

Genomics and the Law

Hellemondt, R.E. van

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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. Advertising¹⁶⁶ 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 ECHR, 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 socalled '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, *LIN* 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 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

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 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/EU²³⁵ 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

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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 <u>https://www.reclamecode.nl/;</u> 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 2006²⁵⁰ 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

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.