/2005, the detection of the heterozygosity status of recessive diseases, the presymptomatic diagnosis of monogenic diseases and the tests for genetic susceptibility in healthy persons can only be carried out by request of a medical geneticist, following a genetic counselling consultation and subject to the express

[286] Van der Maas et al 2000.

[287] *Lei n°12/2005. Informação genética pessoal e informação de saúde [Personal genetic information and health information law]* http://dre.pt/pdf1sdip/2005/01/018A00/06060611.pdf Accessed 19 April 2011, 2005).

written and informed consent of the person in question. Article 9.7 also advances that in situations of risk of severe, late-onset diseases that appear in the beginning of adulthood and that have no cure or proven effective treatment, the performance of any presymptomatic or predictive testing must be preceded by a previous psychological and social evaluation and by the follow-up of the patient after the delivery of the tests results. Besides, Article 17.3 also states that every citizen has the right to receive genetic counselling and, if appropriate, psychological and social support, before and after heterozygosity, presymptomatic, predictive or prenatal genetic tests. In this context, it is also important to state that Portugal ratified the Oviedo Convention,[288] through Presidential Decree n°101/2001, which means that the aforementioned Convention has force of law throughout the national territory. According to Article 12 of this convention, 'tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes and subject to appropriate genetic counselling.'[289] Finally, in July 2008, the National Council of Ethics for the Life Sciences[290] issued an opinion that genetic testing for health purposes should not be offered directly to the public, in compliance with fundamental ethical principles. This document is not a legally binding document.

Based on these provisions, various jurists advance that DTC genetic testing is forbidden in Portugal.[291] However, Article 15 of Law n°12/2005 still attributes responsibility to the Government to regulate the conditions of availability and performance of genetic testing. This is meant to prevent that tests are made available by national or foreign laboratories that do not have the support of a proper and multidisciplinary medical team, and to avoid the possible over-the counter marketing of this type of tests. Notwithstanding this legal provision and an Order, issued in September 2008, by the Ministry of Health,[292] creating a work force to regulate the Law n°12/2005, there are still no regulations that determine measures for accreditation, certification and licensing of public and private laboratories responsible for genetic testing. As a consequence, there is no specific legislation addressing DTC genetic testing enacted yet, and according to some authors, no real legal provisions prohibiting DTC genetic testing services.

[288] Council of Europe: Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. Oviedo: Council of Europe, 1997.

[289] Council of Europe: Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. Oviedo: Council of Europe, 1997.

[290] National Council for Ethics in the Life Sciences: Opinion no. 56 on direct marketing of genetic tests to the public 2008, http://www.cnecv.pt/admin/files/data/docs/

[291] Sequeiros J: Personal Communication, e-mail 3 March 2011.

[292] Direcção-Geral da Saúde *Despacho N° 22784/2008* http://dre.pt/pdf2sdip/2008/09/172000000/3874338743.pdf Accessed 19 April 2011, 2011).

Switzerland

In Switzerland, the conditions under which human genetic testing may be performed has been regulated under the *Federal Act on Human Genetic Testing*[293] from 8 October 2004.[294] The genetic tests offered directly-to-consumers correspond to the definition of 'genetic *in vitro* diagnostic medical devices' as formulated by Article 3j of the above mentioned law: 'ready-to-use products for the determination of characteristics of human genetic material'. Those tests are covered by Article 9 of this Act that reads as follow: '(1) It is forbidden to supply genetic *in vitro* diagnostic medical devices to individuals for a purpose which cannot be considered part of those individuals' professional or commercial activities; (2) The Federal Council may, having consulted the Expert Commission for Human Genetic Testing, make provision for exceptions to this prohibition provided the products are used under medical supervision and misinterpretation of the test result is not possible'.

The Act has been completed by two ordinances: the Federal Council Ordinance on Human Genetic Testing from 14 February 2007[295] and the Federal Department of Home Affairs Ordinance on Human Genetic Testing from 14 February 2007.[296] None of these regulations provide for an exception to Article 9 of the Act prohibition for DTC genetic testing. To the best of our knowledge, no one has yet requested from the competent authorities the right to benefit from the exceptions mentioned in the Act. One could therefore conclude that such tests remain unlawful in Switzerland.

In fact, the Act[297] makes it a criminal penalty to infringe this prohibition as stated in Article 38: '(1) Any person who, in contravention of Article 9 paragraph 1, wilfully supplies genetic *in vitro* diagnostic medical devices to individuals for a purpose which cannot be considered part of those individuals' professional or commercial activities shall be liable to a fine; (2) If the act is committed for commercial gain, the penalty shall be a custodial sentence not exceeding three years or a monetary penalty'.

Yet, it should be underlined that the prohibition or at least the severe restriction of the law is limited to putting those devices on the market, and not the use of them. There is no explicit sanction in the law against someone who imported such test for his or her personal use. The issue is indeed very similar to the one importing any therapeutic products. In practice, this is tolerated by the law as long as it remains limited to personal use and does not present a risk in terms of public health. For genetic testing, there is still another dimension as there are many companies advertising on the internet

[293] Federal Assembly of the Swiss Confederation: Federal Act on Human Genetic Testing 810.12 2004, http://www.admin.ch/ch/e/rs/8/810.12.en.pdf (accessed 19 April 2011).

[294] Sprumont 2004, p. 71–88.

[295] Federal Assembly of the Swiss Confederation: Federal Council Ordinance on Human Genetic Testing. 810.122.1 2007, http://www.admin.ch/ch/f/rs/8/810.122.1.fr.pdf (accessed 19 April 2011).

[296] Federal Department of Home Affairs: Ordinance on Human Genetic Testing 810.122.122.

[297] Federal Assembly of the Swiss Confederation: Federal Act on Human Genetic Testing 810.12 2004, http://www.admin.ch/ch/e/rs/8/810.12.en.pdf (accessed 19 April 2011).

that offer simple and rather inexpensive paternity tests.[298] The key point in this case is that the test requires testing not only the potential father(s) but also the child. When the latter is a minor, there is a clear conflict of interest for the 'father' to consent for him or her, especially when he is not actually the legal father. Courts have already decided that such tests are invalid and could not be used to challenge the family links between a man and a child. There could also be an issue of liability as the test could be considered as an infringement of the personal rights of each person whose DNA is analysed without their consent[299] – without mentioning his or her legal parents if their family relationship is denied – and therefore open the way for obtaining indemnities.

United Kingdom

Within the UK, there is no specific legislation that relates to genetic testing in general and nothing that addresses DTC in particular. However, if a DTC genetic testing company operated in, and from, the UK, it would have to comply with a wide range of legislation and other regulatory factors. There are a number of statute-based Laws that a UK-based DTC company should be aware of, all of which are at least partly anchored in the realm of consumer protection. These legal instruments – variously acts (or 'primary legislation' made by the UK Parliament) and regulations (or 'secondary legislation' typically made by a senior Minister authorized by primary legislation) – for the most part reflect a wider, harmonized European position (i.e. on medical devices, general consumer protection, advertisements, contractual terms or data protection). While these laws are not unique to the UK, there are provisions in the UK Human Tissue Act 2004 – legislation primarily concerned with the use of biological samples rather than data – that criminalize genetic analysis of human tissue without the consent of the donor. Obtaining the valid consent of genetic test consumers in the UK is therefore extremely important.

The common law system in the UK provides another layer of law, through which judge-made decisions can either serve to clarify the application of existing legislation or 'fill in the gaps' where there are no appropriate acts or regulations. There have, as yet, been no court or tribunal decisions concerning matters pertinent to DTC genetic tests, meaning that the most relevant aspect of the common law will be the general obligations of confidentiality applicable to the test results provided to consumers. Such obligations will, of course, overlap with many of the responsibilities created by Data Protection Law.

The most relevant, and recent, regulatory instrument that applies to DTC genetic tests in the UK comes in the form of a voluntary set of guidelines drawn up by the UK HGC: an advisory, rather than a regulatory body. The 2010 'Common Framework of Principles'

[298] Sprumont et al. 2003, p. 1280-1290.
[299] Büchler 2005, p. 32-44.

aims to 'promote high standards and consistency' in the provision of DTC genetic tests by commercial providers, so as to 'safeguard the interests' of consumers and their families.[300] The HGC Principles cover matters such as information to be provided to prospective consumers, counselling and continuing support, the role of consent, laboratory processes, the provision and interpretation of results, and complaints procedures. It will be interesting to see how many companies – based in the UK and elsewhere – make a point of demonstrating compliance with the HGC Principles, particularly as the HGC is soon to be disbanded as part of the UK Government's current cost-cutting drive. Finally, other regulatory schemes that DTC genetic test companies should be aware of include voluntary accreditation schemes for testing undertaken in laboratories (for example, those offered by the United Kingdom Accreditation Service), codes of practice relevant to certain types of advertising and general consumer-facing business practices. (Dealt with the Advertising Standard Authority and The Office of Fair Trading, respectively).

5.4. DISCUSSION

This report provides an overview of national legislation in seven EU countries with regard to DTC genetic testing services. All countries discussed have national legislation that partly or fully applies to DTC genetic testing. However, none have legislation that was created specifically to regulate DTC genetic testing services and therefore it was necessary to use analogy or interpretation of existing legislation. A common pattern was that the legislation in many of the countries stipulated that genetic tests should be offered only under medical supervision and with genetic counselling. This is the case in France, Germany, the Netherlands, Portugal and Switzerland. In these countries, the underlying premise is that individuals should be given the opportunity to make their decisions freely and this should be based on adequate information about the limitations of (DTC) genetic tests and their (physical, psychological and social) implications.

This position is in line with the latest developments within Europe regarding the regulatory control of genetic testing, which is found in the 2008 Additional Protocol to the 1997 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the application of Biology and Medicine, concerning Genetic Testing for Health Purposes.[301] This Additional Protocol (although not currently binding) is the first European legal instrument in this area and has been opened for signing since

[300] Human Genetics Commission: A Common Framework of Principles for Direct-to-Consumer Genetic Testing Services 2010, http://www.hgc.gov.uk/Client/document.asp?DocId=280&CAtegoryId=10 (accessed 2 May 2011).

[301] Council of Europe: Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes 2008, http:// conventions.coe.int/treaty/en/treaties/html/203.htm (accessed 17 January 2012).

November 2008. The original European Convention on Human Rights and Biomedicine states in Article 12 that 'tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling'. The 2008 Additional Protocol on genetic testing stated in Article 7 §1 that 'a genetic test for health purposes may only be performed under individualised medical supervision'.[302]

In the Explanatory Memorandum to the Protocol, which is important for the interpretation of the Protocol, it is explained that Article 7 §1 has been 'driven by the concern to enable the person concerned to have suitable preliminary information with a view to an informed decision regarding the carrying out of this test and, if appropriate, to have access to appropriate genetic counselling. A precise evaluation of the situation of the person concerned, involving direct contact with him of her, is a determining element in that respect. A mere telephone conversation with a medical doctor, for example, does not allow for such evaluation'.[303] In addition, the protocol states that genetic tests should meet well-accepted criteria of scientific validity and clinical validity (Article 5), and that clinical utility of genetic tests should be an essential criterion for deciding to offer a test to a group of persons (Article 6). Moreover, it underlines that individuals should be provided with prior appropriate information and appropriate genetic counselling (Article 8). This legislation mirrors the recommendation that was expressed by some professional organizations. For example, the American Medical Association advanced in a letter to the American Food and Drug Administration that 'genetic testing, except under the most limited circumstances, should be carried out under the personal supervision of a qualified health-care professional, and provide individuals interested in obtaining genetic testing access to qualified health-care professionals for further information'.[304] Although the Committee of Ministers of the Council of Europe approved the additional protocol, this document has until now only been signed in Finland, France, Iceland, Luxembourg, Moldavia and Slovenia. The two last countries have also ratified it in their internal legislation.

It is also evident that there will need to be further debate to define the type of services (and information) offered by DTC genetic testing companies, and whether or not this is relevant in legal terms. There have been attempts to clearly distinguish 'medical

[302] Council of Europe: Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes 2008, http:// conventions.coe.int/treaty/en/treaties/html/203.htm (accessed 17 January 2012).

[303] Council of Europe: Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes 2008, http://conventions.coe.int/Treaty/EN/Reports/Html/203.htm (accessed 17 January 2012).

[304] American Medical Association: AMA letter to the FDA regarding molecular and clinical genetics panel of medical devices advisory committee 2011, http://www.ama-assn.org/ama1/pub/upload/mm/399/consumer-genetic-testing-letter.pdf (accessed 27 April 2011).

genetic tests' (which are to be ordered by a healthcare provider and which are used to make a treatment decision or diagnosis) and 'informational genetic tests' (which could be ordered directly by an individual and which aim to gain a better understanding of general health and disease susceptibility).[305] Most DTC genetic testing companies are adamant that the genetic information they provide to consumers is 'not intended to substitute for professional medical advice, diagnosis or treatment' and that this information is only for informational purposes.[306]Almost every company provides disclaimers on their website and consent forms with the aim to inform consumers of the limitations of the tests that they are providing as well as to give themselves some protection from liability. In countries such as France, the Netherlands, Portugal and Switzerland such a distinction doesn't seem to influence the application of the relevant regulation, but in Belgium and Germany such a distinction has a role in the interpretation whether or not a DTC genetic test would be covered by the law.

The Netherlands have a quite unique permit system that guarantees normative criteria for DTC genetic tests aimed at detecting risk indicators of cancer and of 'incurable' diseases. This legal framework aims to prevent individuals from getting access to DTC genetic tests with a questionable validity and clinical utility in the Netherlands. The problem with these different regulatory approaches is enforcement. National enforcement measures can easily by bypassed because DTC tests are offered through the internet. Without an international regulatory framework, the enforcement of whether or not a company is adhering to several national or regional legislations is based on voluntary compliance by the company. We observed that some DTC genetic testing companies respect the fact that DTC genetic testing is outlawed in certain American States, and state on their website that they do not process samples submitted from citizens from these states.

The protection of individuals against questionable testing services calls for international vigilance and comprehensive measures by the international community. As international regulatory oversight is difficult to achieve, considerable effort has put into working with the DTC industry in order to develop a code of practice.[307] It has also been suggested that an international product quality certificate (such as an International Standards Organisation (ISO)) should be introduced that controls for compliance with ethical standards, provisions for counselling and stringent standards of scientific validity.[308]

[305] Personalized Medicine Coalition: An Introduction to Informational Genetic Testing 2008, http://www.personalizedmedicinecoalition.org/sites/all/themes/zen_pmc/documents/Medco-PMC-consumer-genetics.pdf (accessed 17 January 2012).

[306] Howard & Borry 2009, p. 11–13; Kaye 2008, p. 180–183.

[307] Human Genetics Commission: A Common Framework of Principles for Direct-to-Consumer Genetic Testing Services 2010, http://www.hgc.gov.uk/Client/ document.asp?DocId=280&CAtegoryId=10 (accessed 2 May 2011).

[308] Hauskeller 2011, p. 2317.

Effort is also being put into improving the functioning of *in vitro* diagnostics medical devices regulations.[309]

5.5. CONCLUSION

In this paper, we have focussed on national initiatives from European countries rather than on the European Union Framework itself. We have demonstrated that there are differences in approaches as well as similarities between countries within Europe. However, as Europe is a *sui generis* multilevel system of governance, Europe's regulatory framework is required to respond not only to processes of economic and political integration but also seek to harmonize rules at a transnational level regarding health and consumers protection. Therefore, in the challenge is whether it is possible to provide uniform normative guidance for DTC genetic testing across all European States, when there are different national legal systems and different methods have been used to regulate DTC.

ACKNOWLEDGEMENTS

HCH is funded by the European Commission FP7 Marie Curie initiative. REV is funded by the Centre for Society and Genomics in the framework of the Netherlands Genomics Initiative. JK is funded by the Welcome Trust WT081407/Z/06/Z; LC is funded by the European Commission FP7 project BIOSHARE; ERS is supported by the TEGALSI contract Institut de recherché en sante´ publique (Services de sante´–politiques publiques et sante´ 2009).

[309] Eurogentest: Official Response of the EuroGentest Network of Excellence in Genetic Testing to the Public Consultation on the Revision of Directive 98/79/ec of the European Parliament and of the Council of 27 October 1998 on in vitro Diagnostic Medical Devices 2010, https://www.eshg.org/fileadmin/www.eshg.org/documents/received/Euro-GentestResponseToIVDDRevisionConsultation.pdf (accessed 2 March 2011); European Society of Human Genetics: Official Response of the European Society of Human Genetics to the Public Consultation on the Revision of Directive 98/79/ec of the European Parliament and of the Council of 27 October 1998 on in vitro Diagnostic Medical Devices 2010, https://www.eshg.org/fileadmin/www.eshg.org/documents/ ESHG/ESHG-IVD-def.pdf (accessed 2 March 2011).

CHAPTER 6

DUTCH POPULATION SCREENING ACT IS AT ODDS WITH EU LAW

Abstract: *The Dutch Government is concerned that individuals may have their genetic map decoded via internet and without the intervention of medical specialists or other experts. Although companies established in other countries are able to carry out this testing, Dutch companies also make use of services from providers located across abroad. In this way the individual receives information concerning the risk of contracting hereditary diseases. This online sale is at odds with Dutch legislation. As a result, a 'foreign route' has been created, whereby consumers and companies can quite easily sidestep Dutch law. This chapter examines the freedom of the Dutch State as an EU-Member to regulate the access to and supply of commercial genome sequencing. At the same time Dutch legislation is examined in light of European yardsticks and appears not to be EU-proof.*

R.E. van Hellemondt, A.C. Hendriks & M.H. Breuning, 'Wet bevolkingsonderzoek op gespannen voet met EU recht', *Nederlands Tijdschrift voor Europees Recht* 2010, p. 245-251.

6.1. INTRODUCTION

Health is for sale and manageable if we are to believe the website of the company 23andMe.[310] VARA-presenter Menno Bentveld put it to the test in the programme 'Nieuwslicht'. He sent a DNA sample to the provider[311] for the 'decoding' of his genetic map via a toolkit ordered on the internet. This is known as the sequencing of the genome. After a few weeks, a password gave access to the results on internet. The results show that the presenter has a 24 percent risk of getting prostate cancer. This is 33 percent more than the reference value of 18 percent. Besides this, he has a risk of 1.3 percent of diabetes mellitus, compared to the reference value 1 percent. For a layman the significance of these risks given in percentages is difficult to grasp. The presenter asked clinical geneticist Martijn Breuning to interpret the test results. The risk that Bentveld will die *with* a mild type of prostate cancer is many times higher than that he dies *of* prostate cancer.

Sequencing the genome of people without health problems and/or indications of hereditary diseases or disorders in the family, from the point of healthcare does not have any added value at the moment. Nevertheless, the provision of genome sequencing is a lucrative market where businesses are able to grow. Dutch consumers also make use of these companies. Foreign providers of commercial genome sequencing are not 'hindered' by the Dutch laws due to the fact that companies make use of 'foreign constructions',[312] thus enabling cross-border movement.

In the Netherlands strict requirements apply to screenings, that is to say: restrictive measures. This is due to the specialised nature of the process and the associated legal, ethical and social implications. The Dutch Act on population screening[313] (hereinafter abbreviated to WBO)[314] sets quality requirements for screenings, which are classified as population screening. Dutch policymakers feel the need to regulate[315] the cross-border access to, and supply of, commercial genome sequencing in accordance with the Dutch legal framework.[316] This is synonymous with curbing the industry. Banning, licensing or setting up a quality mark for commercial genome sequencing on the internal market is a barrier to the free movement of services and the freedom of establishment. This leads to interesting questions of European Union law regarding the freedom for Member States regarding the regulation of health services.

[310] https://www.23andme.com/

[311] In general the suppliers of DTC genetic tests are also the providers of these tests.

[312] Companies in the Netherlands make use of the services of companies and/or healthcare workers that are established in Belgium, Germany or elsewhere, or these companies have branches or institutions outside the Netherlands and use these branches for the genome analyses.

[313] Wet op het bevolkingsonderzoek.

[314] *Stb.* 1992, 611(Wet op het bevolkingsonderzoek).

[315] Commercial genome analysis refers to the sequencing of the genome without a medical indication by private companies.

[316] Roscam Abbing 2009, p. 535; GR 2008; RVZ 2008.

The subject of this chapter is the freedom of EU Member States to regulate the access to, and supply of, commercial genome sequencing within their national borders and the consequences that this may have for the Netherlands. This chapter opens with a short description of the concept of sequencing the genome and the risks of analysing the genome for healthcare purposes. thereafter, attention shifts to a description of how the Netherlands currently regulates the access to commercial genome sequencing (section 6.3). Subsequently, the case law of the Court of Justice of the EU (henceforth: ECJ) regarding the freedom for States to regulate health services will be examined. At the same time, the extent to which the Dutch methods for regulating commercial genome sequencing against the European yardstick (section 6.4) will be determined. After that attention is paid to the importance of the E-Commerce Directive[317] for the access to commercial genome sequencing on the internet. Lastly, an answer will be provided to the central question of this chapter, thus concluding that the current methods employed in the Netherlands to regulate commercial genome sequencing is not EU-proof (section 6.5).

6.2. SEQUENCING THE GENOME AND THE RISKS

The genome is the genetic material of a body cell. In practice, the sequencing of the genome means the examination of a part of the genome for certain variations and mutations that are associated with hereditary diseases and disorders. The distinction between monogenetic and multifactorial hereditary diseases and disorders is of importance in this process. Monogenetic hereditary diseases are caused by a mutation of one gene and multifactorial genetic disorders by a combination of genetic and non-genetic factors, such as lifestyle and environmental factors.[318] In genetic mutations, which correspond with monogenetic disorders, it can be determined with great certainty if someone has a hereditary disorder and is going to develop symptoms of the disease in the future.[319] Testing for multifactorial genetic diseases provides information about the risk of getting certain hereditary diseases.

In commercial genome analyses, fragments of the genome are screened mainly for multifactorial genetic diseases. Consumers can order a toolkit via internet, without a medical reason[320] and without the intervention of a medical specialist. The toolkit comprises a laboratory tube to collect a DNA sample, usually saliva. The consumer then sends the DNA sample to the provider. The DNA-material is first decoded in a laboratory

[317] Directive 2000/31/EC, *OJ* 2000, L 178/1.
[318] Pieters & Meijman 2008, p. 291.
[319] Maassen 2006, p. 772-775.
[320] A medical indication is a medical reason for a medical examination (DNA diagnostics) established by a professional.

(the genome is broken into small pieces and reassembled in the right order) and then analysed using software (compare variations and mutations). The provider calculates on the bases of the collected data the risks of certain hereditary diseases. The risk profile is established using the scientific knowledge of that moment. The risk calculations and the test results are influenced by the number of people who are tested, the number of variations and mutations which are found, the available knowledge about the interplay between genes and the environmental factors. The way in which providers inform the consumers about the test results varies. Consumer often receive an internet account from the provider for viewing and regular *'upgrading'* the test results.
In relation to the current scientific knowledge about the interaction of genes and external factors, the benefit of commercial genome sequencing is minimal. It calls into question whether consumers are actually aware of the limited predicted value of commercial genome sequencing. Furthermore, commercial genome sequencing can lead to false negative or false positive test results and thus to unjustified reassurance or anxiety. Moreover, health costs can increase due to the demand for reappraisal of test results, follow-up tests and overtreatment in the 'mainstream circuit'.
In short, the predictive value of commercial genome sequencing is limited, certainly in multifactorial diseases, and there are few treatments available. At present, the health risks of commercial genome sequencing are considerably greater for the person concerned than the benefits

6.3. DUTCH ACT ON POPULATION SCREENING

Dutch legislation sets requirements for the access to and supply of commercial genome sequencing in order to protect individuals against harmful screenings. A licence is required to offer and/or perform commercial genome sequencing, because the variations and mutations which are found during the analysis are compared with variations and mutations which are associated with hereditary forms of cancer and untreatable disorders.[321]
The WBO provide quality safeguards for screenings which are classified as population screening. The Act aims to protect individuals from population screening that can be harmful to the physical or mental health of the people being tested.[322] Article 1(c) defines population screening as follows: 'a medical examination which is carried out to an offer made to the entire population or to a section thereof and to detect of diseases of a certain kind or certain risk indicators, either wholly or partly for the benefit of the persons examined'. 'Offer' is according to the WBO not just actively inviting individuals,

[321] GR 2009, p. 13.
[322] Van der Maas *et al*. 2000, p. 7.

but also the passive 'seduction' of people via adverts on websites and magazines and newspapers to undergo a screening.[323]

Due to the (potential) health risks, a licence is required for the offering and/or performing of population screening using ionising radiation, for (risk-indicators for) cancer and untreatable diseases due to the (potential) health risks. In accordance with the WBO the Minister of Health, Welfare and Sports grants a licence when the population screening is scientifically sound, in accordance with the professional medical practice standard and the expected benefits offset the risks.[324] Before the Minister grants the licence he or she obtains the advice of the Dutch Health Council.

The practice is strict. In practice offering commercial genome sequencing without a licence is tolerated. The Healthcare Inspectorate is assigned the task to enforce the permit system of the WBO. However, the enforcement of the licence obligation is difficult.[325] Since the WBO came into force, confusion has surrounded its scope, and thus uncertainty has arisen with respect to the requirements imposed to obtain a license. We will cover this more depth in the following sections.

6.4. COMMERCIAL GENOME SEQUENCING AND THE FREE MOVEMENT REGIME FOR SERVICES AND ESTABLISHMENT

6.4.1. Commercial genome sequencing: a service

In the European Union a free movement regime exists for services (Article 56 TFEU) and for goods (Article 28 TFEU). Commercial genome sequencing is a service and not a good, as some authors have argued in academic literature.[326] The use of a toolkit for the collection of the DNA sample does not justify the qualification of commercial genome sequencing as a medical device for in-vitro diagnostics. Products for general laboratory use also fall outside the scope of the IVD-Directive.[327] Even when the toolkit is not regarded as a product for general laboratory use, the free movement regime for goods does not apply to commercial genome sequencing. To distinguish services and goods from each other the ECJ uses 'the centre of gravity' test. This means that the ECJ shall appraise a national restrictive measure in relation to one freedom. The ECJ adjudicates the measure in relation to two freedoms only if it appears from the circumstances of the situation that one of the freedoms is not entirely secondary to the other one.[328] The toolkit and the collection tube, the goods, are not essential for

[323] IGZ 2008, p. 14.
[324] Art. 7 lid 1 WBO.
[325] Art. 10 WBO; IGZ 2008, p. 17-20.
[326] Borry 2008, p. 736-737; GR 2008, p. 31-32 & 94-95.
[327] Art. 2(b) Directive 98/79/EC, *OJ* 1998, L 331 (IVD-Directive).
[328] C-20/03, *Burmanjer et al.* [2005] ECR I-4133, para. 35; C-390/99, *Canal Satélite/Administración General del Estado* [2002] ECR I-607, para. 31-33; C-275/92, *Her Majesty's Customs & Excise/Gerhart Schindler & Jörg Schindler* [1994] ECR I-1039, para. 19-30.

carrying out commercial genome sequencing. The main focal point in the sequencing of the genome is the laboratory analysis and informing the consumer appropriately.
The distribution of power between the EU and the Member States in the area of public health does not hamper the qualification of medical and care activities as services (Article 57 TFEU). This means that the fundamental freedoms regarding the free movement of services (Article 56 TFEU), the freedom of establishment (Article 49 TFEU) and the public health exception (Article 52 TFEU) apply.[329] It is not relevant whether the service has a private or public nature, nor whether it occurs in a hospital or elsewhere.[330]

6.4.2. Restrictive measures

It is settled case law case law of the ECJ that Member States choose their own health security level.[331] That does not alter the fact that the free movement regime restricts the freedom of Member States to regulate health services in the case of cross-border activities.[332] This applies to screening which falls under the scope of the WBO. The permit system of the WBO applies to the provision (the offer and the performing) of population screening in the Netherlands that is mostly permitted in other countries, or at least not prohibited. The licence system affects the access to providers located outside the Netherlands. The application for a licence, as will be argued later, bring with it uncertainties and possible adverse effects for non-Dutch licence applicants. The Dutch State *de facto* tolerates the performing of genome sequencing, which is not allowed in the Netherlands, which may be an example of *reverse discrimination*.[333] Although EU law does not prohibit this, it does not alter the fact that the rules of free movement are at stake.
In the meantime there is a 'crystallised jurisprudence line' of the ECJ regarding the regulation and reimbursement of cross-border medical services.[334] The cases *Hartlauer, Apothekerskammer des Saarlandes* and *Commission/Italy* confirm this case law regarding the freedom of establishment of healthcare providers.[335]
The prohibition, the licensing or the setting up of a quality assurance standard for commercial genome sequencing must be defined as a restriction. Restrictive measures discourage and derogate the free movement of services and the free movement of

[329] Van der Steen 2001; C-157/99, *Geraets-Smits* [2001] ECR I-5473, para. 54-58; C-385/99, *Müller-Fauré & Van Riet* [2003] ECR I-4509, para. 39; Stergiou 2006; Van Eijken, 2008, p. 3-4.
[330] Stergiou 2007, p. 238-245, para. 22; C-372/04, *Watts* [2006] ECR I-4325, para. 86.
[331] Stergiou 2006.
[332] C-212/06, *Government of the French Community & Walloon Government/Flemish Government* [2008] ECR I-1683.
[333] C-98/86, *Mathot* [1987] ECR I-809.
[334] See also Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.
[335] Maasdam & Sluijs 2009; C-171/07 & C-172/07, *Apothekerkammer des Saarlandes et al.* [2009] ECR I-4171; C-531/06, Commission/Italy [2009] ECR I-4103.

establishment.[336] The same is true of setting requirements for advertising commercial genome analyses,[337] because forbidding advertising has an impact on the purchasing of this service.[338]

6.4.3. The protection of (public) health

Imperative requirements of general interest can objectively justify the restriction of the free movement of services and establishment.[339] The public health exception, recognised in Article 52 TFEU and the case law of the ECJ, is aimed at guaranteeing accessible healthcare, realising a high level of health protection and for securing the financial balance to prevent serious damage to the social security system.[340] The ECJ recently confirmed its earlier decision regarding the justified restriction of services that have been placed legally on the internal market in the country of establishment.[341] In the absence of EU legislation, the Member States are allowed to take restrictive measures, in accordance with their own fundamental norms and values, in situations in which considerable moral, religious and cultural differences exist between Member States.[342]

The licence obligation of the WBO for offering and performing commercial genome sequencing aims to protect individuals against physical or mental health damage.[343] The presence of a real risk of health damage in the use of not-valid commercial genome sequencing does not have to be fully proven (precautionary principle).[344] We can assume that a licensing system for commercial genome sequencing protects health and maintains a financial balance. Establishing quality requirements protects individuals from harm and unnecessary costs due to overtreatment and unnecessary follow-up tests as a result of false positive test results.

[336] C-171/07 & C-172/07*, Apothekerkammer des Saalandes et al.* [2009] ECR I-4171, para.22-23; C-531/06, *Commission/Italy* [2009] ECR I-4103, para. 43-44; Case C-169/07, *Hartlauer Handelsgesellschaft mbH/ Wiener Landesregierung, Oberösterreichische Landesregierung* [2009] ECR I-1721, para. 33-36.

[337] C-500/06*, Corporación Dermoestética/ To Me Group Advertising Media* [2008] ECR I-5785, para. 35-36.

[338] C-500/06*, Corporación Dermoestética/ To Me Group Advertising Media* [2008] ECR I-5785, para. 32-33.

[339] C-171/07 & C-172/07, Apothekerkammer des Saarlandes et al. [2009] ECR I-4171, para. 25; C-531/06, Commission/Italy [2009] ECR I-4103, para. 49; C-169/07*, Hartlauer Handelsgesellschaft mbH/Wiener Landesregierung, Oberösterreichische Landesregierung* [2009] ECR I-1721, para. 39-47; Maasdam & Sluijs 2009.

[340] -169/07, *Hartlauer Handelsgesellschaft mbH/Wiener Landesregierung, Oberösterreichische Landesregierung* [2009] ECR I-1721, para. 46-49; C-444/05, *Aikaterini Stamatelaki/NPDD Organismos Asfaliseos Eleftheron Epagelmation* [2007] ECR I-3185, para. 31; C-372/04, *Watts* [2006] ECR I-4325, para. 108-109; C-385/99, *Müller-Fauré & Van Riet* [2003] ECR I-4509, para. 80; C-157/99, Smits & Peerbooms [2001] ECR I-5473, para. 76-80.

[341] C-42/07, *Liga Portuguesa de Futebol Profissional & Bwin International* [2009] ECR I-7633.

[342] C-447/08 & C-448/08, Otto Sjöberg & Anders Gerdin [2010] ECR I-6921; C-258/08, *Ladbrokes Betting & Gaming Ltd & Ladbrokes International Ltd/Stichting de Nationale Sporttotalisator* [2010] ECR I-4757.

[343] Van der Maas *et al.* 2000, p. 7.

[344] C-171/07 & C-172/07, *Apothekerkammer des Saarlandes et al.*[2009] ECR I-4171, para. 30; C-531/06, Commission/ Italy [2009] ECR I-4103, para. 54.

6.4.4. Non-discrimination and proportionality

According to the WBO, a licence is necessary for performing commercial genome sequencing. The licences requirement also applies to companies established outside the Netherlands that offer their services in the Netherlands. This permit system of the WBO is not a justifiable barrier to the free movement of services and establishment. On the one hand, the licence obligation does not pursue its public health goal coherently and systematically, whilst on the other the permit system does not meet the conditions of foreseeable and accessible criteria to prevent discretionary action from national authorities.

It is settled case law of the ECJ that a restrictive measure, which is necessary for the protection of public health, should meet the requirements of non-discrimination and proportionality.[345] The licence obligation for commercial genome sequencing (ostensibly) meets the first condition, as the same regime applies to both Dutch companies and businesses from other Member States. To meet the second criterion, i.e., proportionality, the restriction of commercial genome sequencing should not go beyond that which is objectively necessary for attaining the objective of the restriction. The WBO licence requirements for offering and the performing of commercial genome sequencing meets this condition.[346] The licensing system seeks to ban non-valid tests from the Dutch market to prevent health dangers and unnecessary costs. Less restrictive measures, such as a quality assurance standard, discourage the consumer from using (certain) commercial genome sequencing, but not-valid genome analyses are still available on the Dutch market.

Moreover, national legislation is appropriate for realising objectives pursued if it pursues its goal in a consistently and systematically way.[347] A permit system, in which the provision of commercial genome sequencing without a licence is tolerated if this service is performed outside the Netherlands, is difficult to regard as consistent and systematic. The performance of commercial genome sequencing outside the Netherlands is no less harmful than such a procedure executed in the Netherlands. Enforcement of the permit system of the WBO, as mentioned earlier, is difficult, due to the fact that offering and performing of certain categories of population screening is unlawful, but only performing commercial genome sequencing without a licence is

[345] C-169/07, *Hartlauer Handelsgesellschaft mbH/Wiener Landesregierung, Oberösterreichische Landesregierung* [2009] ECR I-1721, para. 44; C-444/05, *Aikaterini Stamatelaki/NPDD Organismos Asfaliseos Eleftheron Epagelmation* [2007] ECR I-3185, para. 34; C-385/99, Müller-Fauré & Van Riet [2003] ECR I-4509, para. 68.

[346] C-171/07 & C-172/07, *Apothekerkammer des Saarlandes et al.* [2009] ECR I-4171, para. 57; C-531/06, Commission/Italy [2009] ECR I-4103, para. 82; *Aikaterini Stamatelaki/NPDD Organismos Asfaliseos Eleftheron Epagelmation* [2007] ECR I-3185, para. 35; C-385/99, Müller-Fauré & Van Riet, [2003] ECR I-4509, para. 68.

[347] C-171/07 & C-172/07, *Apothekerkammer des Saarlandes et al.* [2009] ECR I- 4171, para. 41-42; C-531/06, *Commission/Italy* [2009] ECR I-4103, para. 66; C-169/07, *Hartlauer Handelsgesellschaft mbH/Wiener Landesregierung, Oberösterreichische Landesregierung* [2009] ECR I-1721, para. 55.

punishable.[348] A licence obligation for offering and performing of population screening in which only the performing is made punishable does not meet the requirement of being consistent and systematic.

Systems of prior administrative authorisation may not be used to justify discretionary action by national authorities, absolutely not if the discretionary power – intended or unintended – is detrimental to providers establish in other Member States that want to provide their service in the Netherlands. A system of prior administrative authorisation must be based on objective criteria that do not discriminate and are known in advance.[349] This limits the discretionary powers of national authorities thus avoiding arbitrariness and discrimination. Furthermore, such a system must be based on a procedural system, which is easily accessible to guarantee that the request for authorisation is assessed objectively and impartially and within a reasonable time.[350] The Dutch licensing system for the offering and the carrying out of commercial genome sequencing contains no objective advance announcement criteria. Since the WBO came into force, confusion surrounds its scope and thus the criteria for obtaining a licence. Due to this the Minister of Health, Welfare and Sports and the Dutch Health Council have a great deal of discretionary power in assessing licence applications. The Dutch Health Council advises the Minister with regard to the granting of licences under the WBO. During the execution of this advisory role the Dutch Health Council not only compares the licence applications with the legal criteria, but also the Dutch Health Council interprets the Act. In the past years the Dutch Health Council, at the request of the Minister, published seven advisory reports seeking to clarify the realm of the Act. These advisory reports are often drawn up during a pending licence application and as a result of confusion about the scope of the WBO.[351] Within this framework, the Dutch Health Council redefined concepts such as 'untreatable' and 'offer'.[352] At the Health Care Inspectorate and the various providers of screenings there is still a lack of clarity regarding the scope of the WBO.[353] The great discretionary power of the Minister in the granting of a licence under the WBO invites improper use in sensitive ethical issues. The Dutch Health Council stated in its advisory report, *Between hope and hype,* that the introduction of prenatal screening for all pregnant woman had resulted in unnecessary delays.[354] The lack of clarity can moreover be detrimental to providers located outside the Netherlands that want to explore the Dutch market.

[348] Art. 1 WBO & Art. 3 lid 1 in conjunction with Art. 13 WBO & IGZ 2008, p. 17-20.

[349] C-169/07, *Hartlauer Handelsgesellschaft mbH/Wiener Landesregierung, Oberösterreichische Landesregierung*, [2009] ECR I-1721, para. 64.

[350] C-169/07, *Hartlauer Handelsgesellschaft mbH/Wiener Landesregierung, Oberösterreichische Landesregierung*, [2009] ECR I-1721, para. 64; C-385/99, *Müller-Fauré & Van Riet* [2003] ECR I-4509, para. 84-85; C-157/99, *Smits & Peerbooms*, [2001] ECR I-5473, para. 90.

[351] See letter regarding Gezondheidsraad, Wet bevolkingsonderzoek: de reikwijdte (7), de begrippen 'aanbod' en 'medische indicatie' (advies 2007/02WBO), not numbered pages; overview advices GR regarding the scope of the WBO till 2000 see Van der Maas et al. 2000, p. 27-33.

[352] GR 2006b; GR 2007b.

[353] GR 2009; IGZ 2008.

[354] GR 2008, p. 98.

In conclusion, it can be noted that restrictive measures of cross-border commercial genome sequencing can be justified by the public health exception (Article. 52 TFEU). An objectively justified barrier to the free movement of services and establishment must meet the requirements of non-discrimination and proportionality. The permit system of the WBO, which also applies to commercial genome sequencing, is at odds with the free movement regime, as it does not satisfy the proportionality requirement. The E-Commerce Directive [355] applies to the online supply of commercial genome sequencing. The significance of this Directive for the regulation of commercial genome sequencing is discussed below.

6.4.5. The E-Commerce Directive

Advertisements in the media (offline advertising) could give rise to consumers purchasing commercial genome sequencing online. These online services and the related online contract fall within the scope of the E-Commerce Directive and the Distance Selling Directive.[356] These Directives have been implemented[357] in the Dutch Civil Code,[358] the Dutch Code of Civil Procedure,[359] the Dutch Criminal Code[360] and the Economic Offences Act.[361] The Distance Selling Directive seeks to harmonise some rights and duties for providers and consumers regarding distance-selling contracts to protect the consumer. The most important stipulation is the information requirements of the provider about his identity and the right for consumers to cancel the contract.

The E-Commerce Directive aims to remove a number of legal barriers that restrict the free movement of services and the right of establishment of the information society.[362] The online access to and supply of commercial genome sequencing is an information society service where in principle the E-Commerce Directive applies. Information society services are services that are normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services.[363] In the case of offline advertising that invites consumers to order a commercial genome sequencing online, although the offline advertisement does not fall within the scope of this Directive, the order options and the (commercial) communication concerning the product on the website do.

Member States can restrict the online access to and supply of commercial genome sequencing from other Member States in order to protect the public health of its own

[355] *OJ* 2000, L 178/16.
[356] *OJ* 1997, L 144/19.
[357] *Stb*. 2004, 210 & *Stb*. 2000, 617.
[358] Burgerlijk Wetboek
[359] Wetboek van Burgerlijke rechtsvordering.
[360] Wetboek van Strafrecht
[361] Wet economische delicten.
[362] Preamble and Art. 1 Directive 2000/31/EC.
[363] Art. 2 Directive 2000/31/EC; Stuurman & Wefers Bettink 2006, p. 13.

citizens. These restrictive measures must be in proportion to their objectives.[364] It is expected that when the occasion arises the ECJ would use the same judicial review standards for the exception in the E-Commerce Directive, as have been used regarding the public health exception (Article 52 TFEU) discussed in the previous section.[365] Restrictive measures of the free movement of services of the information society must be reported in advance to the European Commission.

'The country-of-origin' principle applies for establishment.[366] The place of establishment is the place where the company has the centre of its activities. Member States are not allowed to make the taking up and pursuit of the activity of an information society service, subject to prior authorisation or any other requirement having equivalent effect.[367] The E-Commerce Directive does not forbid licensing systems that are not specifically and exclusively targeted at information society services.[368] This means that with respect to the online supply of commercial genome sequencing, the Dutch legislature may make offering and performing of this service dependent upon the acquisition of a licence. The licensing system of the WBO is not just applicable to the online access to commercial genome sequencing, but also to the offline offering and performing of this service.

It can be concluded that the E- Commerce Directive allows restrictive measures in regard to commercial genome sequencing for the protection of health unless these restrictions are not proportional to the pursued goal. The Directive leaves the licensing system of the WBO unimpeded because this permit system is not specifically and exclusively targeted at the online access to and supply of commercial genome sequencing.

6.5. DUTCH REGULATION NOT EU-PROOF

With the WBO and other legislation the Dutch State aims to protect its citizens against health hazards, for example against threats from unwarranted screenings. Nevertheless, it is relatively easy - and legislation does not preclude this - to order commercial genome sequencing over the internet. The example of VARA-presenter Bentveld is illustrative of this. Has the Dutch State, given the EU rules of the free movements, sufficient regulatory freedom to prevent people such as Bentveld from decoding their genome?

[364] Art. 3 Directive 2000/31/EC.

[365] C-169/07, Hartlauer Handelsgesellschaft mbH/Wiener Landesregierung, Oberösterreichische Landesregierung [2009] ECR I-1721; C-444/05, Aikaterini Stamatelaki/NPDD Organismos Asfaliseos Eleftheron Epagelmation [2007] ECR I-3185; C-385/99, Müller-Fauré & Van Riet [2003] ECR I-4509.

[366] Preambule Directive 200/31/EC, para. 19.

[367] Art, 4(1) Directive 2000/31/EC.

[368] Art. 4 (2) Directive 2000/31/EC.

Member States have a degree of discretion in the regulation of health services such as commercial genome sequencing. The EU treaty provisions according the free movements of services and establishment and the treaties public health exception, apply to cross-border offline advertising and the performing of commercial genome sequencing. The fundamental freedoms of service and establish will be frustrated through measures, like a ban, a permit system or a quality mark for services. These restrictive measures can be justified for public health reasons if they meet the requirements of non-discrimination and proportionality. The way in which the Netherlands regulates commercial genome sequencing is at odds with EU law. The licence system of the WBO regarding offline access to and supply of commercial genome sequencing conflicts with the EU free movement regime for establishment because it is not proportional to the pursued goal due to the enforcement and scope problems of this Act.[369] This can cause problems in situations in which a company from another Member States establishes itself in the Netherlands and wants to offer and perform commercial genome sequencing in our country.

The E-Commerce Directive is applicable to the online access to and supply of commercial genome sequencing. The Dutch permit system of the WBO for the provision of commercial genome sequencing is also applicable to companies from other Member States that provide their services in the Netherlands. The E-Commerce permits barriers for services from the information society for the protection of public health. Offering commercial genome sequencing without a licence is tolerated in practice, but that does not alter the fact that the Dutch licensing system conflicts with the E-Commerce Directive because it does not meet the proportionality requirement.

In accordance with the case law of the ECJ regarding the freedom of establishment and the E-Commerce Directive, a revision of the WBO is necessary. A revision of the WBO should focus on clarifying the definition of population screening and the licence criteria, so that the licence criteria are clear and known in advance. The powers of the Minister of Health, Welfare and Sports and the Dutch Health Council in regard to the granting the licence must be clearly defined. Besides, it is undesirable that during a decision on a licence application the scope of licence criteria 'is once again being explored'. This gives the impression of arbitrariness. It is still somewhat convoluted to qualify individual commercial genome sequencing as population screening in which, on his own initiative, the consumer visits the website of the provider.

[369] GR 2006b; GR 2007c; IGZ 2008, p. 14.

CHAPTER 7

REGULATING THE USE OF GENETIC TESTS: IS DUTCH LAW AN EXAMPLE FOR OTHER COUNTRIES WITH REGARD TO DTC GENETIC TESTING?

Abstract: *Several European countries are considering the regulation of Direct-To-Consumer genetic tests via internet in order to protect the public. This chapter addresses the question whether the Dutch Act on population screening, an internationally widely praised piece of legislation, could serve as an example for other European countries. While the Act adequately protects individuals against (potential) harmful screenings programmes, it falls short when it comes to offering protection against genetic tests offered to the public through the internet by commercial firms. It is therefore argued that the Act should be amended, also to secure consistency with European legal standards.*

R.E. Hellemondt, A.C. Hendriks & M.H. Breuning, 'Regulating the use of genetic tests: is Dutch law an example for other countries with regard to DTC genetic testing?', *Amsterdam Law Forum* 2011, p.13-24.

7.1. INTRODUCTION

Scientific knowledge of genetics is expanding rapidly, which generates many possibilities for predicting and improving human health and life.[370] Individuals have high expectations about the potential benefits of genetics and are also increasingly eager to learn more about their genetic profile and future health. Commercial companies seek to appease the hunger for genetic information by offering Direct-To-Consumer (DTC) genetic tests, also via internet. These tests are carried out without the involvement of a healthcare provider, fail to provide adequate information and are not foreseen in genetic counselling services.[371]

After undergoing a DTC genetic test individuals will receive information about the presence of genetic risks and hereditary diseases. The validity of these tests is, however, questionable. The use of DTC genetic tests may thus easily cause unjustified anxiety and spur individuals to undergo unnecessary follow-up tests and medical treatment, at considerable personal and societal expense. Despite these shortcomings, it can be argued from a legal point of view that unrestricted access to DTC genetic tests strengthens the personal autonomy of individuals. It empowers them to take independent responsibility for their health and future,[372] and it leaves them the decision of whether they want adequate information and genetic counselling. At the same time, States have the obligation to protect individuals against (potential) health risks, including exposure to misleading information upon the basis of which individuals may make decisions they would otherwise have rejected. This positive obligation is well entrenched in international human rights law.[373]

Several European States are at present considering the introduction of legislation to regulate the supply of and access to DTC genetic tests.[374] The Netherlands is one of the few countries that already have such legislation in place, in an effort to save the general public from harm resulting from preventive screening tools. The internationally widely praised Wet op het bevolkingsonderzoek (Act on population screening) seeks to offer protection against harmful screening programmes by way of a permit system.

The Netherlands is a Member State of the Council of Europe and the European Union. These organisations influence, in their own specific way, the freedom of Member States to regulate the supply of and access to DTC genetic tests. National measures seeking to protect the public against harm from these tests have to abide by the standards adopted by these organisations.

[370] Calsbeek et al. 2007, p. 493.
[371] Hogarth et al. 2008, p. 162-165; McBride et al. 2010, p. 429-432; GAO 2010.
[372] McGregor 2008, p. 9-10.
[373] See for instance Art. 25 of the UN Universal Declaration on Human Rights (1966) & Art. 14 of the UNESCO Universal Declaration on Bioethics and Human Rights (2005).
[374] Brower 2010, p. 1611; the UK Human Genetic Commission 2010.

This paper seeks to examine whether the Wet op het bevolkingsonderzoek can serve as an example for other European countries. It aims to assess the effectiveness of this Act as well as its compliance with European standards. We start by describing the normative questions surrounding the access tot and supply of DTC genetic testing by internet in section 7.2 en 7.3. Then, we unravel the international, but particularly European, patchwork of (legal) standards concerning the access to and supply of DTC genetic tests through Internet in section 7.4. Section 7.5. provides an overview of Dutch legal standards and problems that emerge in practice when seeking to regulate the supply of screening programmes, including DTC genetic tests. Lastly, in section 7.6. we formulate an answer to the above questions, followed by conclusions.

7.2. DTC GENETIC TESTING

Genetic screening can be defined as any kind of test being offered to a person or group of individuals with the aim of detecting or ruling out a hereditary disease, a predisposition to such a disease or to determine whether a person carries a genetic variant that may produce a hereditary disease in their offspring.[375] Individuals can buy a test kit for screening their DNA on the internet without the involvement of a physician or genetic counselling. After visiting the online shop and ordering a genetic test, the individual will receive a test kit from the company. This kit commonly includes a tube for taking a DNA sample, such as saliva or a hair, to be returned to the company. Upon receiving the DNA sample, the company's laboratory starts the analytic process. A few weeks later the individual can download the test results using a simple code.
In this respect it is important to make a distinction between presymptomatic diagnosis and susceptibility genetic tests. Presymptomatic diagnostic genetic tests are mostly aimed at discovering a monogenetic disease, that is to say a gene mutation which, by definition, will almost inevitably lead to the development of disease at some point in later in life.[376] By contrast, testing for multiple genetic variants is generally associated with low risks of developing common health conditions and traits. A 'positive' test result – meaning that an affected gene has been detected – generally implies a(n enhanced) statistical risk but not a certainty of developing the disease later in life.[377] The results of the latter susceptibility tests do not necessarily accurately establish the risk of developing a disorder, because in most cases not all risk factors are included and additional relevant factors, such as family history and lifestyle, are not taken into account by the test. Furthermore, there are carrier tests that have been developed to determine whether a healthy person or couple carries a relevant mutation for an

[375] Godard et al. 2003, p. 49-50.
[376] Borry 2009, p. 1-2.
[377] McBride, Wade & Kaphingst 2010, p. 430.

autosomal recessive disorder.[378] The majority of DTC genetic tests concern susceptibility tests, sometimes in combination with presymptomatic diagnosis tests or carrier tests. Against this background it is not a surprise that the interpretation of test results can be challenging for a person, particularly for those with limited knowledge of genetics and medical statistics. It is well known from various studies on genetic counselling that complex information on risk factors is particularly difficult to handle for a layman, regardless of their background or education.[379]

7.3. NORMATIVE QUESTIONS SURROUNDING ACCESS TO DTC GENETIC TESTING

DTC genetic tests have the potential to empower individuals to take more responsibility for their health and life by providing risk assessment information.[380] However, individuals often overestimate the benefits of DTC genetic tests now that these tests are generally offered without adequate information. It is well known that individuals may take important health decisions concerning prevention or prophylactic treatment based on incomplete or misunderstood information about their expected health.[381]
The validity and clinical utility of these tests are questionable and can even have detrimental effects for the individual concerned as well as others due to needless and invasive follow-up tests or unnecessary medical treatment.[382] Under human rights law, States are bound to protect individuals against such serious risks. Unrestricted access to DTC genetic tests can also interfere with other fundamental human rights and interests of others. Individual genetic health information can, for example, reveal information about family members and could have implications for their health, thus directly impacting on their rights and interests. If follow-up tests and unnecessary medical treatment happen on a large scale, unrestricted access to DTC genetic tests may also indirectly threaten the accessibility of the health care system.
States are then torn between Scylla and Charybdis[383] when confronted with the shortcomings of DTC genetic tests. Should they allow individuals to freely make use of tests of questionable quality for the sake of respecting autonomous decision making, or should health concerns prevail, thus restricting the commercial activities of companies and inhibiting individual use of their products?

7

[378] McBride, Wade & Kaphingst 2010, p. 430.
[379] Van Dijk et al. 2004, p. 47-48.
[380] Marietta & McGuire 2009, p. 370.
[381] Marietta & McGuire 2009, p. 371.
[382] Marietta & McGuire 2009, p. 370.
[383] In Greek mythology, monster Scylla and whirlpool Charybdis were both dangerous to sailors. They lived on opposite sides of the Strait of Messina. 'Between Scylla and Charybdis' therefore means a situation in which one has to choose between two equally unattractive options.

7.4. EUROPEAN STANDARDS

DTC genetic testing offered by internet companies is a cross border activity affecting millions of people across the European region. In order to uphold the same standards with respect to autonomy and protection it is important that convergence is sought between the law and policies on screening in different jurisdictions.[384] The main regional organisations in Europe, being the Council of Europe (Council) and the European Union (EU), have developed standards regulating the supply of and access to genetic tests for health purposes. These instruments also, and sometimes specifically, apply to DTC genetic tests. In this section we describe and examine the most important standards adopted within the context of the Council and the EU, relevant for the use of DTC genetic tests.

7.4.1. European Convention on Human Rights

The Council of Europe's most important legal instrument, the European Convention for the Protection on Human Rights and Fundamental Freedoms (ECHR),[385] is of crucial importance when it comes to regulating the use of DTC genetic tests, even though the Convention does not contain a reference to the right to health or a right to health care. From the European Court of Human Rights' (ECtHR) case law it can, however, be seen that compliance with ECHR established rights also requires contracting States to the ECHR (henceforth: States Parties) to take adequate measures in the area of health promotion and the prevention of health risks. These duties to protect and ensure the enjoyment of Convention rights are known as positive obligations, as opposed to negative obligations that are imposed on States Parties not to interfere with human behaviour and inter-human relations.

The ECtHR's doctrine of positive obligations is essential for health law, notably now that these obligations do not confine themselves to the vertical relations, but extend to horizontal ones. In other words, by imposing positive obligations regulating human conduct with respect to other private parties, the ECtHR acknowledges that States Parties should also uphold respect for human rights in the relations between private parties. By way of example, it can be recalled that the ECtHR has held that States Parties are obliged to formulate adequate legislation to protect the integrity of individuals against violations by others.[386]

According to the ECtHR's standing case law, States Parties are bound by the positive obligation to protect their citizens against (potential) health risks.[387] The State has

[384] Gevers 2009, p. 6.

[385] All Council of Europe treaties, incl. those referred to in this paragraph, can be found on http://conventions.coe.int/ > treaties > full lisv.

[386] ECtHR 26 March 1985, *X & Y/ Netherlands,* no. 8978/80.

[387] ECtHR 9 June 1998, *L.C.B./ the UK*, no. 23413/94.

equally emphasised the importance of adequate information, including informing the patient about health risks, as a precondition for informed consent.[388] In a number of cases the ECtHR concluded that the failure to provide adequate information prior to a health intervention results in a violation of an individual's physical integrity, which is protected by Article 8 of the ECHR.[389]

It can be argued that free access to DTC genetic tests strengthens the individuals' autonomy, as protected by the right to private and family life.[390] Autonomy, particularly relevant in the field of health care,[391] also means that States have to respect the choices of harmful activities from mentally competent individuals.[392] However, autonomous decisions have to be compatible with human dignity, the principle underlying all human rights. This explains why the ECtHR has held that an individual cannot legally consent to practices deemed to be at odds with human dignity, such as being tossed around to entertain others and gain oneself an income (dwarf tossing) or to engage in extremely violent sexual practices.[393]

It can be maintained that the requirement to obtain the individual's informed consent prior to a health intervention also entails obligations for companies offering DTC genetic tests – or at least a duty for States to ensure that these companies abide by the informed consent requirement.[394] From the case law of the ECtHR it follows that an individual can only agree with an interference with his/her private life in the field of health care after he/she has voluntarily and unambiguously consented to this on the basis of prior and adequate information. It can be debated whether there is lawful consent when companies offering DTC genetic tests fail to provide adequate information on such issues as the scientific validity of these tests, their limitations and the benefits as well as the risks.

In conclusion, the obligation to provide adequate information about the health benefits and risks prior to obtaining the consent of an individual is a well-established requirement recognised under the ECHR. States should ensure that this requirement is also upheld in the so-called horizontal relations. From a human rights perspective there are therefore good reasons for States to regulate the supply of and access to DTC genetic tests because of the (potential) health risks to individuals and the deficiencies with respect to adequate information and valid consent.

7

[388] ECtHR 5 October 2006, *Trocellier/ France* (Dec.), no. 75725/01; ECtHR 2 June 2009, *Codarcea/ Romania*, no. 31675/04.
[389] ECtHR 12 July, *Testa/ Croatia,* no. 20877/04.
[390] ECtHR 7 February 2002, *Mikulic/ Croatia*, no. 53176/99; ECtHR 29 April 2002, *Pretty/ the UK*, no. 2346/02; ECtHR 11 July 2002, *Christine Goodwin/ the UK* (GC), no. 28957/95.
[391] ECtHR 14 December 2010, *Ternovszky/ Hungary*, no. 67545/09.
[392] ECtHR 20 January 2011, *Haas/ Switzerland*, no. 31332/07.
[393] ECtHR 16 October 1996, *Wackenheim/ France*, no. 29961/96; ECtHR 19 February 1997 *Laskey, Jaggard & Brown/ United Kingdom*, no. 21627/93; 21826/93 & 21974/93; ECtHR 17 February *2005, K.A. & A.D./ Belgium*, no. 42758/98 & 45558/99.
[394] ECtHR 2 June 2009, *Codarcea/ Romania,* no. 31675/04.

7.4.2. Biomedicine Convention

Particularly relevant with respect to the use of DTC genetic tests is the Council's Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Biomedicine Convention). The Convention itself consists of principles, rights, and standards applying to specific fields of biology and medicine. Yet only a certain number of principles, rights and standards have been clarified by the drafters. Other issues, including those on which it is difficult to achieve consensus, have been or will be dealt with in Additional Protocols.

The Protocol concerning Genetic Testing for Health Purposes (the Protocol) deserves special attention. The Protocol, to be read in conjunction with the Biomedicine Convention itself, came into force on 1 December 2009. The Protocol seeks to protect the human dignity and the fundamental rights and freedoms of individuals with regard to genetic testing for health purposes. The Protocol applies to all genetic tests whether they are provided publicly or privately. It also covers genetic tests that are carried out for health purposes, such as DTC genetic presymptomatic diagnostic, predictive and carrier tests. Genetic tests carried out on the human embryo or foetus and for research purposes are, however, excluded from its scope.[395] The Protocol requires States Parties to take the necessary measures to ensure that genetic tests meet generally accepted criteria of scientific validity and clinical validity. Clinical utility of genetic tests must, according to the Protocol, be an essential criterion for deciding to offer genetic tests to the public.[396]

The Protocol furthermore stipulates that when a genetic test is considered, the persons concerned shall be provided with prior appropriate information, notably about the purpose and the nature of the test, as well the implications of its results.[397] Appropriate genetic counselling should also be provided.[398]

States that have ratified this instrument need to uphold these standards,[399] which are considered to reflect European *minimum standards*. States are explicitly also allowed to grant potential test subjects a higher level of protection.[400] It follows that the supply of and access to DTC genetic tests in European States, at least in those countries that have ratified the Protocol, should be in conformity with these standards. Failure to guarantee these standards equals a violation of human rights for which States eventually can be held accountable.

7.4.3. The Internal Market Rules of the European Union

Despite the considerable powers of the EU in various areas of social life, the main responsibility for health policy and provision for health care rests with the Member

[395] Art. 2 Protocol, http://conventions.coe.int/Treaty/en/Treaties/html/203.htm (27/11/2008).
[396] Art. 6 Protocol.
[397] Art. 8(1) Protocol.
[398] Art. 8(2) Protocol.
[399] By December 2010 5 States had ratified the Protocol.
[400] Art. 22 Protocol.

States.[401] It is settled case law of the European Court of Justice (ECJ) that EU law does not detract from the freedom of Member States to choose their own health security level.[402] Nevertheless, notably in the case of cross border activities, EU law indirectly regulates access to DTC genetic tests. States have the obligation to comply with the rules of European Free Market that prohibit – amongst others – measures that impair free-market competitions. Thus Member States are in principle required to respect the free movement of goods, services and establishment when exercising their power in the field of health.

As for EU law, it is important how to qualify DTC genetic tests. It is settled case law that the ECJ[403] will examine in principle a national measure in relation to one freedom if a restriction relates to several fundamental freedoms. It shall appraise a national measure in relation to two fundamental freedoms if it appears that one of them is not entirely secondary to the other one.[404]

In our opinion a DTC genetic test is not a good but rather a service because the test kit with the tube (good) is entirely secondary to the analytic process in the laboratory (service). In connection with this discussion, some authors argue that DTC genetic tests fall within the scope of Directive 98/79/EC on in vitro diagnostic medical devices. This Directive ensures a quality review before 'high risk' self-tests (for instance self-tests for HIV) are marketed.[405] In our opinion DTC genetic tests are not covered by this Directive. In the first place this Directive does not apply to services. In the second place products of general laboratory use are not in vitro diagnostic.[406] The tube for taking a DNA sample has no particular diagnostic value and is not produced with special characteristics for testing.

In the absence of harmonisation of DTC genetic tests EU Member States are under certain circumstances allowed to take measures, which restrict the free movement of services and establishment to protect their citizens against (potential) health risks.[407] These measures have to be objectively necessary for the purpose, and the result could not be achieved through less restrictive rules. In addition, these measures should not discriminate services or the establishment on grounds of nationality.[408] Furthermore

7

[401] Art. 152 TFEU; European Commission, Together for Health: A Strategic Approach for the EU 2008-2013, COM (2007) 630 final.

[402] Case C-372/04, *Watts/ United Kingdom* [2006] ECR I-4325.

[403] The Court of Justice of the European Union has the power to interpret the EU treaties, to measure the interpretation of these treaties by EU bodies and institutions, and to judge a limited number of conflicts within the realm of the EU law.

[404] Case C-20/03, *Burmanjer et al.* [2005] ECR I-4133; Case C-390/99, *Canal Satélite / Administración General del Estado* [2002] ECR I-607;Case C-275/92, *Her Majesty's Customs & Excise/ Gerhart Schindler en Jörg Schindler* [1994] ECR I-1039.

[405] Borry 2008, p. 736-737.

[406] Art. 1(2b) Directive 98/79/EC.

[407] Case C-108/09, *Ker Optika* [2010] ECR I-12113.

[408] Case C-169/07, *Hartlauer Handelsgesellschaft mbH/ Wiener Landesregierung, Oberösterreichische Landesregierung* [2009] ECR I-1721; Case C-444/05, *Aikaterini Stamatelaki/NPDD Organismos Asfaliseos Eleftheron Epagelmation* [2007] ECR I-3185; Case C-385/99, *Müller-Fauré & Van Riet* [2003] ECR I-4509.

when measures derogate the free movement of services or establishment they must pursue its goal in a consistent and systematic way.[409] Prior administrative authorisation, like permit systems, must be based on objective announce criteria that are stated well in advance.[410]

Reference should also be made to Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (E- Commerce Directive). This Directive covers the online services by which DTC genetic tests are offered on internet. In principle this Directive allows a permit system, which is meant to be exclusively for information society services. Information society services are services that are normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services.[411] Member States may take measures to derogate the freedom to provide information society services to protect health under the same conditions as we have described above.

7.4.4. Recommendations and White Paper

In 2004 the European Commission published 25 recommendations on the ethical, legal and social implications of genetic testing.[412] A multidisciplinary expert group was invited by the Commission to discuss the implications of genetic testing. The 25 recommendations are the results of the expert groups work. They seek to be a starting point for the EU and Member States to consider an action plan for genetic testing and the recommendations can be used for implementation by policy-makers.

According to the report underlying these recommendations, genetic testing should only be carried out in specialised laboratories under the supervision of a trained geneticist. The application of genetic testing for non-medical reasons requires careful consideration with regard to its potential consequences for society. The report also requires that genetic testing in Europe has to be based on high quality scientific knowledge. A system for the validation of tests should be established by the EU. In the context, of human healthcare genetic tests should be offered only when there is a sound medical reason for testing. Furthermore the report stipulates that medical relevant genetic testing has always be a free personal choice. Therefore comprehensive information about genetic test should be available. Informed consent, the right to know and not to know, and genetic counselling must be guaranteed and are essential requirements for genetic

[409] Case C-171/07 & C-172/07, *Apothekerkammer des Saarlandes et al.* [2009] ECR I-4171; Case C-531/106 *Commission/ Italy* [2009] ECR I-4103.

[410] Case C-169/07, *Hartlauer Handelsgesellschaft mbH/ Wiener Landesregierung, Oberösterreichische Landesregierung* [2009] ECR I-1721; Case C-385/99, *Müller-Fauré & Van Riet* [2003] ECR I-4509.

[411] Art. 1(2) Directive 98/34/EC M1 aying down a procedure for the provision of information in the field of technical standards and regulations and rules on Information Society services.

[412] European Commission, *25 Recommendations on the ethical, legal and social implications of genetic testing*, Brussels 2004, at: http://ec.europa.eu/research/conferences/2004/genetic/pdf/recommendations_en.pdf (06/05/2004); at http://ec.europa.eu/research/conferences/2004/genetic/pdf/report_en.pdf (06/052004).

tests, in particular for highly predictive tests for serious disorders. The report demands test providers to ensure that the information they provide is accurate and in agreement with international quality standards according to the recommendations.
The EU has presented its strategy toward health in a so called White Paper.[413] This Paper sets out a framework to give direction to EU health policy until 2013. The EU has pinpointed out objectives key areas to develop more specific activities to promote health. Two of these key areas are protection of consumers against health threats and supporting new technologies and considering their implications.

7.4.5. Preliminary conclusions

The ECHR, the Biomedicine Convention and the Protocol offer an authoritative framework for the regulation of the use of DTC genetic tests across Europe. Not all States Parties to the ECHR, including the Netherlands, have, however, ratified the Biomedicine Convention, let alone the Protocol. That does not mean that these standards have no meaning for these countries. It can be argued that the adopted norms reflect emerging European standards that cannot always be enforced throughout Europe yet. When regulating the use of DTC genetic tests, the obligations enshrined in the ECHR, the Biomedicine Convention and the Protocol therefore have to be taken into account.
The supply of and access to DTC genetic tests is in principle also regulated by the Internal Market Rules of the EU, even though there is discussion with respect to the precise qualification of a DTC genetic test. This body of legislation has to be respected by Member States considering the regulation of the use of DTC genetic testing. The EU has as yet not adopted a Directive setting specific normative criteria for access to DTC genetic tests. The EU Commissions recently adopted 25 recommendations on the ethical, legal and social implications of genetic testing that provide normative guidance as it relates to the supply of and access to DTC genetic tests.
In the absence of more elaborate standards with respect to the supply of and access to DTC genetic tests at the European level, States enjoy a considerable *margin of appreciation* to regulate the supply of and access to DTC genetic tests in the way they deem most appropriate to find a fair balance between personal autonomy and the need to protect individuals against the disadvantages of these tests.

7.5. DUTCH LEGAL STANDARDS

7.5.1. The Dutch Act on population screening

In the Netherlands companies and health professionals are in principle free to offer health testing kits to the public. Some forms of screening can, however, only be carried

[413] European Commission, Together for Health: A Strategic Approach for the EU 2008-2013, COM (2007) 630 final.

out with a permit issued by the Minister of Health, Welfare and Sports. The criteria to be met by the applicant for these forms of 'high risk screening' are laid down in the Act, 'Wet op het bevolkingsonderzoek' (the Act). This system was introduced to establish and guarantee a fair balance between the right of self-determination of individuals and the need to protect them against (potentially) harmful screenings techniques.[414]
In the Act, population screening is defined as: 'a medical examination which is carried out in response to an offer made to the entire population or to a section thereof and to detect diseases of a certain kind or certain risk indicators, either wholly or partly for the benefit of the persons to be examined'.[415] Offering and practicing tests for detecting (risk indicators of) cancer and 'incurable diseases' without a licence is unlawful.[416] Moreover, performing these screening methods without permission is a punishable offence.[417]
According to the Act, the Dutch Minister of Health, Welfare and Sports grants the licence for screening (risk indicators for) of cancer or (risk indicators for) untreatable diseases, provided that the screening is scientifically sound, in accordance with the professional medical practice standards and maintains proper balance between health risks and benefits.[418] The Act does not set quality norms for the information to be provided to the (potential) test subjects, consent, the use of samples, and counselling to be provided. Nevertheless, health care workers and companies wishing to perform a population screening programme have to comply with the professional medical practice standards that entail the main rights of the patient as laid down in the Dutch Civil Code.

7.5.2. Interpretation and enforcement problems

The Act came into force in 1996. From the very beginning there was confusion about its scope, and thus uncertainty about the requirements of obtaining a license. Over the last fourteen years the Dutch Health Council, a scientific advisory body that has been allotted the task of advising the Minister on the provision of a license to applicants under the Act, has written seven reports seeking to clarify the realm of the Act.[419] Despite these helpful contributions certain uncertainties remain that are probably inherent to the use of terms like 'population screening', 'offer' and 'incurable'. There has therefore been a call to revise this Act to enhance its effectiveness.[420]
Moreover, the Act has several loopholes. Companies use these for their own benefit, for example in the area DTC genetic screening. Enforcement of the Act is difficult

[414] Van der Maas 2000, p. 7.
[415] GR 1994, p. 18; Art. 1(c) WBO.
[416] Art. 2 Wet op het bevolkingsonderzoek (WBO).
[417] Art. 3(1) jo 13 WBO.
[418] Art. 7 WBO.
[419] Van der Maas et al. 2000, p. 37-33.
[420] Van der Maas et al. 2000.

because offering and performing screening for the (risk of) hereditary cancer and incurable diseases without a licence are prohibited, but only practicing without a legal permission is actionable. Dutch companies offer screening directly to the public on internet sites, in newspapers and in magazines. They do this without a licence in their homeland and practice screening across the border. Furthermore the Act does not cover DTC carrier tests whilst these tests can have serious psychological and familial implications. The Act does not regulate the access to these tests because they do not detect the (risk of) hereditary disease of the individual but provides information about the risk of having a child with a genetic condition.

7.5.3. Preliminary conclusions

The Dutch Act was not developed for nor does it exclusively regulate the use of DTC genetic tests. Nevertheless the Act does apply to DTC genetic tests due to the fact that these tests fall within the definition of population screening, as laid down in the Act. Therefore, the Act does apply legal quality standards to 'high risk' DTC genetic tests.
DTC genetic testing is classified as population screening because companies offer their genetic services directly to the public. The key word in the definition of the Act is 'offer'. The fact that individuals visit the web shop on their own initiative makes no difference when classifying DTC genetic tests as population screening. This means that in the Netherlands offering and practicing screening for detecting the (risk indicators of) cancer and untreatable diseases without a licence is unlawful[421] and practicing without permission is a punishable offence.[422]

7.6. DISCUSSION

Can the Dutch Act serve as an example for other European countries, when regulating the use of DTC genetic tests in a way that is consistent with European legal standards? Despite various initiatives there is as yet no comprehensive European legal framework regulating the supply of and access to DTC genetic tests. When studying the different existing instruments and documents adopted by the Council of Europe and the EU, there appears to be a prevailing opinion that the validity and utility of genetic tests are essential preconditions for allowing them to be offered to the public. Moreover, there is widespread (international) support for the idea that genetic tests, including DTC genetic tests, should be offered only under medical supervision.[423] DTC genetic

[421] Art. 2 WBO.
[422] Art. 3(1) jo 13 WBO.
[423] ESHG, official response of the EuroGentest network of Excellence in Genetic Testing to the Public consultation on the revision of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, Vienna 2010. This document is available through the Internet https://www.eshg.org/fileadmin/www.eshg.org/documents/ESHG/ESHG-IVD-def.pdf (2010), p. 7 (question 11).

tests with risks that can have far reaching implications for the person concerned or his or her relatives should not be allowed without appropriate non-directive genetic counselling. Furthermore, there is a common opinion that individuals should be given the opportunity to make their decision freely and based on adequate information about the limitations of the test and its physical, psychology and social implications, meaning giving informed consent.

The Dutch Act, despite interpretations and enforcement problems, provides a basic level of protection against population screening activities that could potentially threaten the health of individuals. Yet, we doubt whether the Act in its current form can serve as an example for other countries considering regulating the use of DTC genetic tests. On the one hand, the Act appears to be too liberal compared to the European normative criteria in place.[424] For example, the Act does not regulate access to all genetic tests and only guarantees the European normative criteria for DTC genetic tests aimed at detecting the (risk indicators of) cancer and (risk indicators of) untreatable diseases. On the other hand, the permit system established under the Act effectively prevents individuals from getting access to DTC genetic tests in the Netherlands if they have questionable validity and utility. However, the permit system only applies to the Dutch jurisdiction, seemingly not taking into account that its guarantees can easily be by-passed by offering DTC genetic tests through the internet and performing the tests outside of the Netherlands.

Besides these practical problems and shortcoming it should be noted that the Act is not in accordance with EU law. The definition of population screening and the licence requirements are ambiguous. The permit system of the Act does not meet the rules of the Internal Market because of the absence of objective advance announce criteria. A permit system without foreseeable and accessible licence criteria could be an invitation to arbitrariness. It could be used to avoid sharp ethical discussions or decisions and inhibit scientific knowledge.[425] Furthermore, the Act conflicts with EU law because of its enforcement problems. It does not pursue its goal consistently and systematically, now that offering and practicing of DTC genetic tests for detecting (risk indicators of) cancer and untreatable diseases without a licence is unlawful[426] and practicing without permission is punishable. In addition, the Act conflicts with the Protocol[427] because it seems to be too liberal. Lastly, it could only be used with necessary adjustments as an example for other EU Member States, because it conflicts with the European law due to its interpretation and enforcement problems.[428]

[424] ESHG, official response of the EuroGentest network of Excellence in Genetic Testing to the Public consultation on the revision of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, Vienna 2010. This document is available through the Internet https://www.eshg.org/fileadmin/www.eshg.org/documents/ESHG/ESHG-IVD-def.pdf (2010), p 1.

[425] GR 2008.

[426] Art. 2 WBO.

[427] It should be noted that the Netherlands has not yet ratified the Biomedicine Convention.

[428] R.E. van Hellemondt, A.C. Hendriks & M.H. Breuning, 'Wet bevolkingsonderzoek op gespannen voet met EU recht', *Nederlands Tijdschrift voor Europees Recht* 2010, p. 245-251.

7.7. CONCLUSION

Worldwide there is growing concern about the availability of DTC genetic tests. Individuals can easily access these tests without adequate information and genetic counselling services being provided, let alone safeguards with respect to the validity and utility of the tests. This raises the question of whether making use of these testing methods to obtain information about the presence of genetic risks and hereditary diseases, and thus one's future health, truly reflects an expression of personal autonomy. It was argued here that there are good public health and human rights reasons to protect individuals from subjecting themselves to these tests.

The need to regulate the use of DTC genetic tests follows from the standards adopted within the context of the Council of Europe and the EU. Despite the absence of a comprehensive European normative framework, important principles and norms relevant to the use of DTC genetic tests, and thus its supply and access to, have gained recognition on a European level, which implies that the validity and utility of DTC genetic tests are crucial factors when deciding on allowing the marketing of such a test. Furthermore, DTC genetic tests with far reaching implications for individuals should not be allowed without the supervision of a healthcare worker and appropriate non-directive genetic counselling being offered. Moreover, access to DTC genetic tests should be accompanied by rigorous informed consent procedures.

The Dutch Act on population screening is a unique piece of legislation regulating the use of screening programmes and also applying to DTC genetic tests. Yet in its present form, the Act cannot serve as an example for other countries considering the regulation of DTC genetic screening. The Act not only suffers from a number of practical problems and shortcomings, but is also inconsistent with some EU legal standards.

To conclude, a broad consensus exists among professionals in genetics that the implications of DTC genetic tests are far reaching and complex. Such testing should not be left to the free forces of the market, but should be accompanied by adequate information, and informed consent. There is – also in view of these concerns expressed by professionals – not only a need to revise the Dutch Act; it is above all important to elaborate on the emerging body of European legal standards applicable to DTC genetic screening. Offering genetic tests directly to individuals via internet raises complex legal questions that cannot merely be answered by individual States. National measures can, moreover, easily be bypassed by making use of cross border constructions. Adequately protecting individuals against questionable testing kits therefore calls for international vigilance and comprehensive measures by the international community, in Europe to start with the Council of Europe and the European Union.

CHAPTER 8

WHICH LESSONS CAN WE LEARN FROM THE EUROPEAN UNION LEGAL FRAMEWORK OF MEDICINES FOR THE REGULATION OF DIRECT-TO-CONSUMER GENETIC TESTS?

Abstract: *The legal framework of the European Union (EU) for regulating access to and supply of direct-to-consumer (DTC) genetic tests is very liberal compared to the legal and regulatory framework for (internet) medicines. Nevertheless, both health related products can cause equally serious damage to the wellbeing of individuals. In this chapter we examine whether the legal framework of the EU for the safety and responsible use of (internet) medicines could be an example for regulating access to and supply of DTC genetic tests. The EU laws governing medicines can, notwithstanding their shortcomings, serve as an example for (central) authorising the marketing of DTC genetic tests on the internal market in accordance with strict criteria regarding predictive value and clinical usefulness. Furthermore, a legal framework controlling DTC genetic tests also should introduce system supervision as well as quality criteria with respect to the information to be provided to consumers in order to enhance health protection. However, DTC genetic tests purchased through online ordering are difficult to supervise by any agency. Adequately protecting individuals against questionable testing kits calls for international vigilance and comprehensive measures by the international community. For Europe, it is important to rank the regulation of DTC genetic tests on the 'European regulatory agenda'*.

R.E. van Hellemondt, A.C. Hendriks & M.H. Breuning, 'Which lessons from the European Union Legal framework of medicines would be useful to the regulation of DTC genetic tests?', *Law and the Human Genome Review 2012*, nr. 36 (January- June edition).

8.1. INTRODUCTION

internet is a 'global virtual shopping mall'. Almost everything can be purchased through the World Wide Web and delivered to the front door. Internet is also increasingly used for 'Distance Health'. Distance Health encompasses not only free access to health information, medical education and electronic medical records, but it also includes promoting and selling health related services and goods.[429] On the 'E-commerce market' for example there are hundreds of direct-to-consumer (DTC) genetic tests for human diseases and conditions available.

The legal framework of the European Union (EU) for regulating access and supply of DTC genetic tests is very liberal compared to the legal and regulatory framework for (internet) medicines. Due to the rules pertaining to the latter framework access to and supply of (internet) drugs are strictly regulated within the EU.[430] Although both health related products can cause serious damage to the wellbeing of individuals, the rules regulating access to both sets of products differ substantially from each other.

With DTC genetic tests individuals can acquire future health information with a simple mouse click on the button.[431] They will receive information from these tests about the presence of genetic risks and hereditary diseases. The adverts of companies selling DTC genetic tests promise (potential) consumers the opportunity to control their health by identifying diseases earlier, thus enabling them to lead a longer and healthier life.

Supporters of 'Distance Health' argue that unrestricted access to DTC genetic tests strengthens an individual's autonomy. In their opinion these tests empower people to take more control over their health and life. However, DTC genetic tests are frequently offered without information about their, in general, limited predictive value while the received health information could be used to form the basis of profound decisions.[432] And accurate information is an important condition of empowerment and for being able to make autonomous choices.

Most Member States of the European Union (EU) have no legislation that specifically addresses DTC genetic tests. Several Member States have, however, legislation that partly or fully applies to DTC genetic testing services.[433] Nevertheless, there is growing concern in Europe about the seemingly unrestricted access to DTC genetic tests because of the potential health hazards of testing services of questionable quality. Policymakers of several European countries are considering national and European Union (legal) quality standards for the safety and responsible use of these tests.[434]

[429] Schafer 2008, p. 191-197.
[430] cordina 2010, p. 4.
[431] McBride 2010, p. 427-448; Brower 2010, p. 1610-1617.
[432] Marietta & McGuire 2010, p. 369-374.
[433] For information regarding the legalisation of DTC genetic tests in several European countries and the laws on European level which addresses DTC genetic tests see: Carmen & Borry 2011; Chapter 5 of this thesis.
[434] See for example: http://ec.europa.eu/health/medical-devices/files/recast_docs_2008/ivd_pc_outcome_en.pdf (02/04/2012).

In this contribution we examine whether the legal framework of the EU for the safety and responsible use of (internet) medicines could be an example for regulating access to and supply of DTC genetic tests particularly on the level of the EU. We start by describing the impact of the European Law on national health services in section 8.2. We then unravel the European patchwork of legal standards concerning access to and supply of DTC genetic tests in section 8.3. Section 8.4 provides an overview of the legal EU framework regarding (internet) medicines. Lastly, in section 8.5 we formulate an answer to the above question, followed by conclusions.

8.2. THE IMPACT OF EU LAW ON NATIONAL HEALTH SERVICES

EU health policy has in practice a fundamental contradiction at its core.[435] The *Treaty of Lisbon* (signed in 2007) states clearly that health policy and health care are the responsibility of the Member States (Article 168 TFEU). EU initiatives in the field of (public) health must balance universal rules and respect for Member States sovereignty. Moreover, it is settled case law of the Court of Justice of the EU (ECJ) that EU law does not detract from the freedom of Member States to choose their own health security level.[436] However, the rules of the internal market have an impact on national health matters. The rules of this market are generally aimed at obtaining the economic benefits associated with increased competition and reduced barriers to trade by creating a free movement of people, services, goods and capital. According to Article 168 TFEU the Union should ensure in its policies and activities a high level of human health protection. Nevertheless, the free movement and equal access of goods and services within the EU has a major impact on (public) health. Due to the fact that in cross border situations Member States are in principle required to respect the free movement of health related goods (Articles 30, 34 and 35 TFEU), services (Article 56 TFEU) and establishment (Article 49 TFEU) when exercising their power in the field of health. They have to comply with the rules of the internal market when they take measures to have a high level of health. Furthermore, the EU develops specific legislation to achieve uniformity in laws of Member States in order to promote economic integration. The legislative body of the EU adopted specific legislation which covers also products related to the health sector. In the absence of harmonisation EU Member States are under certain circumstances allowed to take measures, which restrict the free movement of goods and services to protect their citizens against (potential) health risks.[437]

[435] Mossialios et al. 2010, p. 4.
[436] Services & establishment art. 52 VWEU; Case C-372/04, *Watts/ United Kingdom* [2006] ECR I-4325.
[437] Case C-108/09, *Ker Optika* [2010] ECR I-12113.

To conclude, the relationship between the law of the EU and health matters is complex. Formally, health policy is the responsibility of EU Member States. Health policy thus falls outside the scope of the EU's legislative competence. Nevertheless, the rules of the free movement of goods, service and establishment could (in)directly apply to DTC genetic tests and (internet) medicines, as we shall notice in the sections below.

8.3. THE LEGAL FRAMEWORK OF THE EU FOR THE SAFETY AND RESPONSIBLE USE OF DTC GENETIC TESTS

8.3.1. DTC genetic testing

Genetic screening can be defined as any kind of test being offered to a person or group of individuals with the aim of detecting or ruling out a hereditary disease, a predisposition to such a disease or to determine whether a person carries a genetic variant that may produce a hereditary disease in its offspring.[438]

Individuals can buy a test kit for screening their DNA on the internet without the involvement of a physician or genetic counselling. After visiting the online shop and ordering a genetic test, the individual will receive a test kit from the company. This kit commonly includes a tube for taking a DNA sample, such as saliva or a hair, to be returned to the company. Upon receiving the DNA sample, the company's laboratory starts the analytic process. A few weeks later the individual can download the test results using a simple code.

Some companies make a distinction between making claims that directly affect healthcare decisions (genetic tests for health purposes) and making health-related claims (genetic tests not for health, but for informational genetic purposes), the so-called 'informational genetic tests'.[439] Companies use this distinction to protect themselves against liability and to skirt round the laws.[440]

In this respect it is important to make a distinction between pre-symptomatic diagnosis tests and susceptibility genetic tests. Pre-symptomatic diagnostic genetic tests are mostly aimed at discovering a monogenetic disease, that is to say a gene mutation which, by definition, will almost inevitably lead to the development of a disease at some point in later in life.[441] By contrast, testing for multiple genetic variants is generally associated with low risks of developing common health conditions and traits. A positive test result—meaning that an affected gene has been detected— generally implies a(n enhanced) statistical risk but not a certainty of developing the disease later in life.[442]

[438] Godard et al. 2003, p. 49-50.
[439] Borry 2008, p. 736.
[440] Borry et al., 'Legislation on direct-to-consumer genetic testing in seven European countries', *European Journal of Human Genetics* 2012, p. 715-721.
[441] Borry 2009, p. 1-2.
[442] McBride et al. 2010, p. 430.

The results of the latter, known as susceptibility tests do not necessarily accurately establish the risk of developing a disorder, because in most cases not all risk factors are included and additional relevant factors, such as family history and lifestyle, are not taken into account by the test. The majority of DTC genetic tests concern susceptibility tests, sometimes in combination with pre-symptomatic diagnostic tests or carrier tests. Thus DTC genetic tests can be seen as an online fortune teller.

The marketing and availability of DTC genetic tests through the internet has been criticized for the absence of individualized medical supervision and the lack of adequate pre- and post-test information provisions. Furthermore, concerns exist about the limited predictive value and clinical utility of a number of the DTC genetic tests being sold directly to individuals without the involvement of a healthcare worker. Individuals have often high expectations about the benefits of DTC genetic tests due to the fact that in general they are offered without adequate information about their limited value and without genetic counselling services. Therefore the interpretation of test results can be challenging for a person,[443] particularly for those with limited knowledge of genetics and medical statistics. It is well known from various studies on genetic counselling that complex information on risk factors is particularly difficult to handle for a layman, regardless of his background or education.[444] Accordingly, individuals could make important health decisions concerning prevention or prophylactic treatment based on incomplete or misunderstood information about their expected health.[445] Moreover, the use of questionable genetic tests can result in health damage and higher healthcare costs as a result of follow-up tests and unnecessary medical treatment. The free access to genetic information outside the 'hospital care' and the doctor-patient relation also gives rise to concerns regarding confidentially and privacy of individuals. Not at least because an individual genetic profile does not only give information about the genetic constitution of the tested person, but provides also information about the genetic makeup of its relatives.

Although the concerns regarding DTC genetic testing associated with the loss of privacy and individual autonomy (self-determination) are important and legitimate, it falls beyond the scope of our contribution. In this Article we shall concentrate on the EU legal framework of DTC genetic testing and the EU legislation regarding (internet) medicines which relates to reliability, medical supervision and the pre- and post-information provision.

8.3.2. DTC genetic tests is a service

The EU has not developed legislation which specifically covers the responsible use of DTC genetic tests. However, some Directives also apply to these tests although they are not primarily aimed at the access to and supply of them. As for EU law, it is important

[443] Hogarth et al. 2008, p. 162-165; McBride et al. 2010, p. 429-432; GAO 2010.
[444] Van Dijk et al. 2004, p. 47-48; Marietta & McGuire *2009*, p. 370.
[445] Marietta & McGuire 2009, p. 371.

how DTC genetic tests are qualified because distinctions are made between goods and services, and different legal regimes apply to each respectively. Moreover, certain Regulations and Directives only address one of the four fundamental freedoms (free movement of goods, capital, services and establishment, and people).

It is settled case law that the ECJ[446] examines, in principle, a national measure in relation to one freedom if a restriction relates to several fundamental freedoms. It will appraise a national measure in relation to two fundamental freedoms if it appears that one of them is not entirely secondary to the other one.[447] In our opinion DTC genetic testing, thus a DTC genetic test, is not a 'good' but rather a 'service' because the test kit with the tube (good) is entirely secondary to the analytic process in the laboratory (service) and the communication process of test results to consumers (service).[448]

In relation to this discussion, some authors argue that DTC genetic testing falls within the scope of Directive 98/79/EC on in vitro diagnostic medical devices. This Directive ensures a quality review before 'high risk' self-tests (for instance self-tests for HIV) are marketed.[449] In our opinion DTC genetic tests are not covered by this Directive. In the first place this Directive does not apply to services; secondly products of general laboratory use are not in vitro diagnostic.[450] The tube for taking a DNA sample has no particular diagnostic value and is not produced with special characteristics for testing.

Directive 98/79/EC regulates a pre-market review for in vitro medical devices. The current pre-market evaluation mechanisms do not apply to DTC genetic tests - even if we qualified them as goods- because their present risk classification is low. Directive 98/79/EC classifies devices according to the perceived level of risk. Each group of in vitro medical devices is subject to regulatory degree that reflects the perceived risk.

Recently, the EU Commission consulted several organisations in the field of genetics about the revision of Directive 98/79/EC.[451] Many respondents have advised to extend the scope of this Directive to genetic tests independently from their proposals. Hence, 86% of the respondents supported additional requirements/ restrictions for DTC genetic tests.[452]

8

[446] The Court of Justice of the European Union has the power to interpret the EU treaties, to measure the interpretation of these treaties by EU bodies and institutions, and to judge a limited number of conflicts within the realm of the EU law.

[447] Case C-20/03, *Burmanjer et el.* [2005] ECR I-4133; Case C-390/99, *Canal Satélite/ Administración General del Estado* [2002] ECR I-607; Case C-275/92, *Her Majesty's Customs & Excise/ Gerhart Schindler & Jörg Schindler* [1994] ECR I-1039.

[448] More detailed R.E. van Hellemondt, A.C. Hendriks & M.H. Breuning, 'Wet bevolkingsonderzoek op gespannen voet met EU recht', *Nederlands Tijdschrift voor Europees Recht* 2010, p. 245-251 ;The software which is used in the laboratory, to sequence the DNA sample, could be qualified as a good.

[449] GR 2008, p 31-32; p. 94-95.

[450] Art. 1(2b) Directive 98/79/EC.

[451] See for example ESHG official response of the EuroGentest network of Excellence in Genetic Testing to the Public consultation on the revision of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices. This document is available at: https://www.eshg.org/eshgdocs.0.html (02/04/2012).

[452] European Commission, *Revision of Directive 98/79/EC of the European Parliament and of the Council of*

8.3.3. The EU legal framework of DTC genetic testing services regarding information

The E-Commerce Directive (Directive 2000/31/EC) sets up an internal market framework for electronic commerce. It covers also the online services by which health related goods and services are offered on the internet. The E-Commerce Directive regulates certain legal aspects of information society services. Information society services are services that are normally provided for remuneration, from a distance, by electronic means and at the individual request of a recipient of services.[453] Furthermore, the Directive established harmonised rules on the information and transparency of online companies which provide (health related) goods and services. Information society services are in principle subject to the legislation of the Member State in which the internet company is established. The E-Commerce Directive requires internet companies to provide certain key information regarding the identity of the company such as name, the geographic address, the company's email address, and the applicable (professional) rules, the relevant regulatory bodies and the supervisory authority.

Member States may take measures to derogate the freedom to provide information society services in order to protect health.[454] These measures have to be objectively necessary for the purpose and the result cannot be achieved by less restrictive measure. In addition these measures should not discriminate services or the establishment on grounds of nationality.[455] Furthermore when measures derogate from the fundamental right of free movement of services or establishment they must pursue their goal in a consistent and systematic way.[456]

The Distance Selling Directive (Directive 97/7/EC on the protection of consumers in respect of distance contracts) applies to any contract concerning (health related) goods and services concluded between a supplier and an individual under organised distance sales.[457] This Directive requires that anyone selling goods and services at a distance, including internet, should provide information to consumers about some basic rights of consumers. It stipulates that consumers shall be provided with sufficient information on the identity of the provider, the main characterises of the services, the price, the arrangements for payment and delivery performance.[458] Furthermore the Directive creates the right for consumers to cancel the contract within seven working days after

27 October 1998 on in vitro diagnostic medical devices, Summary of responses to the public consultation, EC, Brussels, Belgium : 2010, http://ec.europa.eu/health/medicaldevices/files/recast_docs_2008/ivd_pc_outcome_en.pdf (02/04/2012).

[453] Art. 1(2) Directive 98/34/EC.

[454] Art. 3(4) Directive 2000/31/EC.

[455] Case 169/07, *Hartlauer Handelsgesellschaft mbH/ Wiener Landesregierung, Oberösterreichische Landesregierung*, [2009] ECR I-1721; Case 444/05, *Aikaterini Stamatelaki/NPDD Organismos Asfaliseos Eleftheron Epagelmation* [2007] ECR I-3185; Case 385/99, *Müller-Fauré & Van Riet* [2003] ECR I-4509.

[456] See for instance Case 171/07 & 172/07 *Apothekerkammer des Saarlandes et al.* [2009] ECR I-4171; Case 531/106 *Commission/ Italy* [2009] ECR I-4103.

[457] Art. 1-3 Directive 97/7/EC.

[458] Art. 4 Directive 97/7/EC.

its conclusion without giving any reason.[459] This Directive also allows Member States to introduce more stringent measures with regard to ensuring a higher level of consumer protection.

On 22 November 2011 the Directive on Consumer Rights was published in the Official Journal of the EU.[460] It merges four Directives into one and will replace the Distance Selling Directive. The highlights of this Directive are an EU-wide right for consumers to reject goods or cancel a service contract within two weeks, a requirement for companies to give consumers information in a clear and comprehensible manner, the duty to provide certain information regarding the main characteristics of the (online) products and the precise details on their total price, and the prohibition of 'pre-ticked boxes' which are (sometimes) used on shopping websites.[461]

8.3.4. Preliminary conclusion

The access to and supply of DTC genetic tests is, in principle, also (indirectly) regulated by the rules governing the internal market of the EU. However, the European legal framework regarding the access to and supply of DTC genetic tests does not guarantee sufficiently normative criteria for safeguarding the predictive value of tests, medical supervision and quality standards for providing information.

8.4. LEGAL FRAMEWORK OF THE EU FOR THE SAFETY AND RESPONSIBLE USE OF (INTERNET) MEDICINES

8.4.1. Introduction

The pharmaceutical sector is an important part of the EU economy. This sector has been governed by an increasingly comprehensive body of EU law relating to quality standards for the development, manufacturing, supply and use of (internet) medicines and (internet) pharmaceutical services. The EU pursues two major objectives in its policy on (internet) medicines. It strives to secure a high level of health protection and, at the same time, to support a competitive industry that ensures that European citizens continue to benefit from new drugs.[462]

The first goal requires that medicines are safe and effective, but also, that individuals should receive the information necessary to make informed choices regarding the use of medicines.[463] In terms of the free movement of goods the EU has developed and

[459] Art. 6 Directive 97/7/EC.

[460] Directive 2011/83/EU, *OJ* 2011, L304/64. For further information: http://ec.europa.eu/justice/consumer-marketing/rights-contracts/directive/index_en.htm (10-05-2012).

[461] Pre-ticked boxes require consumers to opt out of buying services on websites, such as travel insurance or car hire when buying an airline ticket online.

[462] Mossialos et al. 2010, p. 635.

[463] Mossialos et al. 2010, p. 635.

adopted a regulatory framework for the authorisation, marketing and free movement of medicines.

The body for this legal framework of medicinal products is Directive 2001/83/EC on the Community code relating to medicinal products for human use, recently, amended by Directive 2010/84/EU and Regulation 2004/726, recently, amended by Regulation 2010/1235.[464] Directive 2001/83/EC regulates, for example, which information has to be provided and in which form pharmaceutical products have to be presented to individuals.[465] Regulation 2004/726 lays down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and for the establishment of *European Medicines Agency* (EMA). The Community code defines a medicinal product as 'any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances which may be used in or administered to human beings with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological, or metabolic action, or to making a medical diagnosis.'[466]

In this contribution it is not our intention to examine and analyse the complex and detailed legal framework of medicines. In this section, however, we will describe certain legal issues regarding (internet) medicines which we think are relevant for the regulation of DTC genetic tests, namely premarket review, medical supervision and information.

8.4.2. Review before market

Launching a new drug into the internal market of the EU and/or on national markets is subject to extensive regulatory procedures. The EU has created a centralised licensing agency, the EMA for authorising the marketing of new medicines in accordance with strict criteria regarding safety, quality and efficacy. The EMA is responsible for licensing new medicines as well as drafting guidelines on various stages in development and administration of new medicines.

According to Directive 2001/83/EC and Regulation 2004/726 there are two procedures for obtaining a marketing authorisation for pharmaceutical companies. The first procedure is a centralised application to the EMA for a marketing authorisation regarding the entire EU.[467] The second is a decentralized application for an authorisation covering

[464] Directive 2010/84/EU and Regulation 1235/2010 strengthen and rationalise the current system for monitoring the safety of medicines on the European market. They were published on 31 December 2010 and came into force in January 2011. Both instruments have to be transposed into national law by July 2012.

[465] Feah 2011, p. 31.

[466] Art. 1, Directive 2001/83/EC as amended by Directive 2004/27/EC and Directive 2010/84/EU.

[467] Art. 31 Regulation 726/2004 as amended by Regulation 1235/2010.

only a Member State.[468] This authorisation can be recognised by other Member States of the EU through the mutual recognition procedure.

Under the centralised procedure,[469] a drug manufacturer must submit for consideration a detailed dossier containing data on quality, safety and efficacy to the EMA.[470] The marketing authorisation will be valid in all EU Member States. The centralised procedure is obligatory for biotechnological medicines, medicinal products with a new chemical entity for the treatment of certain diseases.[471] The centralised procedure is optional for other drugs containing new chemical entities and sufficiently innovative medicines. Under the decentralised procedure[472] the pharmaceutical company grants one or more national marketing authorisations. The pharmaceutical company chooses one of the EU Member States 'drugs regulatory agencies to serve as Reference Member States.[473] The application will be submitted by that agency for review. The pharmaceutical company in question decides for itself which markets of EU Member States have its commercial interests. Each chosen Member State – Concerned Member State - makes a submission seeking mutual recognition of the Reference Member States authorisation decision. Unless a Concerned Member State raises an objection the pharmaceutical company grants an authorisation for marketing the medicines on the markets of the Member States he has indicated.[474]

The safety of pharmaceutical products is also affected by activities after placing these products on the internal market during the distribution and consumption of the medicine.[475] Despite the strict regulation concerning new drugs entering the internal market, falsified medicines[476] has been identified as a serious concern for individuals' safety within the European Union.

On December 10th, 2008, the Commission adopted the 'Pharmaceutical package'. The 'Pharmaceutical package' is a series of measures proposed by the European Commission impacting the pharmaceutical industry. The aim of one of these initiatives, Directive 2011/62/EU, is to address the risk of falsified medicines entering the legal supply chain of medicines in the EU. It aims to make sure that no fake medicines are legally distributed across and within Europe.[477]

8

[468] Art. 27 Directive 2001/83/EC.
[469] Regulation 726/2004.
[470] Chapter 1 Regulation 726/2004.
[471] Art. 3(2) Directive 2001/83/EC.
[472] Chapter 4 Directive 2001/83/EC.
[473] Art. 28 Directive 2001/83/EC.
[474] Art. 36 Directive 2001/83/EC.
[475] Bausschke 2011, p. 92.
[476] Art. 1 Directive 2011/62/EU amending Directive 2001/83/EC on the Community code relating medicinal products for human use, as regards the prevention of the entry into legal supply chain of falsified medicinal products defines falsified medicines as any medicinal product with a false representation of (a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients; (b) its source, including its manufacturer, its country of manufacture, its country of origin or its marketing authorisation holder; or (c) its history, including the records and documents relating to the distribution channels used.
[477] COM (2008) 663 final. Available at: http://ec.europa.eu/health/human-use/package_en.htm (02/04/2012).

8.4.3. Medical supervision

The introduction of new drugs into the internal market is closely harmonised by EU legislation. Contrary to this, the classification of prescription medicines is primarily the responsibility of Member States. A prescription drug is a medicinal product that can be purchased or dispensed only with written instructions from a licensed healthcare provider, such as a doctor, dentist, nurse practitioner or physician's assistant, to a pharmacist. These written instructions are known as a prescription.

Non-prescription medicines are available without a prescription; they are called over the counter medicines. According to Article 70 of Directive 2001/83/EC the approving authority is required to specify the classification of prescription drugs and non-prescription drugs. However, Directive 2001/83/EC stipulates that a drug could only be available with a prescription from a health care worker in case they:

- are likely to present a danger either directly or indirectly, even when used correctly, if utilized without medical supervision,
- are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health,
- contain substances or preparations thereof, the activity and/or adverse reactions of which require further investigation,
- are normally prescribed by a doctor to be administered parenterally.[478]

The rapid growth of internet sales of medicines causes new risks for individuals because 'traditional safeguards' not always apply to internet medicines. This is not least by the lack of uniformity in the national regulations concerning medicines. Some authors mention that internet pharmacies can be a huge help to individuals because of their increased access – 24 hours a day –, the lower transactions and production costs, the anonymity and delivery to your home.[479] However, the so-called 'Rogue internet pharmacies' – unapproved pharmacies – sometimes sell drugs without a valid prescription or falsified medicines.[480] Moreover they use sometimes 'cyber doctors', sell drugs without a final authorisation and give misleading information about the medicines.[481]

The facts underlying the *DocMorris* case illustrate what can happen when liberal legislation regarding internet medicines of a Member State is at odds with the more restrict regulations of another Member State of the EU.[482] *DocMorris* is a 'traditional (Dutch)pharmacy' which also operates through internet as an internet pharmacy. A lot of *DocMorris* internet pharmacy consumers lived in Germany. In Germany, some prescription and non-prescription medicines may only be supplied by 'traditional

[478] Art. 71(1) Directive 2001/83/EC.
[479] Fung 2004, p. 188-194.
[480] Cordina 2010, p. 4.
[481] Cordina 2010, p. 4.
[482] Case C-322/01, *DocMorris NV/ Jacques Waterval (Deutscher Apothekerverband)* [2003] ECR I-14887; Pickering 2007.

pharmacies'. According to German law internet sales of medicines and mail order services are only permitted in exceptional cases. In a preliminary ruling, interpreting the existing EU legal framework, the ECJ concluded that a national prohibition of mail order sales of drugs is contrary to EU law, when medicines are authorised in and are not subject to prescription in the 'received Member Sates'.[483] Furthermore, the ECJ found that the mail order prohibition concerning non-prescription medicines was not justified now the risk for individuals is the same as if they were supplied through a 'traditional pharmacy'.[484]

Dispensing prescription drugs without an adequate review of an individuals' medical history and selling unproven drugs can lead to serious consumer injury. The health care worker which is authorised to prescribe medicines is the main decision maker concerning the use of prescription medicines.[485] The health care workers have the obligation to give individuals sufficient information when they prescribe a medicine, in order to enable them to exercise their right of making an informed decision.[486] However, in certain situations there is no health care worker involved in the decision-making process regarding the use of a medicine.

8.4.4. Information

Directive 2001/83/EC and Regulation 2004/726 contain numerous provisions for advertising, information and transparency. Directive 2001/83/EC, for example, banned advertisement of medicines, subject to prescription, to the public and only allowed advertising for other drugs under certain conditions.[487] Hence, Regulation 2004/726 embodies requirements concerning the publication of a European Public Assessment Report which includes a summary written in a manner that is understandable to the public. Furthermore, Directive 2001/83/EC regulates the information and the form in which medicines have to be presented to the end users.[488] These normative criteria for packing and labelling apply to drugs which are subject to the centralised procedure as well as the decentralised procedure.[489] In accordance with the Directive 2001/83/EC the competent authority shall refuse the marketing authorisation if the labelling or the package leaflet does not comply with the provisions of the Directive or if they are not in conformity with the particulars listed in the summary of product characteristics (*European Public Assessment Report*).[490] The Directive stipulates which information

[483] Case C-322/01, *DocMorris NV/ Jacques Waterval (Deutscher Apothekerverband)* [2003] ECR I-14887, para. 16.
[484] Case C-322/01, *DocMorris NV/ Jacques Waterval (Deutscher Apothekerverband)* [2003] ECR I-14887, para. 114.
[485] Faeh 2011, p. 30-41.
[486] Faeh 2011, p. 30-31.
[487] Art. 86-88 Directive 2001/83/EC.
[488] Art. 21, Chapter 4, Title 5 Directive 2001/83/EC; Feah 2011, p. 31.
[489] Chapter 4, Title 5 Directive 2001/83/EC; Art. 9 Regulation 726/2004.
[490] Art. 61 (2) Directive 2001/83/EC.

must be printed on the packaging and written in the package leaflet.[491] The package leaflet must be written and designed to be clear and understandable enabling the users to act appropriately, when necessary with the help of health professionals.[492] Moreover, amending Regulation 2010/1235 and amending Directive 2010/84/EU require the EMA and national agencies to set up (European) medicines web-portals in order to increase public transparency regarding pharmacovigilance issues.[493]

The framework for providing information concerning medicines, which is merely product specific, is not always directly aimed at end users and it is above all very technical.[494] Moreover, it does not restrict the freedom of Member States from developing their own approaches regarding the provision of information concerning medicines as long as they respect Regulation 2004/726 and Directive 2001/83/EC.[495] These approaches of Member States to additional factual information differ widely from Member State to Member Sate.[496] In some Member States the provision of information is mainly ensured by public authorities. They provide, for example, only product specific information. Amongst these Member States, there are some, for example Portugal, which go beyond the provision of product related information by covering other types of information, such as guidelines on treatments, or comparative information on the value of medicines.[497] Moreover, there are also Member States, such as Germany, which have in place public private partnerships or similar initiatives to provide information specifically intended to cover wider patient needs, such as treatment options or guides covering specific diseases or therapeutic areas.[498] This practice gives rise to a number of concerns, namely; EU citizens have unequal access to information, the lack of quality standards for information within the EU increases the risk that individuals receive wrong, misleading or confusing information, and the lack of information may result in uninformed choices.[499]

The 'Pharmaceutical package' contains also a legislative proposal for providing EU citizens with understandable good quality, objective, reliable and non-promotional information about the benefits and the risks of medicines and treatments. It will maintain the current ban on direct advertising of prescription medicines and aims to clear differentiation between advertising and non-promotional information.[500]

[491] Art. 62 (2) Directive 20011/83/EC.
[492] Art. 59 Directive 200/83/EC.
[493] Art. 106 Directive 2001/83/EC; art. 26 Regulation 726/2004.
[494] Art. 59 Directive 200/83/EC; Valverde 2010, p. 198.
[495] Valverde 2010, p. 194.
[496] COM (2007) 862 final, p. 8.
[497] COM (2007) 862 final, p. 4-5.
[498] COM (2007) 862 final, p. 4-5.
[499] COM (2007) 862 final, p. 9.
[500] COM (2008) 663 final.

8.4.5. Preliminary conclusion

The pharmaceutical sector is an important part of the EU economy. This sector has been governed by an increasingly comprehensive legal framework of EU law relating to quality standards for the safety and responsible use of (internet) medicines. Introducing a new drug into the internal or national market is subject to extensive regulatory procedures. Contrary to the authorisation of medicines, classification of prescription drugs and the provision of end users are primarily the responsibility of Member States. Legislation aimed at responsible use of medicines has been designed to achieve certain goals while many vital aspects remain outside the regulatory body.[501] The efficacy and safety of pharmaceutical products can neither be guaranteed on the national level nor by a single necessarily premarket review, but rather calls for a procedural long-term perspective on European level and/or the awareness of the public for their role in pharmaceutical safety.[502]

8.5. DISCUSSION

Can the legal framework of the EU for the safety and responsible use of (internet) medicines be an example for regulating access to and supply of DTC genetic tests? In other words, which lessons can be learned from analysing the strict regulation of drugs and its effectiveness within the EU?

EU regulation of access to and supply of (internet) medicines entails a comprehensive framework which aims to remove disparities between national measures in order to ensure the proper functioning of the internal market, whilst at the same time safeguarding human and public health.[503] By contrast, access to and supply of DTC genetic tests are poorly regulated in the EU, or at least on an EU level. As a result, in various Member States individuals have unrestricted access to these tests.

Admittedly, DTC genetic tests and (internet) drugs have different legal characteristics as well as features concerning their contents. Medicines are for example goods with therapeutic value and a DTC genetic test is a service with a questionable diagnostic result. However, both health related products could have serious adverse health effects (section 8.3.1, 8.4.2 and 8.4.3). In this respect DTC genetic tests have been criticized for its absence of premarket review, medical supervision and provision of adequate information (section 8.3). These safety risks are harmonised under specific Directives and regulations concerning access to and supply of medicines to ensure the same level of health protection of individuals across the whole EU. (internet) medicines and DTC genetic test moreover, have in common that they easily cross borders –through internet - which posing complex problems of jurisdiction and conflicts of law.

[501] Bauschke 2011, p. 111.
[502] Bauschke 2011, p. 111.
[503] Bauschke 2011, p. 111; COM (2008) 663 final, p. 3.

When studying Directive 2001/83/EC and Regulation 2004/726 we have to conclude that these legal documents have made a major contribution to the achievement of the objective that (internet) medicines have to be authorised prior to their introduction into the internal market. Despite this comprehensive legal framework current concerns –of falsified medicines, the lack of uniformity between Member States regarding prescription (internet) medicines and the unequal access to information- related to (internet) drugs illustrate that effective regulation should start with an EU legal framework of authorisation and end with legislation on matters concerning the safety and responsible use of health related goods and services, the 'post-authorisation process'.[504] Hence, in order to increase the effectiveness of a legal framework of access to and supply of DTC genetic tests a premarket review should be the first step in the 'regulatory lifecycle'. It should therefore be seen as an important part of the whole 'regulatory lifecycle' in regard to the responsible use of DTC genetic tests.

It should be noted that some companies which offer DTC genetic tests make a distinction between genetic tests for health purposes and genetic tests for informational purposes.[505] For that reason it is important that the 'regulatory lifecycle' applies to *all* DTC genetic tests which could detect or rule out human diseases, conditions and/or acquire future health information. This means that no distinction should be made between several primary test purposes. And it also implies that a clear definition of DTC genetic tests and/or testing service, without a reference to possibilities of consumer or company intentions, is very important.

The EU legal framework of (internet) medicines can serve as an example for (central) authorisation of the marketing of DTC genetic tests on the internal market in accordance with strict criteria regarding predictive value and clinical usefulness. However, the responsible use of DTC genetic tests maybe calls for an authorisation system which applies to DTC genetic testing services and/or the test company. The main concerns are the quality of the service, inter alia the limited predictive value of the tests, the lack of proper information and the absence of medical supervision. Therefore, only a premarket review of the predictive value and clinical usefulness concerning DTC genetic tests is not enough to guarantee the responsible use of these tests.

The *DocMorris* case demonstrated that uniformity of laws regarding DTC genetic testing service is a necessary condition for the responsible use of genetic tests within the EU. As mentioned before, contrary to the authorisation of (internet) medicines the classification of drugs - thus the free access to medicines - is the responsibility of Member states. Using (internet) medicines and DTC genetic tests without the involvement of a health care worker could have far reaching implications (section 8.3.1 and 8.4.3). Dispensing (internet) medicines without an adequate review of an

[504] Bauschke 2011, p. 92; COM (2008) 663 final.
[505] Borry 2008, p. 736.

individual's medical history can lead to health hazards. The same can be said of DTC genetic testing services. Testing without the involvement of a health care worker and/ or genetic counsellor can lead to serious consumer injury, because interpretation of the test results is difficult for a layman. Moreover, genetic testing could have psychological and social implications. The 'regulatory lifecycle' concerning the responsible use of DTC genetic testing, therefore, also has to stipulate medical supervision and quality criteria for the information that has to be provided during the genetic testing services. The health care worker and/ or the genetic counsellor will be able to provide individuals with adequate information about DTC genetic testing service in order to enable individuals for making an informed decision, just like the health care worker which is authorised to prescribe medicines. As we have described in section 8.4.4. the information on the package leaflet is often very technical. Nevertheless, the normative criteria for packing and labelling (internet) drugs could be a model, to supply individuals with complementary objective information about the characteristics of DTC genetic tests.
DTC genetic tests traded via online markets are difficult, and may be impossible, to supervise.[506] Offering genetic tests directly to individuals via internet raises complex legal questions that cannot merely be answered by individual States or the EU. In this respect adequate protection of individuals against questionable DTC genetic testing services demands quality standards which provide (potential) users with non-promotional information about the benefits and risks of DTC genetic tests.
Protecting individuals against questionable genetic testing kits calls for international vigilance and comprehensive measures by the international community. However, a legal EU framework regarding access to and use of DTC genetic tests is not meaningless because some DTC genetic testing companies respect the fact that DTC genetic testing is outlawed in certain (American) States, and announce on their website that they don't process samples submitted from citizens from these States.[507] And more importantly, EU quality standards for information concerning DTC genetic testing could help individuals to make informed decisions. It decreases the risk that individuals make their decisions based on wrong and misleading information.

8.6. CONCLUSION

In Europe there is growing concern about the unrestricted access to DTC genetic tests because of the potential health hazards for consumers of testing services of questionable quality.

[506] Bauschke 2011, p.104.
[507] Borry et al., 'Legislation on direct-to-consumer genetic testing in seven European countries', *European Journal of Human Genetics* 2012, p. 715-721.

The legal framework of the EU for regulating access to and supply of DTC genetic tests is very liberal compared to the legal framework of (internet) medicines.[508] Although both health related products can cause serious damage to the wellbeing of individuals, the accessibility to both is quite different. This raises the question whether the legal framework of the EU for the responsible use of (internet) medicines could be an example for regulating access to and supply of DTC genetic tests. It was argued here that efficacy and safety of pharmaceutical products can neither be guaranteed on the national level nor by a single necessarily premarket review but rather calls for a procedural and long-term perspective on a European level and/or the awareness of the public about their role in pharmaceutical safety.
To conclude, the EU legal framework of (internet) medicines could, notwithstanding its shortcomings, serve as an example for (central) authorisation of the marketing of DTC genetic testing services on the internal market in accordance with strict criteria regarding clinical utility and predictive value and usefulness. However, a legal framework of DTC genetic testing service also should introduce medical supervision and quality criteria for the information that have to be provided during the genetic testing procedure in order to increase the effectiveness of health protection. The normative criteria for packing and labelling (internet) drugs could serve as a model for supplying individuals with complementary objective information about the characteristics of DTC genetic tests.

DTC genetic testing services traded via online markets are difficult, and may be impossible, to supervise. In this respect, EU quality standards concerning information to be provided will help individuals to make informed decisions regarding the use of DTC genetic tests and consequently decrease health risks. Adequately protecting individuals against questionable testing kits calls for international vigilance and comprehensive measures by the international community. For Europe, it is important to rank the regulation of DTC genetic tests on the European regulatory agenda.

[508] Cordina 2010, p. 4.

CHAPTER 9

CONCLUDING REMARKS

9.1. INTRODUCTION

This thesis contains the findings of the research project: 'Use of predictive medicines, large scale applications of genomics in the field of predictive medicine in the Netherlands: the role of the law'. This project was carried out in the period May 2009 to June 2013. The first objective of the research project was to seek an answer to the question what, from a constitutional law perspective, are the responsibilities and obligations of the Dutch State with regard to access of individuals to genetic screening. In order to find an answer to this question I studied the case of direct-to-consumer (DTC) genetic tests, an application of genetic screening. The results of this study are described in Part A. The second aim of the project was to identify normative criteria to apply to genetic screening, in particular access to and supply of DTC genetic tests. The research findings of this part of the project are reflected in Part B. In this chapter I will summarise the most important findings of this study and make some concluding remarks.

9.2. BACKGROUND

Ever since the human genome has been unravelled, developments in the field of genomics have advanced at a breakneck speed. In recent years several companies have discovered an attractive market. They offer all kinds of DNA tests directly to customers without a doctor's involvement or consultation with a genetic counsellor, frequently via Internet.

In keeping with the Dutch State's positive obligation to protect individuals against health threats, the access to and the supply of direct-to-consumer genetic tests are discouraged by law. The licensing system of the Act on population screening (in Dutch: 'Wet op het bevolkingsonderzoek' (WBO)) wards off these DTC genetic tests from the Dutch 'screening market'. This meets with criticism in society. Individuals experience the strict quality criteria regulating access to DTC genetic tests as an unnecessary restriction of their self-determination. DTC genetic tests have the potential to empower individuals to take more responsibility for their health. With these tests individuals obtain knowledge about their risks of getting diseases or disorders in later life.

Frequently, with a DTC genetic test thousands of polymorphisms are typed, some of which modify the risk of disease. Genetic testing on multi-factorial inherited diseases is about risks and probabilities. The future is not only shaped by genes, but also by other factors such as life style. It has been noted that the scientific evidence supporting the association between a gene variant and a disease or preventive advice for many of the DTC genetic tests is limited.[509] And in general the suppliers[510] of DTC genetic tests - who

[509] Kalf et al. 2013.
[510] The party that supplies goods and services.

as a rule are also the providers[511] of the tests - are not very generous with providing information about the narrow predictive value of these tests and their (potential) risks. This raises the question: 'what are from constitutional and European law perspectives the normative criteria for access to and supply of DTC genetic tests?'

9.3. PART A: SELF-DETERMINATION AND PROTECTION

9.3.1. Research findings part A

In the first chapter it was noted that by allowing DTC genetic tests to be freely obtainable, the answer to the question how to regulate the availability of DTC genetic tests is dependent on the question how to balance the fundamental notions of self-determination and protection. Neither of these notions is given absolute value in the academic literature or in the case law of the ECtHR(chapter 2). Member States of the Council of Europe have the responsibility to take measures for the promotion and protection of health. States Parties of the ECHR have the obligation to ensure the enjoyment of ECHR rights to all individuals within their territories. According to the case law of the ECtHR regarding articles 2, 3 and 8 ECHR States Parties have a positive obligation to protect residents from (potential) serious health threats (part A).

However, the Dutch State is also obliged to respect the self-determination of individuals. Respecting self-determination, according to the ECtHR jurisprudence implies that individuals have the freedom to choose behaviour which can cause (health) damage. This freedom can be restricted in case the decision was not based on *informed consent*, if human dignity is affected or if the interests of others are at issue (chapter 2).

In this respect it is important to notice that the question whether a right to screening or self-determination as a claim right exists, must be answered in the negative, in the light of the ECtHR's case law (chapter 2 and 4).

The requirement of *informed consent* for medical treatment forms an essential safeguard for the right to respect for the private life and the self-determination of the individual. According to the ECtHR the information must be complete, reliable and accessible in good time. Articles 8 and 10 ECHR entail, according to the ECtHR, a general right to information. The principle of *informed consent* is above all a norm which creates an obligation for the State, the health care worker and the supplier towards consumers. From a legal perspective healthcare providers and suppliers of genetic screening must do everything in their power to guarantee so that consumers have the opportunity to make an informed choice. This is not just important for respecting self-determination but it is also a criterion for conducting a 'good' commercial practice and 'fair' advertising (chapter 2 and 4).

[511] The party that perform the services.

In conclusion: Under the ECHR the Dutch State has the responsibility to protect citizens from health damage stemming from unsound screening (chapter 2-5).

9.3.2. Case study

The principle of *informed consent* and the interest of others were given special attention in the case study DTC genetic tests. DTC genetic tests are criticised in academic literature due to the limited predictive value, the failure by suppliers to provide adequate information and the absence of medical supervision and counselling during the process of genetic testing.

In the framework of the concepts protection and self-determination States Parties of the ECHR should promote that prior to genetic testing individuals have the opportunity to make a choice based on information regarding the predictive value, advantages and possible side-effects of DTC genetic tests. It can be debated whether the supplier of certain tests spend sufficient effort to ensure that consumers can make informed choices, by working the way they do now. It can also be questioned if consumers give lawful consent. However, burdening (family) doctors with the responsibility to inform consumers about DTC genetic tests and interpreting the test results, instead of the provider, would be unacceptable to the physicians. Above all it is a curtailment of consumer self-determination.

The Dutch State is, according to the case law of the ECtHR, not just obliged to respect the fundamental rights and freedoms of individuals. States Parties have also the duty to guarantee these rights and freedoms, also with regard to horizontal relations. Horizontal relations are relationships between 'equals', for example the relationship between a doctor and a patient or a company and a consumer. The discussion about the desirability of 'free' access to DTC genetic tests does not just affect the self-determination of (potential) users of these tests. It also touches the fundamental rights and freedoms of others as mentioned in part A and B. DTC genetic tests have the special characteristic, just like other forms of genetic screening, that they do not just give information about the genetic constitution of the 'tested individual' but also about his or her blood relatives. In such situations blood relatives, without counselling or prior consent, can be confronted with health information which they would have preferred to remain unaware of.

Recent research shows that free access to DTC genetic testing can have implications especially for the cost of healthcare and the rights of individuals who are by legally or factually not in a position to make health care decisions themselves, such as minors.[512] Interests of others also can be at stake as avoidable follow-up tests and overtreatment as a result of DTC genetic tests are an unnecessary drain on the general financial resources. This might have consequences in the long-term on the accessibility of healthcare.

[512] Bloss et al. 2013, p. 5; Borry & Howard 2013.

Conclusion part A:
On account of the two core values, protection and self-determination, there are good reasons for the Dutch State to regulate the use of DTC genetic tests, notably by making access to and supply of these tests conditional to quality standards. The Dutch State should regulate the access to and the supply of DTC genetic tests because of their limited predictive value, the deficiencies with respect to adequate information and valid consent. Regulating the use of DTC genetic tests is also justified in order to guarantee the right and freedoms of others.
In the respect of a fair balance between the right to self-determination of individuals and the need to protect them against (potentially) harmful screenings. A conclusion of Part A is that regulation should be based on the differentiation of quality requirements for the risk manifestation, the seriousness of damage and the social, psychology implications of unsound genetic screening.

9.3.3. Remarks

Protective regulation for screening to ensure self-determination seems to be a contradiction in terms. Legislation which aims to protect individuals against unsound genetic screening could limit the free availability of DTC genetic tests and thus limit the self-determination of individuals. However, unrestricted access to genetic screening can affect the level of protection against potential harmful genetic screening. Self-determination and health protection are communicating vessels. Self-determination in literature and jurisprudence is often regarded and interpreted as the *'right to be left alone'*.
In my view self-determination has to be explained from different perspectives. Self-determination also implies the possibility of organising life as one sees fit, self-determination in the dimension of *freedom to choose* how life is organised and in the meaning of *freedom of self-development.*[513] In this view taking measures that provide protection against (health)damage or that respect the principle of *informed consent,* do not detract from the self-determination. They rather strengthen this notion in the perspective of *freedom of choice* and *freedom of self-development.* In this context the protection of *freedom of development* means the prevention of individual health hazards or harm from others that affect the freedom to organise life to our own wishes.[514]
Attempts have been made by several esteemed institutions like the Dutch Health Council, RVZ[515], the Minister of Health, Welfare and Sport and the European Commission to find the key to solve the problem of inappropriate screening in the Dutch and European 'healthcare market'. The solution in the Netherlands and the EU appears to have been

[513] Hendriks et al. 2013, p. 41-45.
[514] Hendriks et al. 2013, p. 41-45.
[515] Council for Public Health and Care recommendation.

found by setting requirements to the information provided with DTC genetic tests by suppliers and providers, as well as to its technical specification.[516] The idea is to arm the public with knowledge so that individuals can make informed choices.[517] This fits in with a healthcare system that is driven by an open-market where the emphasis is on people's own responsibility, freedom of choice and self-management. Within the dominant open-market oriented view of healthcare it is evidently assumed that we are (all) competent to be able to make informed decisions, which is however debatable. Apart from that sensible well-informed people can take damage-causing decisions. I can broadly agree with the theory that individuals, when of sound mind, also have the right to take decisions which can be damaging to their health. This is different when there is no valid consent or when the rights and freedoms of others or society are affected, or human dignity is at stake (chapter 2). Consent is just one of the requirements for carrying out a DTC genetic tests.[518] The State, the physician and the company that provide screening after a clear *informed consent* from an individual still have an 'own' (professional) responsibility.[519] In my view physicians and companies should not be offering and performing DTC genetic tests on patients and consumers if the (potential) individual (health) risks overshadow the (health) benefits, even in situations where consumers, after reliable information about advantages and disadvantages, still wish a DTC genetic test or another screening.
The difficulty regarding the competency and the capacity to make decisions regarding health and/or treatment of patients is beyond the objective of this thesis. However, I would like to make one comment regarding this subject. It is not easy for physicians in 'regular' circumstances to be certain whether patients can make reasonable assessment of their interests in matters of health. This is even harder when the doctor has no 'face to face' contact with the patient because they only communicate through the telephone or internet. With DTC genetic testing the involvement of a physician is absent. Who then determines the competence and capacity of consumers to make decisions regarding their health?

To sum up, it must be kept in mind by States and suppliers that, when individuals seek access to DTC genetic tests, the substantive norm self-determination is not sufficiently warranted by standardised or general information about the characteristics (chapter 3). The same is true for the provision of global information about the interpretation of the test results of certain tests. Within the framework of safeguarding self-determination, there is a lot to be said for a standard offer of individual counselling in

[516] COM (2012) 541 final; Multidisciplinaire Richtlijn Preventief Medisch Onderzoek. Koninklijke Nederlandsche Maatschappij tot bevordering der Geneeskunst. Utrecht May 2013; Van der Maas 2000; GR 2008; RVZ 2008.
[517] GR 2008, p. 18.
[518] Van Beers 2009, p. 109.
[519] Van Beers 2009, p. 218.

which the information about DTC genetic tests is tailored to the information needs of the consumer (chapter 3).
More importantly, only providing information regarding the benefits and risks of DTC genetic tests by States and suppliers is in my opinion not enough nor an effective way of protecting individuals against potential health risks.[520] Neither is it an adequate way of guaranteeing the rights and freedoms of others than the potential tested person. It is true, 'Forewarned is forearmed'. But there is only one problem: the harmful screening, which can cause health damage to people, is still freely available.

9.4. PART B EUROPEAN LEGAL FRAMEWORK

9.4.1. Research findings

Regulating genetic screening on a European level
Although a comprehensive European normative framework is absent, important principles and norms, relevant to the access to and supply of genetic screening for health purposes, have gained recognition on a European level. I examined in part A the legal instruments of the EU and the Council of Europe which apply to genetic screening. These legal documents stipulate that the validity, specificity, sensitivity and clinical benefits are crucial factors if marketing and/ or implementing genetic screening is allowed. Furthermore, according to these documents genetic screening with far reaching implications for individuals or their relatives should not be permitted without the supervision of a healthcare worker. And appropriate non-directive genetic counselling should be offered before and after testing. Moreover, access to and the supply of genetic screening should be accompanied by rigorous *informed consent* procedures owing to the examined legal instruments of the EU and the Council of Europe (part B).

Regulating genetic screening on national level
In the Netherlands, the 'Act on Public Health' [521] together with the WBO forms the legal framework that primarily aims to protect and to promote health at population level. Both Acts regulate matters in the field of public health which the legislator deems fit for a 'healthy society' (chapter 2).[522] The first Act assigns duties and the powers of the Dutch State in the field of public health. The WBO is the most important legal instrument which regulates the access to and the supply of screening classified as population screening. This system was introduced to establish a fair balance between

[520] Dute 2013, p. 19.
[521] De Wet publieke gezondheid.
[522] Drewes 2009, p. 159.

the right to self-determination of individuals and the need to protect them against (potentially) harmful screenings.[523] The WBO sets quality requirements through a licensing system for certain forms of screening, namely high risk population screening (part A and B).

The Dutch 'National Programme Population Screening' (NPPS)[524] is part of the domain of public health. The NPPS contains a number of large-scale, national screenings offered by the State.[525] The NPPS is not legally entrenched and has no (formal) legal basis in the WBO nor in the Act on Public Health. This is remarkable. In the framework of the NPPS the Dutch State intrudes uninvited into the life of citizens, sometimes strongly urging them to avail themselves of the screening offer. It is generally accepted that population screening should be carried out with sufficient warrants for the self-determination of individuals due to the general risks of screening and the uninvited offer to healthy individuals.[526]

Furthermore, the Dutch 'Act Medical Treatment Contracts'[527] as part of the Dutch Civil Code, applies to contracts in which a supplier provides medical services. This act lays down the rights and obligations of care providers and the patients and also in certain situations customers (chapter 2 en 3).

9.4.2. Case study.

In the Netherlands, traditionally DNA diagnostics have been available through the Clinical genetic departments of the University Medical Centres (chapter 2.4). According to the Dutch Act 'Exceptional Medical Procedures'[528] these departments have been granted a licence for complex genetic counselling and clinical DNA diagnostics. In general DTC genetic tests cannot be defined as a clinical genetic examination, due to the fact that certain tests mostly are performed outside the hospital care system.

DTC genetic tests are qualified under the WBO as population screening. These tests come under the scope of this Act because the Dutch Minister of Health, Welfare and Sports and the Dutch Health Council take the position that the initiative (the offer) for a DTC genetic test rests with the (healthcare)provider. In their opinion businesses invite consumers via Internet or the media, with a financial contribution in return, to take part in a screening to detect (risk-indicators for) or exclude diseases. The fact that the individuals themselves are often actively searching for information about DTC genetic tests, for example via a browser on Internet, does not affect this.

[523] Van der Maas 2000, p.7.
[524] Nationaal Programma Bevolkingsonderzoek.
[525] http://www.rivm.nl/Onderwerpen/Onderwerpen/B/Bevolkingsonderzoeken_en_screeningen/Achtergrondinformatie/Bevolkingsonderzoek_de_organisatie/Nationaal_Programma_Bevolkingsonderzoek_de_cijfers
[526] Hendriks et al. 2013, p. 64-67 & 69-71.
[527] Wet op de geneeskundige behandelingsovereenkomst (art. 7:446 BW etc.).
[528] Wet op bijzondere medische verrichtingen.

The WBO conflicts with the Protocol concerning Genetic testing for Health purposes. The Netherlands has not yet ratified this Protocol (Chapter 7). The WBO, contrary to the Protocol concerning Genetic testing for Health purposes, does not regulate access to an supply of all genetic tests and only guarantees the Council of Europe's normative criteria for DTC genetic tests aimed at detecting the (risk indicators of) cancer and (risk indicators of) untreatable diseases.

In part B I took the position that the IVD-Directive[529] does not cover DTC genetic tests because the tube in the toolkit has no separate value and is nothing more than a product for general laboratory use. For the sake of completeness, the software which is used by analysts in the laboratories could be classified in some circumstances as medical devices which are under certain conditions covered by the Medical Devices Directive[530] (6.2 and 8.3.2).

In part B I concluded on the basis of the case study that the WBO and the way that it is applied, are not in accordance with the Internal Market rules of the EU regarding services and establishment (chapter 6). The principle of freedom of establishment enables a provider to offer and perform genetic screening in a stable and continuous way in one or more Member States of the EU. The principle of the freedom to provide services enables a provider in one Member State to offer and perform genetic screening on a temporary basis in another Member State, without being established over there. In accordance with Article 62 TFEU the exceptions regarding the freedom of establishment also apply to the free movement of services.

It can be debated why the EU's primary law regarding the free movement of goods does not apply to the *toolkit*, now the IVD-Directive does not cover the supply of DTC genetic tests.

In my opinion the licence criteria of the WBO, which is a restrictive measure, have to be examined in relation to the free movement of service. It is true that no case law of the ECJ exists regarding the free movement of DTC genetic tests. However, during the past twenty years several cases - *Her Majesty's Customs and Excise/Gerhart Schindler & Jörg Schindler (1994)*[531]*, Canal Satélite/Administración General del Estado (2002)*[532]*, Burmanjer et al.* (2005)[533] and *Ker Optika* (2010)[534] – were brought before the ECJ regarding a measure which restricted directly or indirectly the free movement of several fundamental freedoms, mostly goods and services. As I have mentioned before it is settled case law in certain situations that the ECJ examines a restriction in relation to one freedom. In the past years, as far as I know, the ECJ only once examined

[529] Directive 98/79/EC.
[530] Directive 93/42/EC as amended by Directive 2007/47/EC.
[531] Case C-275/92, *Her Majesty's Customs and Excise/Gerhart Schindler & Jörg Schindler* [1994] ECR I-1039.
[532] Case C-390/99, *Canal Satélite/Administración General del Estado* [2002] ECR I-607.
[533] Case C-20/03, *Burmanjer et al.*[2005] ECR I-4133.
[534] Case C-108/09, *Ker Optika* [2010] ECR I-12113.

a measure in relation to two fundamental freedoms in a similar situation.[535] In this case it appeared that the good, the decoder, was not entirely secondary to the connected service. The cases where the ECJ examined a measure affecting several freedoms in relation to the free movement of goods, the concerned good had a separate value, like a contact lens, a magazine.[536] In the case *Her Majesty's Customs and Excise/Gerhart Schindler & Jörg Schindler* regarding a lottery, the ECJ has judged that the importation and distribution of the lottery tickets (the good) are not ends in themselves. They are important to participate in the lottery (the service). The same applies to the toolkit with the tube which is used for the performing of DTC genetic tests. People like to have the service, the sequencing of their genome and the risk calculations regarding disorders and diseases. DTC genetic tests could be compared with urinalysis: contrary to DTC genetic tests nobody shall question if urinalysis is a service, even though a good is used for taking a urine sample at home.

In part B I concluded that the WBO is at odds with EU law (as argued in chapters 6, 4 and 8). The prohibition, the licensing or the introduction of a quality mark for DTC genetic tests by national States are restrictions because these measures discourage and derogate the free movement of services and establishment (chapter 6). Imperative requirements of general interest can objectively justify the restriction of the free movement of services and establishment. These restrictive measures can be justified for public health reasons if they meet the requirements of non-direct discrimination on grounds of nationality and proportionality. Before answering the question whether the restriction does not go further than necessary for its aim, the suitability of the restricted measure has to be verified (chapter 6). The licences requirement of the WBO conflicts however with the law of the EU. This is partially the result of the fact that the definition of population screening and the licence requirements of the WBO are ambiguous. The licences criteria of the WBO are not foreseeable and accessible. Furthermore, the WBO conflicts with EU law regarding the free movement of service and establishment because of its enforcement problems. It does not pursue its goal consistently and systematically (chapter 6).

The existing Dutch legislation can easily be side-stepped by the so-called 'foreign routes'. These deficiencies that affect the protective function of the WBO are increasingly becoming an encumbrance with the growing free availability of DTC genetic tests. As I pointed out in chapter 8 DTC genetic tests traded via Internet are difficult to supervise. Protecting individuals against questionable genetic testing calls for international measures by the international community. However, regulation on national and European level is not meaningless. Firstly, the WBO provides a basic level of protection against (potential) harmful screenings. It effectively prevents individuals from getting

[535] Case C-390/99, *Canal Satélite/Administración General del Estado* [2002] ECR I-607.

[536] Case C-108/09, *Ker Optika* [2010] ECR I-12113; Case C-390/99, *Canal Satélite/Administración General del Estado* [2002] ECR I-607; Case C-20/03, *Burmanjer et al.*[2005] ECR I-4133.

access to unsound screening. Secondly, some DTC genetic test companies respect the fact that DTC genetic tests are outlawed in some countries. And lastly, national and European quality standards for information help individuals to make decisions based on adequate information.

Conclusion part B:
Within Europe there seems to be a consensus on the fact that genetic screening should not be offered without medical supervision, non-directive genetic counselling and rigorous *informed consent* procedures. The test instrument used for genetic screening, moreover, should be reliable and valid.
In the Netherlands DTC genetic tests falls under the scope of the WBO. This Act is a unique and effective piece of legislation (chapter 5). Despite interpretations and enforcement problems it provides a basic level of protection against (potential) harmful population screening. Nevertheless, a revision of the WBO in line with the European legal standards is necessary. The Act conflicts with the legal standards of the Council of Europe and the legislation of the European Union.

9.4.3. New developments[537]

New developments on European level
With respect to the relations between the WBO and European legislation, it is significant that the European Commission has adopted a proposal that has now been submitted to the European Parliament and the Council of Ministers with regard to a Regulation concerning in vitro diagnostic medical devices.[538] In this proposal a radical change has been presented with regard to the legal framework of the EU for DTC genetic tests. This Regulation can have far-reaching consequences for Dutch legislation for genetic screening and the values underpinning it. It is early days to formulate a comment here and now because it is still unclear what the definition of DTC genetic test is or will be in the concept Regulation. Also it is not clear when a genetic test should be classified as a good (possibly in the future regulated by the 'new' IVD Regulation) and when as a service (regulated by the free movement regime with regard to services). Furthermore, various amendments have been proposed, for instance an amendment regarding the freedom of Member States of the EU to restrict supply of such tests due to the ethical and social implications.

New developments on a national level
Recently the multidisciplinary Guideline Preventive Medical Examination (PMO-guideline) was published by the Royal Dutch Medical Association (KNMG).[539] This

[537] The last chapter of this thesis have been completed at 18 October 2013.
[538] COM (2012) 541 final.
[539] KNMG 2013.

Guideline sets quality requirements for DTC (genetic) screening through conditioned self-regulation. In conditioned self-regulation the State establishes intrinsic or process requirements for the regulation. The aim of this PMO-guideline is to formulate quality criteria and to make recommendations for the provision and carrying out of PMOs. The guideline includes an information system to inform individuals about PMOs. Furthermore, it is intended to design a certification assessment system for the supervision and enforcement of the PMO-guideline. The guideline is complementary to the already existing legislation. A population screening for which a licence is required under the WBO and screening programmes from the NPPS do not fall under the scope of the PMO-guideline. This also applies to (self)tests where the IVD-Directive is applicable.

9.4.4. REMARKS

Regulation

Based on the research findings from previous chapters it have to be concluded that from a constitutional and European Union Law perspective there are good reasons for the Dutch State to regulate the access to and supply of DTC genetic tests. Member States of the Council of Europe and the EU have freedom of policy with regard to regulatory and enforcement systems to realise the objectives of the treaty provisions and EU-directives. It must be kept in mind that if the Dutch State chooses the instrument of self-regulation by setting authorisation and quality requirements for DTC (genetic) screening, the Dutch State remains fully responsible for the compliance with fundamental rights and freedoms.

In my opinion self-regulation is not an effective way for guaranteeing the rights and freedoms of others. The strict (licensing) requirements of the current WBO provide an effective protection against unjustified infringement of the rights and freedoms of others. In the discussion about the WBO and permitting DTC (genetic) screening, for that matter in this study too, little attention has been paid to an important subject: the position of individuals for whom the self-determination (temporarily) is actually exercised by others. Not infrequently this subject is approached from the perspective of the representative.

Care must be taken by States, physicians and suppliers of (genetic) screening that the concept self-determination regarding individuals for whom the self-determination is exercised by others does not just become ‘a snapshot of irreversible choices’. The way in which the fundamental rights and freedoms of unborn, minors and incapable adults can be met in relation to DTC (genetic) screening requires further research.

Same normative criteria

In the previous chapters we saw on national and also European level that in the field of genetics different legal regimes can apply to the same technical medical procedure

which is used for DNA diagnostics. Which legal regime applies, depends on the context in which the genetic examinations take place. Nationally, it can be questioned why not *all* DTC genetic tests are classified as 'special procedures' where legal access and quality requirements are set on the grounds of the Act 'Exceptional Medical Procedures' to protect the self-determination of the individual and others. It is difficult to see why *clinical* DNA diagnostic and complex genetic counselling are regarded as 'special procedures' on account of the social and ethical implications, and DTC genetic tests are not regarded as such (chapter 2). In principle the techniques which are used to examine the DNA and the possible physical, social and psychological implications are fundamentally the same.

The way I see it the same minimal normative quality criteria should apply to individual clinical genetic diagnostics, national screening programmes and DTC genetic tests, given the fact that many advantages and disadvantages are not just typical of DTC genetic tests but also apply to clinical genetic diagnostics at (regular) hospitals and national screening programmes. It is hard to see why in practice different quality requirements and patient/ consumer rights should apply, depending on the type of testing and the person who takes the initiative to do this.

The future of the WBO

Based on the evaluation of the WBO, the recommendations of the Dutch Health Council, the advice of the RVZ and the reports of the Healthcare Inspectorate and the findings of this research, a revision of the WBO seems inevitable. Since the WBO came into force its scope has caused problems due to the unclear definitions and ambiguous licensing criteria. It is worrying that these deficiencies of the WBO affect the protective function of the Act. A permit system without foreseeable and accessible licence criteria is an invitation to arbitrariness. It can be used to avoid sharp ethical discussions or decisions and inhibit scientific knowledge. This undermines, in my beliefs unnecessarily, the level of support in the Dutch society for the WBO. In the Netherlands protection in the framework of (genetic) screening is often directly associated with the inhibitory effect of the licence obligation of the WBO.

I think the basic assumption for genetic screening, such as DTC genetic tests, which is not included in the NPPS,[540] should be that in principle the provision and carrying out of screening is permitted, unless the screening is done according to unsound scientific standards or the patient and consumer rights are not complied with. This means in effect the withdrawal of the current WBO. Instead it should be replaced by a 'screening act' with minimal quality criteria for the access to and supply of screening. The 'screening act' would have to contain a flexible licensing system, in which in a very exceptional situation extra quality requirements can be defined for certain types of screening. At

[540] Nationaal Programma Bevolkingsonderzoek (The Dutch National Screening Programme).

the national level the use of the term population screening should be reserved for national screening programmes. The term population screening in the current WBO creates confusion and legal insecurity because the term population screening is in the first place associated with large scale screening programmes coordinated by the State. National Programme Population Screening should get a legal basis in the 'Act on Public Health'.[541] In this way it becomes apparent to citizens that the Minister of Health, Welfare and Sports has a large discretionary power in the integration of population screening in the NPPS, through which the decision-making process can be influenced by political choices, moral and ethical objections and financial considerations. In accordance with the thematic evaluation of self-determination legislation, this provision could be worded as follows:
'The Minister of Health bears the responsibility for a national population screening programme and for the implementation of national screening programmes which are reimbursed under the Health Insurance Act. The Minister lays down requirements by or under the law for the implementation of the programme.'

Final remark
As it was formulated in part B effective regulation at a global, European or national level should start with a legal framework of authorisation. And it should end with legislation on matters concerning the safety and use of health-related goods and services, the post-authorisation processes. Therefore only a premarket review and and/or a national or European quality mark on the software or the toolkit is not sufficient for setting quality requirements for the provision of DTC genetic tests. It does not guard individuals against (potential) health hazards. Furthermore, it does not protect others against the violation of their right and freedom of others. Given that, the main problem is not the fact that DTC genetic testing companies use unreliable equipment or use software of an extremely poor quality for drawing up the genetic profile. As a rule the criticism focuses primarily on the way in which such businesses interpret the data obtained by the sequencing of the genome, and the way this interpretation is conveyed to the customer, lacking proper support and counselling.

[541] Kamerstukken II 2007/08, 22894, nr. 179, p. 7.

CHAPTER 10

SUMMARY

ABSTRACT

Consumers have many possibilities to undergo a form of screening to acquire (future) health information via the Internet or otherwise by purchasing health checks, medical check-ups, total body scans and direct-to-consumer (DTC) genetic tests. More and more providers place such screenings on the market before they have been assessed properly. In the Netherlands the Act on population screening (in Dutch: 'Wet op het bevolkingsonderzoek' (WBO)) sets strict quality criteria for screening. In accordance with this Act a licence is required for offering and performing screening with ionising radiation or for detecting (risk factors of) cancer and untreatable diseases. This system, which aims to protect individuals against health damage and also to ensure patients (rights), wards off 'commercial screening'[542] of the Dutch market. In society this meets with criticism. Individuals increasingly perceive the limited access to screening as an unnecessary restriction of their self-determination. However, besides the duty to guarantee the right of self-determination the State has a special responsibility regarding the health of individuals. This thesis focuses on the following central question: 'What are the normative criteria for the access to and supply of genetic screening from constitutional and European law perspectives?' As a corollary, I will explore what this means for the Dutch legal framework regulating genetic screening, particularly DTC genetic tests.

In ***Chapter 1*** the author explains the aim of this thesis and how the central question and sub-questions are being examined and answered in the chapters that follow. An explanation is given why this study devotes great attention to the legal documents of the Council of Europe and the European Union (EU), the case law of European Court of Human Rights (ECtHR) and the European Court of Justice (ECJ). The chapter further describes the scope of the study and the relevance of the research findings for other fields than genetics and genomics.

The central question in ***Chapter 2*** concerns the extent to which a State is obliged to respond to the 'unregulated' access to and supply of DNA (self)tests to prevent individual damage to health and to protect the rights and freedoms of others? The answer to this question partly depends on the value accorded to self-determination and protection, important human rights and health law principles. The chapter starts with an explanation of the way in which DNA (self)diagnostics can play a part in the identification of carrier status or (latent) present diseases which can benefit the people concerned. Also an overview is given of the benefits and risks of DNA diagnostics, particularly DTC genetic tests.

[542] Screening outside the regular healthcare.

Based on a academic literature study and in accordance with the case law of the ECtHR regarding article 2 (the right to life), article 3 (the prohibition of torture) and article 8 (private and family life) there are good arguments to set strict (quality) requirements for the access to DNA (self)tests. Not only can it be questioned whether there is always *informed consent* by the consumer; also DNA (self)tests can infringe on the rights and freedoms of others. Moreover, there is the risk of false concern (or reassurance) and rising health costs as a result of the fact that the interpretation of the results of those tests is complex.

The principle of *informed consent* is an expression of self-determination. In the implementation of national screening programmes various dimensions of self-determination play a role: self-determination as the right '*to be left alone'*, self-determination as *'freedom to choice'* and self-determination as '*claim to self-development'.* In order to make use of all these dimensions of self-determination, adequate information is of essential importance. ***Chapter 3*** describes the guarantees for self-determination within the scope of the national programme of prenatal screening for Down syndrome in the Netherlands. The main conclusions in this chapter are; that pregnant women have the right to self-determination and thereby have the right to decide on whether they want to procreate or not and, if so, whether they want to undergo prenatal screening. Information is of great importance for exercising self-determination in prenatal screening. According to the ECtHR this information must be complete, reliable and timely accessible.
In the advisory reports of the Dutch Health Council regarding prenatal screening for Down syndrome the dominant dimension of self-determination is *freedom of choice*. In this chapter it turns out that besides factual information pregnant women need help from health care workers in order to be able to apply the information to their own situation. To support self-determination the professional groups and implementing agencies related to prenatal screening should reformulate the principle of non-directivity. It should be formulated in such a way that it expresses more clearly that informing pregnant women about prenatal screening goes beyond providing factual information. Furthermore, it is important that the Minister of Health, Welfare and Sports reconsiders the age limit for the reimbursement of the costs related to prenatal screening for Down syndrome. In this way the procedural and the material norm of article 8 ECHR is guaranteed for all pregnant women: actually having and experiencing freedom of choice.

In commercial screening it is often difficult to distinguish between the concepts 'offer', 'invitation' and 'advertisement'. Companies target consumers through promotional texts on websites or advertising messages in newspapers and magazines to purchase forms of screening, for example DTC genetic tests. In this way consumers are invited to buy a health care service, screening.

Chapter 4 includes a study of the EU and constitutional law regarding health services advertisement in relation to the freedom of expression. In this chapter one of the findings is that licensing or banning of health services advertising on grounds of health protection will not quickly be regarded as an unjustified infringement. States Parties of the ECHR have a wide *margin of appreciation* in the regulation of advertising.
EU law provides a more effective protection against violations of the freedom of expression in relation to health services advertising than the ECHR. Furthermore, fewer conditions are attached to banning advertising than to systems of prior administrative permission under EU law. The proportionality of a ban or prior administrative authorization for DTC genetic tests and the desired objective is questionable. These objectives can also be achieved with measures which encroach less on the fundamental rights and freedoms of individuals and providers of such tests.

Chapter 5 contains a report of the regulatory frameworks of seven European countries that apply to DTC genetic testing. France, Germany, Portugal and Switzerland have specific legislation stating that genetic tests can only be carried out by a medical doctor. In these countries the physician can only carry out a DTC genetic test with the consent of the patient/ consumer just as in the Netherlands, Belgium and the United Kingdom. Physicians have the duty to give adequate information about the character, the meaning and the implications of DTC genetic tests before the patient/ consumer is tested. The Netherlands has a licence system for screening. This is unique in the world. Belgium and the United Kingdom allow the provision of DTC genetic tests without restrictions.

From a human right perspective there are good reasons to regulate the access to and the supply of DTC genetic tests. The Netherlands is a Member State of the Council of Europe and the European Union. These organisations influence the freedom of Member States to regulate the supply of and access to DTC genetic tests. The subject of ***Chapter 6*** is the freedom of EU Member States to regulate the access to and the supply of commercial genome sequencing within their national borders and the consequences of this for the Netherlands. In this chapter the view of the authors is that commercial genome sequencing is a service and not a good. As a consequence in cross-border situations the Dutch licence system is a barrier to the free movement of services and the freedom of establishment. Dutch legislation appears not to be EU-proof. The licence system of the WBO regarding access to and the supply of commercial genome sequencing conflicts with the E-Commerce Directive and the EU free movement regime for establishment. The WBO conflicts with EU law because the restricted measure – the licence system – is not proportional to the pursued goal. This is the result of the scope problems of the WBO. This can cause problems in situations in which a company from another Member State establishes itself in the Netherlands, and wants to offer and perform commercial genome sequencing in the Netherlands. The authors plead

for a revision of the WBO. This revision should focus on clarifying the definition of population screening and the licence criteria, in a manner that the licence criteria are foreseeable and accessible before the licence is requested and judged.

In ***Chapter 7*** the authors examine whether the WBO can serve as an example for other European countries. The following conclusions can be drawn after studying the different binding instruments and legal documents adopted by the Council of Europe and the EU. There appears to be a common opinion that the validity and utility of genetic tests are essential preconditions for allowing them to be offered to the public. Moreover, there is widespread support for the idea that genetic tests should be provided only under medical supervision. Furthermore genetic tests with risks that can have far reaching implications for the person concerned or his or her relatives should not be supplied without appropriate non-directive genetic counselling.
The WBO cannot serve as an example for other countries which are Members States or States Parties of the EU or ECHR. In the first place the WBO is too liberal compared to the European normative criteria because it does not regulate access to all genetic tests. The Act only warrants the European normative criteria for DTC genetic tests aimed at detecting the (risk indicators of) cancer and (risk indicators of) untreatable diseases. In the second place the WBO conflicts with the EU law as described in the previous chapter.

In ***Chapter 8*** the authors compare EU law regarding medicines with EU law applied to DTC genetic tests. The aim of this comparison is to examine whether the legal framework of the EU for the safety and responsible use of (Internet) medicines could be an example for regulating access to and supply of DTC genetic tests. The EU legal framework with respect to (internet) medicines could serve as an example for (central) authorisation of the marketing of DTC genetic testing services on the internal market. However, only a premarket review is not enough to guarantee the quality, clinical usefulness, reliability and the safe use of such tests. An effective regulation of DTC genetic tests consisting of a premarket review, stipulates medical supervision and sets up quality criteria for the information that has to be provided during the genetic testing service.

Chapter 9 contains the most important findings of this study and some concluding remarks. It is argued that self-determination has not only the meaning of the right *to be left alone*. Self-determination also implies the possibility of organising life as one sees fit. This is self-determination in the dimension of *freedom to choose* how life is organised and in the meaning of *freedom of self-development.* In this view taking measures that provide protection against (health) damage or that respect the principle of *informed consent,* do not detract from self-determination. They rather strengthen

this notion in the perspective of *freedom of choice* and freedom *of self-development.* However, self-determination is not sufficiently warranted by standardised or general information about the characteristics. Therefore individual counselling is necessary. During counselling the provider/ healthcare worker can tailor the information to the needs of the consumer. Just providing information and/or giving better information to patients/ consumers is not enough nor an effective way of protecting individuals against potential health risks.

One important recommendation from this study is that the current WBO should be withdrawn and should be replaced by a 'screening act' with minimal quality criteria for the access to and supply of screening. In principle the provision and carrying out of screening should be permitted, unless the screening is done according to unsound scientific standards or the patient and consumer general rights are not complied with. At the national level the use of the term population screening should be reserved for national screening programmes. The chapter ends with the take home massage that only a premarket review and/or a quality mark does not guard individuals against (potential) health hazards nor protects people against the violation of their right and freedom by others. The main problem is not the fact that DTC genetic testing companies may use unreliable equipment or use software of poor quality for drawing up the genetic profile. As a rule the criticism focuses primarily on the way in which such businesses interpret the data obtained by the sequencing of the genome, and the way this interpretation is conveyed to the customer, lacking proper support and counselling.

ADDENDUM

BOOKS & REPORTS

A

Ach & Taureck 2009
Ach & Taureck in: Ch. Thies (ed.), *Der Wert der Menschenwürde*, Paderborn: Ferdinand Schöningh 2009.

Van Agt 2012
H.M.E. van Agt, H.M.H.J.D. Schoonen, J. Fracheboud & H.J. de Koning, *Monitor geïnformeerde besluitvorming prenatale screening 2011. Landelijke en regionale uitkomsten*, Rotterdam: Erasmus MC, afdeling Maatschappelijke Gezondheidszorg februari 2012.

Asscher 2002
L.F. Asscher, *Communicatiegrondrechten*: *een onderzoek naar de constitutionele bescherming van het recht op vrijheid van meningsuiting en het communicatiegeheim in de informatiesamenleving* (diss. Amsterdam UvA), Amsterdam: Otto Cramwinckel Uitgever 2002.

B

Van Beers 2009
B.C. van Beers, *Persoon en lichaam in het recht* (diss. VU-Amsterdam), Den Haag: Boom Juridische uitgevers 2009.

Bijlsma et al. 2005
E.K. Bijlsma, J.C. Oosterwijk, N.J. Leschot, J.P.M. Geraedts & J.C. Pronk. 2005, *Leerboek medische genetica,* Maarsen: Elsevier gezondheidszorg 2005.

Brug et al. 2005
J.Brug, L.J. Gunning-Schepers & J.D.F. Habbema, 'Theorie en methoden van preventie', in: J.P. Mackenbach & P.J. van der Maas (red.), *Volksgezondheid en gezondheidszorg*, Maarssen: Elsevier gezondheidszorg 2005.

C

Centraal Orgaan & RIVM 2011
Centraal Orgaan & RIVM, *Draaiboek Prenatale Screening Downsyndroom en Structureel Echoscopisch Onderzoek*, Versie 2.0 2011.

Commissie Franken 2000
Rapport van de Commissie Franken, *Commissie Grondrechten in het digitale tijdperk*, Den Haag: 2000.

Commissie Van de Pol 2003
Commissie Van de Pol, *Toepassing van de genetica in de gezondheidszorg*, Den Haag: ZonMw 2003.

D

Van Dam 2009
C. van Dam, *De gemiddelde Euroconsument - een pluriform fenomeen. Over de Richtlijn Oneerlijke Handelspraktijken en de rechtspraak van het Hof van Justitie,* 2009, *http://www.ceesvandam.info/default.asp?fileid=446,*

Drewes 2013
Y.M. Drewes, 'Preventieve gezondheidszorg', in: D.P. Engberts & L.E. Kalkman-Bogerd (red.), *Gezondheidsrecht*, Houten: Bohn Stafleu van Loghum 2013, p. 195-207.

Dommering et al. 2000
E.J. Dommering e.a., *Informatierecht, fundamentele rechten voor de informatie-samenleving*, Amsterdam: Otto Cramwinckel 2000.

Dute 2013
J.C.J. Dute, *De vrijblijvendheid voorbij, over het recht op preventie,* (oratie Nijmegen), Nijmegen: Radboud Universiteit 2013.

E

EASAC & FEAM 2012
EASAC & FEAM, *Direct-to-consumer genetic testing for health-related purposes in the European Union: the view from EASAC and FEAM*, Halle: German National Academy of Sciences Leopoldina 2012.

Eide 1987
Speciaal Rapporteur Eide *'The new international economic order and the promotion of human rights'*, UN Doc E/CN.4/Sub2/1987.23

G

GAO 2010
GAO, *DIRECT-TO-CONSUMER GENETIC TESTS, Misleading Test Results Are Further Complicated by Deceptive Marketing and Other Questionable Practices*, Washington: GAO 2010. The report of the Study is available on internet at: http://www.gao.gov/products/GAO-10-847T

Geelen et al. 2004
E. Geelen, D. Schipper, A. Krumeich, K. Horstman & G. Widdershoven, *Opgelucht, maar ook aangedaan. Ervaringen van vrouwen met risicoschattende testen in de zwangerschap*, Universiteit Maastricht 2004.

GR 1994
Gezondheidsraad, *Genetische screening* (advies 1994/22), Den Haag: GR 1994.

GR 2001a
Gezondheidsraad*, Familiaire hypercholesterolemie en de Wet op de medische keuringen*, Den Haag: GR 2001.

GR 2001b
Gezondheidsraad, Downsyndroom, *neuralebuisdefecten, routine-echoscopie (advies 2001/11),* Den Haag: GR 2001.

GR 2004
Gezondheidsraad, *Wet bevolkingsonderzoek: Prenatale screening (2) Downsyndroom, neuralebuisdefecten* (advies 2004/06 WBO), Den Haag: GR 2004.

GR 2005
Gezondheidsraad, *Neonatale screening* (nr. 2005/11), Den Haag: GR2005.

GR 2006a
Gezondheidsraad, *Wet bevolkingsonderzoek: aanzet tot een landelijk programma voor prenatale screening, downsyndroom en neuralebuisdefecten* (advies 2006/03 WBO), Den Haag: GR 2006.

GR 2006b
Gezondheidsraad, *Behandelbaarheid; Het begrip '(niet-)behandelbaar' in de Wet op het bevolkingsonderzoek* (WBO) en de Wet op de medische keuringen (WMK), (advies 2006/02), Den Haag: GR 2006.

GR 2007a
Gezondheidsraad, *Wet bevolkingsonderzoek: prenatale screening op downsyndroom en neuralebuisdefecten* (advies 2007/05 WBO), Den Haag: GR 2007.

GR 2007b
Gezondheidsraad*, Wet bevolkingsonderzoek: de reikwijdte (7), de begrippen 'aanbod' en 'medische indicatie'* (advies 2007/02WBO), Den Haag: GR 2007.

GR 2007c
Gezondheidsraad, *Jaarbericht op bevolkingsonderzoek 2007, zelftests op lichaamsmateriaal,* (advies 2007/26), Den Haag: GR 2007.

GR 2008
Gezondheidsraad, *Screening tussen hoop en hype* (advies 2008/05), Den Haag: GR 2008.

GR 2009.
Gezondheidsraad, *Wet bevolkingsonderzoek: knelpunten in de toepassing* (advies 2009/04), Den Haag: GR 2009.

H

Hendriks 2012a
A.C. Hendriks, 'The Council of Europe', in: B. Toebes, M. Hartlev, A.C. Hendriks & J. Rothmar Herrmann (ed.), *Health and Human Rights in Europe*, Antwerpen: Intersentia 2012

Hendriks 2012b
A.C. Hendriks, 'De IGZ als overheidstoezichthouder in Europees perspectief', in: J.G. Sijmons, J.K.M. Gevers & J.H.H.M. Dorscheidt (red.), *Rechten en zorg van kwaliteit.* Liber Amicorum voor J.H. Hubben, Den Haag: Sdu uitgevers 2012.

Hendriks 2010
A.C. Hendriks, 'Het recht op informatie als overheidsplicht', in: A.C. Hendriks, J.H. Hubben, J. Legemaate & B. Sluijters (red.), *Grondrechten in de gezondheidszorg*. Liber Amicorum voor J.K.M. Gevers, Houten: Bohn Stafleu van Loghum 2010.

Hendriks 2006
A.C. Hendriks, *In beginsel. De gezondheidsrechtelijke beginselen uitgediept* (oratie Leiden), Leiden: NJCM-Boekerij 2006.

K

Kabel 2003
J.J.C Kabel, 'Vijfentwintig jaar uitingsvrijheid voor handelsreclame in de rechtspraak', in: A.W. Hins & A.J. Nieuwenhuis (red.), *Van ontvanger naar zender.* Liber Amicorum voor prof. mr. J.M. de Meij, Amsterdam: Otto Cramwinckel 2003.

KNMG 2013
Koninklijke Nederlandsche Maatschappij tot bevordering der Geneeskunst, Multidisciplinaire, *Richtlijn Preventief Medisch Onderzoek*, Utrecht: KNMG mei 2013.

Koffeman 2010
N.R. Koffeman, *(The right to) personal autonomy in the case law of the European Court of Human Rights, Voorstudie voor de Staatscommissie Grondwet*, Leiden: juni 2010.

L

Lawson 2009
R.A. Lawson, 'Dwelling on the threshold: On the interaction between the European Convention on Human Rights and the Biomedicine Convention', In: A.P. Exter (red), *Human Rights and Biomedicine,* Apeldoorn: Maklu 2009.

Leenen et al. 2007
H.J.J. Leenen, J.K.M. Gevers & J. Legemaate, *Handboek gezondheidsrecht. Deel I,* Houten: BSL 2007.

Leenen et al. 2008
H.J.J. Leenen, J.C.J. Dute & W.R. Kastelein, *Handboek gezondheidsrecht. Deel II*, Houten: BSL 2008.

M

Van der Maas et al. 2000
P.J. van der Maas, C.A. Baan, I.J. Korfage, J.K.M. Gevers & H.D.C. Roscam Abbing, *Evaluatie Wet op het bevolkingsonderzoek*, Den Haag: Zorg- Onderzoek Nederland 2000.

E. Mossialos et al. 2010
E. Mossialos, G.Permanand, R. Baeten & T. Hervey, *Health systems governance in Europe: the role of European Union law and policy*, Cambridge: Cambridge University Press 2010.

I

IGZ 2008
IGZ, *Toezicht op preventief medisch onderzoek* (08/17), Den Haag: IGZ 2008.

R

RVZ 2008
RVZ, *Screening en de rol van de overheid* (advies 08/03), Den Haag: RVZ 2008.

RVZ 1999
RVZ, *zelftests*, Den Haag: RVZ 1999.

S

San Giorgi 2012
M. San Giorgi, *The Human Right to Equal Access to Health Care* (diss. Rotterdam), Antwerpen: Intersentia 2012.

Shue 1980
H. Shue, *Basic Rights*, Princeton: Princeton University Press 1980.

Slagboom 2011
J. M. Slagboom, *Echo. Prenataal onderzoek en keuzevrijheid*, Amsterdam: Atlas-Contact augustus 2011.

Sinding 2009
H. Sinding Aasen, R. Halvorsen & A. Barbosa da Silva, *Human Rights, Dignity and Autonomy in Health Care and Social Services*, Antwerpen: Intersentia 2009.

Somsen 2009
H. Somsen, J.A. Bovenberg & B.C. van Beers, *Humane biotechnologie en recht (Handelingen NJV 2009-1),* Deventer: Kluwer 2009.

Sprumont 2004
D. Sprumont, 'Quelle réglementation des trousses d'analyse génétique' in: C. Joye (ed), *L'analyse génétique humaine: quelles perspectives législatives*, Geneva: Schulthess 2004.

Staatscommissie Grondwet 2010
Staatscommissie Grondwet, *Rapport van de Staatscommissie Grondwet 2010*, Den Haag: november 2010.

Stuurman & Wefers Bettink 2006
C. Stuurman & H.W. Wefers Bettink, *Elektronisch contracteren*, Den Haag: Sdu Uitgevers 2006.

T

Timmermans 2009
D.R.M. Timmermans, *Een kwestie van kiezen: over gezondheidsrisico's en beslissingen* (oratie VU), Amsterdam: VU 2009.

U

UK Human Genetic Commission 2010
UK Human Genetic Commission, *A Common Framework of Principles for direct-to-consumer genetic testing services*, London: the UK Human Genetic Commission 2010, www.hgc.gov.UK

W

Van der Weijden 2007
T. van der Weijden, G. Ronda, R. Norg & P. Portegrijs, *Diagnostische zelftests op lichaamsmateriaal. Aanbod, validiteit en gebruik door de consument,* Maastricht: Caphri 2007.

WHO 2002
World Health Organization, *Genomics and World Health: Report of the Advisory Committee on Health research,* Geneva: WHO 2002.

Wilson & Jungner 1968
J.M.G. Wilson & G. Jungner, *Principles and practice of screening for disease*, Genève: World Health Organization 1968.

JOURNALS

A

Aartsen 1996
J.G.M. Aartsen, 'De wet op het bevolkingsonderzoek', *Tijdschrift voor Gezondheidsrecht* 1996, p. 71-84.

Allison 2010
M. Allison, 'Genetic testing clamp down', *Nature Biotechnology* 2010-28, p. 633.

Asscher & Koops 2009
E.C.A. Asscher & E.J. Koops, 'Embryoselectie, Huntington en het recht om niet te weten', *Rechtsgeleerdheid Magazine Themis* 2009, p. 27-35.

B

Bauduin 2000
D. Bauduin, 'Respect als basis', *Medium voor ggz en verslavingszorg* 2000, p. 40-52.

Bauschke 2011
R. Bauschke, 'A public health perspective on the effectiveness of European pharmaceutical regulation', *Pharmaceutical policy and Law* 2011, p. 91-114.

Van der Beek 2009
J.C.M. van der Beek, 'Het Nederlandse hoofdstuk in de Europese goksaga', *Nederlands Tijdschrift voor Europees Recht* 2009, p. 305-317.

Bloss 2013
C.S. Bloss, 'Impact of direct-to-consumer genomic testing at long term follow-up', *Journal of Medical Genetics* 2013, only published online, http://dx. doi.org/ 10.1136/ jmedgenet-2012-101207, p.1-8.

Boom & Giessen 2001
W.H. Boom & I. Giessen, 'Civielrechtelijke overheidsaansprakelijkheid voor het niet voorkomen van gezondheidsschade door rampen', *Nederlands Juristenblad* 2001, p. 1675-1691.

Borry et al. 2009a
P. Borry, H.C. Howard, K. Senecal & D. Avard, 'Direct-to-consumer genome scanning services. Also for children?', *Nature Review Genetics* 2009, only published online, www.nature.com/nrg/journal/v10/n1/pdf/nrg2501.pdf

Borry et al 2009b
P. Borry, H.C. Howard, K. Senecal & D. Avard, 'Health-related direct-to-consumer genetic testing: a review of companies' policies with regard to genetic testing in minors', *Familial Cancer* 2009-9, p. 51–59.

Borry 2009
P. Borry, 'Genetic testing in asymptomatic minors: recommendations of the European Society of Human Genetics,' *European Journal of Human Genetics* 2009, p. 1-2.

Borry & Howard 2008
P. Borry & H. Howard, 'DTC Genetic Services: A Look Across the Pond', *American Journal of Bioethics* 2008-6, p. 14-16.

Borry 2008
P. Borry, 'Europe to ban direct-to-consumer genetic tests?' *Nature Biotechnology* 2008, p. 736-737.

Boukema & Drijber 2009
H.J.M. Boukema & B.J. Drijber, 'Vergelijkende reclame vergeleken', *Intellectuele Eigendom & Reclamerecht* 2004, p. 70.

Brower 2010
V. Brower, 'FDA To regulate Direct-to-consumer Genetic Tests,' *Journal of the National Cancer Institute* 2010, p. 1610-1617.

Büchler 2005
A. Büchler, 'Aussergerichtliche Abstammungsuntersuchungen - Die neuen Bestimmungen des Bundesgesetzes über die genetischen Untersuchungen beim Menschen (GUMG)', *ZVW* 2005, p. 32–44.

Buijsen 2009
M.A.J.M. Buijsen, 'Autonomie in het gezondheidsrecht', *Ars Aequi* 2004, p. 425-429.

Bunnik et al. 2009
E.M. Bunnik, A.C.J.W. Janssens & M. Schermer, 'How Attitudes Research Contributes to Overoptimistic Expectations of Personal Genome Testing', *American Journal of Bioethics* 2009-6/7, p. 23-25.

C

Calsbeek 2009
H. Calsbeek, M. Morren, J. Besing & M. Rijken, 'Knowlegde en Attitudes Towards Genetic Testing: A Two Year Follow-Up Study in Patients with Asthma, Diabetes Mellitus and Cardiovascular Disease', *Journal of Genetic Counselling* 2009, p. 493-504.

Carmen & Borry 2011
H. Carmen & B. Borry, 'Europe and direct-to-consumer genetic tests', *Nature Reviews Genetics, only published* online 13 December 2011, http://www.nature.com/nrg/journal/v13/n2/full/nrg3073-c1.html

Coggon & Miola 2011
J. Coggon & J. Miola, 'Autonomy, liberty, and medical decision-making', *Cambridge Law Journal* 2011, p. 523-547.

Cordina 2010
M Cordina., 'Counterfeit medicines', *Journal of the Malta College of Pharmacy Practice*, 2010-16, p. 4-6.

D

Van Dijk et al. 2004
S. van Dijk, W. Otten, C. J. van Asperen, D.R.M. Timmermans, A. Tibben, M.W. Zoeteweij, S.Silberg, M. H. Breuning & J. Kievit, 'Feeling at risk: How woman interpret their familial breast cancer risk', *American Journal of Medical Genetics* 2004, p. 42-49.

Dondorp 2010
W. Dondorp, A. de Jong & G. de Wert, 'Echo zorgt voor onverwachte dilemma's', *NRC Handelsblad* 16 februari 2010.

Drewes et al. 2009
Y.M. Drewes, J.P. Meesters, J. Gussekloo, B. J.C. Middelkoop & A.C. Hendriks 'Tucht-rechtuitspraken over screening en preventieve diagnostiek', *Nederlands Tijdschrift voor Geneeskunde* 2009, p. 1660-1664.

Dupuis 2004
H.P. Dupuis, 'Eigen keuzen van patiënten: schildrecht en claimrecht', *Pro Vita Humana* 2004-2, p. 56-58.

E

Van Eijken 2008
H. van Eijken,'Onderwijsdiensten: een burgerrecht, maar wie betaalt de rekening', *Nederlands Tijdschrift voor Europees Recht* 2008, p.1-7.

Einsiedel & Geransar 2009
E.F. Eindsiedel & R. Geransar, 'Framing genetic risk: trust and credibility markers in online direct-to-consumer advertising for genetic testing, *New Genetic and Society* 2009, p. 339-362.

F

Faeh 2011
Faeh, 'Pharmaceutical information: Does the Directive 2001/83/EC protect such a right for the end-user?' *Amsterdam Law Forum* 2011, http://www.amsterdamlawforum.org/, p. 31,

Foster 2009
M.W. Foster, J.J. Mulvihill, R.R. Sharp, 'Evaluating the utility of personal genomic information', *Genetics Medicine* 2009, p. 570–574.

Foster et al. 2006
M.W. Foster, C.D.M. Royal & R.R. Sharp, 'The routinisation of genomics and genetics: implications for ethical practices', *Journal of Medical Ethics* 2006, p. 635–638.

Fung et al. 2004
C. H. Fung, H.E. Woo & S. M. Asch, 'Controversies and legal Issues of prescribing and Dispending Medications Using the internet', *Mayo Clinic Proceedings*, 2004, p. 188-194.

G

Gevers 2009
J.K.M. Gevers, 'Health Screening Services Supplied Directly to the Public', *European Journal of Health Law* 2009-3, p. 6.

Godard et al. 2003
B. Godard, L. ten Kate, G. Evers-Kiebooms & S. Aymé, 'Population genetic screening programmes: principles, techniques, practices and policies', *European Journal of Human Genetics* 2003, p. 49-50.

Goldsmith et al. 2012
L. Goldsmith, L. Jackson, A. O'Connor & H. Skirton, 'Direct-to-consumer genomic testing: systematic review of the literature on user perspectives', *European Journal of Human Genetics* 2012, p. 811-816.

De Graaf 2010
G. de Graaf, C. van Os, R. Borstlap & E. de Graaf, 'Ervaringen van ouders met prenatale screening', *Down+Up* 2010- 91, p. 37-48.

Grann & Jacobson 2002
V.R. Grann & J. Jacobson, 'Population screening for cancer-related germline gene mutations,' *Lancet Oncology* 2002, p. 341-34.

H

Hauskeller 2011
C. Hauskeller, ' Direct to consumer genetic testing', *British Medical Journal* 2011, p. 342.

Heerma van Voss & Zwaan 2010
M.J. Heerma van Voss & V.A. Zwaan, 'Google AdWords: het Hof maakt veel duidelijk, maar we zijn er nog niet', *Nederlands Tijdschrift voor Europees Recht* 2010, p. 207-217.

Hendriks et al. 2008
A.C. Hendriks, B.J.M. Frederiks & M.A. Verkerk, 'Het recht op autonomie in samenhang met goede zorg bezien', *Tijdschrift voor Gezondheidsrecht* 2008, p. 2-18.

Hendriks & Gevers 2004
A.C. Hendriks & J.K.M Gevers, 'Juridische bescherming tegen ongerechtvaardigd gebruik van genetische informatie buiten de gezondheidszorg', *Nederlands Juristen Comité Mensenrechten-Bulletin* 2004, p. 1114-1130.

Herderschee 2011
R. Herderschee, 'Non-invasieve Downtest geeft zekerheid', *Medisch Contact* 2011, p. 679.

Hogarth 2008
S. Hogarth, G. Javitt & D. Melzer, 'The Current Landscape for Direct-to-Consumer Genetic Testing: Legal, Ethical, and Policy Issues', *Annual Review of Genomics and Human Genetics* 2008, p. 162-165.

Howard & Borry 2011
H.C. Howard & P. Borry, 'Is there a doctor in the house? The presence of physicians in the direct-to-consumer genetic testing context', *Journal Community Genet* 2011, p. 105-112.

Howard & Borry 2009
H.C. Howard & P. Borry, 'Personal genome testing: do you know what you are buying?', *The American Journal of Bioethics* 2009-6/7, p. 11–13.

Howard et al. 2010
H.C. Howard, B.M. Knoppers, P. Borry, 'Blurring lines. The research activities of direct-to-consumer genetic testing companies raise questions about consumers as research subjects' *EMBO Reports* 2010, p. 579–582.

J

Janssens 2008
A.C. Janssens, M. Gwinn, L.A. Bradley, B.A. Oostra, C.M. van Duijn & M.J. Khoury 'A critical appraisal of the scientific basis of commercial genomic profiles used to assess health risks and personalize health interventions', *American Journal of Human Genetic* 2008, p. 593–599.

De Jong 2011
A. de Jong, W.J. Dondorp, S.G.M. Frints, C.E.M. de Die-Smulders & G.M.W.R. de Wert 'Advances in prenatal screening the ethical dimension', *Nature Reviews Genetics* 2011, p. 657-663.

Jonkers 2006
P. Jonkers, 'Autonomie, kritische vragen bij een ideaal', *Filosofie & Praktijk* 2006, p. 57-67.

K

Kalf et al. 2013
R.J. Kalf, R. Mihaescu, S. Kundu, P. de Knijff, R. C. Green & A.C. J.W. Janssens, 'variations in predicted risk in personal genome testing for common complex diseases', *Genetics in Medicine* 2013, p. 85-91.

Kaye 2008
J. Kaye, 'The regulation of direct-to-consumer genetic tests,' *Human Molecular Genetics* 2008, p. 180-183.

G. Katz & S.O. Schweitzer 2010
G. Katz & S.O. Schweitzer, ' Implications of Genetic Testing for Health Policy', *Yale Journal of Health Policy, Law, and Ethics* 2010, p. 90–197.

De Kort 2008
S.J. de Kort, 'Verkeerde routine, 20 wekenecho is zoektocht naar alle mogelijke afwijkingen geworden', *Tijdschrift voor verloskundigen* 2008 (nov), p. 36-37.

L

Ledley 2002
F. Ledley, 'A consumer charter for genomic services', *Nature Biotechnology* 2002, p. 767.

M

Maassen 2006
H. Maassen, 'Huntington in beeld', *Medisch Contact* 2006, p. 772-775.

Maasdam & Sluijs 2009
Y.A. Maasdam & J.J.M. Sluijs, 'Hartlauer: reguleren van zorgverlening begrensd', *Nederlands Tijdschrift voor Europees Recht* 2009, p. 214-219.

Marietta & McGuire 2009
C. Marietta & A.L. McGuire, 'Direct-to-Consumer Genetic Testing: Is it the Practice of Medicine', *Pharmaceutical regulations* 2009, p. 370.

McBride et al. 2010
C.M. McBride C.H. Wade & K.A. Kaphingst, 'Consumers' Views of Direct-to-Consumers Genetic Information', *Annual Review Genome Human Genome* 2010, p. 429-432.

MacLean 2006
A. MacLean, 'Autonomy, Consent and Persuasion', *European Journal of Health Law* 2006. p. 321-338.

McGregor 2008
J. L. McGregor, 'Why John Stuart Mill Would Support Restriction on DTC Marketing of Genetic Tests', *American Journal of Bioethics*, 2008; 8(6): 9-10.

McGuire et al. 2009
A. McGuire, C.M. Diaz, T. Wang & S. Hilsenbeck, 'Social networkers' attitudes toward direct-to-consumer personal genome testing', *American Journal of Bioethics* 2009-9, p. 3–10.

Mihaescu 2009
R. Mihaescu, M. Van Hoek, E.J.G Sijbrands, A.G Uitterlinden, J.C.M Witteman, A. Hofman, C.M. van Duijn & A.C.J.W. Janssens, 'Evaluation of risk prediction updates from commercial genome-wide scans' *Genetic in Medicine* 2009-11, p. 588–594.

Mitchel et al. 2010
P.B. Mitchell, B. Meiser, A. Wilde, J. Fullerton, J. Donald, K. Wilhelm & P.R. Schofield, 'Predictive and diagnostic genetic testing in psychiatry', *Journal of Laboratory and Clinical Medicin*e 2010, p. 829–846.

N

Nielen 2009
M.M.J. Nielen, F.G. Schellevis & R.A. Verheij, 'The usefulness of a free self-test for albuminuria in the general population: a cross-sectional survey', *BMC Public Health* 2009, p. 381 et. seq.

Nieuwenhuis 2012
A.J. Nieuwenhuis, 'De kernbenadering bij de grondrechten', *Tijdschrift voor Constitutioneel Recht* 2012, p. 138-159.

O

Oepkes & Wierenga 2008
D. Oepkes & J. Wierenga, 'Recht op prenatale kennis, 20-wekenecho maakt weloverwogen keuze mogelijk', *Tijdschrift voor verloskundigen* 2008 (nov), p. 38-40.

Olsthoorn-Heim 1996
E.T.M. Olsthoorn-Heim, 'Wet Bevolkingsonderzoek vraagt om bedachtzaamheid', *Tijdschrift voor Gezondheidsrecht* 1996, p. 57.

Olsthoorn-Heim et al. 2012
E.T.M. Olsthoorn- Heim, M.F. Verweij & S. van der Burg, 'Dragerschap als nevenbevinding van de hielprikscreening: informeren of negeren?', *Tijdschrift voor Gezondheidsrecht* 2012, p. 218-225.

Van Os & Hendriks 2010
E.C.C. van Os & A.C. Hendriks, 'Wie is de baas over de baarmoeder? Mensenrechtelijke aspecten van de bescherming aan ongeborenen', *Tijdschrift voor Jeugd- en Familierecht* 2010, p. 180-186.

Van Osselen 2011
E. van Osselen, 'Syndroom van Down detecteren in maternaal bloed: nu nog onderzoek in algemene populatie', *Nederlands Tijdschrift voor Geneeskunde* 2011, p. 1163.

P

Pickering 2007
G. Pickering, 'Internet Pharmacy in the European Union', *Reed Smith Richards Butler LLP* 2007, http://www.reedsmith.com/_db/_documents/Internet__Pharmacy_article.pdf (last visit October 2011).

Pieters & Meijman 2008
T. Pieters & E.J. Meijman, 'Het reveil van de triomferende biologie', *Medisch Contact* 2008, p. 290-292.

R

Roscam Abbbing 2010
H.D.C. Roscam Abbbing, 'Patient's Rights in a Technology and Market Driven-Europe', *European Journal of Health Law* 2010-1, p. 11-22.

Roscam Abbing 2009
H.D.C. Roscam Abbing, 'Humane biotechnologie en recht, preadviezen van de Nederlandse Juristen Vereniging' *Tijdschrift voor Gezondheidsrecht,* p. 531-537.

S

Schafer 2008
A. Schafer, 'Canadian internet pharmacies: Some ethical and economics issues', *Canadian pharmaceutical journal*, 2008, p. 191-197.

Schmitz & Reinacher 2006
D. Schmitz & P.C. Reinacher, 'Informed Consent in Neurosurgery. Translating Ethical Theory into Action (Clinical Ethics)', *Journal of Medical Ethics* 2006, p. 497-498.

Singleton et al. 2012
A. Singleton, L. Hamby Erby, K.V. Foisie & K. A. Kaphingst, 'Informed Choice in Direct-to-Consumer Genetic Testing (DTCGT) Websites: A Content Analysis of Benefits, Risks, and Limitations', *Journal Genet Counsel* 2012, p. 433–439.

Soini 2012
S. Soini, 'Genetic testing legislation in Western Europe- a fluctuating regulatory target', *Journal Community Genetics* 2012, p. 143-153.

Sprumont et al. 2003
D. Sprumont, N. Quéloz N, A. Benoît, et al, 'Conditions de liciéité des tests de paternité par l'analyse d'ADN en dehors du cadre judiciaire', *Pratique Juridique Actuelle* 2003, p. 1280–1290.

Steen 2001
I. van der Steen, 'Het arrest Smits en Peerebooms; toestemmingsvereisten voor ziekenhuiszorg in een andere lidstaat getoetst aan het vrije dienstenverkeer', *Nederlands Tijdschrift voor Europees Recht,* 2001, p. 213-221.

Stergiou 2007
H.M. Stergiou, *'Kalimera dear doctor: het arrest-Stamatelaki en ander recente ontwikkelingen op het terrein van grensoverschrijdende patiëntenmobiliteit'*, *Nederlands Tijdschrift voor Europees Recht* 2007, p. 238-245.

Stergiou 2006
H.M. Stergiou, *'Op één been kan men niet lopen, Het arrest Watts een stap dichterbij harmonisatie van patiëntenmobiliteit'*, *Nederlands Tijdschrift voor Europees Recht* 2006, p. 219-226.

Stirrat & Gill 2005
G.M. Stirrat & R. Gill, 'Autonomy in medical ethics after O'Neill', *Journal of Medical Ethics* 2005, p. 127-130.

Van der Stouwe 2008
R. van der Stouwe, 'Morele kwesties agenderen zonder te moraliseren', *Tijdschrift voor Verloskundigen* 2008 (nov) p. 43.

Swiss Society of Medical Genetics Tests 2011
Swiss Society of Medical Genetics Tests, 'génétiques sur Internet' *Bulletin Des Medecins Suisses* 2011-9.

T

Tamir 2010
S. Tamir, 'Direct-to-consumer genetic testing: ethical-legal perspective and practical considerations', *Medicine Law Review* 2010, p. 213-238.

V

Valverde 2010
J.L. Valverde, 'New challenges for the information on medicines in the EU', *Pharmaceuticals Policy and Law,* 2010, p. 193-204.

Verweij et al. 2012
E.J. Verweij, J.M.E. van den Oever, M.A. de Boer, E.M.J. Boon & D. Oepkes, 'Diagnostic Accuracy of Noninvasive Detection of Fetal Trisomy 21 in Maternal blood: A Systematic Review, *Fetal Diagnosis and Therapy* 2012, p. 81-86.

W

Wade & Wilfond 2006
C.H. Wade & B.S. Wilfond, ' Ethical and clinical practice considerations for genetic counsellors related to direct-to-consumer marketing of genetic tests'*, American Journal of Medical Genetics Part C: Seminars in Medical Genetics 2006,* p. 284–292.

Wasson 2008
K. Wasson, 'Ethical Issues Raised By the Sale of Genetic Tests Directly to Consumers', *American Journal of Bioethics* 2008-6, p. 16-18.

De Wert 2004
G.M.W.R. De Wert, 'Een bom onder de wet', *Medisch Contact* 2004, p. 212-214.

Z

Zeeman 2008
K. Zeeman, 'Grote voorkeur voor SEO boven screening Downsyndroom', *Tijdschrift voor verloskundigen* 2008 (nov), p. 40.

REFERRED CASE LAW OF THE EUROPEAN COURT OF HUMAN RIGHTS

ECtHR 13 November 2012, Hristizov et al./ Bulgaria, no. 47039/11 & 358/12
ECtHR 25 September 2012, *Godelli/ Italy,* no. 33783/09
ECtHR 28 August 2012, *Costa en Pavan/ Italy*, no. 54270/10
ECtHR 12 June 2012, *Tatár & Fáber/ Hungary,* no. 26005/08 & 26160/08
ECtHR 28 February 2012, *Kolyadenko et.al./ Russia*, no. 17423/05
ECtHR 9 February 2012, *Vejdeland et al./ Sweden*, no. 1813/07
ECtHR 17 January 2012, *Krone Verlag GmbH & Co. KG & Krone Multimedia GmbH & Co. KG/ Austria*, no. 33497/07
ECtHR 8 November 2011, *V.C/ Slovakia*, no. 18968/07
ECtHR 18 October 2011, *Sosinowska/ Poland*, no. 10247/09
ECtHR 26 July 2011, *George & Georgeta Stoicescu/ Romania,* (admissibility decision), no. 9718/03
ECtHR 21 July 2011, *Heinisch/ Germany*, no. 26274/08
ECtHR 26 May 2011, *R.R./ Poland*, no. 27617/04
ECtHR 1 February 2011, *Yazgul/ Turkey*, no. 36369/06
ECtHR 20 January 2011, *Haas/ Switzerland*, no. 31332/07
ECtHR 16 December 2010, *A., B. & C./ Ireland,* no. 25579/05
ECtHR 14 December 2010, *Ternovszky/ Hungary*, no. 67545/09
ECtHR 7 December 2010, *Poyraz/ Turkey,* no. 15966/06
ECtHR 15 December 2009, *Abdulhadi Yildrim/ Turkey*, no. 13694/04
ECtHR 15 December 2009, *Kalender/ Turkey*, no. 4314/02
ECtHR 1 December 2009, *G.N. et al./ Italy*, no. 43134/05
ECtHR 6 November 2009, *Leela Forderkreis et al./ Germany,* no. 58911/00
ECtHR 6 October 2009, *Kulis & Rozycki / Poland*, no. 27209/03
ECtHR 2 June 2009, *Codarcea/ Romania*, no. 31675/04
ECtHR 7 May 2009, *Kalacheva/ Russia*, no. 3451/05
ECtHR 5 March 2009, *Hachette Filipacchi Presse Automobile & Dupuy/ France*, no. 13353/05
ECtHR 5 March 2009, Société de Conception de Presse & d'Edition and Ponson/ *France*, no. 26935/05
ECtHR 27 January 2009, *Tatar/ Romania*, no. 67021/01
ECtHR 16 December 2008, *Frankowicz/ Poland*, no. 53025/99
ECtHR 11 December 2008, *TV Vest/ Norway*, no. 21132/05
ECtHR 4 December 2008, *S. & Marper/ the UK* (GC), no. 30562/04 & 30566/04
ECtHR 7 October 2008, *Bogumil/ Portugal*, no. 35228/03
ECtHR January2008, *Villnow/ Belgium*, (admissibility decision), no. 16938/05
ECtHR 5 October 2006, *Trocellier/ France*, no. 75725/01
ECtHR 17 July 2007, *Jevremović/ Serbia*, no. 3150/05

ECtHR 12 July 2007, *Testa/ Croatia,* no. 20877/04
ECtHR 10 April 2007, *Evans/ the UK* (GC), no. 6339/05
ECtHR 20 March 2007, *Tysiąc/ Poland*, no. 5410/03
ECtHR 2 November 2006, *Giacomelli/ Italy*, no. 59909/00
ECtHR 10 October 2006, *L.L./ France*, no. 7508/02
ECtHR 11 July 2006, *Jalloh/ Germany* (GC), no. 54810/00
ECtHR 10 July 2006, *Sdružení Jihočeské Matky/* Czech Republic*,* (admissibility decision), no. 19101/03
ECtHR 23 May 2006, *Taïs/ France* (GC), no. 39922/03
ECtHR 19 October 2005, *Roche/ the UK,* no. 32555/96
ECtHR 22 September 2005, *Gheorghe/ Romania*, no. 19215/04
ECtHR 26 July 2005, Şimşek *et al./ Turkey*, no. 35072/97 & 37194/97
ECtHR 30 June 2005, *Bosphorus Airways/ Ireland* (GC), no. 45036/98
ECtHR 5 April 2005, *Nevmerzhitsky/ Ukraine*, no. 54825/00
ECtHR 1 March 2005, *Bône/ France*, (admissibility decision), no. 69869/01
ECtHR 17 February *2005, K.A. & A.D./ Belgium*, no. 42758/98 & 45558/99
ECtHR 9 March 2004, *Glass/ the UK*, no. 61827/00
ECtHR 10 February 2004, *Gennadi Naoumenko/ Ukraine,* no. 42023/98
ECtHR 15 January 2004, *Matencio/ France*, no. 58749/00
ECtHR 13 February 2003, *Odièvre/ France* (GC), no. 42326/98
ECtHR 26 November 2002, *E. et al./ the UK*, no. 33218/96
ECtHR 14 November 2002, *Mouisel/ France*, no. 67263/01
ECtHR 17 October 2002*, Stambuk/ Germany*, no. 37928/97
ECtHR 11 July 2002, *Christine Goodwin / the UK* (GC), no. 28957/95
ECtHR 29 April 2002, *Pretty/ the UK*, no. 2346/02
ECtHR 7 February 2002, *Mikulic/ Croatia*, no. 53176/99
ECtHR 3 April 2001, *Keenan/ the UK,* no. 27229/95
ECtHR 27 June 2000, *Ilhan/ Turkey* (GC), no. 22277/93
ECtHR 21 March 2000, *Wabl/ Austria*, no. 24773/94
ECtHR 28 October 1998, *Osman/ the UK* (GC), no. 23452/94
ECtHR 19 February 1998, *Guerra et al./ Italy* no. 14967/89
ECtHR 9 June 1998, *McGinley & Egan/ the UK*, no. 21825/93
ECtHR 9 June 1998, *L.C.B/ the UK*, no. 23413/9
ECtHR 25 February 1997, *Z. / Finland*, no. 22009/93
ECtHR 19 February 1997 *Laskey, Jaggard & Brown/ the UK*, no. 21627/93; 21826/93 & 21974/93
ECtHR 16 October 1996, *Wackenheim/ France*, no. 29961/96
ECtHR 9 December 1994, *López Ostra/ Spain*, no. 16798/90
ECtHR 24 February 1994, *Casado Coca/ Spain*, no. 15450/89
ECtHR 28 January 1994, *Hurtado/ Switzerland*, no. 17549/90

ECtHR 29 October 1992, *Open Door and Dublin Well Woman/ Ireland*, no. 14235/88
ECtHR 24 September 1992, *Herczegfalvy/ Austria*, no. 10533/83
ECtHR 20 November 1989, *Markt Intern/ Germany (GC),* no. 10572/83
ECtHR 7 July 1989, *Gaskin/ the UK*, no. 10454/83
ECtHR, 24 May 1988, *Müller/ Switzerland*, no. 10737/84
ECtHR 26 March 1985, *X & Y* / The *Netherlands,* no. 8978/80
ECtHR 28 November 1984, *Rasmussen/ Denmark*, no. 8777/79
ECtHR 26 April 1979, *Sunday Times/ the UK*, no. 6538/74
ECtHR 18 January 1978, *Ireland/ the UK*, no. 5310/71
ECtHR 7 December 1976, *Handyside/ the UK,* no. 5493/72

REFERRED CASE LAW OF THE COURT OF JUSTICE OF THE EUROPEAN UNION

Case C-617/10, Åkerberg Fransson (GC) [2013] (not yet published)
Case C-84/11, *Marja-Liisa Susisalo, Olli Tuomaala & Merja Ritala* [2012] (not yet published)
Case C-544/10, Deutsches Weintor eG / Land Rheinland-Pfalz [2012] (not yet published)
Case C-163/10, *Patriciello* (GC) [2012] ECR I-07565
Case C-482/10, *Cicala* [2011] (not yet published)
Case C-70/10, Scarlet Extended SA / Société belge des auteurs, compositeurs et *éditeurs* SCRL (SABAM) [2011] ECR I-11959
Case C-457/09, Chartry [2011] ECR I-00819
Case C-316/09, MSD Sharp & Dohme GmbH [2011] ECR I-03249
Case C-339/10, *Estov et al.* [2010] ECR I-11465
Case C-108/09, *Ker Optika* [2010] ECR I-12113
Case C- 447/08 & C-448/08, *Otto Sjöberg & Anders Gerdin* [2010] ECR I-6921
Case C-258/08, *Ladbrokes Betting & Gaming Ltd en Ladbrokes International Ltd/ Stichting de Nationale Sportstotalisator* [2010] ECR I-4757
Case C-570/07 & C571/07, *Blanco Pérez & Chao Gómez* (GC)[2010] ECR I-04629
Case C-531/06, *Commission / Italy* [2009](GC) ECR I-4103
Case C-421/07, *Damgaard* [2009] ECR I2629
Case C-171/07 & C-172/07, *Apothekerkammer des Saarlandes et al.* (GC)[2009] ECR I-4171
Case C-169/07, *Hartlauer Handelsgesellschaft mbH/Wiener Landesregierung, Oberösterreichische Landesregierung* (GC) [2009] ECR I-1721
Case C-42/07, *Liga Portuguesa de Futebol Profissional & Bwin International* (GC)[2009] ECR I-7633
Case C-500/06, *Corporación Dermoestética/ To Me Group Advertising Media* [2008] ECR I-578
Case C-212/06, *Government of the French Community and Walloon Government/ Flemish Government* [2008] ECR 1-01683

Case C-444/05, *Aikaterini Stamatelaki/ NPDD Organismos Asfaliseos Eleftheron Epagelmation* [2007] ECR I-3185
Case C-372/04, *Watts/ United Kingdom* (GC)[2006] ECR I-4325
Case C-71/02, Herbert Karner Industrie-Auktionen GmbH [2005] ECR I-3025
Case C-20/03, *Burmanjer et al.* [2005] ECR I-4133
Case C-322/01, *DocMorris NV/ Jacques Waterval (Deutscher Apothekerverband* [2003] ECR I-14887
Case C-385/99, *Müller-Fauré & Van Riet* [2003] ECR I-4509
Case C-390/99, *Canal Satélite/ Administración General del Estado* [2002] ECR I-607
Case C-157/99, Geraets-Smits & Peerbooms [2001] ECR I-5473
Case C-210/96, *Gut Springenheide* [1998] ECR 1-04657
Case C-275/92, *Her Majesty's Customs and Excise/ Gerhart Schindler en Jörg Schindler* [1994] ECR I-1039
Case C-98/86, *Mathot* [1987] ECR I-809
Case C36/75, *Rutili/ Ministre de L'Intérieur* [1975] ECR I-1219
Case C-5/77, *Tedeschi/ Denkavit* [1977] ECR 1555

REFERRED NATIONAL CASE LAW

Supreme court of the Netherlands:
HR 12 March 2013, *ECLI*:NL:HR:2013:BY4876
HR 25 October 2005, *ECLI*:NL:HR:2005:AU3030
HR 18 March 2005, *ECLI*:NL:HR:2005:AR5213
HR 23 November 2001, *ECLI*:NL:HR:2001:AB2737
HR 23 November 2001, *ECLI*:NL:HR:2001:AD3963
HR 15 January 1999, *ECLI*:NL:HR:1999:ZC2817
HR 1 April 1997, *ECLI*:HR:1997: ZD 0677
HR 13 February 1987, ECLI:NL:HR:1987:AG5539
HR 28 November 1950 *NJ* 1951, 137

Advertising Code Committee to the Board of Appeal:
College van Beroep Stichting Reclame Code 7 November 2011, nr. 2011/00727

The Advertising Code Committee:
Reclame Code Commissie 6 July 2011, nr. 2011/00489
Reclame Code Commissie 27 September 2010, nr. 2011/ 00874
Reclame Code Commissie 30 July 2007, nr. 2007/070343

PARLIAMENTARY ACTS

Kamerstukken II 1978/1979, 15 463, nr. 1
Kamerstukken II 1978/1979, 15 463, nr. 2
Kamerstukken II 2003/04, 29 323, nr. 1
Kamerstukken II 2003/04, 29 323, nr. 3
Kamerstukken II 2004/05, 29 323, nr. 15
Kamerstukken II 2005/06, 29 323, nr. 17
Kamerstukken II 2006/07, 30928, nr. 3
Kamerstukken II 2007/08, 29 323, nr. 49
Kamerstukken II 2007/08, 22 894, nr. 49
Kamerstukken II 2007/08, 22 894, nr. 179
Kamerstukken II 2011/12, 31 570

LIST OF ABBREVIATIONS

BW Burgerlijk Wetboek
DNA Deoxyribonucleic acid
DTC direct-to-consumer
ECHR European Convention on Human Rights and Fundamental Freedoms
ECtHR European Court of Human Rights
ECJ European Court of Justice of the European Union
EMA European Medicines Agency
EU European Union
EU Charter The Charter of Fundamental Rights of the European Union
ESC European Social Charter
FDA Food and Drugs Adminstration
GC Grand Chamber
GZ Gezondheidsraad
GW Grondwet
ISO International Standards Organisation
IVD In vitro diagnostics
NPPS National Programme Population Screening
NVJ Nederlandse Juristen- Vereniging
US Structural Ultrasound Scan
WBO Wet op het bevolkingsonderzoek
TFEU Treaty on the Functioning of the European Union
RVZ Raad voor de Volksgezondheid & Zorg

SAMENVATTING

Consumenten hebben via internet en anderszins tal van mogelijkheden om via *health checks*, *medische check ups*, *total bodyscans* en *direct-to-consumer* (DTC) genetische testen informatie te verkrijgen over hun (toekomstige) gezondheid. Aanbieders plaatsen dergelijke vormen van screening steeds vaker op de markt zonder dat de veiligheid, de betrouwbaarheid en het (klinisch) nut hiervan vaststaan. In Nederland gelden vanwege de potentiële gezondheidsrisico's voor het aanbieden en verrichten van bepaalde vormen van screening strikte voorwaarden op grond van de Wet op het bevolkingsonderzoek (WBO). De (kwaliteits)waarborgen die de Nederlandse wet- en regelgeving beogen te bieden ten aanzien van screening, niet in de laatste plaats ter bescherming van patiënten(rechten), weren in de praktijk de zogenaamde 'commerciële'[543] screening van de Nederlandse markt. Steeds meer mensen ervaren dit als een inbreuk op hun recht op zelfbeschikking. Echter, op de Staat rust, naast de plicht tot het waarborgen van het recht op zelfbeschikking, ook een bijzondere verantwoordelijkheid met betrekking tot de bescherming van de gezondheid. In dit proefschrift staat de vraag centraal welke normatieve criteria vanuit EU- en grondrechtelijk perspectief gelden voor de toegang tot en de verrichting van genetische screening, in het bijzonder DTC genetische testen en wat dit betekent voor de Nederlandse wet- en regelgeving.

Hoofdstuk 1 bevat een algemene inleiding en een beschrijving van het doel van het proefschrift. In de inleiding wordt uitgelegd op welke wijze de centrale vraag en de deelvragen in de afzonderlijke hoofdstukken worden onderzocht en beantwoord. Hierna volgt een verklaring waarom er in het proefschrift veel aandacht uitgaat naar de juridisch bindende instrumenten van de Europese Unie (EU) en de Raad van Europa en de jurisprudentie van het Europees Hof voor de Rechten van de Mens (EHRM). Tot slot beschrijft de auteur de beperkingen van de studie en de relevantie van dit onderzoek voor andere terreinen dan de genetica (de leer van de erfelijkheid) en genomics (het samenspel tussen de genen).

Hoofdstuk 2 formuleert een antwoord op de vraag in hoeverre de overheid is gehouden het ongereguleerde aanbod van DNA-(zelf)testen aan banden te leggen ter voorkoming van individuele gezondheidsschade en ter bescherming van de rechten en vrijheden van anderen. Het antwoord op die vraag is mede afhankelijk van de betekenis die wordt toegekend aan de belangrijke mensenrechtelijke en gezondheidsrechtelijke beginselen autonomie en bescherming. Het hoofdstuk begint met een uitgebreide beschrijving over de wijze waarop DNA-diagnostiek kan bijdragen aan het opsporen van dragerschap of (latent) aanwezige ziekten waarbij de betrokkenen voordeel kunnen hebben. Ook

[543] Screening buiten het zogenaamde 'reguliere' circuit.

wordt stil gestaan bij de nadelen en risico's van DNA-diagnostiek en in het bijzonder van DNA-(zelf)testen. De belangrijkste conclusie in dit hoofdstuk is dat op er grond van de literatuurstudie en de jurisprudentie van het EHRM over de artikelen 2 (recht op leven), 3 (folterverbod) en 8 (recht op privacy en familie- en gezinsleven) van het Verdrag tot bescherming van de rechten van de mens en de fundamentele vrijheden (EVRM) er vanuit algemeen mensenrechtelijk oogpunt goede redenen zijn om aan het aanbod van DNA-(zelf)testen strikte (kwaliteits)eisen te stellen. Het risico bestaat bijvoorbeeld van onterechte zorg (of geruststelling) en stijgende gezondheidskosten door overdiagnostiek en overbehandeling als gevolg van dergelijk (niet altijd betrouwbaar) onderzoek waarvan het (klinisch) nut twijfelachtig is. Bovendien kunnen DNA-(zelf) testen ook inbreuk maken op de rechten en vrijheden van anderen. En voorts zijn er twijfels of wel altijd sprake is van *geïnformeerde* toestemming van de consument.

Geïnformeerde toestemming – het beginsel van *informed consent* - vormt een uitdrukking van zelfbeschikking. Bij de uitvoering van landelijke screeningprogramma's, maar ook ten aanzien van de toegang tot DTC genetisch testen spelen verschillende noties van zelfbeschikking een rol. Zelfbeschikking in de betekenis van *afweerrecht* tot zelfbeschikking in de notie van *keuzevrijheid* en als aanspraak op *zelfontplooiing*. Om gebruik te kunnen maken van al deze noties is adequate informatie van essentieel belang. ***Hoofdstuk 3*** beschrijft de waarborgen voor zelfbeschikking in het kader van het landelijk programma voor prenatale screening op het syndroom van Down. De belangrijkste bevindingen zijn; dat zwangeren recht hebben op zelfbeschikking en daarmee op keuzen aangaande hun zwangerschap en het ondergaan van prenatale screening. Dat informatie van groot belang is voor de uitoefening van zelfbeschikking. Deze informatie moet, aldus het EHRM, volledig, betrouwbaar en tijdig toegankelijk zijn.
In de adviezen van de Gezondheidsraad over prenatale screening op Downsyndroom voert zelfbeschikking in de vorm van het bieden van mogelijkheden voor het maken van geïnformeerde keuzen de boventoon. In dit hoofdstuk blijkt dat zwangeren naast vooral feitelijke informatie in de praktijk vooral behoefte hebben aan professionele begeleiding door hulpverleners bij het toepassen van de informatie op de eigen situatie. Om die reden zouden de beroepsgroepen en uitvoeringsinstanties het principe van non-directiviteit bij de informatieverstrekking over prenatale screening moeten herformuleren in het kader van zelfbeschikking. Herformuleren op zodanige wijze dat (beter) tot uitdrukking komt dat het informeren van zwangeren over prenatale screening verder reikt dan het enkel geven van feitelijke informatie. Daarnaast is het belangrijk dat de Minister van Volksgezondheid Welzijn en Sport de leeftijdsgrens voor de vergoeding uit het basispakket van de prenatale screening op Downsyndroom heroverweegt, opdat niet alleen de procedurele norm van artikel 8 EVRM is gewaarborgd – de toegang tot prenatale screening en het krijgen van informatie daarover – maar dat ook de materiële norm voor *alle* zwangeren is geborgd: het daadwerkelijk hebben en ervaren van keuzevrijheid.

Bij commerciële screening is er zelden een onderscheid tussen de begrippen aanbieden, uitnodigen en reclame. Dit komt doordat aanbieders met openbare verkoopbevorderende teksten op betaalde websites of met reclameboodschappen in kranten en tijdschriften screening rechtstreeks aanbieden aan consumenten. Ze nodigen consumenten met dergelijke teksten uit om een gezondheidsdienst - screening - te kopen. ***Hoofdstuk 4*** omvat een studie naar de EU- en grondrechtelijke aspecten van reclame voor (internet) gezondheidsdiensten en de toelaatbaarheid van het beperken van deze wijze van meningsuiting. Een bevinding in dit hoofdstuk is dat het EHRM het vergunnen of het verbieden van reclame voor gezondheidsdiensten op gezondheidsbeschermende gronden niet snel zal aanmerken als een ongerechtvaardigde inbreuk op de vrijheid van meningsuiting. Verdragstaten hebben een ruime *margin of appreciation* bij het reguleren van reclame voor gezondheidsdoeleinden. Het blijkt dat het EU-recht met betrekking tot grensoverschrijdende 'pure' reclame voor gezondheidsdiensten een effectievere bescherming biedt tegen inbreuken op de vrijheid van meningsuiting dan het EVRM. Voorts is een conclusie in hoofdstuk 4 dat er op grond van het EU-recht minder voorwaarden aan reclameverboden zijn verbonden dan aan systemen van voorafgaande administratieve toestemming. Specifiek voor DTC genetische testen geldt dat vraagtekens kunnen worden geplaatst bij de evenredigheid tussen een reclameverbod of een vergunningstelsel voor dergelijke testen en het nagestreefde doel. De Staat kan immers ook met minder ver ingrijpende maatregelen op de rechten en vrijheden van consumenten en aanbieders de denkbare doelen voor het beperken van reclame voor DTC genetische testen behalen.

Hoofdstuk 5 bevat een studie naar de wet- en regelgeving van zeven Europese landen die van toepassing is op DTC genetische testen. In Frankrijk, Duitsland, Portugal en Zwitserland zijn op grond van de huidige wetgeving alleen artsen bevoegd om genetische testen te verrichten. Een arts mag in deze landen net als in Nederland, België en het Verenigd Koninkrijk alleen een DTC test verrichten na toestemming van de patiënt/ consument. Op de arts rust de plicht om voorafgaand aan de DTC genetische test de patiënt/ consument zo volledig mogelijk voor te lichten over de aard, de betekenis en de gevolgen van de test(uitslagen). Nederland heeft op grond van de WBO een vergunningensysteem voor bepaalde vormen van screening. Dit vergunningensysteem is uniek in de wereld. In België en het Verenigd Koningrijk gelden geen beperkingen ten aanzien van de toegang en de verstrekking van DTC genetische testen.

Vanuit mensenrechtelijk oogpunt zijn er voor Nederland, zoals we eerder zagen, goede redenen om de toegang tot DTC genetische testen te reguleren. Nederland is lid van de EU en de Raad van Europa. Beide organisaties beperken ieder op hun manier de Nederlandse (beleids)vrijheid ten aanzien van het reguleren van het aanbod van DTC genetische testen. ***Hoofdstuk 6*** gaat over de vrijheid van lidstaten van de EU om het

aanbod van commerciële genoomanalyse binnen hun landsgrenzen te reguleren en de betekenis hiervan voor Nederland. In dit hoofdstuk wordt betoogd dat commerciële genoomanalyses juridisch gekwalificeerd moeten worden als een dienst en niet als een goed. Het Nederlandse vergunningssysteem is aldus een beperking van het vrije verkeer voor diensten en vestiging, althans voor zover sprake is van grensoverschrijdende situaties. De belangrijkste conclusie uit dit hoofdstuk is dat de wijze waarop Nederland de toelating van commerciële genoomanalyses reguleert op gespannen voet staat met het EU-recht. Het op grond van de WBO vergunnen van het aanbod en de verrichting van commerciële genoomanalye is in strijd met de Richtlijn Elektronische handel en met het vrije verkeersregime voor vestiging omdat het niet evenredig is aan het nagestreefde doel vanwege de reikwijdteproblemen van deze wet. Dit kan problemen opleveren in situaties waarbij een bedrijf uit een andere lidstaat zich in Nederland vestigt en/ of alhier commerciële genoomanalyse wil aanbieden en verrichten. In dit hoofdstuk pleiten de auteurs voor herziening van de WBO. Deze herziening zou zich moeten richten op het aanpassen van de definitie van bevolkingsonderzoek en de vergunningcriteria, zodat de wet heldere en vooraf kenbare vergunningcriteria krijgt.

Hoofdstuk 7 is een overzichtsartikel. De auteurs onderzoeken in dit hoofdstuk of de WBO een voorbeeld kan zijn voor andere landen als het gaat om het stellen van kwaliteitseisen aan DTC genetische testen. De bestudeerde relevante juridische bindende instrumenten met betrekking tot DTC genetische testen van de Raad van Europa en de EU hebben met elkaar gemeen dat validiteit en utiliteit belangrijke voorwaarden zijn voor het toestaan van het gebruik van deze testen door het grote publiek. Daarnaast lijkt er brede steun te bestaan voor het standpunt dat DTC genetische testen alleen mogen worden verricht onder supervisie van een arts. De bestudeerde juridische instrumenten bevatten allen een bepaling over het gebruik van DTC genetische testen met vergaande consequenties voor de geteste persoon of zijn bloedverwanten. Op grond van deze bepalingen zouden Staten dergelijke testen alleen mogen toestaan met non-directieve counseling.
Het antwoord op de centrale vraag in dit hoofdstuk luidt dat de WBO in zijn huidige vorm niet als voorbeeld kan dienen voor andere landen van de EU of verdragstaat zijn van het EVRM en het Verdrag inzake de rechten van de mens en de biogeneeskunde en het aanvullend Protocol genetisch testen voor medische doeleinden. Op de eerste plaats is de WBO te liberaal omdat het geen kwaliteitwaarborgen biedt ten aanzien van alle genetisch testen maar alleen aan genetische testen naar kanker en onbehandelbare ziekten. Op de tweede plaats conflicteert de WBO, zoals beschreven in hoofdstuk 6, met het EU-recht.

In ***hoofdstuk 8*** vergelijken de auteurs het EU-recht ten aanzien van medicijnen met het EU-recht voor DTC genetische testen. Het doel hiervan is te onderzoeken of de wijze

waarop de EU de toegang tot, de vervaardiging van en verstrekking van medicijnen reguleert kan dienen als een voorbeeld voor de regulering van DTC genetische testen. Dit blijkt inderdaad zo te zijn, vooral ten aanzien van het systeem van (centrale) autorisatie door middel van 'een *premarket review'* dat geldt voor medicijnen. Echter, 'een *premarket review'* is niet voldoende om de kwaliteit, de betrouwbaarheid, het (klinisch) nut en het veilig gebruik van DTC genetische testen te waarborgen. Effectieve regulering van DTC genetische testen start met *'premarket review'* maar stelt ook (kwaliteits)eisen aan de medische begeleiding tijdens het testen en aan het informeren van personen die zich willen laten testen.

Hoofdstuk 9 bevat een beschrijving van de belangrijkste onderzoeksbevindingen en enkele concluderende opmerkingen. Zelfbeschikking heeft niet alleen de betekenis van afweerrecht. Zelfbeschikking betekent ook de vrijheid om te kiezen en de vrijheid tot zelfontplooiing. Vanuit deze visie bezien zijn maatregelen die beschermen tegen gezondheidsschade of interventies die tot doel hebben een *geïnformeerde keuze* te bevorderen geen inbreuk op de zelfbeschikking. Dergelijke maatregelen waarborgen de zelfbeschikking in de dimensies van keuzevrijheid en zelfontplooiing, de mogelijkheid het leven naar eigen inzichten in te richten. Echter, alleen gestandaardiseerde, globale informatie over DTC genetische testen waarborgt de zelfbeschikking niet. Daarom is counseling gedurende het (DTC) genetische testproces noodzakelijk. Tijdens de counseling kan de dienstverlener/ hulpverlener de informatie afstemmen op de individuele behoefte van de patiënt/ consument.
Alleen beter informeren of voorlichten van (potentiële) consumenten is niet voldoende om individuen te beschermen tegen gezondheidschade als gevolg van ondeugdelijke screening.
Een belangrijke aanbeveling in dit hoofdstuk is het transformeren van de WBO naar een screeningswet waarbij het aanbieden en verrichten van screening in beginsel is toegestaan, mits de screening wetenschappelijk deugdelijk is en de patiënten- en consumtenrechten zijn geëerbiedigd. De auteur stelt voor de term bevolkingsonderzoek alleen te reserveren voor grootschalige screeningprogramma's .
Het hoofdstuk eindigt met de *take home message* dat een *premarket review* of een kwaliteitskeurmerk niet voldoende is voor het beschermen van individuen tegen gezondheidsschade en het borgen van de rechten en vrijheden van anderen. Het grootste probleem is niet dat aanbieders van bedrijven ondeugdelijk apparatuur of software gebruiken voor het opmaken van het genetisch profiel. In de regel richt de kritiek zich vooral op het werkelijke probleem. Dit betreft de wijze waarop de aanbieders de verzamelde data interpreteren en de manier waarop zij de testuitslagen communiceren naar geteste personen.

CURRICULUM VITAE

Rachèl van Hellemondt was born in Voorburg, the Netherlands, on November 15, 1971. After finishing secondary school, she moved to Castricum. There, she was trained to be a psychiatric nurse ('verpleegkundige B') at the Duin & Bosch provincial hospital, now known as Dijk en Duin, a division of the Parnassia Groep mental health institute. After obtaining her nursing degree in June 1993, she settled in Utrecht but continued working as a psychiatric nurse in Castricum. In April 1996 she started her shortened graduate training in nursing at Hogeschool Diemen and at VU University Medical Center Amsterdam (VUmc). After graduating, she worked as a nurse at VUmc. At the same time, she worked as an instructor at an outdoor-sports company based in the Belgian Ardennes.

In 1999 she returned to the mental health field working as a nurse/ social therapist at University Medical Center Utrecht, at its open unit providing mental health care for children and adolescents suffering from eating disorders. In the period from 2001 to 2009, she held several positions in youth care, first at Bureau Jeugdzorg Zuid Holland Noord in Leiden and then, after the Wet op de jeugdzorg came into force, at Stichting Horizon Pleegzorg, a foster care organisation in Alphen aan den Rijn.

She began studying part-time for her Bachelor in Law in 2002 and for her Master in Constitutional and Administrative Law in 2007 at Leiden University. In August 2008 she received her Master's degree, after which she started with her doctoral research at Leids University Medical Center (LUMC) in 2009. Besides her doctoral research, she has been a member of the research team carrying out the disciplinary study on patients' self-determination, together with colleagues attached to Leiden Law School and Leiden University Medical Center.

She is a member of the Medical Ethics Review Committee (Commissie Medische Ethiek) of LUMC and of the Dutch Forum for Biotechnology and Genetics on behalf of the Dutch Association for Health Law. In addition, she is a board member of the Dutch Association for Community Genetics and Public Health Genomics (NACGG).

Rachèl van Hellemondt lives in Leiden together with her wife and their two children.

CURRICULUM VITAE

Rachèl van Hellemondt werd geboren op 15 november 1971 in Voorburg. Na haar middelbare schooltijd in Schoonhoven verhuist ze naar Castricum. Hier kiest ze voor de opleiding tot psychiatrisch verpleegkundige (verpleegkundige B) in het provinciaal ziekenhuis Duin & Bosch, tegenwoordig Dijk en Duin onderdeel van de Parnassia Groep. Na haar diplomering in juni 1993 vestigt ze zich in Utrecht maar blijft ze in Castricum werken als psychiatrisch verpleegkundige/ persoonlijk begeleider. In april 1996 begint ze aan de verkorte verpleegkunde opleiding aan de Hogeschool Diemen en het Vrije Universiteit ziekenhuis in Amsterdam. Ze werkt na het behalen van haar diploma nog enige tijd als verpleegkundige in het VUmc. Daarnaast werkt ze bij een buitensportbedrijf als instructeur in de Belgische Ardennen.

In 1999 keert ze terug in psychiatrie als verpleegkundige/ sociotherapeut en gaat ze werken op de open afdeling (de eetstoornissenkliniek) van de kinder- en jeugdpsychiatrie van het Universitair Medisch Centrum Utrecht. In de periode 2001-2009 vervult ze verschillende functies binnen de jeugdhulpverlening, eerst bij Bureau Jeugdzorg Zuid Holland te Leiden en na de inwerkingtreding van de Wet op de Jeugdzorg bij Stichting Horizon Pleegzorg in Alphen aan den Rijn.

In 2002 begint ze in deeltijd aan de Bachelor Rechtsgeleerdheid en in 2007 aan de Master Staats- en Bestuursrecht aan de Universiteit Leiden. In augustus 2008 behaalt ze haar Master waarna ze in 2009 haar promotieonderzoek start in het Leids Universitair Medisch Centrum. Naast haar promotieonderzoek maakt ze deel uit van de onderzoeksgroep die dan de thematische wetsevaluatie zelfbeschikking in de zorg uitvoert.

Ze is lid van de Commissie Medische Ethiek (CME) van het Leids Universitair Medisch Centrum en van het Forum Biotechnologie namens de Vereniging voor Gezondheidsrecht. Voorts zit ze in het Bestuur van de Nederlandse Associatie voor Community Genetics en Public Health Genomics (NACGG)

Rachèl van Hellemondt woont samen met haar vrouw en hun kinderen in Leiden.

PUBLICATIES:

- A.C. Hendriks, Y.M. Drewes & R.E. van Hellemondt, 'Kroniek van het Gezondheidsrecht', *Nederlands Juristenblad* 2011.
- R.E. van Hellemondt, W. de Ruijter, A.C. Hendriks & M.H. Breuning 'Komt een geteste patiënt bij de dokter …', *Medisch Contact* 2011, p. 202-204.
- R.E. van Hellemondt, 'Maria Lourdes wil haar kind behouden', in: W. de Ruijter, A.C. Hendriks & M.A. Verkerk (eds), *Huisarts tussen individu en familie. Morele dilemma's in de huisartsenpraktijk,* Assen: Koninklijke Van Gorcum 2012, p. 13-17.
- R.E. van Hellemondt & S. Jans, 'De verloskundige bij de tuchtrechter, *Tijdschrift voor V*erloskundigen 2012 (nov), p. 44-48.
- R.E. van Hellemondt 'Neonatale screening in het licht van het Kinderrechtenverdrag', *Tijdschrift voor Familie- en Jeugdrecht* 2013, p. 152-154.
- R.E. van Hellemondt, 'Verslag najaarsvergadering Vereniging voor Gezondheidsrecht', Tijdschrift voor Gezondheidsrecht, p. 281-287.
- Y.M. Drewes, R.E. van Hellemondt & A.C. Hendriks, 'Zelfbeschikking en informed consent', in: A.C. Hendriks, R.D. Friele, J. Legemaate & G.A.M. Widdershoven (red.), *Thematische Wetsevaluatie*, *Zelfbeschikking in de zorg*, Den Haag: ZonMw 2013.
- Y.M. Drewes, R.E. van Hellemondt & A.C. Hendriks, 'Zelfbeschikking en curatieve zorg, met bijzondere aandacht voor de WGBO', in: A.C. Hendriks, R.D. Friele, J. Legemaate & G.A.M. Widdershoven (red.), *Achtergrondstudies Zelfbeschikking in de zorg*, Den Haag: ZonMw 2013.
- R.E. van Hellemondt, Y.M. Drewes & A.C. Hendriks, 'Zelfbeschikking en publieke gezondheid, met bijzondere aandacht voor de WPG en WBO', in: A.C. Hendriks, R.D. Friele, J. Legemaate & G.A.M. Widdershoven (red.), *Achtergrondstudies Zelfbeschikking in de zorg*, Den Haag: ZonMw 2013.
- E.J.T. Verweij, D. Oepkes, E.S.A. van den Akker, M.A. de Boer, R.E. van Hellemondt & D.P. Engberts, 'Déjà vu? Discussie over de non-invasieve prenatale test (NIPT) voor Nederlandse zwangeren', *Nederlands Tijdschrift voor Obstetrie en Gynaecologie* 2013, p. 382-386.
- M.C.I.H. Biesaart & R.E. van Hellemondt, 'Wet op de beroepen in de individuele gezondheidszorg', in: G.R.J. de Groot, T.A.M. van den Ende, L.E. Kalkman-Bogerd & J.J.M. Linders (red.), *Tekst en Commentaar Gezondheidsrecht,* Deventer: Kluwer 2013, p. 59-146 en 210-235.

BRIEVEN EN ANNOTATIES:

- R.E Hellemondt, A.C. Hendriks, M.H. Breuning & W. de Ruijter, 'huisartsen, opgelet bij vragen over genetisch profiel!', *Huisarts en Wetenschap* 2010-12, p. 692.
- Y.M. Drewes & R.E. van Hellemondt, annotatie bij Gerechtshof 's-Gravenhage 9 februari 2010, *Gezondheidszorg Jurisprudentie* 2010, 51.

- R.E. van Hellemondt & Y.M. Drewes, annotatie bij Rechtbank Roermond 26 november 2009, *Gezondheidszorg J*urisprudentie 2010, 18.
- R.E. Hellemondt & Y.M. Drewes, annotatie bij College van Beroep Stichting Reclame Code 7 november 2011, *Gezondheidszorg J*urisprudentie 2012, 19.
- R.E. van Hellemondt & A.C. Hendriks, annotatie bij EHRM 28 augustus 2012, Costa & Pavan t. Italië, nr. 54270/10, *Het Nederlands Tijdschrift voor de Mensenrechten (NTM/NJCM-bulletin)*, 2013, p. 63-75.