

(2009) 7:1 *GenEdit*, 1-14

DIRECT-TO-CONSUMER GENETIC TESTING: OVERVIEW OF APPLICABLE NORMS AND POLICIES

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Summary:

A growing number of private companies are offering, via the Internet, genetic tests "directly to consumers". These types of genetic "services" raise a number of ethical concerns, in particular, the validity and clinical utility of these tests and the fact that they are conducted without a system in place to ensure that consumers understand the scope, limits and the basic meaning of the results. This GenEdit analyzes existing normative documents which address genetic tests offered directly to consumers. It identifies three broad approaches regarding the normative framework that should govern such testing. The first approach generally advocates for the ban of these services, while the second appears to allow them, provided that certain conditions are met. The third approach falls somewhere in the middle. These normative documents were also studied for specific information related to the roles and responsibilities of healthcare professionals, pre-test information, consent and communication of results, as well as the importance of educating the public and healthcare professionals. It concludes by stressing the scientific, social and moral necessity for a consistent and adapted normative framework, and the need to initiate activities for public education and public consultation.

INTRODUCTION

Due in large part to progress in molecular biology and advances in biotechnologies, more and more genetic tests have been made available for an increasing number of genetic conditions (i.e.: breast cancer). Although such tests are usually carried out in a traditional healthcare setting with the support of healthcare professionals, an increasing number of private companies are now offering direct-to-consumer (DTC) genetic testing by way of the Internet. The following conditions usually pertain to these online services:

- 1) the consumer can purchase the test(s) without a medical prescription or doctor's authorization;
- 2) the consumer provides his own biological material;
- 3) test results are communicated directly to the consumer.⁵

For some time now there has been a keen interest in these tests, which we will subsequently refer to as direct-to-consumer (DTC) tests. This is reflected in the fact that in the last few years a large number of private companies, such as 23andMe, deCODE, and My Genome, have become interested in the market for genetic testing services.

Companies offering DTC genetic testing services differ significantly in the type of services they offer and in the ways in which they offer them. The type of information provided by such services can pertain to, among others, paternity, ancestry or health-related traits. Some companies offer complete genome scans, the results of which pertain to all these areas and more. Furthermore, the procedures for obtaining the tests can differ widely from company to company. Some companies will supply or require pre- and post-test telephone consultations with a certified genetic counselor, while other companies will allow consumers to order the test and obtain the test results without any type of medical follow-up or genetic counseling.

Companies engaged in DTC genetic testing are keen to point out the benefits of using such services. They claim that it increases individual autonomy and consumer

empowerment such that individuals can play a more active role in their own healthcare. Secondly, such genetic tests can also increase individual privacy and confidentiality since not only do they bypass a face-to-face meeting with a medical doctor, the results of such tests will not necessarily be part of the traditional health care file (and as such will not necessarily be used when asking for health related insurance).⁶

Whatever the merits of these arguments, it is clear that DTC genetic testing also raises many ethical concerns, especially with regard to the tests' clinical validity and utility.⁷ Furthermore, many tests for complex traits remain mired in uncertainty and interpreting their results requires extreme caution (i.e.: susceptibility testing). In addition, there is an important ethical problem in that DTC genetic testing, can lead to the inappropriate testing of children.⁸ Even in the testing of adults, other questions arise: was there sufficient informed consent, and were the test results clearly understood? Fundamentally the problem is that the results of testing can be difficult to interpret and can lead to a severe misreading of the actual or future health status of the consumer; the consumer may either be too alarmist and think the results mean certain disease or sickness, or alternatively he may be too complacent and believe that because he has no increased risk he does not need to follow a healthy lifestyle. Ethical concerns also arise in the "prediction" of a disease which can be neither prevented nor treated, or when consumer data and biological samples are used for research purposes.

These concerns clearly show why DTC genetic testing is considered by some to be very controversial⁹ and yet, the problematic issues are not limited to those listed above. There is additional debate regarding the need to implement more specific regulatory oversight.¹⁰ Some authors question whether policy makers should take it upon themselves to protect individuals from their own desire for information,¹¹ while others think that a stricter regulatory framework is clearly needed.¹² Yet another position, held by some organizations, is that the advertising and unrestricted offer of genetic testing should be banned altogether, and that genetic tests should be undertaken only on the direct order of a physician.¹³

The goal of this article is to review the normative texts published in either English or French which specifically deal with direct-to-consumer genetic testing. By making a comparative analysis of these texts we wanted to determine the prevailing trends with regard to the ethical dimensions of direct-to-consumer genetic testing. This article will focus on three general themes found in the majority of the texts we analyzed: 1) the roles and responsibilities of healthcare professionals; 2) the type of pre-test information that should be given to consumers, informed consent and the communication of test results; and 3) the education of the public and/or healthcare professionals.

METHODOLOGY

This research was carried out in January 2009 using the databases HumGen International, Web of Science, PubMed and Google Scholar. The following Internet sites were also searched: 1) national bioethics committees (using lists found on the site of the World Health Organization and of the German Reference Center for Ethics in the Life Sciences); 2) organizations devoted to the subject of human genetics (using the list found on the site of the International Federation of Human Genetics Societies as well as associated links); and 3) several national medical associations (using the list of the World Medical Association). Documents were included in our review of normative texts

if their title indicated that they dealt explicitly with the question of direct-to-consumer genetic testing and if they presented a position statement on this issue. Only texts written in English or French or which had been translated into one of these two languages were included.

Private companies selling genetic testing services directly to the public have a wide range of tests on offer. Some of these tests are more prone than others to be carried out without medical consultation. This is particularly true of genetic testing to establish family relationships (paternity tests) or ancestry (genealogy tests), both of which may have large potential markets for direct-to-consumer genetic testing. However, for the purposes of the present research, normative texts dealing exclusively with paternity tests or ancestry tests were specifically excluded.

RESULTS

A total of fourteen normative texts were identified, originating from thirteen different organizations and seven different countries (Table 1). The different types of organizations included: two government organizations; four genetics associations or societies; four medical or professional organizations; and three organizations with an ethical vocation. No normative text with an international or even regional perspective met our criteria for inclusion in this research.

Table 1: List of normative texts dealing explicitly with direct-to-consumer genetic testing

Year	Organization / Country	Title
1. 1997	Advisory Committee on Genetic Testing (ACGT) / United Kingdom	<i>Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public</i> ¹⁴
2. 2003	Human Genetics Commission (HGC) / United Kingdom	<i>Genes direct. Ensuring the Effective Oversight of Genetic Tests Supplied Directly to the Public</i> ¹⁵
3. 2004	Belgian Advisory Committee on Bioethics (BACB) / Belgium	<i>Opinion no. 32 of 5 July 2004 on the Free Availability of Genetic Tests</i> ¹⁶
4. 2004	National Consultative Ethics Committee for Health and Life Sciences (NCEC) / France	<i>Opinion no. 86 – Problems connected to marketing self-test kits for HIV Screening and Diagnosis of Genetic Disease</i> ¹⁷

5.	2005	American Society for Clinical Pathology (ASCP) / United States	<i>Direct Access Testing</i> ¹⁸
6.	2006	American College of Medical Genetics (ACMG) / United States	<i>ACMG Statement on Direct-to-Consumer Genetic Testing</i> ¹⁹
7.	2007	American Society of Human Genetics (ASHG) and American College of Medical Genetics (ACMG) / United States	<i>ASHG Statement on Direct-to-Consumer Genetic Testing in the United States</i> ²⁰
8.	2007	Human Genetics Commission (HGC) / United Kingdom	<i>More Genes Direct. A Report on Developments in the Availability, Marketing and Regulation of Genetic Tests Supplied Directly to the Public</i> ²¹
9.	2007	Human Genetics Society of Australasia (HGSA) / Australia	<i>Direct to Consumer Genetic Testing</i> ²²
10.	2007	National Society of Genetic Counselors (NSGC) / United States	<i>Direct to Consumer Genetic Testing</i> ²³
11.	2008	National Council of Ethics for the Life Sciences (NCELS) / Portugal	<i>Opinion no. 56 of the National Council of Ethics for the Life Sciences – Opinion on Direct Marketing of Genetic Tests to the Public</i> ²⁴
12.	2008	American College of Obstetricians and Gynecologists (ACOG) / United States	<i>Direct-to-Consumer Marketing of Genetic Testing</i> ²⁵
13.	2008	American Medical Association (AMA) / United States	<i>Direct-to-Consumer Advertising and Provision of Genetic Testing</i> ²⁶
14.	2009	Swiss Society of Medical Genetics (SSMG) / Switzerland	<i>Tests génétiques sur Internet</i> ²⁷

The results of this search have been grouped according to the general approach (es) adopted by each organization vis-à-vis DTC genetic testing and specific subtopics related to this service. Albeit to a certain extent relative and subjective, this categorization allows for the identification of the general tendencies adopted by the various normative texts and the specific issues they have examined. Furthermore, it is understood that by addressing only certain specific topics there is the risk of not fully conveying all the subtleties of the texts as a whole.

GENERAL POSITIONS

Three main positions regarding the regulation of DTC genetic testing were identified: two of these represent opposing opinions while the third is classified as a median approach. Some texts advocate banning the free-market sale of genetic tests directly to consumers and stipulate that genetic tests should be carried out under the care of a qualified health care professional.²⁸ For example, the American Medical Association currently opposes direct-to-consumer genetic testing²⁹ and the American College of Medical Genetics states: "[a] knowledgeable professional should be involved in the process of ordering and interpreting a genetic test"³⁰ [our emphasis].

Other texts advocate a more liberal approach, whereby direct-to-consumer genetic testing is allowed as long as certain conditions are met.³¹ The Human Genetics Commission, for example, recommends a stricter control on genetic testing without actually prohibiting it: "[we] recommend stricter controls on direct genetic testing, but we do not believe that there should be statutory prohibition of some, or all, direct genetic tests."³²

Finally there are texts that adopt what we call a median approach³³ which can be explained in one of three ways. In one instance³⁴, the members of the organization signing the normative text are divided about the position to adopt: some of them want to ban the sale of genetic tests directly to the consumer while others would allow the practice if certain conditions were met. In other instances³⁵, the text is included in the median group because the position taken varies according to the type of genetic test: "[w]hereas the DTC model may be contraindicated for certain types of tests, the availability of other tests in the absence of a health care provider may not compromise, and may even foster, patient health."³⁶ The same is true for another text which states that where diagnostic tests or predictive tests are concerned, consumers should not be able to obtain them directly, but it does not address other types of genetic tests (thereby leading one to believe that there is no limit on access to such tests).³⁷ In yet other texts the position taken is subject to interpretation as the authors state that direct-to-consumer genetic testing should be "discouraged".³⁸

With regards to the framework that should govern direct-to-consumer genetic testing, an analysis of the normative documents considered herein reveals that, regardless of the overall position taken, they nearly all attribute responsibilities to healthcare professionals. Therefore, it is useful to determine what roles and responsibilities are advocated.

SPECIFIC POSITIONS

1) Roles and responsibilities of healthcare professionals

The fourteen normative documents examined take differing and sometimes diametrically opposed positions when it comes to determining the roles and responsibilities of healthcare professionals regarding DTC genetic testing services. In summary, however, it appears that when the more restrictive approach is advocated, the stipulation is that genetic testing should take place within the context of a professional medical relationship.³⁹ For example, some members of the Belgian Advisory Committee on Bioethics state that:

"the free availability of genetic self-tests should be prohibited. These members think that genetic tests should always take place in a medical professional relationship in the framework of which sufficient information is provided and counselling is guaranteed. [...] The same members think that a reliable test result with a reliable interpretation and sensible instructions for the parties concerned presupposes that these tests take place within a professional relationship. [...] These members are also of the view that an adequate protection of third parties involved in the test results can only be guaranteed via the filter of a medical professional relationship. [...] these members feel that the limitation of access to genetic tests on a doctor's orders would prevent an excessive commercialisation of the tests."⁴⁰

It is clear from this passage that a great deal of importance is placed on the role of healthcare professionals. However, while some texts that adopt this stance suggest that healthcare professionals in general (i.e.: without a defined speciality), can assume the responsibility for authorizing access to certain genetic tests and for providing genetic counseling,⁴¹ others explicitly state that this responsibility should be given to a health care professional who is specialized in genetics.⁴²

Furthermore, even when normative texts describe a liberal position regarding direct-to-consumer genetic testing, they often place the burden of responsibility on healthcare professionals, or at least assign them a defined role, notably to provide information for patients/consumers and interpret test results. To be more precise, some texts⁴³ adopt an approach which we refer to as "collaborative"; this view advocates that DTC genetic testing companies and healthcare professionals

must act together to ensure, among others, that the pre-test information available to consumers is of high quality and that consumers understand test results. Among the texts advocating this collaborative approach, some⁴⁴ place the responsibility of initiating collaboration squarely on the shoulders of the direct-to-consumer genetic testing companies while others⁴⁵ say the responsibility lies with the consumer. The Advisory Committee on Genetic Testing in the United Kingdom, for example, assigns a set of duties to DTC genetic testing companies, including: the duty to provide the consumer's primary-care physician with the test results once the consumer's consent has been obtained; to work with healthcare professionals in producing information materials destined for consumers; and to refer consumers with abnormal test results to healthcare professionals who are able to provide the necessary support.⁴⁶ On the other hand, the American Society for Clinical Pathology (ASCP) appears to place the responsibility for seeking out the input of a healthcare professional in the hands of the consumer:

"[p]atients should consult with their primary care physician when ever possible after receiving DAT [direct access testing] test results. [...] For optimum patient health outcomes, ASCP recommends that patients consult with their physician for proper interpretation of test results. Laboratory testing helps better identify a patient's health status. Clinicians may have access to the patient's family history and other data that can critically affect test interpretation and can order additional tests to clarify the results or predict risk."⁴⁷

The American Society of Human Genetics (ASHG) *Statement on Direct-to-Consumer Genetic Testing in the United States*⁴⁸ places the burden of responsibility on professional organizations to educate their members so that the latter can then explain to their patients the types of genetic tests offered directly to the consumer, their benefits and their limitations, etc:

"[T]o ensure that providers are aware that genetic tests are being provided DTC and that some of these tests may lack analytic or clinical validity, professional organizations should educate their members regarding the types of genetic tests offered DTC, so that providers can counsel their patients about the potential value and limitations of DTC testing."⁴⁹

This analysis of normative texts regarding the roles and responsibilities of healthcare professionals in the context of DTC genetic testing clearly reveals that whatever the general position taken, healthcare professionals are almost always assigned roles and responsibilities. Similarly, many of these texts⁵⁰ also raise the issues of pre-test information, consumer consent and the communication of test results. It is important, therefore, to review the positions with regard to these three factors in order to identify current thinking on the ethics involved.

2) Pre-test information, consent and the communication of results

Many of the normative texts analyzed⁵¹ are in agreement that DTC genetic testing raises serious concerns, given the difficulty of ensuring that consumers fully understand 1) the implications of the test before they consent to it⁵² and 2) the test results.⁵³

i- Pre-test information

Several of the documents examined single out the inadequacy of the information given to consumers regarding the implications of genetic testing as one of the major concerns raised by DTC genetic testing services.⁵⁴ They emphasize that the individuals undergoing the tests, and maybe even their families, should understand the full implications of results before any testing is performed.⁵⁵ However, once this general statement is made, there is a large variety of solutions offered. Some guidelines⁵⁶ emphasize the duty of the DTC genetic testing companies to provide adequate information. Several of these guidelines discuss the general duty that companies have to provide appropriate information to consumers by giving details about the tests offered (including the scope of the test and its limitations, as well as interpretation of test results).⁵⁷ The Advisory Committee on Genetic Testing in the United Kingdom, for example, says the following:

"[s]uppliers should provide appropriate information to the customer giving details of the tested condition, to ensure that the customer understands the nature of the testing, its scope and limitations, and the

accuracy, significance and use of a result. Such information should be supplied before the test is performed."⁵⁸

Beyond this general duty, some guidelines are more specific and list aspects of genetic testing that must be explained to consumers.⁵⁹ The Swiss Society of Medical Genetics, for example, states that:

"The consumer must be told who will have access to the results, what security measures are in place to protect the privacy of the results, what will happen to the DNA sample once the test is completed, and what the complaint mechanism is in the event of a breakdown in the protection of the data. The consumer should also be made aware of the possibility of future discrimination by an employer and/or an insurance company and of the potential impact on other family members before any genetic testing goes ahead"⁶⁰ [our translation]

Other normative documents⁶¹ have what may be described as a "middle-of-the-road" or "mixed" approach, combining the responsibilities of independent organizations (consumer protection agencies, national human genetics associations and the media, for example) with the duties of the companies offering DTC genetic testing services. Along these lines, the Human Genetics Commission states: "the use of existing web-based information sources to provide comprehensive and independent information for consumers should be explored, and test developers/providers should be encouraged to facilitate consumer access to this information."⁶² In an earlier document, this same organization proposes that funding be made available to a consumer protection agency to enable it to prepare specific and impartial information regarding DTC genetic testing services.⁶³

The National Society of Genetic Counselors (NSGC) in the United States adopts what we consider as being an "isolated position", because it is found in only one of the texts analyzed. It recommends that it is the consumer's responsibility to ensure, before the purchase of any genetic test, that the company from which the test is being purchased offers information which has been developed or reviewed by healthcare professionals specializing in genetics.⁶⁴

The great majority of the texts analyzed express that an understanding of pre-test information is a crucial aspect of direct-to-consumer genetic testing. There can, after all, be no informed consent if the information provided has not been fully understood.

ii- Consent

Fifty percent of the normative texts examined (seven out of fourteen) deal explicitly with the question of consent. Within this group, however, some identify the issues surrounding consent without offering any clear solution. In fact, only three documents take a precise position making it difficult to identify specific approaches regarding this subject. In general, however, we note that two texts⁶⁵ assign responsibility to the direct-to-consumer testing companies, either by assigning obligations to them,⁶⁶ or by advocating self-regulation.⁶⁷ The third document takes a position that places the burden of responsibility on the consumer:

"[i]n order to increase the likelihood that patients receive appropriate genetic testing services through a DTC service delivery model, the NSGC strongly recommends that patients undertaking a direct to consumer genetic testing process assess whether the company has addressed the following issues prior to purchasing a DTC genetic test: [...] 6. Is there a process for obtaining and documenting informed consent in a manner consistent with accepted medical practices as well as state and local regulations?"⁶⁸

As for documents that do not deal explicitly with the question of consent, it is not necessarily correct to conclude that the issue has therefore been dismissed by authors of these texts. The legal concept of consent requires that it be "informed." The informed nature of any consent implies that there be reasonable and adequate knowledge to enable decision-making to occur with full awareness of the facts. In the case of direct-to-consumer genetic testing, there is implicit recognition in all the normative texts that the informed nature of consent is a concern, as is indicated by the great weight they all place on the importance of the availability of pre-test information.

In addition to pre-test information and consent, there is a third major issue: that of

the communication of test results. Here the concerns involve the subtleties associated with the interpretation and correct understanding of results. Several of the texts analyzed herein raise this issue.⁶⁹

iii- Communication of results

Unlike the issue of consent, the issue of the communication of tests results elicits many clear stances in the normative texts studied.⁷⁰ As was done with the issue of consent, positions were divided into two groups. Several texts⁷¹ place the burden of responsibility on the companies by assigning them specific duties. The statement of the American College of Medical Genetics is as follows:

"[t]he interpretation of such results [results of direct-to-consumer genetic testing] is often highly nuanced and such information needs to be communicated to the consumer in the appropriate context and in an understandable fashion that is linguistically and culturally appropriate."⁷²

For its part, the NSGC in the United States puts the burden of responsibility on the consumer:

"[i]n order to increase the likelihood that patients receive appropriate genetic testing services through a DTC service delivery model, the NSGC strongly recommends that patients undertaking a direct to consumer genetic testing process assess whether the company has addressed the following issues prior to purchasing a DTC genetic test: [...] 3. Will results be given in a manner understandable to the average consumer, with a clear explanation of their clinical implications, if any, and including resources providing appropriate follow-up?"⁷³

A crucial aspect of the communication of test results appears to be genetic counseling. Several texts⁷⁴ emphasize the importance of post-test genetic counseling if the consumer is to adequately understand his results. In many of the documents the responsibility for providing this service is seen to lie with the companies offering DTC genetic tests. The American College of Obstetricians and Gynecologists, however, makes an interesting point: while stating that pre- and post-test genetic counseling should be provided,⁷⁵ it also raises the issue that there may be a potential conflict of interest for

genetic counselors employed by the same companies that supply the genetic testing services:

"[a]lthough some companies offer genetic counseling, concerns have been raised regarding a potential conflict of interest when the company providing the testing employs the genetic counselor because a company advertising directly to consumers may receive no compensation for counseling alone and is compensated only if the test is ordered by the consumer."⁷⁶

Communication of results is a particularly problematic aspect of direct-to-consumer genetic testing. In several of the texts analyzed,⁷⁷ the education of the general public and/or of healthcare professionals is considered an important part of the solution for overcoming the possible negative impact of these tests.

3) Education of the general public and/or of healthcare professionals

Most of the texts examined place an emphasis on the importance of educating the general public.⁷⁸ While some consider this as being essentially the responsibility of government⁷⁹ and of independent organizations such as consumer protection agencies,⁸⁰ others are more inclined to see this as the responsibility of government and healthcare professionals.⁸¹ All the members of the Belgian Advisory Committee on Bioethics, for example, are in agreement on a list of general recommendations including the imperative to grant a clear priority to the provision of adequate and complete public information. They specify that: "[h]ealth information at school should also play an important role, as well as the provision of information by the GP [general practitioner] and other first-line health workers."⁸²

Interestingly, at least one of the texts examined considers education as a way of slowing or reducing demand for services provided by the direct-to-consumer genetic testing industry.⁸³ The Human Genetics Society of Australasia states:

"[t]he best way to get rid of the market for DTC genetic testing may be to eliminate consumer demand through education about why DTC genetic testing fails to provide the basis for high

quality medical care and decisions, rather than driving the market underground or overseas."⁸⁴

Meanwhile, in other documents, public education is seen more as a way of reducing the potential harmful outcomes of direct-to-consumer genetic testing. The Human Genetic Commission states: "[w]e think that consumer education about genetic testing will play an important role in minimising the potential harms that may follow from direct genetic tests."⁸⁵

Some texts⁸⁶ highlight the importance of educating healthcare professionals, principally because they believe that doctors have a role to play in patient counseling. The American Medical Association, for example, recommends that doctors be informed about the reality of direct-to-consumer genetic testing, including the lack of scientific validity of certain tests, so that patients can receive appropriate counseling regarding their potential harm.⁸⁷ Although one of the texts advocating the education of professionals does not specify who should take on the responsibility for this education,⁸⁸ others⁸⁹ assign this task to professional organizations:

"[t]o ensure that providers are aware that genetic tests are being provided DTC and that some of these tests may lack analytic or clinical validity, professional organizations should educate their members regarding the types of genetic tests offered DTC, so that providers can counsel their patients about the potential value and limitations of DTC testing."⁹⁰

DISCUSSION

In summary, few⁹¹ normative documents dealing specifically with direct-to-consumer genetic testing were identified. Furthermore, as a whole there was a lack of general agreement or consensus regarding the positions taken and opinions regarding the issues relevant to DTC genetic testing services. This is somewhat surprising considering the potential ethical dilemmas that direct-to-consumer genetic testing raise. Moreover, the existing normative texts identified are very limited in scope, especially when considering the fact that the industry itself uses the Internet as a marketing tool which has neither borders nor jurisdictions. In this regard, there has been

an interesting initiative from the Council of Europe to try and establish minimum, harmonized standards regarding genetic testing.

On November 27, 2008, the Council of Europe adopted a normative instrument with regional, and possibly international, significance:⁹² this was the *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes*. While the protocol does not deal explicitly with direct-to-consumer genetic testing, it contains provisions which could be applied to some of these tests. As stated in Article 2, paragraph 1, the protocol "applies to tests, which are carried out for health purposes, involving analysis⁹³ of biological samples⁹⁴ of human origin and aiming specifically to identify the genetic characteristics of a person which are inherited or acquired during early prenatal development [...]."

Although some direct-to-consumer genetic testing companies state that the tests they offer are not intended for medical purposes,⁹⁵ this opinion is open to debate. According to the American College of Obstetricians and Gynecologists:

"[a]ll genetic testing, including at-home tests, should be considered medical testing because results might have an impact on future medical care and clinical decision making. Although some tests have been marketed as non-medical, [...] these also should be considered medical tests."⁹⁶

Without going as far as to say that all direct-to-consumer tests should be considered medical tests, we believe that **certain** tests offered in the context of direct sale to consumers do have a medical connotation and could therefore be subject to the provisions set out in this Additional Protocol.

Article 7 of the Additional Protocol states: "[a] genetic test⁹⁷ for health purposes may only be performed under individualised medical supervision." According to the details contained in the Explanatory Report accompanying the Additional Protocol, the notion of medical supervision refers to a process within which genetic test will take place.⁹⁸ This provision is motivated primarily by the wish to provide the person concerned

with enough relevant pre-test information to enable him to make an informed decision as to whether or not the test should be performed and, if it is, to receive appropriate genetic counseling.⁹⁹ The Explanatory Report also makes it clear that a genetic test performed for medical purposes must be done solely on the specific order of a physician.¹⁰⁰

In addition, although exceptions to Article 7 may be authorized in certain circumstances, this is not the case when the test has important implications for the health of the persons concerned or members of their family or procreation choices.¹⁰¹ In the remaining circumstances, a genetic test may not be required to respect the provision of individualized supervision as long as the other rules laid down by the Additional Protocol are respected.¹⁰² Specifically, the Additional Protocol states that when a genetic test is under consideration, the person concerned must be provided with appropriate pre-test information¹⁰³ and that when the test is of a predictive nature¹⁰⁴, the person should also receive appropriate and non-directive genetic counseling.¹⁰⁵ Moreover, it is clearly stipulated that a genetic test cannot be performed unless the person has provided written consent to that effect in a voluntary and informed manner.¹⁰⁶

It appears, then, that if it is eventually determined that some genetic tests sold directly to the consumer are for health or medical purposes, this practice would be in violation of Article 7 (1) because it would need to be performed under individualized medical supervision. If, on the other hand, direct-to-consumer genetic testing is determined not to be for medical purposes, then the rules laid down by the Additional Protocol would not be applicable.

It is interesting to note that an organization such as the Council of Europe, whose influence extends not only to its member States but also to non-member States,¹⁰⁷ is seeking to achieve the harmonization of social and legal practices in the field of genetic testing. The *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes* only has the force of law in those countries that accept it. As the

protocol does not have automatic force of law, its effectiveness (i.e. its transformation into legal obligation) depends entirely on its ratification. We hope, however, that the protocol will have an indirect impact, as soft law, on moral standards.

Conclusion

It is difficult to determine whether the current enthusiasm for purchasing genetic tests from private companies without the intermediary of a healthcare professional will continue unabated or whether it will diminish in the months ahead. At the time of writing, we believe that a cautious, even protective, approach emphasizing the need to educate the public and healthcare professionals about the implications of this type of testing, is one part of the solution. This would aid in preventing potential undesirable outcomes of direct-to-consumer genetic testing. We would point out that the Federal Trade Commission (FTC), a U.S. federal agency which acts as a consumer protection body, has produced a public information and education document on the subject of direct-to-consumer genetic testing.¹⁰⁸ In a technical fact sheet the FTC describes the problems of the validity of tests performed in this context, the difficulties associated with the interpretation of the results, and the various aspects to consider if the consumer decides to go ahead regardless and purchase this service. We consider a public information tool of this kind to be essential, because consumers must have access to impartial information.

In addition to the need to educate the public and provide consumers with impartial information, we also consider it a requirement to monitor the quality of laboratories carrying out the tests and to guarantee adequate information for the interpretation of genetic testing results. These requirements should pertain to all genetic testing, including testing performed for DTC services. We conclude, therefore, by emphasizing the scientific, social and moral necessity for an adequate regulatory framework. Considering the great variety of tests on offer and the consequent range of consequences¹⁰⁹, we feel, however, that adopting a single approach for all types of

direct-to-consumer genetic testing would likely not be the best solution.

More specifically, in the short term we feel that the direct-to-consumer genetic testing industry should regulate itself and that independent organizations and public consultation bodies should offer education opportunities to the public. As consumers are increasingly inclined to take steps to control their own healthcare, diagnosis and treatment, they are the principal interested parties and they should be consulted. This will avoid taking a too paternalistic approach, while retaining the focus on the ethical issues. The active involvement of a good many agents, including the public at large and Internet users, should allow for the formation of an informed stance regarding the nature of any regulatory framework governing direct-to-consumer genetic testing, as well as stimulating the social debate surrounding it. One such example of public consultation on the ethical issues

raised by direct-to-consumer genetic testing is the initiative of the Nuffield Council on Bioethics: *Medical Profiling and Online Medicine: The Ethics of Personalised Healthcare in a Consumer Age*, launched in April 2009.¹¹⁰

In the medium term we would like to see a solid regulatory framework that is adapted to the wide variety of genetic testing services offered directly to consumers. This task needs to be undertaken soon. Already laws are being drawn up nationally¹¹¹ to govern this practice and if we wait too long it will be difficult to harmonize all the national legislation on the statute books. Furthermore, harmonization is essential because direct-to-consumer genetic testing is an international phenomenon, played out online where laws and regulations are increasingly ineffective. Given this reality, we recall with interest the Council of Europe's initiative to attempt to set minimal, harmonized standards for genetic testing.

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⁵ Belgian Advisory Committee on Bioethics (BACB), *Opinion no. 32 of 5 July 2004 on the Free Availability of Genetic Tests*, Belgium, 2004

⁶ D. Magnus, M. K. Cho, R. Cook-Deegan, «Direct-to-Consumer Genetic Tests: Beyond Medical Regulation?», (2009) 1:2 *Genome Medicine*, 17

⁷ Institut national de la santé et de la recherche médicale (Inserm), *Tests génétiques. Questions scientifiques, médicales et sociétales – Expertise collective* (Paris : Les Éditions Inserm, 2008)

⁸ P. Borry, H.C. Howard, K. Sénécal, D. Avard, «Direct-to-consumer Genome Scanning Services. Also for Children?», (2009) *Nature Reviews Genetics*, 8

⁹ A. L. McGuire, «An Unwelcome Side Effect of Direct-to-Consumer Personal Genome Testing – Raiding the Medical Commons», (2008) 300:22 *JAMA*, 2669 ; Human Genetics Society of Australasia (HGSA), *Direct to Consumer Genetic Testing*, Australia, 2007 ; GeneWatch, «The dangers of genetic testing kits», *The Guardian*, January 19 2003 ; Genetics and Public Policy Center, *Direct-to-Consumer Genetic Testing : Empowering or Endangering the Public?*, July 25 2006, [online] http://www.dnapolicy.org/policy_issue.php?action=detail&issuebrief_id=32

¹⁰ C. Patch, J. Sequerios, M. C. Cornel, «Genetic Horoscopes: is it all in the Genes? Points for Regulatory Control of Direct-to-Consumer Genetic Testing», (2009) *European Journal of Human Genetics*, 1 ; D. Gurwitz, Y. Bregman-Eschet, «Personal Genomics Services: Whose Genomes?», (2009) *European Journal of Human Genetics*, 1 ; A. Brand, «Integrative Genomics, Personal-Genome Tests and Personalized Healthcare: The Future is Being Built Today», (2009) *European Journal of Human Genetics*, 1 ; B. Praisack, J. Reardon, R. Hindmarsh, H. Gottweiss, U. Naeu, J. E. Lunshof, «Misdirected Precaution – Personal-Genome Tests are Blurring the Boundary Between Experts and Lay People», (2008) 456 *Nature*, 34

¹¹ D. Gurwitz, Y. Bregman-Eschet, «Personal Genomics Services: Whose Genomes?», *loc. cit.* note 10

¹² C. Patch, J. Sequerios, M. C. Cornel, «Genetic Horoscopes: is it all in the Genes? Points for Regulatory Control of Direct-to-Consumer Genetic Testing», *loc. cit.* note 10

¹³ Science and Technology Ethics Commission (STEC), *The Ethical Issues of Genetic Databases : Towards Democratic and Responsible Regulation*, (Sainte-Foy, 2003); BACB, *Opinion no. 32 of 5 July 2004 on the Free Availability of Genetic Tests*, *op. cit.* note 5 [Opinion of some committee members]

¹⁴ Advisory Committee on Genetic Testing (ACGT), *Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public*, London: Health Departments of the United Kingdom, United Kingdom 1997

¹⁵ Human Genetics Commission (HGC), *Genes direct. Ensuring the Effective Oversight of Genetic Tests Supplied Directly to the Public*, United Kingdom, 2003

¹⁶ BACB, *Opinion no. 32 of 5 July 2004 on the Free Availability of Genetic Tests*, *op. cit.* note 5

¹⁷ National Consultative Ethics Committee for Health and Life Sciences (NCEC), *Opinion no. 86: Problems Connected to Marketing Self-Test Kits for HIV Screening and Diagnosis of Genetic Disease*, France, 2004

¹⁸ American Society for Clinical Pathology (ASCP), *Direct Access Testing*, United States, 2005

¹⁹ American College of Medical Genetics (ACMG), *ACMG Statement on Direct-to-Consumer Genetic Testing*, United States, 2006

²⁰ American Society of Human Genetics (ASHG) and American College of Medical Genetics (ACMG), *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, United States, 2007

²¹ Human Genetics Commission (HGC), *More Genes Direct. A report on developments in the availability, marketing and regulation of genetic tests supplied directly to the public*, United Kingdom, 2007

²² Human Genetics Society of Australasia (HGSA), *Direct to Consumer Genetic Testing*, Australia, 2007

²³ National Society of Genetic Counselors (NSGC), *Direct to Consumer Genetic Testing*, United States, 2007

²⁴ National Council of Ethics for the Life Sciences (NCELS), *Opinion no. 56 of the National Council of Ethics for the Life Sciences – Opinion on Direct Marketing of Genetic Tests to the Public*, Portugal, 2008

²⁵ American College of Obstetricians and Gynecologists (ACOG), *Direct-to-Consumer Marketing of Genetic Testing*, United States, 2008

²⁶ American Medical Association (AMA), *Direct-to-Consumer Advertising and Provision of Genetic Testing*, United States, 2008

²⁷ Swiss Society of Medical Genetics (SSMG), *Prise de position de la Société Suisse de Génétique Médicale – Tests génétiques sur Internet*, Switzerland, 2009

²⁸ See, for example, ACMG, *ACMG Statement on Direct-to-Consumer Genetic Testing*, *op. cit.* note 19 ; AMA, *Direct-to-Consumer Advertising and Provision of Genetic Testing*, *op. cit.* note 26

²⁹ «The AMA is currently opposed to DTC genetic testing. AMA policy states that clinical testing should be performed under the care of a qualified health care professional; discourages DTC genetic testing; and states that genetic susceptibility testing, which in some cases is being advertised directly to consumers, should be provided only in the context of fully informed consent and comprehensive pre- and post-test counseling» (AMA, *Direct-to-Consumer Advertising and Provision of Genetic Testing*, *op. cit.* note 26)

³⁰ ACMG, *ACMG Statement on Direct-to-Consumer Genetic Testing*, *op. cit.* note 19

³¹ See especially: HGC, *Genes direct*, *op. cit.* note 15 ; ASCP, *Direct Access Testing*, *op. cit.* note 18 ; HGC, *More Genes Direct*, *op. cit.* note 21

³² HGC, *More Genes Direct*, *op. cit.* note 21 ; HGC, *Genes direct*, *op. cit.* note 15

³³ For example, BACB, *Opinion no. 32 of 5 July 2004 on the Free Availability of Genetic Tests*, *op. cit.* note 5 ; ASHG and ACMG, *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, *op. cit.* note 20 ; ACOG, *Direct-to-Consumer Marketing of Genetic Testing*, *op. cit.* note 25

³⁴ BACB, *Opinion no. 32 of 5 July 2004 on the Free Availability of Genetic Tests*, *op. cit.* note 5

³⁵ ASHG and ACMG, *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, *op. cit.* note 20 ; NSGC, *Direct to Consumer Genetic Testing*, *op. cit.* note 23

³⁶ ASHG and ACMG, *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, *op. cit.* note 20

³⁷ «Health-related genetic tests for diagnostic or predictive purposes should not be made available for direct marketing to the public, in respect for the fundamental ethical principles.» (NSGC, *Direct to Consumer Genetic Testing*, *op. cit.* note 23)

³⁸ «Until all of these considerations are addressed, direct or home genetic testing should be discouraged because of the potential harm of a misinterpreted or inaccurate result.» (ACOG, *Direct-to-Consumer Marketing of Genetic Testing*, *op. cit.* note 25). Similarly, the Swiss Society of Medical Genetics discourages its use at present. SSMG, *Tests génétiques sur Internet*, *op. cit.* note 27

³⁹ BACB, *Opinion no. 32 of 5 July 2004 on the Free Availability of Genetic Tests*, *op. cit.* note 5 [Opinion of some committee members] ; ACMG, *ACMG Statement on Direct-to-Consumer Genetic Testing*, *op. cit.* note 19 ; ACOG, *Direct-to-Consumer Marketing of Genetic Testing*, *op. cit.* note 25 ; AMA, *Direct-to-Consumer Advertising and Provision of Genetic Testing*, *op. cit.* note 26

⁴⁰ BACB, *Opinion no. 32 of 5 July 2004 on the Free Availability of Genetic Tests*, *op. cit.* note 5 [Opinion of some committee members]

⁴¹ «All genetic testing should be provided only after consultation with a qualified health care professional. For complex testing, this may involve referral to a genetic counselor or a medical geneticist.» (ACOG, *Direct-to-Consumer Marketing of Genetic Testing*, *op. cit.* note 25)

⁴² «A knowledgeable professional should be involved in the process of ordering and interpreting a genetic test. Genetic testing is highly technical and complex. A genetics expert such as a certified medical geneticist or genetic counselor can help the consumer determine, for example, whether a genetic test should be performed and how to interpret test results in light of personal and family history.» (ACMG, *ACMG Statement on Direct-to-Consumer Genetic Testing*, *op. cit.* note 19)

⁴³ ACGT, *Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public*, *op. cit.* note 14 ; ASCP, *Direct Access Testing*, *op. cit.* note 18

⁴⁴ ACGT, *Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public*, *op. cit.* note 14

⁴⁵ ASCP, *Direct Access Testing*, *op. cit.* note 18

⁴⁶ «They [suppliers] should also provide the customer with information on appropriate professional and voluntary bodies able to offer support to those with abnormal test results. [...] Suppliers should work with appropriate professional and voluntary bodies when developing advertising and customer information materials. [...] Suppliers should supply a copy of test results, with the customer's written consent, to general medical practitioners for inclusion in the customer's health record.» (ACGT, *Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public*, *op. cit.* note 14)

⁴⁷ ASCP, *Direct Access Testing*, *op. cit.* note 18

⁴⁸ ASHG and ACMG, *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, *op. cit.* note 20

⁴⁹ ASHG and ACMG, *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, *op. cit.* note 20

⁵⁰ ACGT, *Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public*, *op. cit.* note 14 ; HGC, *Genes direct*, *op. cit.* note 15 ; ASCP, *Direct Access Testing*, *op. cit.* note 18 ; NCELS, *Opinion no. 56–Opinion on Direct Marketing of Genetic Tests to the Public*, *op. cit.* note 24

⁵¹ ACGT, *Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public*, *op. cit.* note 14 ; HGC, *Genes direct*, *op. cit.* note 15 ; ASCP, *Direct Access Testing*, *op. cit.* note 18 ; NCELS, *Opinion no. 56–Opinion on Direct Marketing of Genetic Tests to the Public*, *op. cit.* note 24

⁵² ACGT, *Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public*, *op. cit.* note 14 ; HGC, *Genes direct*, *op. cit.* note 15 ; BACB, *Opinion no. 32 of 5 July 2004 on the Free Availability of Genetic Tests*, *op. cit.* note 5 ; NCEC, *Opinion no. 86: Problems Connected to Marketing Self-Test Kits for HIV Screening and Diagnosis of Genetic Disease*, *op. cit.* note 17 ; ACMG, *ACMG Statement on Direct-to-Consumer Genetic Testing*, *op. cit.* note 19 ; ASHG and ACMG, *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, *op. cit.* note 20 ; HGC, *More Genes Direct*, *op. cit.* note 21 ; AMA, *Direct-to-Consumer Advertising and Provision of Genetic Testing*, *op. cit.* note 26

⁵³ BACB, *Opinion no. 32 of 5 July 2004 on the Free Availability of Genetic Tests*, *op. cit.* note 5 ; NCEC, *Opinion no. 86: Problems Connected to Marketing Self-Test Kits for HIV Screening and Diagnosis of Genetic Disease*, *op. cit.* note 17 ; ASHG and ACMG, *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, *op. cit.* note 20 ; HGSA, *Direct to Consumer Genetic Testing*, *op. cit.* note 22 ; NSGC, *Direct to Consumer Genetic Testing*, *op. cit.* note 23 ; NCELS, *Opinion no. 56–Opinion on Direct Marketing of Genetic Tests to the Public*, *op. cit.* note 24 ; AMA, *Direct-to-Consumer Advertising and Provision of Genetic Testing*, *op. cit.* note 26

⁵⁴ (1) (2) (some of 3) (4) (6) (7)(9) 13

⁵⁵ ACGT, *Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public*, *op. cit.* note 14, HGC, *Genes direct*, *op. cit.* note 15 ; BACB, *Opinion no. 32 of 5 July 2004 on the Free Availability of Genetic Tests*,

op. cit. note 5 [Opinion of some committee members]; NCEC, *Opinion no. 86: Problems Connected to Marketing Self-Test Kits for HIV Screening and Diagnosis of Genetic Disease*, op. cit. note 17; ACMG, *ACMG Statement on Direct-to-Consumer Genetic Testing*, op. cit. note 19; HGC, *More Genes Direct*, op. cit. note 21

⁵⁶ ACGT, *Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public*, op. cit. note 14; ASCP, *Direct Access Testing*, op. cit. note 18; ASHG et ACMG, *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, op. cit. note 20; NCELS, *Opinion no. 56 – Opinion on Direct Marketing of Genetic Tests to the Public*, op. cit. note 24

⁵⁷ ACGT, *Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public*, op. cit. note 14; ASHG and ACMG, *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, op. cit. note 20; NCELS, *Opinion no. 56 – Opinion on Direct Marketing of Genetic Tests to the Public*, op. cit. note 24

⁵⁸ ACGT, *Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public*, op. cit. note 14

⁵⁹ ACGT, *Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public*, op. cit. note 14; ASCP, *Direct Access Testing*, op. cit. note 18; ASHG and ACMG, *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, op. cit. note 20; SSMG, *Tests génétiques sur Internet*, op. cit. note 27

⁶⁰ SSMG, *Tests génétiques sur Internet*, op. cit. note 27

⁶¹ HGC, *Genes direct*, op. cit. note 15; HGC, *More Genes Direct*, op. cit. note 21; AMA, *Direct-to-Consumer Advertising and Provision of Genetic Testing*, op. cit. note 26

⁶² HGC, *More Genes Direct*, op. cit. note 21

⁶³ « We believe that funding should be made available to an independent consumer body in order to prepare specific and impartial information on any direct genetic testing services that are marketed. The aim should be to equip customers with sufficient information to judge the relevance of that service for them. » (HGC, *Genes direct*, op. cit. note 15)

⁶⁴ NSGC, *Direct to Consumer Genetic Testing*, op. cit. note 23

⁶⁵ ACGT, *Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public*, op. cit. note 14; HGC, *Genes direct*, op. cit. note 15

⁶⁶ ACGT, *Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public*, op. cit. note 14

⁶⁷ HGC, *Genes direct*, op. cit. note 15

⁶⁸ NSGC, *Direct to Consumer Genetic Testing*, op. cit. note 23

⁶⁹ BACB, *Opinion no. 32 of 5 July 2004 on the Free Availability of Genetic Tests*, op. cit. note 5; NCEC, *Opinion no. 86: Problems Connected to Marketing Self-Test Kits for HIV Screening and Diagnosis of Genetic Disease*, op. cit. note 17; ASHG and ACMG, *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, op. cit. note 20; HGSA, *Direct to Consumer Genetic Testing*, op. cit. note 22; NSGC, *Direct to Consumer Genetic Testing*, op. cit. note 23; NCELS, *Opinion no. 56 – Opinion on Direct Marketing of Genetic Tests to the Public*, op. cit. note 24; AMA, *Direct-to-Consumer Advertising and Provision of Genetic Testing*, op. cit. note 26

⁷⁰ ACGT, *Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public*, op. cit. note 14; ASCP, *Direct Access Testing*, op. cit. note 18; ASCP, *Direct Access Testing*, op. cit. note 19; HGSA, *Direct to Consumer Genetic Testing*, op. cit. note 22; ACOG, *Direct-to-Consumer Marketing of Genetic Testing*, op. cit. note 25

⁷¹ ACGT, *Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public*, op. cit. note 14; ASCP, *Direct Access Testing*, op. cit. note 18; ACMG, *ACMG Statement on Direct-to-Consumer Genetic Testing*, op. cit. note 19

⁷² ACMG, *ACMG Statement on Direct-to-Consumer Genetic Testing*, op. cit. note 19

⁷³ NSGC, *Direct to Consumer Genetic Testing*, op. cit. note 23

⁷⁴ ACGT, *Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public*, op. cit. note 14; BACB, *Opinion no. 32 of 5 July 2004 on the Free Availability of Genetic Tests*, op. cit. note 5; HGSA, *Direct to Consumer Genetic Testing*, op. cit. note 22; NCELS, *Opinion no. 56 – Opinion on Direct Marketing of Genetic Tests to the Public*, op. cit. note 24; ACOG, *Direct-to-Consumer Marketing of Genetic Testing*, op. cit. note 25

⁷⁵ «Appropriate pretest and posttest counseling should be provided, including a discussion of the risks, benefits, and limitations of the testing. » (ACOG, *Direct-to-Consumer Marketing of Genetic Testing*, op. cit. note 25)

⁷⁶ ACOG, *Direct-to-Consumer Marketing of Genetic Testing*, op. cit. note 25

⁷⁷ HGC, *Genes direct*, op. cit. note 15; BACB, *Opinion no. 32 of 5 July 2004 on the Free Availability of Genetic Tests*, op. cit. note 5; ASHG and ACMG, *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, op. cit. note 20; HGC, *More Genes Direct*, op. cit. note 21; HGSA, *Direct to Consumer Genetic Testing*, op. cit. note 22; NCELS, *Opinion no. 56 – Opinion on Direct Marketing of Genetic Tests to the Public*, op. cit. note 24; AMA, *Direct-to-Consumer Advertising and Provision of Genetic Testing*, op. cit. note 26

⁷⁸ HGC, *Genes direct*, op. cit. note 15; BACB, *Opinion no. 32 of 5 July 2004 on the Free Availability of Genetic Tests*, op. cit. note 5; HGC, *More Genes Direct*, op. cit. note 21; HGSA, *Direct to Consumer Genetic Testing*, op. cit. note 22; NCELS, *Opinion no. 56 – Opinion on Direct Marketing of Genetic Tests to the Public*, op. cit. note 24

⁷⁹ «In addition, we would like to see a broader Government effort to educate consumers about genetic testing and, in particular, predictive genetic testing. Such a campaign will be of wider value to ensure that any marketing or publicity around commercial genetic testing services [...] does not impose undue burdens on NHS resources. We look forward to seeing the proposed national strategy on patient information that is being developed by the Department of Health. We also suggest that advice and guidance material on direct genetic testing services is made available on established UK Internet sites, such as NHS Direct and the HGC

website.” (HGC, *Genes direct*, op. cit. note 15). Also, BACB, *Opinion no. 32 of 5 July 2004 on the Free Availability of Genetic Tests*, op. cit. note 5

⁸⁰ « We believe that funding should be made available to an independent consumer body in order to prepare specific and impartial information on any direct genetic testing services that are marketed. The aim should be to equip customers with sufficient information to judge the relevance of that service for them. [...] » (HGC, *Genes direct*, op. cit. note 15)

⁸¹ For example, BACB, *Opinion no. 32 of 5 July 2004 on the Free Availability of Genetic Tests*, op. cit. note 5 [Opinion of some committee members]

⁸² BACB, *Opinion no. 32 of 5 July 2004 on the Free Availability of Genetic Tests*, op. cit. note 5 [Opinion of some committee members]

⁸³ HGSA, *Direct to Consumer Genetic Testing*, op. cit. note 22

⁸⁴ HGSA, *Direct to Consumer Genetic Testing*, op. cit. note 22

⁸⁵ HGC, *Genes direct*, op. cit. note 15; HGC, *More Genes Direct*, op. cit. note 21

⁸⁶ ASHG and ACMG, *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, op. cit. note 20; NCELS, *Opinion no. 56 – Opinion on Direct Marketing of Genetic Tests to the Public*, op. cit. note 24; AMA, *Direct-to-Consumer Advertising and Provision of Genetic Testing*, op. cit. note 26

⁸⁷ «The Board recommends modifying AMA Directive D-480.987, “Direct-to-Consumer Genetic Testing” (AMA Policy Database). Modifications include recommendations [...] that physicians be educated about DTC genetic testing [...]. (5) will work to educate and inform physicians regarding the types of genetic tests that are available directly to consumers, including information about the lack of scientific validity associated with some direct-to-consumer genetic tests, so that patients can be appropriately counseled on the potential harms. (Modify Current HOD Directive)” (AMA, *Direct-to-Consumer Advertising and Provision of Genetic Testing*, op. cit. note 26)

⁸⁸ NCELS, *Opinion no. 56 – Opinion on Direct Marketing of Genetic Tests to the Public*, op. cit. note 24

⁸⁹ ASHG and ACMG, *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, op. cit. note 20; AMA, *Direct-to-Consumer Advertising and Provision of Genetic Testing*, op. cit. note 26

⁹⁰ ASHG and ACMG, *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, op. cit. note 20

⁹¹ At the time of our research there were approximately 14 specific normative texts, coming primarily from the United States, Australia and Europe.

⁹² According to Article 24, para 1, “This Protocol shall be open for signature by Signatories to the Convention on Human Rights and Biomedicine [...]” The Convention for Human Rights and Biomedicine is open for signature and ratification by non-member States of the Council of Europe. (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, 4. IV.1997, Art. 33 para. 1 and Art 34 para.1). Canada has neither signed nor ratified this Convention. Countries that do accept it must ensure that their legislation is in conformity with the provisions of the Convention. Legal sanctions must be laid down in the event of contravention of the provisions. And the law must contain provision for indemnifying persons who have sustained unjustified damage resulting from any medical intervention or treatment. Council of Europe, *Bioethics: Fact Sheet*, [online] <http://www.coe.int>.)

⁹³ The concept of “analysis” is defined in Article 2, para. 3(a), as being : “ i) chromosomal analysis, ii) DNA or RNA analysis , iii) analysis of any other element enabling information to be obtained with the methods referred to in subparagraphs a.i and a.ii;” (Council of Europe, *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes* Strasbourg, 27 November 2008, Article 2, para. 3(a))

⁹⁴ The concept of “biological samples” is defined in Article 2, para. 3(b), as being: «i) biological materials removed for the purpose of the test concerned, ii) biological materials previously removed for another purpose. » (Council of Europe, *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes* op. cit. note 93, Article 2, para., 3(b)

⁹⁵ The company 23andMe, for example (<http://www.23andme.com>). On this subject, see P. Borry, «Europe to ban direct-to-consumer genetic tests?», (2008), 26 :7 *Nature Biotechnology*, 736

⁹⁶ ACOG, *Direct-to-Consumer Marketing of Genetic Testing*, op. cit. note 25

⁹⁷ According to the Explanatory Report accompanying the protocol, the genetic tests covered include diagnostic, predictive or healthy carrier tests. (Council of Europe, *Explanatory Report on the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes*, Strasbourg, 27 November 2008, paragraph 30)

⁹⁸ Council of Europe, *Explanatory Report on the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes*, op. cit. note 97, par. 63

⁹⁹ Council of Europe, *Explanatory Report on the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes*, op. cit. note 97, par. 64

¹⁰⁰ Council of Europe, *Explanatory Report on the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes*, op. cit. note 97, par. 65

¹⁰¹ Council of Europe, *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes*, op. cit. note 93, Art. 7(2)

¹⁰² Council of Europe, *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes*, op. cit. note 93, art. 7(2); Council of Europe, *Explanatory Report on the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes*, op. cit. note 97, par. 66 to 70

¹⁰³ Council of Europe, *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes*, op. cit. note 93, s. 8(1)

¹⁰⁴ Predictive genetic tests are:

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- tests predictive of a monogenic disease,
 - tests serving to detect a genetic predisposition or genetic susceptibility to a disease,
 - tests serving to identify the subject as a healthy carrier of a gene responsible for a disease. (Council of Europe, *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes*, *op. cit.* note 93, s. 8(2))

¹⁰⁵ Council of Europe, *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes*, *op. cit.* note 93, s. 8(2)

¹⁰⁶ Council of Europe, *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes*, *op. cit.* note 93, s. 9

¹⁰⁷ This organization has a definite influence on its 45 member States, but it can also have an influence on non-member States. In effect, many normative texts may be signed or accepted by non-member States of the Council of Europe, although some may only be signed and/or ratified by European States, while others may be signed and/or ratified by non-member and non-European States.

¹⁰⁸ Federal Trade Commission, *At-Home Genetic Tests : A Healthy Dose of Scepticism May be the Best Prescription*, [online]

<http://www.ftc.gov/bcp/edu/pubs/consumer/health/hea02.pdf>

¹⁰⁹ ASHG and ACMG, *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, *op. cit.* note 20

¹¹⁰ Nuffield Council on Bioethics, *Medical Profiling and Online Medicine : the Ethics of Personalised Healthcare in a Consumer Age – Consultation Paper*, [online] http://www.nuffieldbioethics.org/fileLibrary/pdf/Medical_profiling_online_healthcare_consultation_paper.pdf

¹¹¹ For example, Assemblée fédérale de la Confédération suisse, *Loi fédérale sur l'analyse génétique humaine*, RS, 810.12, October 8, 2004 (effective April 1, 2007) [online] <http://www.admin.ch/clv/f/ff/2004/5145.pdf> ; German Federal Parliament/Bundestag [Bundesregierung], *Genetic Testing Must Comply with Rigorous Requirements*, April 24, 2009, [online] http://www.bundesregierung.de/nn_6538/Content/EN/Artikel/2009/04/2009-04-24-gendiagnostik_en.html