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### Citation

Gerards, J. H., & Janssen, H. L. (2006). Regulation of Genetic and Other Health Information in a Comparative Perspective. *European Journal Of Health Law*, 13, 339-398. Retrieved from <https://hdl.handle.net/1887/13051>

Version: Not Applicable (or Unknown)

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**Note:** To cite this publication please use the final published version (if applicable).

## **Regulation of Genetic and Other Health Information in a Comparative Perspective**

JANNEKE H. GERARDS & HELEEN L. JANSSEN\*

### **Abstract**

In the present article, the authors provide a general overview of the academic and legal debate on the regulation of access to and use of genetic information by non-medical actors. Their aim is to give some insight in the academic views on the need to introduce specific genetics legislation and on the balance that might be struck between the various interests concerned. Furthermore, by analyzing relevant legislation and policy measures in the US and in Europe, they identify the issues that are deemed relevant in considering and, eventually, introducing regulative measures with respect to genetic information.

### **1. Introduction**

As a result of the fast developments in genetic science, much information is presently available about the influence of genetic factors on the onset of illness and disease. By means of genetic testing, genetic anomalies and defects can be detected that may contribute to the development of diseases and disorders, or that may aggravate health risks related to specific working or living circumstances. The availability of such information about individual health risks is highly valuable because of the possibility of prevention and early treatment of serious diseases, but it has also caused social unrest and concern. Some concern is effected by the fact that it is now possible for individuals to learn about the possibility of getting

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ill in the future with much more certainty, while there is not always a certainty of there being a medical remedy – awareness of genetic risks may thus cause strong feelings of anxiety. For another part, the concern is caused by the fact that genetic information may also become available to non-medical actors such as insurers and employers. For insurers, predictive health information is of great importance to risk classification: the more precisely an insurer can estimate the health or mortality risks of an individual, the more accurate his risk classification will be. This may be favourable to individuals with demonstrable low health risks, who will need to pay lower insurance premiums, but to high risk persons, there may be a danger of the rates becoming so high that they are effectively excluded from the possibility of getting health, life or disability insurance. Employers may likewise be interested in genetic information about (prospective) employees, as high risk employees may pose high business risks and may lead to high costs. If such risks and costs can be avoided by genetic screening and by excluding or dismissing any high risk employees, some employers will clearly be willing to do so. Many fear that this would, in the end, pose a risk for complete exclusion of high risk individuals from the employment market. To these concerns should be added that individual rights of confidentiality of personal medical information, the right ‘not to know’ about serious health risks and the right to non-discrimination may be seriously at risk if non-medical actors have unlimited access to genetic information.

These concerns are by now well-known. A large body of literature is available on the ethical, social and legal implications of the availability of genetic information. Furthermore, policy makers and legislators, as well as employers and the insurance industry have reacted to the situation of social unrest by introducing restrictive legislation, policy measures and self-regulation. This has resulted in a wide variety of policy approaches, varying from the adoption of highly detailed provisions restricting the use of genetic information, to constitutional provisions protecting genetic privacy and non-discrimination interests in general. Varying answers have also been given to questions with respect to the definition of genetic information; the scope of genetics legislation; the difference between genetic information and other types of predictive health information; and the instruments that must be chosen to defy genetic discrimination and protect genetic privacy.

In the present article, we would like to provide a general overview of the academic and legal debate on the regulation of access to and use of genetic information by non-medical actors. We will endeavour to provide some insight in the academic views on the need to introduce specific genetics legislation and on the balance that might be struck between the various interests concerned. Furthermore, by analyzing relevant legislation and policy measures in the US and in Europe, we aim to provide some insight in the issues that are deemed relevant in considering and, eventually, introducing regulative measures with respect to genetic information. In doing so, this article draws on the results of the research

project “Genetic Discrimination and Genetic Privacy in a Comparative Perspective”, which the present authors, together with Prof. A.W. Heringa, have conducted as part of a larger project concerning “Genetic Traits and Non-Discrimination”.<sup>1</sup> We mainly aim to present a further developed and updated version of the main conclusions of this research project. The academic and comparative studies on which these conclusions are based are reflected in a far more elaborate and detailed fashion in other publications.<sup>2</sup>

The present article is structured in three parts. In the first part, we will provide some insight in the academic debate about genetics exceptionalism and the definition of genetic information (§ 2) and we will give an overview of the various interests which may be concerned by restricting access to and use of genetic information by insurers and employers (§ 3). In the second part, we present a concise overview of the way a number of important regulatory issues have been dealt with in the United States, the EU and a number of European states (§ 4). Such an overview enables a comparison to be made between theoretical and practical approaches and makes it possible to discern important points of consensus and disagreement. In the third part of this article, we combine the academic insights discussed in the first part with the experience in the member states as described in the second part, in order to provide an outline of the way in which a variety of issues relating to the regulation of genetic and other forms of predictive health information may be solved in the future (§ 5).

## **2. ‘Genetic’ information as a basis for regulation? The case against genetics exceptionalism**

### **2.1 Introduction**

An important topic in the debate about the use of genetic information by insurers and employers is the appropriateness of what is often called the theory of ‘genetics exceptionalism’. According to this theory, genetic information is notably different

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<sup>1</sup> The latter project formed part of the research programme “The Societal Component of Genomics Research” of the Netherlands Organisation of Scientific Research. The research project also resulted in a report in the Dutch language on protection against genetic discrimination: J.K.M. Gevers, A.C. Hendriks, J.H. Gerards, H.L. Janssen and A.W. Heringa, *Bescherming tegen genetische discriminatie. Een juridische analyse*, Leiden: Stichting NJCM-Boekerij 2004.

<sup>2</sup> See in particular J.H. Gerards, A.W. Heringa and H.L. Janssen, *Genetic Discrimination and Genetic Privacy in a Comparative Perspective*, Antwerp: Intersentia 2005.

from all other kinds of health information, including other kinds of predictive health information. It is often argued that the special character of genetic information would easily lead to misuse by non-medical actors, which would call for special and well-tailored legislative protection. Whether genetic information is indeed so special as to warrant exceptional treatment is, however, subject to debate. Some have opposed the argument that genetic information can be distinguished from other information, while others acknowledge the exceptional character of genetic information, but deny the need to single out such information for special protection. Furthermore, even if there is a good reason to distinguish genetic information from other types of personal health information, the question remains what kind of information can be considered to constitute 'genetic' information. According to some, a narrow definition should be preferred, which means that only the information provided by DNA tests could properly be called 'genetic information'. Others have argued that such a definition is underinclusive and that there are many other types of health information that give insight in someone's genetic makeup, such as family medical history. These definitional problems are sometimes considered to provide an additional reason against the introduction of legislation solely geared to genetic information. Further, even adherents of the theory of genetics exceptionalism agree that it is difficult to opt for a proper definition of the notion of genetic information.

In this section, we will shortly discuss the various arguments that have been put forward in the academic debate about genetics exceptionalism and the debate relating to the definition of genetic information. We will then formulate some conclusions as to the reasonableness of taking genetics exceptionalism as a basis for regulation.

## 2.2 *Arguments in favour of genetics exceptionalism*

### *Limited (actual) predictive character*

Although the value of genetic data is widely recognized, the actual predictive value of most genetic information is still rather limited. Many genetic tests often provide relatively inaccurate information and test results are difficult to interpret.<sup>3</sup> Although this will certainly change with the rapid scientific developments in this area, genetic

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3 Cf. *Genetic Testing: Preliminary Policy Guidelines*, Report by the Council for Responsible Genetics, June 2006, <[www.gene-watch.org/programs/privacy/guidelines.html](http://www.gene-watch.org/programs/privacy/guidelines.html)> (last accessed 23 August 2006); *Promoting Safe and Effective Genetic Testing in the United States. Final Report of the Task Force on Genetic Testing*, September 1997; and H.T. Greely, 'Genotype Discrimination: The Complex Case for Some Legislative Protection', 149 *University of Pennsylvania Law Review* 1483 (2001), p. 1501.

data thus not always provide reliable information about actual health risks. It is well-known, moreover, that by far the most 'genetic' diseases are not purely genetic in character, but are caused by a complex combination of genetic and environmental factors.<sup>4</sup> In such cases of multi-factorial disease, it is difficult to predict whether a genetic defect will indeed bring about the onset of a certain illness or disease. In many cases, such may depend on lifestyle (smoking habits, diet, physical exercise) or on exposure to certain toxins or stress. Moreover, even in the case of monogenic diseases (e.g. Huntington's disease) the actual predictive value of genetic data is relatively limited. A genetic test may in that case accurately predict that the disease will develop, but it will not provide any information as to the exact date on which the condition will manifest itself, nor to the seriousness of the symptoms.<sup>5</sup> Some commentators contend that it is precisely this limited probability and reliability that sets genetic information apart from other medical data.

*Uniquely private character of genetic information*

Another reason to treat genetic information differently lies in the highly personal character of such information. An individual's genotype is unalterable and unique, which implies, according to some authors, that disclosure of information about someone's genotype would expose the essence of his being.<sup>6</sup> As a result, genetic information is highly important to the individual and his ability to make personal

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4 See further R. Hoedemakers and H. ten Have, 'Genetic Health and Genetic Disease', in: V. Launis, J. Pietarinen and J. Räikkä (eds.), *Genes and Morality. New Essays*, Amsterdam/Atlanta: Rodopi 1999, p. 134-135 and *Schlussbericht der Enquete-Kommission 'Recht und Ethik der modernen Medizin'*, *Deutscher Bundestag, 14. Wahlperiode, Drucksache 14/9020, 14 May 2002*, p. 121.

5 Cf. L. Gostin, 'Genetic Discrimination: the Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers', 17 *American Journal of Law and Medicine* 109 (1991), p. 113, H.T. Greely, *supra* (footnote 4), p. 1486 and E. Oscapeella, *Genetics, Privacy and Discrimination. Report prepared for the Canadian Biotechnology Advisory Committee; Project Steering Committee on Genetic Privacy*, October 2000, available via <www.cbac-cccb.ca> (last accessed 23 August 2006), p. 22.

6 See e.g. J.A. Colby, 'An Analysis of Genetic Discrimination Legislation Proposed by the 105th Congress', 24 *American Journal of Law and Medicine* 443 (1998), p. 457, M. Powers, 'Justice and Genetics: Privacy Protection and the Moral Basis of Public Policy', in: M.A. Rothstein (ed.), *Genetic Secrets. Protecting Privacy and Confidentiality in the Genetic Era*, Yale University Press: New Haven and London 1997, p. 368 and G.J. Annas, L.H. Glantz and P.A. Roche, 'Drafting the Genetic Privacy Act: Science, Policy, and Practical Considerations', 23 *Journal of Law, Medicine & Ethics* 360 (1995), p. 360.

choices, for instance with respect to lifestyle or reproduction.<sup>7</sup> This importance is even greater because of the present existence of the so-called 'therapeutic gap': Although it is possible to detect a large number of genetic anomalies by means of genetic testing, the development of therapies for the resulting disease lags behind. As a consequence a person who would undergo a genetic test, for instance to obtain a life insurance policy, might well discover that he is genetically predisposed to develop a disease that is currently untreatable. It is not difficult to imagine the stress and anxiety caused by such a discovery, especially if regard is also being had to the fact that the information may be relevant to the individual's relation to his relatives and his reproductive choices.<sup>8</sup> Unwarranted disclosure of genetic information should be avoided precisely for that reason.

*Risk for discrimination against certain groups; eugenics*

Some genetic predispositions are particular to racial or ethnic groups (e.g. predisposition to sickle cell anaemia, cystic fibrosis and Tay Sachs disease), or to one of the sexes (e.g. predisposition to breast cancer).<sup>9</sup> If such genetic information were used to a negative effect by employers and insurers, such might impede the access of these groups to employment or health care.

Further, it is sometimes argued that the use of genetic information in decision-making may lead to stigmatisation.<sup>10</sup> Just like personal characteristics such as ethnicity and sex, and unlike other factors that may influence one's state of health (e.g. dietary and smoking habits), genetic features are currently unalterable.<sup>11</sup>

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7 It may happen, for example, that a person discovers that he is the carrier of a gene which might result in the development of a genetic disease in his offspring, or that he has a genetic anomaly that may result in the onset of a disease in combination with certain lifestyle factors (such as smoking habits or stress).

8 Difficult ethical questions may arise with respect to the disclosure of genetic information to blood relatives and their right "not to know". See G. Laurie, *Genetic Privacy. A Challenge to Medico-Legal Norms*, Cambridge: Cambridge University Press 2002, p. 93 and A. Silvers and M.A. Stein, 'An Equality Paradigm for Preventing Genetic Discrimination', 55 *Vanderbilt Law Review* 1341 (2002), p. 1357.

9 See e.g. J.L. Dolgin, 'Personhood, Discrimination and the New Genetics', 66 *Brooklyn Law Review* 755 (2000), p. 790/791.

10 Cf. S. Mezooff, 'Forcing a Square Peg into a Round Hole: The Negative Ramifications of Misaligned Protection for Predisposed Individuals under the ADA', 85 *Boston University Law Review* 323 (2005), p. 338 and J.L. Dolgin, *supra* (footnote 9), p. 772/773.

11 Cf. L. Gostin, *supra* (footnote 6), p. 110; see also S.M. Suter, 'The Allure and Peril of Genetics Exceptionalism: Do We Need Special Genetics Legislation?', 79 *Washington University Law Quarterly* 669 (2001), p. 712, who accepts that it is important that a certain factor is out of someone's control, even though she denies that genetic risks belong to the category of factors that cannot be influenced by the individual.

Genetic information is for that reason considered to constitute an unfair basis for distinction.<sup>12</sup>

The fear for such forms of direct or indirect discrimination is particularly present in the US and Germany, where the negative consequences of (mis)use of genetic information have been experienced in the past. Various sources mention the American history of large-scale screening of African-Americans for sickle cell anaemia and sterilisation of convicts whose criminal behaviour was suspected to be inheritable, or recall the dreadful experiments of Nazi-German 'eugenics'.<sup>13</sup> In both countries, these experiences have increased the awareness of the danger of abuse, resulting in a strong call for special protection and strict regulation. In the US, the negative experiences in the past are even mentioned as one of the main reasons for introducing federal legislation to protect genetic information.<sup>14</sup>

#### *Combination of characteristics*

Many academic commentators acknowledge that the aforementioned features may, in themselves, not be unique to genetic information, but may also be relevant to certain types of non-genetic health information. They argue, however, that genetic information is different from other health information, as all factors mentioned above appear in combination. In addition it is sometimes stressed that genetic information is unique because society regards it as unique.<sup>15</sup> This social rather than scientific reason for distinguishing between genetic and other types of health information is considered to be sufficient to justify special legislative treatment of genetic information.

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12 See E. Wright Clayton, 'Informed Consent and Genetic Research', in: M.A. Rothstein (ed.), *Genetic Secrets. Protecting Privacy and Confidentiality in the Genetic Era*, Yale/London: Yale University Press 1997, p. 127, B.M. Knoppers, 'Who Should have Access to Genetic Information?', in: J. Burley (ed.), *The Genetic Revolution and Human Rights*, Oxford: Oxford University Press 1999, p. 45 and J.L. Dolgin 2000, *supra* (footnote 9), p. 772/773.

13 E.g. C.S. Diver and J.M. Cohen, 'Genophobia: What is Wrong with Genetic Discrimination?', 149 *University of Pennsylvania Law Review* 1439 (2001), pp. 100 and 107, G.J. Annas, 'Genetic Privacy: There Ought to be a Law', 4 *Texas Review of Law and Politics* 9 (1999), p. 12 and D. Hellman, 'What Makes Genetic Discrimination Exceptional?', 29 *American Journal of Law & Medicine* 77 (2003), p. 106ff.

14 See in particular the findings included in the new bill for the Genetic Information Nondiscrimination Act of 2005 (S. 206, introduced in the Senate on 7 February 2005 by Senator Olympia Snowe), which was passed by the US Senate in February 2005, §§ 2 and 3.

15 M.A. Rothstein, 'Genetic Secrets: A Policy Framework', in: M.A. Rothstein (ed.), *Genetic Secrets. Protecting Privacy and Confidentiality in the Genetic Era*, Yale/London: Yale University Press 1997, p. 459.

### 2.3 *Arguments against genetics exceptionalism*

According to opponents of the theory of genetics exceptionalism, none of the features discussed above would justify singling out genetic information for special protection. Opponents defend their point of view primarily by rebutting the aforementioned arguments. The argument that genetic information is uniquely personal in character is, for example, refuted by stating that this may also be true for other personal information, such as finger prints or iris scans.<sup>16</sup> Further it is often argued that non-genetic health information may have just as much relevance for close relatives as genetic information has.<sup>17</sup> Even the argument of stigmatisation is sometimes called into question, pointing out that HIV patients also have been (and are still being) stigmatised and discriminated against.<sup>18</sup> Further, it is stressed that the information content of non-genetic predictive information may often be higher than that of genetic information. Genetic information relating to multi-factorial or polygenic diseases may not always have strong predictive value, while this can be very different for information about HIV or high cholesterol level.<sup>19</sup> Finally, it is often argued that, as long as no effective therapies are discovered for a certain disease, the fact that a known risk for developing such a disease is genetic or non-genetic in character will not make any difference for

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16 Cf. L.O. Gostin and J.G. Hodge, 'Genetic Privacy and the Law: An End to Genetics Exceptionalism', 40 *Jurimetrics Journal* 21 (1999), p. 35.

17 The information is different to the extent that genetic predispositions can only be transmitted from parent to child, while non-genetic predispositions can be transmitted in a variety of ways. See M.J. Green and J.R. Botkin, 'Genetic Exceptionalism' in Medicine: Clarifying the Differences between Genetic and Nongenetic Tests', 138 *Annals of Internal Medicine* 2003, p. 572.

18 Cf. L.F. Ross, 'Genetic Exceptionalism vs. Paradigm Shift: Lessons from HIV', 29 *Journal of Law, Medicine and Ethics* 141 (2001), p. 141/142; see also S.M. Suter, *supra* (footnote 12), p. 710, stating that virtually every group is at increased risk for a few genetic conditions, meaning that genetic information in practice never singles out particular groups more than others.

19 Cf. *Ethical, legal and social aspects of genetic testing: research, development and clinical applications*, Report of the Independent Expert Group, Brussels: European Commission 2004, p. 32 (available via < [http://europa.eu.int/comm/research/science-society/index\\_en.html](http://europa.eu.int/comm/research/science-society/index_en.html) >, last visited 23 August 2006). Of course, certain genetic anomalies may indicate a more positive and substantial risk to future illness than abnormalities discovered by non-genetic tests, especially if monogenic diseases are concerned. Cf. M.J. Green and J.R. Botkin 2003, *supra* (footnote 19), p. 572. The point is, however, that genetic information does not *per se* have a higher information content and predictive value than other individual health information. See also A. Silvers and M.A. Stein, 'Human Rights and Genetic Discrimination: Protecting Genomics Promise for Public Health', 31 *Journal of Law, Medicine & Ethics* 377 (2003), p. 381/382.

the stress and anxiety that an individual will experience if the risk factor is detected.<sup>20</sup>

Finally, opponents of genetics exceptionalism point out that special treatment of genetic information might lead to unjustified distinctions between persons who are and who are not genetically predisposed to a certain disease.<sup>21</sup> The risk to develop a disease in the future may sometimes be predicted by genetic anomalies, but the same condition may be caused by a range of other factors such as life-style. In the case of breast cancer or heart failure, for instance, some persons will have a genetic predisposition to develop the condition or disease, whereas others will develop the disease as a result of other (known or yet unknown) causes. A prohibition of the use of genetic information by employers and insurers may thus have the result that a person with a genetic predisposition is well-protected against negative insurance or employment decisions, while such protection is withheld from a person whose enlarged risk is clear from environmental factors.<sup>22</sup> Seen from the perspective of optimally inclusive protection against misuse of personal information in general, the differences between genetic information and other kinds of predictive health information seem to be too small to justify different treatment.<sup>23</sup>

From this perspective it is often stated that there is no reason to single out genetic information for protection against misuse by insurers and employers. Instead, commentators have argued that legislation should be drafted that is protective of all predictive health information, regardless of its source or the character of the disease it is predicting.<sup>24</sup> Such comprehensive legislation would have the clear advantage of offering more inclusive protection against the use of private health information by employers and insurers.

## 2.4 *Additional difficulties: how to define ‘genetic information’*

In addition to these arguments against genetics exceptionalism, the point has been made that genetic information is highly difficult to define. At present, two general approaches to the definition of genetic information can be distinguished in aca-

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20 Cf. M.J. Green and J.R. Botkin 2003, *supra* (footnote 17), p. 573. *Mutatis mutandis*, advances in therapy may lead to normalization of practices and policies, as is shown by the example of HIV; see L.F. Ross 2001, *supra* (footnote 18), p. 142.

21 Cf. L.O. Gostin and J.G. Hodge 1999, *supra* (footnote 17), p. 23/24.

22 Cf. M.A. Rothstein, *supra* (footnote 16), p. 459.

23 Cf. M.J. Green and J.R. Botkin 2003, *supra* (footnote 17), p. 571.

24 E.g. L.O. Gostin and J.G. Hodge, *supra* (footnote 16), p. 56.

demic literature.<sup>25</sup> Some have argued that only the results of the DNA-test that may yield information about an individual's DNA can truly be considered as genetic information. This approach is generally known as the *source-based* approach: the information exclusively originates from genetic tests. Within the source-based approach, subdivisions are also possible. Some definitions only consider data from a DNA-test as genetic data,<sup>26</sup> whereas others also include the results of RNA-tests or results of a cholesterol-test from which genetic information can be derived.<sup>27</sup> The Swiss legislation on genetic research on humans provides an excellent example.<sup>28</sup> A number of other commentators have contended that the term should be given a broader definition – these commentators adhere to the *content-based* approach. In this approach, the notion of genetic information should also be held to cover information that has been disclosed by genetic tests

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25 See J.K.M. Gevers *et al.*, *supra* (footnote 1), p. 5 and D. Hellman, *supra* (footnote 13), p. 82.

26 See G.J. Annas, L.H. Glantz and P.A. Roche, *supra* (footnote 6), p. 362, defining 'private genetic information' as 'any information about an identifiable individual that is derived from the presence, absence, alteration, or mutation of a gene or genes, or the presence or absence of a specific DNA marker or markers, and which has been obtained 1) from the analysis of the individual's DNA or (2) from an analysis of the DNA of a person to whom the individual is related'. The Austrian Gentechnikgesetz defines genetic data as data originating from genetic analysis. See art. 4 (23) of the *Gentechnikgesetz* (*Gene technology act*): 'Genetische Analyse: Laboranalyse, die zu Aussagen über konkrete Eigenschaften hinsichtlich Anzahl, Struktur oder Sequenz von Chromosomen, Genen oder DNA – Abschnitten oder von Produkten der DNA und deren konkrete chemische Modifikationen führt, und die damit nach dem Stand von Wissenschaft und Technik Aussagen über einen Überträgerstatus, ein Krankheitsrisiko, eine vorliegende Krankheit oder einen Krankheits- oder Therapieverlauf an einem Menschen ermöglicht'.

27 Such as the analysis of proteins or metabolites which does not primarily aim at the revelation of genetic information, but at the same time may disclose information about genetic anomalies.

28 Art. 3 of the *Bundesgesetz über genetische Untersuchungen beim Menschen* (*Federal act on genetic testing on human being*). 'Genetic information' encompasses 'Informationen über das Erbgut einer Person, die durch eine genetische Untersuchung gewonnen werden, einschliesslich des DNA-Profiles' (art. 3 l). 'Genetische Untersuchungen' encompass in their turn 'zytogenetische und molekulargenetische Untersuchungen zur Abklärung ererbter oder während der Embryonalphase erworbener Eigenschaften des Erbguts des Menschen sowie alle weiteren Laboruntersuchungen, die unmittelbar darauf abzielen, solche Informationen über das Erbgut zu erhalten' (art. 3 a) and the DNA-profil 'die für ein Individuum spezifische Information, die mit Hilfe molekulargenetischer Techniken aus den nicht-codierenden Abschnitten der DNA gewonnen wird' (art. 3 k).

of family members or by medical data about family members that reveal information about inheritable characteristics.<sup>29</sup>

In academic literature, it is often pointed out that a source-based approach may lead to underinclusiveness, which means that information that is deemed desirable to be covered, may not be covered at all. Information that may be predictive about a person's future health status can also be derived from other sources than from a DNA-test. Information deriving from observance of behaviour of an individual or from the medical family history can be equally informative about one's future health status. Characteristics that can only be known from DNA-tests would then be treated differently from other sources of information, even if both types of information provide knowledge about the individuals' genotype and future health risks. For reasons of underinclusiveness, the broader content-based definition has been favoured in academic literature. In the content-based approach, the notion of genetic information covers a broad range of predictive and diagnostic medical information which is obtained from various tests, not only tests of DNA. Genetic information may be derived from family medical history, from testing (tests either directed immediately to genetic information or tests that are directed to other health information but that may also yield genetic information, such as blood tests or urine tests) but also from information derived from observance of an individual's behaviour.

On the other hand, it is clear that the content-based definition, regardless of its strongly protective character, brings some problems of its own. It is clear in particular that such a definition will almost certainly cause problems for insurers and employers in acquiring and using genetic information. Especially the fact that both family medical history and information about inheritable characteristics revealed by such history are covered by content-based definitions of genetic information is troublesome to insurers. Many insurers presently ask for information about family medical history in the contracting procedure. A prohibition on the use of this type of information would thwart a commonly used and accepted

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<sup>29</sup> This does not only cover genetic information which is revealed by genetic or medical tests or by information about family medical history, but also information which is derived from observance of an individual's behaviour (for example, a child's behaviour may disclose characteristics of Down's syndrome, enabling a physician to detect a genetic defect without asking for family medical history or conducting a genetic test) or from personal health information. The Dutch Law on Medical Examination that applies to medical examinations for insurance and employment refers to 'gezondheidstoestand' (*health status*) and not specifically to 'genetic information'. See also C.S. Diver and J.M. Cohen 2001, *supra* (footnote 13), p. 1453.

insurance practice and would obstruct the process of risk calculation for insurers. A broad definition may also hamper the interests of employers who for instance may wish to protect their employees against exposure to toxins for which a particular genetic sensitivity exists.<sup>30</sup> For that reason, legislation and policy measures that are based on the content based approach should at least include a number of exceptions and justification clauses.<sup>31</sup>

Thus, it is difficult to decide for one definition or the other. The uncertainty with respect to the probabilistic value of genetic tests results urges many legislators for precaution with regard to balancing the various interests. In the United Kingdom and in Germany, the definitional uncertainty was one of the reasons to await further developments with regard to genetic information, before initiating legislation.<sup>32</sup> In those states where action has been taken, the dilemma is solved in highly differing ways. In the US, the genetic non-discrimination bills show a variant of the content-based approach, covering an individual's genetic test (including tests of DNA and RNA, chromosomes, proteins, and metabolites that detect genotypes, mutations or chromosomal changes), information about genetic tests of family members of the individual, and information about the occurrence of a disease or disorder in family members. This wide definition and the resulting scope of protection is narrowed, however, by excluding any information about the sex or age of an individual and information about chemical, blood or urine analyses, unless these analyses are genetic tests, and information about physical exams of the individuals or other information that indicates the current health status of the individual. Comparable wide definitions are visible in the Dutch legislation which covers genetic information in the broader content-based definition, *i.e.* "health information". On the other hand, much more narrow definitions have been adopted in Austria, Belgium and France. There, genetic information is defined as information derived from genetic testing.<sup>33</sup> Interestingly, however, this definition does not expressly exclude family medical history.<sup>34</sup>

There seems to be no consensus at all with respect to the proper definition of genetic information. Although the content-based definition is mostly preferred

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30 The broad definition could have counterproductive effects, since it could stand in the way of (accommodating) measures which are meant to prevent the onset of a genetic disease or reduce its symptoms, such as specific measures to prevent exposure to work toxins of a person with a genetically determined heightened susceptibility to such toxins.

31 J.H. Gerards, 'General Issues concerning Genetic Information', in: *Genetic discrimination and Genetic Privacy*, *supra* (footnote 2), p. 12.

32 See Section 4.4 below on regulative possibilities.

33 See also Section 4.6 below on wide and narrow exceptions.

34 See Section 4.4.2 below.

because of the level of protection it provides, this definition also has disadvantages to the market sectors at issue. These differences are currently reflected in the approach taken by the various states, which does not seem to show any conceptual agreement.

### **2.5 Conclusion: (predictive) health information as a basis for regulation**

Although the arguments pro and contra genetics exceptionalism have not much changed over the last decade, the outcome of the debate seems to have shifted somewhat. Ten years ago, by far the most academic commentators seemed to favour special genetics legislation because of the exceptional character of genetic data and because of the special risk of misuse by non-medical actors. However, more recent reports and articles seem to voice a different opinion. The view has developed that, to some extent, genetic information may be considered exceptional indeed, yet is not so different from other kinds of predictive health information that it would deserve much stronger protection. It is now argued that regulation of access to and use of health information should not be limited to genetic information. An additional reason for this is found in the problems relating to the definition of genetic information. As long as there is no common ground as to the types of genetic information that should be protected (e.g. only DNA test results or a broader category of information, including even family medical history), it would not seem to be wise to take genetic information as a starting point for all kinds legislative and policy measures. Various alternatives have been offered, such as strengthening the protection of confidentiality of all health information; limitation of the possibility to collect all kinds of predictive health information; or taking the ‘information content’ of health information as a starting point for regulation.<sup>35</sup>

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35 Cf. M.J. Green and J.R. Botkin 2003, *supra* (footnote 17), p. 573, suggesting that four factors should be considered relevant in defining health information worthy of special protection: the degree to which information learned from a test can be stigmatising; the effect of the test result on others; the availability of effective interventions to alter the natural course predicted by the information; and the complexity involved in interpreting the results. One solution approaching this suggestion can be found in the Dutch Act on Medical Examinations, which prohibits medical tests in the context of insurance underwriting if the expected usefulness of the test results for the insurer are not in balance with the risks thereof for the insured. This would be the case with a test intended to provide information regarding the likelihood of the subject developing a serious condition which is untreatable or which cannot be stabilised or prevented by medical intervention, or regarding the presence of a serious, untreatable condition which might not become manifest

In our opinion, it is not desirable to limit regulatory activities to genetic information, whatever definition is chosen. We agree that genetic information is exceptional in that it shows a unique combination of features. Although it is understandable that genetic information attracts much attention and concern, we perceive no apparent reason why the protection given to genetic information should not also be offered to other kinds of health information. Individual privacy would certainly be improved if a wider category of health information were protected, while it would then also be easier to combat misuse of such information by non-medical actors.

It is important to note, however, that the debate about regulation of health information is not only inspired by the character of the information itself. The interests of market actors such as insurers and employers are also relevant to regulatory activities in this area and to choices regarding the scope of protection. Although privacy interests would be protected by a broad ban on the collection and use of health information, such protection might have unacceptable consequences for the insurance market, or might stand in the way of valuable screening of employees for susceptibility to workplace toxins. Furthermore, the discussion of the definition of genetic information has shown that the choice for a certain definitional approach is closely connected to the desired level of protection against misuse of genetic information and the effects of a certain definition for the interests of employers and insurers. Choices as to the covered categories of information will therefore not only depend on the debate about genetics exceptionalism, but also on the balance that is struck between the various interests involved.

### **3. Interests involved in regulating genetic and other (predictive) health information**

#### **3.1 Introduction**

Dilemmas concerning the confidentiality of medical information and privacy questions relating to the use of health information are, of course, not new. In most legal systems, an intricate legal system protecting confidentiality and privacy is already in place. However, many of these regulations only deal with the use of medical information within the medical sector and the confidentiality of medical information that is in possession of medical practitioners. Questions as to when

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until some time after the medical examination (see Section 3, subsection 2(a) of the Act on Medical Examinations). Cf. also D. Crosbie, *Protection of Genetic Information: An International Comparison*, Report to the Human Genetics Commission, September 2000.

and under what circumstances employers or insurers could request or require an individual to undergo a genetic test, or disclose all health information that is known to him, often remain unanswered. It is exactly this kind of questions on which the debate about the use of genetic information centres.

To a certain extent, the present debate about (genetic) privacy and discrimination resembles the earlier debate about the confidentiality of medical data – indeed, comparable individual interests are at stake. However, the shift of focus of the debate has made matters more complicated. Legislation with respect to non-medical uses of health information will not only need to take account of individual privacy and non-discrimination concerns, but also of the interests of market actors such as employers and insurers and the interests of individuals of having access to the social goods these actors hold the key to.

In this section, we provide a short overview of the most important of these interests and their value for the debate about regulation. A detailed analysis of the individual rights to privacy, self-determination and non-discrimination will be left out, since these rights have been elaborately discussed and explored elsewhere. Instead, we focus on the specific interests relating to the use of genetic and other (predictive) health information by employers and insurers.<sup>36</sup> The interests related to insurance will be discussed in section 3.2, in which we will give an overview of the arguments pro and contra the access to predictive health information by insurers. In section 3.3, we will shortly discuss the various interests connected to the availability of genetic information to employers.

## 3.2 *Insurance*

### 3.2.1 *Actuarial fairness and the risk for adverse selection*

The importance of genetic information to the insurance market is strongly connected with the character of the insurance system in place. On a very general level, it is possible to distinguish two types of insurance. In the first place there are solidarity-based insurance systems, in which everybody is insured against a certain type of risk, such as that of high costs of health care, without there being a clear relation between an individual's risk level and the contribution he pays to the insurance system. Premiums in a solidarity-based system are not based on risk

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36 Although such information may be of relevance to a wide range of other market actors, varying from reproductive counsellors to schools, insurers and employers have shown most interest in obtaining and using genetic information. For that reason, we will concentrate on their particular interests.

categorisation, but are set uniformly or according to the individual's ability to pay. An element of compulsion is necessary to render a solidarity-based system workable: without such an element, 'low risks' (paying relatively high premiums in comparison to their risk) would be tempted to leave the pool and seek private, cheaper insurance schemes.<sup>37</sup> In a solidarity-based system access to the relevant social goods (such as health care) is guaranteed to everyone, which means that the situation is avoided that an indigent high risk individual cannot afford the costs of insurance and is thereby excluded from necessary help. These specific features of solidarity-based insurance make that most of these schemes are public instead of private in character. The most common form of solidarity-based insurance schemes are the national health and disability insurance plans that exist in European countries.

By contrast, most private insurance systems are based on mutuality. In such insurance schemes an accurate classification is made in risk groups, each risk group being charged a premium that closely corresponds with the estimated group risk.<sup>38</sup> An important advantage of such a system is its actuarial fairness or risk-equity: an individual will not contribute more to the insurance scheme than is reasonable in the light of his personal risk level.<sup>39</sup> In addition, no element of compulsion is needed to render the system effective, since the insured will only be asked to pay a premium that is fair in relation to his risk. In the United States, almost all health and disability insurance schemes are based on risk classification, public insurance schemes being the exception rather than the rule. In Europe, mutuality-based insurance schemes are common for life insurance and long-term care insurance.<sup>40</sup>

In mutuality based insurance systems, it is essential to obtain as accurate information as possible about each individual's risk level. The more information about someone's health or mortality risks is available, the more accurately the premium can be fitted to the risk of the insured. It is for that reason that the principle of *uberrima fides* ('utmost good faith') is of particular importance to the private

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37 Cf. O. O'Neill, 'Insurance and Genetics: The Current State of Play', 61 *Modern Law Review* 716 (1998), p. 716 and *The Implication of Genetic Testing for Insurance*, Report of the Human Genetics Advisory Commission, December 1997, section 1.

38 See R.J. Pokorski, 'Use of Genetic Information by Private Insurers', in: T.F. Murphy and M.A. Lappé (eds.), *Justice and the Human Genome Project*, Berkeley/Los Angeles/London: University of California Press 1994, p. 93.

39 Cf. R.B. Meyer, 'The Insurer Perspective', in: M.A. Rothstein (ed.), *Genetics and Life Insurance. Medical Underwriting and Social Policy*, Cambridge, Mass.: The MIT Press 2004, p. 31.

40 See O. O'Neill, *supra* (footnote 37), p. 720.

insurance industry, as it requires the (potential) insured to notify the insurer of all known factors that might affect the risk classification. It will thus be clear that predictive health information, such as genetic information, is of great value to the private insurance industry. If genetic test results can be used to predict the onset or development of a certain disease, health and mortality risks may be estimated with great accuracy. Such accuracy is clearly beneficial to the industry, but also to the individual, who will only pay a premium that is in accordance with his own health risks.

Against this background, it is perhaps surprising that private insurers have not yet shown much interest in obtaining genetic test results. This may be explained by the fact that genetic tests do not always provide accurate and reliable results and that it is still difficult to establish a clear and actuarially relevant link between a genetic defect and a measurable health or mortality risk.<sup>41</sup> Many insurance companies would seem to await further technological developments before requiring individuals to undergo a genetic test or to disclose any genetic information known to them in the process of underwriting. Indeed, it is clear that other forms of predictive health information (whether or not genetic in character) are already used in the underwriting process, provided that the information is considered to be actuarially relevant and where the use of such information is not prohibited by legislation. This is the case, for example, with information about HIV or Hepatitis B infection, information relating to monogenic diseases such as Huntington's disease or cystic fibrosis, and family medical history. It may be expected, for that reason, that the interest of insurers in obtaining genetic data will increase as soon as its actuarial value becomes more strongly established. The risk to individual privacy interests is thus not negligible and it may still be desirable to adopt measures to prevent any risk of unwarranted use in the future. For the same reason, the fact that insurers do not at present attempt to obtain access to genetic information on a large scale must not be taken mean that a broad prohibition on the use

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41 See e.g. O. O'Neill 1998, *supra* (footnote 37), p. 721 and American Academy of Actuaries, *The Use of Genetic Information in Disability Income and Long-Term Care Insurance*, Issue Brief Spring 2002, p. 6. The limited actuarial value is, of course, especially relevant for multi-factorial diseases, the onset and development of which may be determined by a wide range of factors, including combinations of genes and environmental factors. For that reason the insurance industry itself has developed codes of practice in which it is stated that genetic information (when available and accessible) can be used only if they are valid for insurance purposes, *i.e.* if it has been established that the information is reliable and relevant because it indicates an increased risk (see e.g. Association of British Insurers, *Genetic Testing – ABI Code of Practice*, adopted August 1999, section 6 and the recommendations made by the American Academy of Actuaries, cited above, p. 9).

of such information would not be problematic to the industry in the future. It is in particular these future risks that have been stressed in academic comment.

In the first place, it is argued that restrictions of access to information might lead to actuarial unfairness, since a lack of information would stand in the way of accurate risk calculation and equitable premium rating. This might be particularly disadvantageous for individuals with established low health risks, who would be charged higher premium rates than appropriate.<sup>42</sup> These groups thus have a relatively strong interest in being allowed to disclose such information to insurers.<sup>43</sup> In the second place, a widely recognised problem is that restrictions on access to predictive health information would result in an information imbalance and could thus lead to adverse selection. By undergoing a medical (*e.g.* genetic) test, an individual might learn that he has a heightened risk to develop a serious disorder or disease in the future, without having the obligation to inform (or even being prohibited from informing) his insurance company. The individual might then be tempted to use his knowledge to his own advantage by trying to obtain an inclusive insurance contract to cover his expectedly high costs of health care, or to obtain substantial amounts of life insurance against a relatively low premium.<sup>44</sup> If the insurer is not aware of the individual's extraordinary health risks, he will classify the individual as a normal or even low risk on the basis of normal underwriting principles, charging him a premium which is not at all in correspondence with the actual risk. When the risk materialises in high costs of health care or in premature death, the insurer will be compelled to pay out more claims than he could have expected on the basis of the information known to him. If this happens more often, the insurer will need to raise the premiums to avoid further loss. Since he

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42 See *e.g.* R.J. Pokorski, *supra* (footnote 38), p. 103/104.

43 It is therefore sometimes argued that individuals should be allowed to disclose information if such would be to their advantage. The setback of such an approach is, however, that if a question is added to a questionnaire to allow for disclosure of favorable genetic information, this might lead insurers to follow an *a contrario* line of reasoning with respect to individuals who have left the question open.

44 The process of adverse selection does not require wilful behaviour in the sense that an individual actively engages in finding the best possible insurance against the lowest possible price. It is also possible that he starts off a process of adverse selection by doing nothing at all. After all, if a person learns about a genetic risk but omits to inform the insurer about it, he will remain in a risk group where he does not belong according to the newly discovered information. Since research has made clear that individuals will be easily tempted to withhold genetic information from their insurer (see M.A. Rothstein and C.A. Hornung, 'Public Attitudes', in: M.A. Rothstein (ed.), *Genetics and Life Insurance. Medical Underwriting and Social Policy*, Cambridge: The MIT Press 2004, p. 12/13), this risk that adverse selection is triggered in this way is clearly present.

does not have any means to detect which persons are withholding information, he will need to do so indiscriminately.<sup>45</sup> This could result in a situation in which low risk groups lose their interest in their insurance contract, because they consider the premiums overly high. They may even prefer to bear the risk themselves over paying a high monthly premium. If this happens, more premium raises will be necessary to retain profitability, which in turn might lead to a further outflow of relatively low risks. The final result of this development could be a 'death spiral', resulting in the situation in which only the highest and most unprofitable risks can be tempted to underwrite.<sup>46</sup> The process of adverse selection, set about by information imbalance, may thus result in the collapse of the entire insurance industry.<sup>47</sup> Even if adverse selection does not result in a 'death spiral', the process may have negative effects. One problem is that insurers will set limits to the amount of insurance individuals can buy in order to prevent high risks from buying high amounts of insurance against a disproportionately low rate.<sup>48</sup> As a result, risk-avoiding low risk groups will not be able to buy as much insurance as they would like to, or may only be able to do so against a relatively high price. This would be disadvantageous to both the insurer and the potential insured. It is probable, moreover, that the costs of insurance will rise, since higher premiums are needed to compensate for the higher level of claims that have to be paid out.<sup>49</sup> Once more, this would be disadvantageous to low risk groups, who will need to pay a price that is higher than would be reasonable from an actuarial point of view.

This risk for adverse selection as a result of information imbalance is often considered to be the most important argument to allow insurers to acquire (genetic) health information. Still, the force of the argument is disputed. Siegelman has shown, for instance, that the process of adverse selection is not only dependent on the existence of informational asymmetry, but also on a range of other factors. His own research shows that psychological factors may cause individuals not to act rationally and to remain with their current insurer in their current risk group.

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45 Cf. M.A. Hall and S.S. Rich, 'Laws Restricting Health Insurers' Use of Genetic Information: Impact on Genetic Discrimination', 66 *American Journal of Human Genetics* 293 (2000), p. 301.

46 See P. Siegelman, 'Adverse Selection in Insurance Markets: An Exaggerated Threat', 113 *Yale Law Journal* 1223 (2004), p. 1224.

47 Cf. e.g. C.S. Diver and J.M. Cohen, *supra* (footnote 13), p. 1467.

48 P. Siegelman, *supra* (footnote 46), p. 1239.

49 Cf. R.B. Meyer, *supra* (footnote 39), p. 30.

This means that a death spiral will not easily be triggered.<sup>50</sup> Others have shown that insurers will only try to obtain information if such is cost effective and relatively easy to do, which has led to the conclusion that insurers are less concerned about access to all relevant actuarial information than is sometimes made to believe.<sup>51</sup> Lastly, research has shown that not every process of adverse selection will result in a death spiral. In the end a new equilibrium will mostly be reached between the risks insured and the premiums paid, even though the new situation might be less profitable to the insurer.<sup>52</sup> Thus far, no extreme cases of adverse selection have been known to occur.<sup>53</sup>

For reasons such as these, the necessity to obtain access to genetic information in order to avoid collapse of the entire industry seems somewhat less pressing. This may be different for other types of (predictive) health information, but even there the risk seems to be relatively mild. At least, it can be argued that the extent to which the interests of insurers would be harmed by restrictions is dependent on a number of factors that could well be taken into account in drafting legislation.

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50 P. Siegelman, *supra* (footnote 46), p. 1248/1249 and p. 1264ff, explaining that the negative effects of adverse selection may be partly undone by the inverse process of propitious selection: there seems to be a negative correlation between risk aversion and riskiness, in the sense that insurance seems to be most attractive to low-risk individuals, not to those with the highest risks. If this is true, they will be willing to buy insurance even at rates that would be too high from an actuarial perspective. When a low-risk group is sufficiently risk-averse, a new equilibrium will be reached relatively fast, even in a case of informational asymmetry.

51 E.g. T. Sorell, 'Freedom within Limits. Underwriting and Ethics', in: Sorell, T., *Health Care, Ethics and Insurance*, Routledge: London/New York 1998, p. 103 and N. Daniels, 'The Genome Project, Individual Differences and Just Health Care', in: T.F. Murphy and M.A. Lappé (eds.), *Justice and the Human Genome Project*, Berkeley, Los Angeles, London: University of California Press, 1994, p. 115ff.

52 Cf. M.A. Hall and S.S. Rich, *supra* (footnote 45), p. 301. This is true in particular because even low risks will be unable or unwilling to pay for all eventual health costs (being the result of viral infections, accidents, etc.) and will need some insurance. It is therefore improbable that all low risk individuals will fall out the insurance system as a result of adverse selection.

53 P. Siegelman, *supra* (footnote 46), p. 1254ff and R.B. Meyer, *supra* (footnote 39), p. 30. Meyer argues, however, that this may also be due to the fact that, thus far, insurers have not been deprived of the possibilities to control the mechanism.

### 3.2.2 *The relation between insurance and access to important social goods*

In mutuality-based insurance systems, premiums are typically fitted as closely as possible to the expected individual risk. If the risk is very high, for instance because a predisposition to a monogenic disease is discovered, insurance premiums will necessarily be equally high. In a state in which health insurance is primarily based on mutuality and insurers are not obliged to accept high health risks, as is the case in the United States, the result may be that persons with extremely high health risks cannot (or only at a very high price) be insured against the costs of health care. As a result, access to health care for such persons might be effectively blocked. It is often stressed that this is not an acceptable result. Health care is such an important social good that access to it should be guaranteed to everyone at all times.<sup>54</sup> Affordable disability and long term care insurance are likewise important to guarantee a means of subsistence to disabled and chronic ill persons, especially where a safety net of inclusive social security benefits is not provided for.<sup>55</sup>

Other forms of insurance, such as life insurance, may be considered to be related to less important social goods.<sup>56</sup> However, even life insurance may be of great importance to an individual's private life, since it can be used to secure a reasonable standard of living for one's family or to obtain a mortgage.<sup>57</sup>

Hence, all forms of insurance to which individual health information is of any relevance would seem to relate to important social goods. It might even be said that some forms of insurance concern social rights, such as the right to health care and subsistence. If unrestricted access to individual health information would lead

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54 See e.g. T. Lemmens, 'Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?', 45 *McGill Law Journal* 347 (2000), p. 388/389 and N. Daniels, 'The Functions of Insurance', in: M.A. Rothstein (ed.), *Genetics and Life Insurance. Medical Underwriting and Social Policy*, Cambridge, Mass.: The MIT Press 2004, p. 130ff.

55 Cf. O. O'Neill, *supra* (footnote 37), p. 722.

56 E.g. N.E. Kass, 'The Implications of Genetic Testing for Health and Life Insurance', in: Rothstein, M.A. (ed.), *Genetic Secrets. Protecting Privacy and Confidentiality in the Genetic Era*, Yale University Press: Yale, London 1997, p. 305.

57 The importance of life insurance to individuals is supported by research of public attitudes towards life and health insurance, in which 62% of the respondents stated that everyone needs life insurance and even 82% that everyone has a right to life insurance (see M.A. Rothstein and C.A. Hornung, 'Public Attitudes', in M.A. Rothstein (ed.), *Genetics and Life Insurance. Medical Underwriting and Social Policy*, Cambridge: The MIT Press 2004, p. 23).

to undue interference with such rights, this would seem to provide a strong argument for strict regulation.

### 3.2.3 Conclusion

In contemplating restrictions to the use of individual health information by the insurance industry, it is necessary to strike a balance between the various conflicting interests discussed above. Exactly where this balance should be struck depends on a number of circumstances. In solidarity-based insurance systems, there seems to be no need for balancing at all, as there is no risk classification and therefore no need to obtain detailed individual health information. This is clearly different for mutuality-based, private insurance systems. We have found that the balance may be struck differently for the various type of insurance. With health insurance, the individual right of access to affordable health care needs utmost protection, as the situation must be avoided that the neediest persons are deprived of health care.<sup>58</sup> The same is true for disability insurance and long term care insurance.<sup>59</sup> Whatever solution is chosen here, it is important that these individual interests be respected and protected. Of course, this can be done by the harsh measure of prohibiting all access to individual health information with a predictive character. As long as the therapeutic gap is as large as it is now, and as long as the actuarial character of much predictive information is still limited, this would seem to be the best solution. At present this solution would not seem to be overly restrictive to insurers either, since most insurers do not yet try to obtain genetic information and there is not much evidence of a problematic asymmetry of information.<sup>60</sup>

In the long run, when genetic research develops and more remedies become available, and when such information grows more important as a means for risk classification, access to genetic information may be allowed under strict conditions. Such conditions would obviously include strict confidentiality of information, but also protection of the individual against the distress caused by disclosure of test results.<sup>61</sup> Further, it is submitted that genetic information may only be used or

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58 Cf. N. Daniels, *supra* (footnote 54), p. 130ff.

59 Cf. also N. Daniels, *supra* (footnote 54), p. 134/135. This does not *per se* imply that everyone must be able to continue his present style of living, but at least should be entitled to a reasonable income.

60 Cf. C.S. Diver and J.M. Cohen, *supra* (footnote 13), p. 1454.

61 Examples of protective measures are that test results may only be disclosed by a medical practitioner and should be accompanied by genetic counselling.

asked for if its actuarial value is clearly established.<sup>62</sup> In order to secure affordable health care for high-risk individuals who cannot afford to pay high insurance premiums, accompanying measures should be taken. Such measures might be that the premiums of high risk groups are partly subsidised out of general revenues;<sup>63</sup> private insurers are obliged to accept high risks;<sup>64</sup> or the existing social security safety nets are strengthened.<sup>65</sup>

For life insurance, the individual interest connected to the insured good seems to be less overriding. An individual who does not want to know about his individual health risks may decide to forego of a life insurance policy, without this having far reaching consequences for his health or standard of living.<sup>66</sup> This does not mean, however, that life insurers should have unlimited access to predictive health information. The concerns about the actuarial value of predictive health information and the quality of genetic test results are as valid here as they are with respect to health care insurance. Access to predictive health information should only be allowed under very strict conditions. A workable solution might be found in ceiling-setting, an approach which is currently chosen in many self-regulative systems and national legislation.<sup>67</sup> We will further explore this possibility in Section 4.4 below.

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62 In this regard, an independent expert group of the European Commission has made the interesting recommendation to establish a consistent framework assuring the quality of genetic testing services. Others have suggested that close collaboration between researchers, the insurance industry and the government is needed to establish the actuarial value of genetic discoveries. For some criteria, see also R.K. Gleeson, 'Medical Underwriting', in: M.A. Rothstein (ed.), *Genetics and Life Insurance. Medical Underwriting and Social Policy*, Cambridge, Mass.: The MIT Press 2004, p. 89/90.

63 See also A.A. Dicke, 'The Economics of Risk Selection', in: M.A. Rothstein (ed.), *Genetics and Life Insurance. Medical Underwriting and Social Policy*, Cambridge, Mass.: The MIT Press 2004, p. 69, offering several interesting alternative forms of subsidization.

64 See T. Sorell, *supra* (footnote 51), p. 402 and N. Daniels, *supra* (footnote 54), p. 119/120.

65 Cf. N. Daniels, *supra* (footnote 54), p. 131.

66 It must be stressed, though, that life insurance can relate to important social goods. The needs for which life insurance is bought differ widely, but mostly such insurance is acquired to provide a relative with an appropriate income after one's death (cf. A.A. Dicke, *supra* footnote 63, p. 58). In that situation the purpose of the insurance is that of providing reasonable means of existence, which is clearly highly important. See, however, N. Daniels 2004, *supra* (footnote 54), p. 135, arguing that this interest could (at least partly) be served by private insurance without this leading to unfair results.

67 See the examples of the Dutch Medical Examinations Act (in which the ceiling for life insurance was set at €159,505 in 2004) and the Genetic Testing Code of Practice of the Association of British Insurers (August 1999, in which the ceiling was set at approximately €150,000). We will come back to this issue in Section 4.4 below.

### 3.3 *Employment*

#### 3.3.1 *Financial interests of employers*

Genetic information and other forms of (predictive) health information are not only of interest to insurers, but also to employers. This is particularly true for systems in which the employer also acts as insurer, as is often the case in the United States. In that situation, the employer obviously has an interest in gaining access to genetic information that is comparable to those discussed above.

Even if employers are not engaged in insurance activities, they might be interested in knowing about genetic predispositions and health risks of their (potential) employees. After all, if it is clear that an employee will become seriously ill in the future, this will probably imply frequent absence, increased costs of temporary replacement and decreased efficiency and productivity.<sup>68</sup> For economic and financial reasons, an employer may find it useful to test each job applicant for relevant health risks or genetic anomalies.<sup>69</sup> It has been argued, however, that this argument should not be taken too seriously. As explained previously, many genetic predispositions may never manifest themselves in the form of a disease or disorder that is so serious as to severely limit one's ability to work. It would be undesirable to keep well-functioning and productive employees from working without any justification other than the fear of future costs. Such employer behaviour would necessitate the payment of unemployment benefits, while the individuals concerned could be highly productive and useful, perhaps for the rest of their working lives.<sup>70</sup> It may thus be less problematic to restrict the use of genetic information as a basis for employment decisions than is sometimes contended.

#### 3.3.2 *Health and safety of employees; public and consumer safety*

One further employment concern relates to the health and safety of employees. If an employee has to work with toxins or chemicals, it may be necessary for the employer to know if he has a heightened susceptibility to certain toxins, in order to enable him to take adequate preventive or accommodating measures. The same

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68 On itself, this may then lead to reduced economic profits and competitiveness of the company. Cf. M.A. Rothstein and B.M. Knoppers, 'Legal Aspects of Genetics, Work and Insurance in North American and Europe', *European Journal of Health Law* 1996, p. 144/145 and C.S. Diver and J.M. Cohen, *supra* (footnote 13), p. 1458-1459 and 1462-1463.

69 See C.S. Diver and J.M. Cohen, *supra* (footnote 13), p. 1464.

70 Cf. A. Silvers and M.A. Stein 2003, *supra* (footnote 19), p. 385.

is true for other predictable health risks which are work-related, such as carpal tunnel syndrome or vision problems.<sup>71</sup> If a job applicant or employee would appear to be unable to perform his daily functions, and reasonable accommodation appears to be impossible, the employer might even refuse or discharge a job applicant or employee.<sup>72</sup> Access to predictive health information, including genetic information, has thus clear economic advantages for the employer.<sup>73</sup> For the individual employee or job applicant, the advantage is equally clear. Periodic genetic screening of employees working under hazardous conditions or being exposed to dangerous toxins with the aim of detecting problematic genetic changes, or pre-employment testing for heightened susceptibility, may induce the employer to introduce adequate workplace modifications or preventive measures, or to offer (potential) employees a different function that does not entail a heightened risk to disease.

Some employers further have an interest in obtaining predictive health information about (prospective) employees because of the need to guarantee public or customer safety. An airline company or public transport service will not easily accept a job applicant whose medical files show a high likelihood of getting a sudden heart attack or acute vision impairment. Still, this should only be accepted if there is clear medical proof of actual safety risks or threats and those risks and threats which cannot be effectively reduced or controlled by frequent medical examinations, preventive measures or adequate medication.

### 3.3.3 Access to employment

The individual interests concerned with the use of predictive health information by employers obviously relate to access to employment. It is unacceptable if individuals are unable to get a job, merely because of the risk that they might develop a certain disease in the future. Although the economic and financial

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71 Cf. A. Silvers and M.A. Stein 2002, *supra* (footnote 19), p. 1366 and *Schlussbericht der Enquete-Kommission 'Recht und Ethik der modernen Medizin'*, Deutscher Bundestag, 14. Wahlperiode, Drucksache 14/9020, 14 May 2002, p. 139/140.

72 The extent to which an employer is allowed to refuse or discharge an individual because of future health risks depends, of course, on choices made in national legislation.

73 Cf. E. Draper, 'The Screening of America: The Social and Legal Framework of Employers' Use of Genetic Information', 20 *Berkeley Journal of Employment and the Law* 286 (1999), p. 289/290.

concerns of employers are realistic and important, they would seem to be outweighed by the individual right to access to employment.<sup>74</sup>

### *3.3.4 Conclusion*

As with insurance, it is clear that employers may have a legitimate interest in being informed about future health risks of his employees. Careful legislation may be drafted that allows for job-related testing and monitoring for functions to which a certain state of health is really relevant. The use of such information as a basis for negative employment decisions should be restricted to situations where prevention or accommodation would be impossible or would lead to an unreasonable burden for the employer. In addition, employers may be allowed to introduce systems of genetic monitoring or genetic screening if they use it to the benefit of employees or job applicants.

## **4. General issues regarding the regulation of genetic and other (predictive) health information**

### *4.1 Introduction*

In the preceding paragraphs we have provided an overview of some important issues pertinent to the question how to regulate the access to and use of genetic information by non-medical actors. We have made clear that the theory of genetics exceptionalism by now finds only limited academic support and that the notion of genetic information is difficult to define. For that reason, we have argued that it might be preferable to broaden the scope of any new policy or legislative measures to the broader category of (predictive) health information and refrain from focusing on genetic information (whether or not broadly defined). The case for the introduction of such legislation is a strong one, as we have made clear in Section 3. Restrictive measures do not only protect individual non-discrimination and privacy interests, but are also necessary to secure adequate access to important social goods such as health care, employment and disability benefits. On the other hand, we have clarified that strongly protective legislation in this area may seriously hamper a wide range of important interests, varying from economic interests of insurers to the interests of employees in being protected against health risks

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<sup>74</sup> This individual interest is even protected as a social right by many international instruments, such as the International Covenant on Economic, Social and Cultural Rights (Article 6) and the European Social Charter (Article 1).

in the workplace. In that regard we have also drawn some theoretical conclusions as to where the balance between these interests might be reasonably struck.

In Sections 2 and 3 we noted that, in practice, many regulatory choices have already been made. Many states have introduced some form of regulation of non-medical access to predictive health information, in particular genetic information. They have struggled to find a solution to the dilemmas described in Section 3, but they have also dealt with a number of other important issues which are pertinent to the regulation of predictive health information. These issues are strongly related to regulatory choices, which themselves interrelate with the substantive balance that is struck between the various relevant interests. In our study, we have distinguished five different issues which seem to be of relevance to each regulatory decision relating to genetic or other predictive health information:

1. The choice for certain policy areas to be regulated (*e.g.* only employment and insurance or a wider range);
2. The 'level' of regulation (*i.e.* the introduction of legislative measures on a federal or supranational level, or on the level of the (member) states);
3. The choice for certain policy or legislative instruments;
4. The choice for a privacy or non-discrimination approach (*i.e.* protection by privacy regulations or by a prohibition of discrimination);
5. The choice for widely or rigidly formulated legislative measures, with wide or narrowly formulated exception clauses.

We have investigated how each of these issues have been dealt with in the United States, a variety of European States and the European Union. In this section, we will concisely report the results of this study, where necessary supported by an explanation of the background of a certain approach.<sup>75</sup>

## 4.2 *Which areas should be regulated?*

### 4.2.1 *Europe*

With regard to the choice of policy areas to be regulated, some general lines can be drawn from the legislative situations in a selected number of European states: Austria, Belgium, Germany, Greece, France, the Netherlands, Norway, Switzerland

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<sup>75</sup> The results of the comparative study have been reported in detail in J.H. Gerards, A.W. Heringa and H.L. Janssen, *supra* (footnote 2).

and the United Kingdom.<sup>76</sup> In addition to legal activities in European states, legislative initiatives and policy measures within the framework of the European Union deserve attention, since this supranational legal system has jurisdiction with regard to matters of privacy, the prohibition of discrimination and the protection of health.<sup>77</sup>

In Europe, it is felt that genetic information might be of interest to a broad range of non-medical actors, ranging from commercial genetic research laboratories, educators, health care suppliers and employers to insurers' companies. In many legal systems, legislative and policy steps have therefore been taken with respect to employment- and insurance related situations. General prohibitions were for example inserted in existing legislation: Greece inserted the protection of genetic information in the Greek Constitution,<sup>78</sup> while Switzerland has amended its Constitution to include a prohibition on the use of genetic information without the consent of the individual.<sup>79</sup> In legal systems such as Switzerland, the domains of insurance law and labour law are thus under the influence of constitutional protection, which has important expressive value. At the same time, it must be noted that constitutional protection applies primarily in vertical relations, *i.e.* the relation between state and individual, whereas the use of genetic information predominantly takes place in horizontal insurance and employment settings. From this perspective, additional legislation seems essential to guarantee effective protection.

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76 This choice is based on the quick-scan that was made for the research project on genetic discrimination and genetic privacy in a comparative perspective (see *supra* footnote 2 and accompanying text). The legislative systems in the quick-scan were chosen for reasons of providing adequate information with regard to possible policy options and choices in legislation techniques. The variety of options and choices was of prime interest for our study, but we are aware that other European legal systems could have provided valuable examples as well.

77 The EC-Treaty is most relevant here. The Charter on Fundamental Rights of the EU (Nice, 2000) contains important references with regard to genetic privacy and genetic discrimination, but is not legally binding. The European institutions can furthermore issue Regulations which are binding on its 25 member states in all aspects and means. The member states must implement these Regulations. The European Union can also issue Directives, which are binding as for their results, but leave the choice as to the proper means to implement their substantive provisions to the member states. For Regulations and Directives, the EC-Treaty must provide a legal basis, otherwise the institutions are not allowed to act.

78 See Section 4.2 on regulative possibilities.

79 See Section 4.2 on regulative possibilities and art. 119 (2) f of the Swiss Constitution.

Pre-employment genetic tests are in most legal systems not (yet) subject to specific legislation on genetic information. Where regulations do exist, they often allow general medical examinations with regard to health related situations or for particular jobs, rather than restricting the use of genetic tests or providing protection to the employees. Since specific genetics legislation is absent here, more general principles apply, such as the confidentiality of the patient-doctor relationship or the contractual freedom principle. In some legal systems, however, it is felt that these principles offer insufficient protection to individual health information. The employer's possibilities to ask for an employee or job applicant to be tested or to collect genetic information are subject to severe regulation in some of the states that have been studied. Presently, Belgium, Austria, and France explicitly prohibit genetic testing, collection and disclosure by law. Germany and the United Kingdom do not have specific legislation with regard to job requirements, but the need for regulation of predictive health information in the sphere of employment is currently under debate in these countries. Legislation in the Netherlands seeks the middle way: the Medical Examination Act seeks to regulate the use of medical examinations and to restrict the scope of health inquiries in the context of access to employment, without imposing a complete prohibition of the use of any predictive health information.

The European market for insurance has a patchwork character. There is no single European market here, since the European Union does not have the competence to legislate in the sphere of insurance. Moreover, the legal systems show a variety of arrangements with regard to the design of insurances, depending on the traditional way in which, for instance, the health insurance systems have been organised. Various types of insurance where predictive health information is of interest to the insurers' risk management deserve attention here. Generally, life-, health-, and disability insurers and mortgage providers have been interested in predictive health information since the life expectancy and/or the health condition of the insurance taker are prime criteria for the determination of the premium or the payment. European states generally show a concern for the implications of access to and use of genetic information. The various legal systems arrange partly the same and partly different types of use of genetic information in the field of insurance. Some legal systems restrict or prohibit the collection and disclosure of genetic information for commercial purposes, among which insurance purposes. Other legal systems have not yet regulated the collection or disclosure of genetic information with regard to insurance, or have only supported the introduction of ceiling setting systems. In such a system, genetic information may play a role in the process of underwriting if the amount of insurance asked for surpasses a certain level. Most European states have ensured some sort of universal access to health-, life- and disability-insurance. Health insurance is in principle accessible for every

individual and has a public insurance character. Insurance legislation in many European states indicates at least to some extent that there is a need to provide a basic service to which all should have access. Standards for access are thus not solely determined by market oriented criteria.<sup>80</sup>

#### 4.2.2 *United States*

The theory of genetics exceptionalism is prevailing in the United States. Other types of health information have been given far less consideration, even if such information is of more interest to non-medical actors than genetic information and poses a considerable threat to individual privacy and non-discrimination interests. As a result of the focus on genetic information, ideas about regulation have concentrated on the areas in which there is a clear interest in obtaining and using such information.<sup>81</sup> Inquiries and research have shown that in particular insurers and employers are interested in having access to individual health information. Anecdotal evidence from various sources has demonstrated that these actors are already trying to obtain access to genetic information.<sup>82</sup> In comparison to these actors, other potentially interested parties (banks, reproductive consultants, schools, etc.) seem to constitute a less immediate risk and, consequently, the need to bring them under the scope of restrictive legislation is considered less pressing. Although it is generally agreed upon that, in the long range, solutions should be extended to cover these areas, an incremental approach is thus considered acceptable.<sup>83</sup>

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80 See e.g. the Dutch Act on Medical Examinations. The basic principle of the Act is that individuals must have unimpeded access to socially important facilities such as work and certain insurance; the Act may pose a barrier to the use of genetic testing for insurance purposes, without fully excluding them. As far as insurance contracts are concerned which are concluded by the employer, no medical examination can be required with regard to retirement or disablement insurance policies. Use of genetic tests is allowed if an insurance policy is contracted by an individual or if a self-employed person wants to conclude a civil occupational disability insurance contract.

81 See e.g. H.T. Greely, *supra* (footnote 3), p. 1504.

82 Cf. J.L. Dolgin, *supra* (footnote 9), p. 774ff. It must be admitted that such anecdotal evidence is hardly supported by strong empirical evidence (see e.g. J. Hustead and J. Goldman, 'The Genetics Revolution: Conflicts, Challenges and Conundra: Genetics and Privacy', 28 *American Journal of Law & Medicine* 285 (2002), p. 294 and M.A. Hall and S.S. Rich, *supra* (footnote 45), p. 302). Both studies however show an increasing interest in genetic information, which may even further increase if genetic testing becomes a more regular part of medical practice; cf. e.g. N.E. Kass, *supra* (footnote 56), p. 303/304.

83 See H.T. Greely, *supra* (footnote 3), p. 1505, K.L. Pickens, 'Don't Judge me by my Genes: A Survey of Federal Genetic Discrimination Legislation', 34 *Tulsa Law Journal* 1998, p. 180, D. Hellman, *supra* (footnote 13), p. 83 and S.M. Suter, *supra* (footnote 11), p. 727.

The opinion that regulation should be first and foremost concerned with genetic information in insurance and employment finds clear expression in the regulative activities hitherto employed at both the federal level and the level of the states.<sup>84</sup> The focus on health insurance may be explained by the particular features of the American health insurance system. Private health insurance in the shape of individual and group health insurance plans is prevailing in the United States.<sup>85</sup> Private health insurers do not have any obligation to accept potential insureds and there is no universal coverage.<sup>86</sup> A number of government-sponsored public health insurance plans are in place (such as Medicare and Medicaid), but these programs are limited to specific groups (eligible low income groups and the elderly).<sup>87</sup> As a result, a relatively large number of American citizens are presently uninsured.<sup>88</sup> If these facts are combined with the knowledge that access to health care is effectively determined by the availability of health insurance, it is understandable that access to genetic information by insurers is considered to constitute an important risk.<sup>89</sup>

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84 For an overview of relevant existing and proposed federal legislation, see J.H. Gerards, 'Regulation of Genetic Information in the United States', in: *Genetic Discrimination and Genetic Privacy in a Comparative Perspective*, *supra* (footnote 2), p. 153ff. A recent overview of state legislation can be found via < [www.genome.gov/PolicyEthics/LegDatabase/pubsearch.cfm](http://www.genome.gov/PolicyEthics/LegDatabase/pubsearch.cfm) > (last visited 23 August 2006). See further the bills presented by the 109<sup>th</sup> Congress. Bill S. 306 (Genetic Information Nondiscrimination Act of 2005, introduced in the Senate by Sen. Snowe on 7 February 2005 and passed by the Senate on 17 February 2005), is solely concerned with health insurance and employment, just like the textually almost identical bill H.R. 1227 (introduced in the House of Representatives by Rep. Biggert on 10 March 2005).

85 Approximately 83% of the American citizens have private health insurance (N.E. Kass, *supra* (footnote 56), p. 300).

86 Cf. Ph.L. Barton, *Understanding the U.S. Health Services System*, Chicago/Washington, AUPHA/HAP 1999, p. 96 and H.T. Greely, *supra* (footnote 3), p. 1488.

87 See further M.D. Reagan, *The Accidental System. Health Care Policy in America*, Boulder: Westview Press 1999, p. 24.

88 An estimated 17% of the American population (about 40 million Americans) is presently uninsured; see G.E. Rejda, *Principles of Risk Management and Insurance*, 6<sup>th</sup> Ed., Reading, Mass.: Addison-Wesley 1998, p. 389 and N.E. Kass, *supra* (footnote 56), p. 300 (mentioning a percentage of 15).

89 This is exacerbated by the fact that most health services in the United States are also organized by the private sector, which leads to enormous costs that have to be borne by the government and employers offering health insurance plans. See Ph.L. Barton, *supra* (footnote 86), p. 77, M.D. Reagan, *supra* (footnote 87), p. 64 and G.E. Rejda, *supra* (footnote 88), p. 388.

By contrast, and different from the European situation, the American life insurance industry has been left relatively undisturbed by legislative activity.<sup>90</sup> Where any restrictions of access to genetic information by life insurers have been introduced at all, they are contained in state legislation.<sup>91</sup> The reasons for this are not quite clear, but an explanation might be found in the fact that the individual interests harmed by the inability to obtain a life insurance policy are perceived to be of less importance, or the life insurance industry is able to protect the interests of actuarial fairness and individual risk classification more strongly than the health insurance industry is.

### 4.3 *'Level' of regulation: regulation by federal/supranational or national authorities?*

#### 4.3.1 *Introduction*

In general, it is possible to characterise legal systems as centralised or federal. The United States and Germany are federal legal systems; France and the Netherlands are legal systems with a more centralized approach. The European Union is a supranational legal system. Federal or supranational legal systems are typically 'multi-level' in character and are characterised by a more or less complex division of powers between the various levels. In such legal systems, an answer will unavoidably need to be given to the question whether genetics legislation or other regulatory measures can be most appropriately and effectively introduced at federal or supranational level, or on the level of the (member) states.<sup>92</sup> Whether genetics legislation may be introduced on the federal/supranational or the state level depends on the constitutional division of powers in a particular legal system and the way the various relevant constitutional or treaty provisions have been interpreted by

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90 Cf. B.M. Knoppers, B. Godard and Y. Joly, 'A Comparative International Overview', in: M.A. Rothstein, *Genetics and Life Insurance. Medical Underwriting and Social Policy*, Cambridge, Mass./London: MIT Press 2004, p. 173 and D. Crosbie, *supra* (footnote 35), p. 34.

91 About one-third of the states have enacted some protection against inappropriate use of genetic information by life insurers; see National Conference of State Legislatures 2003, <<http://www.ncsl.org/programs/health/genetics/ndislife.htm>> (last accessed 23 August 2006).

92 The situation is even more complex in states such as Belgium or Germany, which are federal states themselves, but also take part in the European Union. In these states, an additional level is present, and thereby there are additional choices to be made as to the proper level of regulation. We will not, however, pay attention to this specific situation in this Section.

the courts. As regards the effectiveness of regulation on one or the other level, it is clear that all choices have advantages and disadvantages. An advantage of national regulation or regulation at state level is, for instance, the possible tailoring of measures to local needs. A disadvantage might be that a patchwork of standards of protection is being created. That may be undesirable because of varying levels of protection between states, especially in states in which insurance companies and employers offer both intrastate and interstate service. The result may not only be that individual rights are protected more strongly in one state than the other, but also that the economic interests of insurers and employers are harmed because of high administrative overhead costs. As far as the legal division of competence allows for a choice between the various levels, such factors surely need to be taken into account. In the sections below, we will discuss the preferred levels of regulation in Europe and the United States and the legal possibilities for regulation on such levels.

#### 4.3.2 *Europe*<sup>93</sup>

In the European states under study, wide variation is visible as to regulation of health financing and employment, legal protection of medical privacy and equality legislation. Legislation on the supranational level of the European Union would undoubtedly result in more uniform regulation of the access to and use of genetic information and possibly also in more effective protection of individual privacy. It remains to be seen, however, whether such legislation can actually be introduced and whether there is sufficient political support to do so. Both policy reasons and variations in the legal organisation of health insurance and other kinds of insurance seem to hamper introduction of EU-legislation on the short term. Possibly as a consequence of this, hardly any attention seems to be paid at the European level to the possibility of supranational regulation of genetic discrimination or genetic privacy. Although there is a Directive on privacy covering the protection of personal data<sup>94</sup> which also covers health information<sup>95</sup> and possibly genetic data,

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93 See also A.W. Heringa, 'International and National Legal Instruments, in: Genetic Discrimination and Genetic Privacy in a Comparative Perspective', in: J.H. Gerards, A.W. Heringa and H.L. Janssen, *supra* (footnote 2), p. 44/45.

94 Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ L 281/31. The Directive provide a number of important safeguards, including a duty to inform the individual (Articles 10 and 11), the individual's right of access to data (Article 12), the right to object (Article 14) and rules with respect to confidentiality (Articles 16 and 17).

as well as a (non-binding) Charter of Fundamental Rights which contains a general prohibition of discrimination (including disability discrimination),<sup>96</sup> no initiatives have been introduced thus far that envisage supranational regulation of the use of genetic information by insurers or employers. An important question in this regard is whether it would be legally possible to introduce such regulation in the future. A number of legal bases for such regulation might be found in the EC Treaty, but it is highly questionable whether they will prove to be sufficient.

An interesting legal basis for the introduction of non-discrimination legislation pertaining to genetic information could be found in Article 13 EC-Treaty. On the basis of this Article, the Council of Ministers of the EU may take action against discrimination on any of the grounds mentioned in Article 13 by means of Directives. Although Article 13 itself does not mention 'genetic information' or 'health' as a prohibited ground, a hypothetical possibility is that discrimination on grounds of genetic makeup is covered by the wider ground of (future) disability. Such a wide interpretation should not be expected too easily, however, as the European Court of Justice has thus far shown restraint both in its interpretation of the grounds contained in Article 13 and in its acceptance of 'new' grounds of discrimination.<sup>97</sup> Furthermore, as far as it is possible to show a (statistical) relation

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95 As far as the use of genetic information in health care is concerned, the Directive provides for an exception if "the processing of the data is required for the purpose of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy" (Article 8 (3)).

96 See Article 20 which stipulates that everyone is equal before the law and Article 21 which prohibits discrimination on grounds such as disability and genetic features. With respect to privacy, the Charter covers the protection of private life (Article 7) and the protection of personal data (Article 8).

97 See for the ECJ's approach for example the refusal of recognition of a prohibition of discrimination on the ground of sexual orientation in *P v. S and Cornwall City Council*, Case C-13/94, [1996] ECR I-2143, par. 18-22 and *Grant v. South West Trains*, Case C-249/96, [1998] ECR I-621. See also *Sonia Chacón Navas v. Spain*, Case C-13/05, judgment of 11 July 2006, not yet published, in which the ECJ gave an interpretation of the notion of 'disability' as laid down in the Employment Equality Directive which specifies a general framework for the prohibition of discrimination on the ground of disability (Council Directive 2000/78/EC of 27 November 2000, OJ 2000 L 303/16). The ECJ paid attention to the question whether the ground of 'sickness' should be deemed to be covered by the notion of 'disability', or, if not, if it should be added to the prohibited grounds of discrimination mentioned in the Directive. The ECJ did not want to provide such a wide inter-

between genetic discrimination and grounds such as sex, race and ethnicity, genetic discrimination might be combated by application of the concept of indirect discrimination.<sup>98</sup> To that extent, relatively effective protection is offered at the supranational level indeed. Thus far, only the regulation of disability-, life- and health insurance was exclusively dealt with by the member states, although the Gender Goods and Services Directive contains provisions with respect to the use of sex as an actuarial factor in insurance.<sup>99</sup>

It is not entirely clear though, whether the European Union institutions would have the competence to enact regulations in the field of insurance and employment law with the aim to harmonize genetic testing and the use of genetic information. Article 152 EC-Treaty potentially seems to create a legal basis for the regulation of access to health care and could thus constitute a platform for regulative action. So far, however, this has not taken place. This reluctance could be explained from the perspective of national differences in the fundamentals of insurance and employment regulation in the member states. These differences result in a need for specific, well-tailored legislation on the national level, which may well explain a more reserved attitude by the EU in introducing harmonising regulations. Moreover, it is important to note that the issue of the protection of genetic information does not exclusively and specifically affect the area of health care, but that it is also relevant in other fields where it is much less clear how far the competence of the EU stretches.

Thus, Article 13 of the EU Treaty would presently seem provide the most solid basis for legislation at the supranational level, even though it is far from certain if this provision really leaves room for the inclusion of grounds that are currently not explicitly mentioned. Even if this Article was used as a legal basis, however,

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pretation, however, limiting the prohibition of discrimination to long-term impairments affecting the possibility to engage in professional life.

<sup>98</sup> See the Employment Equality Directive which specifies a general framework for the prohibition of discrimination on the ground of disability (Council Directive 2000/78/EC, *supra* (footnote 97)). In the same year the Race Equality Directive was adopted, which covers the grounds of race and ethnic origin (Council Directive 2000/43/EC, OJ 2000 L 180/22). It may be noted, however, that the material scope of these Directives is limited – with regard to disability, for example, only employment and employment-related matters are covered. The Race Equality Directive has a somewhat wider scope, also covering social security and social advantages – to all probability, its coverage thereby also extends to the domain of health care and may thereby be of relevance to discrimination which is based on health information and which disproportionately affects a specific racial or ethnic group.

<sup>99</sup> See Council Directive 2004/113/EC of 13 December on equal treatment of men and women in the supply of goods and services, OJ 2004 L 373.

difficult questions would arise with regard to the European principle of subsidiarity, which means that regulation on the supranational level is only called for if the member states are not able to regulate the matter as effectively and fruitfully.<sup>100</sup> This is particularly true, since it is clear that most member states are already in a process of adopting regulatory measures in this area, which are specifically geared to their national legal systems and which fit in well with the fundamentals of their systems of health regulation. Comprehensive, uniform and exclusive regulation at EU-level could harm local traditions with regard to employment and insurance regulation. Nevertheless, a lack of uniformity could evidently result in an unworkable patchwork of protection.

#### 4.3.3 *United States*

In the last decade, many of the American states have introduced specific genetics legislation, restricting the access to and use of genetic and other (predictive) health information by employers and insurers. Although a high level of protection might thus seem to be guaranteed, academic commentators and federal legislators have adopted a critical attitude towards the current situation. A particular point of criticism concerns the wide variation in scope and contents of the state legislative measures. Some legislation starts from a source-based definition of genetic information, other legislation shows a content-based definition, and even other legislation covers all personal health information, including non-genetic information. The material scope also varies, ranging from coverage of all types of employment and insurance (including life insurance) to coverage of only a few specified types of health insurance.<sup>101</sup> The result is a patchwork of protection which is considered to offer incomplete and unequal protection and which results in practical burdens for insurance companies or employers operating in different states.<sup>102</sup> Many com-

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<sup>100</sup> Even if there is a legal basis for the European Union to enact legislation, the question if the matter can be better arranged by the national member states must still be answered (see art. 5 EC-Treaty).

<sup>101</sup> See e.g. K.L. Pickens, *supra* (footnote 83), p. 170ff, D. Gridley, 'Genetic Testing under the ADA: A Case for Protecting from Employment Discrimination', 89 *Georgetown Law Journal* 973 (2001), p. 980-981 and R.B. Lanman, 'An Analysis of Current Law in Protecting Against Genetic Discrimination in Health Insurance and Employment', Report to the Secretary's Advisory Committee on Genetics, Health and Society, May 2005, <[www4.od.nih.gov/oba/sacghs/reports/legal\\_analysis\\_May2005.pdf](http://www4.od.nih.gov/oba/sacghs/reports/legal_analysis_May2005.pdf)> (last accessed 23 August 2006), p. 11/12.

<sup>102</sup> Cf. S. Burris and L.O. Gostin, 'Genetic Screening from a Public Health Perspective: Some Lessons from the HIV Experience', in: M.A. Rothstein (ed.), *Genetic Secrets. Protecting Privacy and Confidentiality in the Genetic Era*, New Haven/London: Yale University Press 1997, p. 151, J.G. Kodge and K.G. Gostin, 'Challenging Themes in American Health

mentators therefore favour the introduction of federal legislation, which is a plea that is supported by a relatively large number of Congress members.<sup>103</sup> The fact that a variety of bills have been introduced in Congress during the last ten years bears clear witness to the perceived need for federal legislation.

Still, the issue of federal legislation is controversial, which finds clear expression in the fact that none of the bills introduced since 1995 have been adopted thus far. Next to political reasons,<sup>104</sup> an explanation for this may be found in the limited powers of Congress to introduce legislation in the relevant area. The division of competence between the US government and the states is at least as complex and sensitive as it is in the European Union.<sup>105</sup> Insurance matters are traditionally left to the states and will only be regulated on the federal level if Congress considers state regulation inadequate.<sup>106</sup> Federal competence to regulate employment will only be established if interstate commerce is hampered by the diversity of state legislation,<sup>107</sup> or if federal regulation is necessary to combat persistent and invidious genetic discrimination in the states.<sup>108</sup> Current federal

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Information Privacy and the Public's Health: Historical and Modern Assessments', 32 *Journal of Law, Medicine and Ethics* 670 (2004), p. 671 and R.B. Lanman, *supra* (footnote 101), p. 12.

<sup>103</sup> E.g. J. Chorpene, 'Genetic Disability: A Modest Proposal to Modify the ADA to Protect Against Some Forms of Genetic Discrimination', 82 *North Carolina Law Review* 1441 (2004), p. 1467 and J.A. Colby, *supra* (footnote 6), p. 466.

<sup>104</sup> Cf. A. Silvers and M.A. Stein, *supra* (footnote 19), p. 1375, explaining that Republicans in the House of Representatives have been very reluctant to support earlier bills. The limited political support may be due to rather strong lobbies of insurers and employers, who strongly oppose any restrictions of access to relevant individual information; cf. J.A. Colby, *supra* (footnote 6), p. 468 (footnote 229).

<sup>105</sup> The federal government is entitled to exercise only those powers which are granted expressly and exhaustively to it by the American Constitution. See the Tenth Amendment to the Constitution, but also Section 1 of Article I. In the course of time, the reach of the powers of the federal government has been broadened by means of extensive interpretation of the Constitution. Cf. further L.H. Tribe, *American Constitutional Law. Volume One*, Third. Ed., New York: Foundation Press 2000, p. 789 and 801 ff.

<sup>106</sup> See the *McCarran-Ferguson Act* of 1945 (15 U.S.C. §§ 1011-15). Cf. C.A. Peterson, 'New Twist to an Old Injustice: Genetic Discrimination and Medicare Reform', 36 *Idaho Law Review* 2000, p. 357 and M.A. Rothstein, *supra* (footnote 15), p. 456.

<sup>107</sup> Under the Commerce Clause, the U.S. Congress must show that the regulated activities have a substantial effect on interstate commerce or form an essential part of a larger regulation of economic activity. See *EEOC v. Wyoming*, 460 U.S. 226, at 244 (1997).

<sup>108</sup> See Section 5 of the Fourteenth Amendment as interpreted by the Supreme Court in cases such as *City of Boerne v. Flores*, 521 U.S. 507 (1997) and *Kimel v. Board of Regents*, 528 U.S. 62 (2000). It may be derived from these cases that federal legislation is only acceptable if there is reason to believe that there really is a situation of unconstitutional

bills are all based on the latter argument, stating that genetic discrimination can only be effectively prevented by the introduction of nationwide legislation.<sup>109</sup> It is difficult to predict whether this argument will be accepted by the federal courts, especially since federal age non-discrimination legislation, which was based on a similar line of reasoning, was declared unconstitutional by the Supreme Court in 1997 because it was not sufficiently clear that the legislation responded to a 'significant pattern of unconstitutional discrimination'.<sup>110</sup> It is questionable if such a pattern of discrimination can (already) be considered to exist with respect to genetic information, since, as yet, scientific evidence does not indicate the actual existence of invidious and widespread genetic discrimination. As a constitutional basis for federal legislation, the argument of remedying genetic discrimination would thus seem to be rather weak.<sup>111</sup> It is therefore not unimaginable that constitutional obstacles will stand in the way of federal regulation, even if this would end the situation of fragmentary state legislation.<sup>112</sup>

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discrimination in the states that should be prevented or responded to on the federal level (528 U.S., at 91).

<sup>109</sup> See e.g. S. 306 (*Genetic Information Nondiscrimination Act of 2005*), introduced by the 109<sup>th</sup> Congress, § 2 (4).

<sup>110</sup> The finding of a situation of unconstitutional discrimination strongly depends on the chosen standard of review. With respect to age discrimination, for instance, minimal scrutiny is exercised (see *Kimel*, 521 U.S., at 83 and cf. *Massachusetts Board of Retirement v. Murgia*, 427 U.S. 307, at 312/313). Discrimination is then only considered unconstitutional if it is patently arbitrary (cf. *Flemming v. Nestor*, 363 U.S. 603 (1960)). A stricter test is applied in cases of race and gender discrimination, which are considered 'suspect' and therefore less easily justifiable (see further J.H. Gerards, *Judicial Review in Equal Treatment Cases*, Leiden/Boston: Martinus Nijhoff 2005, p. 465ff). It can be derived from this that congressional action is practically only allowed if there is clear evidence of a significant pattern of patently arbitrary discrimination in the states, or if it is shown that there is widespread discrimination based on a highly suspect ground which would give rise to intermediate or even strict scrutiny. In the latter case, Congress would need to point to a history of purposeful discrimination in the states which reflects prejudice and antipathy against a vulnerable and isolated group (see *Kimel*, 521 U.S., at 83). See also A. Silvers and M.A. Stein, *supra* (footnote 19), p. 1376.

<sup>111</sup> Although it is sometimes argued that genetic information should be seen as a suspect category of information, which would thus constitute a sufficient reason to introduce remedying legislation. Cf. e.g. S. Mezzoff, *supra* (footnote 10), p. 352.

<sup>112</sup> The interest of interstate commerce might be regarded as an alternative basis of federal competence. Thus far, however, this argument has not been used in the federal bills.

## 4.4 *Regulative possibilities*

### 4.4.1 *Introduction*

Once the decision has been made to regulate the use and the collection of genetic or other (predictive) health information on a certain level, it must be decided which regulatory instruments are suitable to achieve the aim of adequate protection of individual interests without overly affecting other relevant interests, such as valid business interests or the interest of the protection of the health of employees. The choice of instruments depends on the desired level of protection to be given to predictive health information and on the question whether existing legislation will be adapted or whether specific and new measures are introduced. Indeed, a wide range of regulatory instruments is available, all having their particular strengths and weaknesses. In this section, we will discuss the various choices made in the United States and in Europe and we will provide some insight in their advantages and disadvantages.

### 4.4.2 *Europe*

#### *Constitutional arrangements*

In the German Constitution, a general prohibition of discrimination and protection of the human personality and human dignity exists.<sup>113</sup> The German Federal Constitutional Court has often interpreted the constitutional provisions into practicable and enforceable rights. The provisions mentioned are broad enough to encompass protection of genetic information, but this interpretation has not yet emerged in the case law of the Federal Constitutional Court.<sup>114</sup> Greece revised its Constitution by including protection for the 'genetic identity' and by strengthening the

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<sup>113</sup> See Art. 1 and 2 of the German Constitution for the right to human dignity and the right to personal development; see Art. 3 for the prohibition of discrimination.

<sup>114</sup> Recently a young teacher in Germany was refused a permanent job on the grounds that members of her family have Huntington's disease and she is therefore at risk of developing the disease herself. The risk was identified on basis of a medical examination that all applicants to the German civil service, including teachers, have to undergo. Under German employment law, government authorities can reject candidates for the civil service on the grounds of ill health to minimise absenteeism and save money. The occupational physician who carried out the medical check reported that the teacher was fit to perform her job but said that there was a 'higher risk' of future absenteeism because of her family medical history. According to the court decision, the woman was denied for the position on incorrect grounds (see Verwaltungsgericht Darmstadt VG Darmstadt: Az.: 1 E 470/04 (3) and see *Frankfurter Allgemeine Zeitung* of 28 June 2004, Nr. 147, p. 30).

protection of personal data.<sup>115</sup> The Swiss Constitution encompasses protection of human genetic material and data since 2002.<sup>116</sup> The Greek and Swiss constitutional provisions provide protection which is oriented towards genetic privacy approach on a more abstract level. The Swiss Constitution explicitly mentions the right to informed consent. The Greek approach aims to include a concept of 'genetic identity'. Protection, enforcement and exceptions have to be arranged by statutory law. Austria, Belgium, Germany, France, the Netherlands and the United Kingdom have no constitutional provisions explicitly referring to genetic information or to a 'genetic identity'.

#### *Statutory legislation*

Constitutional provisions focusing on protection of genetic information may have a politically desirable effect, namely that the protection of genetic information may, as an answer to growing anxiety in a legal system, become more visible and create popular support for initiatives. Constitutional provisions have a strong fundamental value and may serve as an expression of social disapproval of non-medical use of genetic information. But it is questionable if it is sufficient to rely only on this regulative instrument, since the greatest threat of infringements will not be caused by state authorities, but by private parties such as employers and private insurers. Statutory legislation which aims directly at private actors may be necessary in order to regulate such horizontal relationships. Specific regulation at the statutory level has the advantage of creating clarity and enforceability. Looking at the state of affairs in European legal systems, it may be carefully

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<sup>115</sup> The revision took place in 2001; cf. Article 5 of the Greek Constitution. The newly added section in Article 5 reads as follows: "All persons are entitled to the protection of their health and their genetic identity. Matters relating to the protection of every person against biomedical interventions shall be specified by law"; see M. Canellopoulou-Bottis, 'The implementation of Directive 95/46/EC in Greece', *European Journal of Health Law* 2002, p. 211. Article 9A of the Greek Constitution was amended and protects the personal data: "All persons have the right to be protected from the collection, processing and use, especially by electronic means, of their personal data, as specified by law. The protection of personal data is ensured by an independent authority, which is established and operates as specified by law".

<sup>116</sup> Art. 119 of the Swiss Constitution stipulates: "(1) Persons shall be protected against the abuse of medically assisted procreation and gene technology. (2) The Confederation shall legislate on the use of human reproductive and genetic material. It shall ensure the protection of human dignity, of personality, and of family, and in particular it shall respect the following principles: [...] f. A person's genetic material may only be analyzed, registered or disclosed with the consent of that person, or if a statute so provides; g. Every person shall have access to the data concerning his or her ancestry." See <[www.admin.ch/ch/itl/rs/1/c101ENG.pdf](http://www.admin.ch/ch/itl/rs/1/c101ENG.pdf)> (last accessed 23 August 2006).

concluded that the introduction of statutory regulation on genetic information seems to be the main ambition of most states, probably because of its clarity and enforceability. A sectoral approach, in which the collection, disclosure and use of genetic information are laid down in specific regulations for the various relevant areas in which genetic information may be of importance, can be noted in the Austrian, Belgian, Dutch, French, Portuguese, Norwegian and Swiss legislation. In these legal systems, the legislator has opted for 'protection on the spot'. Regulation in these systems focuses directly on insurance and employment and has been introduced in the relevant codes, either by amendment of existing provisions or by insertion of new rules.

The Austrian,<sup>117</sup> Belgian,<sup>118</sup> Dutch,<sup>119</sup> French<sup>120</sup> and Swiss<sup>121</sup> legislators have provided for statutory law with regard to the protection of genetic information. Section 67 of the Austria Gene Technology Act prohibits insurers and employers from obtaining, requesting, accepting or in any other way using the results of genetic analyses of employees, candidate employees, policyholders or insurance applicants. This prohibition is of particular relevance to private insurers, as the public insurance system already provides universal coverage with regard to health insurance. The Austrian Insurance Contract Law was amended in 2000; the prohibition of the use of genetic information by insurers as laid down in the Act remained untouched.<sup>122</sup> The amendment inserted moreover an exhaustive list of the ways in which insurers may obtain personal health data.<sup>123</sup> For employers, no specific legal adjustments have taken place; here the Gene Technology Act still applies. With regard to both insurance and employment, the Federal Personal Data Protection Act applies as well. The Belgian Law on terrestrial insurance contracts (1992) prohibits the use of genetic testing that enables to predict the future state of health. Applicants for insurance are thus prohibited from revealing results of genetic testing to insurers and there is a prohibition on the use, processing and transmission of pre-symptomatic genetic information in insurance. In 2003, the Belgian federal parliament enacted a law prohibiting the use of predictive

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117 *Gentechnik Gesetz* (Austrian Gene Technology Act); see <<http://www.bmbwk.gv.at/forschung/recht/gentechnik/gtg.xml>>.

118 See *Landverzekeringovereenkomst*, Law of 25 June 1992, Belgian Official Journal of 20 August 1992; see also <[www.law.kuleuven.ac.be/icri](http://www.law.kuleuven.ac.be/icri)> (last accessed 23 August 2006).

119 See *Wet Medische keuringen* (Dutch Act on Medical Examinations) 1998, *Staatsblad* (Official Gazette) 1997, 365; see <[www.overheid.nl](http://www.overheid.nl)> (last accessed 23 August 2006).

120 See below.

121 See below.

122 See *Vertragsversicherungsgesetz* 1958, Article 11.

123 *Vertragsversicherungsgesetz* 1958, Article 11 (2) 1-5.

genetic testing (and testing on HIV) for work related purposes as a principle; the Crown may adopt measures that deviate from this principle.<sup>124</sup> A bill (2002) has been launched in Belgium on a prohibition of discrimination on the basis of genetic characteristics with regard to insurance and employment.<sup>125</sup>

In France, sectoral legislation was introduced in 2002.<sup>126</sup> The Civil Code,<sup>127</sup> the Insurance Code,<sup>128</sup> the Criminal Code<sup>129</sup> and the Code on Labour Law<sup>130</sup> have been amended and now offer protection for genetic information. The Civil Code stipulates that the genetic study of an individual's characteristics can only be carried out for medical purposes or for scientific research.

The German Ministry of Justice currently prepares a draft with regard to genetic testing that should limit the use of genetic information by insurers.<sup>131</sup> No specific statutory legislation is in place here yet.

Likewise, the Greek legislator has not yet drafted sectoral legislation; compliance with the prohibition of processing and the use of genetic information is supposed to be covered by Law 2472/97 which protects sensitive health data and inherently genetic information. In the Netherlands, statutory legislation was enacted in the Medical Examinations Act, which regulates medical examinations for the purpose of employment (also in public service), pension- and life-insurance and disability insurance related to employment.<sup>132</sup> This act encompasses the protection of privacy: no questions may be asked, if these questions or medical examinations

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<sup>124</sup> See *Loi relative aux examens médicaux dans le cadre des relations de travail (1)*, 28 January 2003 (Service Public Fédéral Emploi, Travail et Concertation Sociale).

<sup>125</sup> The Belgian Bill on a prohibition of discrimination on the basis of genetic traits has not entered into force yet (see *Voorstel tot instelling van een verbod op discriminatie op grond van genetische kenmerken*, 11 September 2002, <[www.dekamer.be/FLWB/PDF/50/2018/50K2018001.pdf](http://www.dekamer.be/FLWB/PDF/50/2018/50K2018001.pdf)> (last accessed 23 August 2006)).

<sup>126</sup> See for an overview F. Ewald, *The philosophical aspects of genetic testing: the example of insurance*, Working Paper in Report of the European Group on Ethics on new Technologies: Genetic Text in the Workplace, Proceedings of the Round Table Debate, held in Brussels on 6 March 2002.

<sup>127</sup> Art. 16-10 of the Civil Code, see Law no. 94-653 (1994) updating the Civil Code; see also the Ethics Report of the Comité Consultatif National d'Éthique pour les sciences de la vie et de la santé, 30 October 1995.

<sup>128</sup> Art. L 133-1, *Code des Assurances*, updated by law 2002-2)03 (*Journal Officiel* 5 March 2002, see <[www.legifrance.gouv.fr](http://www.legifrance.gouv.fr)> (last accessed 23 August 2006)).

<sup>129</sup> Art. 226-26 of the Criminal Code states that the use of information about an individual which has been obtained by studying his genetic characteristics other than for medical or scientific purposes is punishable with one year imprisonment or a fine of €15.000.

<sup>130</sup> *Code du Travail*, L 122-45, Art. 7.

<sup>131</sup> Bill on *Genetische Untersuchungen beim Menschen*, or 'Gendiagnostikgesetz' (bill of 15 October 2004).

<sup>132</sup> See Dutch Act on Medical Examinations, Art. 1 (a).

lead to a disproportional infringement in the private sphere of the individual.<sup>133</sup> The act specifies the circumstances under which contractual freedom will be set aside.<sup>134</sup> Some cases where the interest of the individual does not outweigh the expected risks – such as the situation in which an examination on whether somebody is a carrier of a severe, untreatable disease (in the future), or the confrontation of the individual with knowledge about his future health perspective – are considered as disproportional infringements.<sup>135</sup> The Norwegian Gene Technology Act and the Act relating to the application of biotechnology in medicine both apply to the use of genetic information.<sup>136</sup> Genetic testing may only be carried out for medical purposes. Insurers and employers cannot inquire after genetic information about genetic testing in the past.<sup>137</sup> The Portuguese legislator implemented the EU-Directive 95/46/EC and added to the list of data disclosure of which is prohibited ‘genetic data’.<sup>138</sup> In 2004, the Swiss Act on genetic research on humans came in force.<sup>139</sup> This Act arranges for a financial ceiling; under a certain amount no predictive genetic testing can be asked for by insurers.<sup>140</sup> Finally, the United Kingdom has not enacted sectoral legislation so far, but this is currently being discussed.

### *Self-regulation*

Although the introduction of statutory legislation has a lot of advantages, it suffers from inflexibility (albeit in a different degree than constitutional provision). The democratic processes which lead to statutory legislation are usually time-consuming

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<sup>133</sup> Art. 3 (1) of the Act on Medical Examinations.

<sup>134</sup> J.K.M. Gevers, *De Wet medische keuringen in het perspectief van mensenrechten*, *NJCM-Bulletin* 1999, p. 448.

<sup>135</sup> J.K.M. Gevers, A.C. Hendriks *et al.*, *supra* (footnote 1), p. 99.

<sup>136</sup> Act No. 56 of 5 August 1994; this law was updated at 30 June 1995, 16 May 1997 and 27 March 1998. EU-Directive 95/46/EC was implemented in Norwegian law as well; Norway was obliged to do so since it is a member of the EEA agreement that determines that the Directive has binding force on the EEA-members.

<sup>137</sup> T. McGleenan and U. Wiesing, ‘Insurance and Genetics: European Policy Options’, *European Journal of Health Law* 2000, p. 377.

<sup>138</sup> Article 7 of Act 67/98 of 26 October 2001 regulates the Protection of Personal Information, in which the EU-Directive was implemented. Article 7 of the Act stipulates: “The processing of personal data revealing [...] data concerning health or sex life, including genetic data, shall be prohibited.”

<sup>139</sup> *Bundesgesetz über genetische Untersuchungen beim Menschen*, Act of 8 October 2004, see <[www.admin.ch/ch/d/ff/2004/5483.pdf](http://www.admin.ch/ch/d/ff/2004/5483.pdf)> (last accessed 23 August 2006). The act determines the circumstances under which insurers and employers may ask for genetic testing (articles 26 and 27 of the Act).

<sup>140</sup> See Article 27 (1) d of the Act.

and progress often depends on a long process of building up political support. It is difficult to adapt statutory legislation to new scientific and social developments, which might be problematic in a fast-evolving area like that of genomics. Soft law instruments such as self-regulation, the imposition of temporary moratoria and the publication of guidelines would seem to meet the need for flexibility and adaptability better than statutory legislation does. On the other hand, the protection offered by those instruments is weaker and thus less well enforceable.<sup>141</sup> Compliance with moratoria, for example, is mostly provided for by the insurance industry itself, and moratoria may be changed or abolished after a certain period of time. No research has been conducted with regard to the effectiveness of moratoria, but it may be expected that they are rather effective under the condition that the insurance has a strong interest in avoiding free-rider behaviour that might disturb regular competitive relationships. Still, the regulation of genetics has thus far exclusively been left to self-regulation by the market (within certain limits) in a number of member states. In the United Kingdom, for example, insurance companies have agreed with the government on a moratorium which will extend the existing voluntary moratorium on insurers' use of predictive test results by five years to 1 November 2011.<sup>142</sup> As a result, insurance customers will not be required to disclose the results of genetic tests for insurance policies up to £ 500.000 of life insurance, or £ 300.000 for critical illness insurance or paying annual benefits of £ 30.000 for income protection insurance. A moratorium was accepted in Germany as well and has been validated until 2011 for policies over €250.000.<sup>143</sup> The Netherlands allows a similar construction, determining ceilings

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<sup>141</sup> The moratorium in the United Kingdom has been criticised for this reason: not all insurance companies are members of the Association who concluded the concordat; 97% of the insurance industry is a member. See Gene Watch UK, 'Genetic discrimination by insurers and employers: still looming on the horizon. An update on the use of genetic test results by employers and insurers', February 2006, see <http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/GeneticTestingUpdate2006.pdf>.

<sup>142</sup> *Concordat and Moratorium on Genetics and Insurance*, HM Government and Association of British Insurers, March 2005. The concordat will be reviewed in 2008. Most importantly, it stipulates that insurers should not treat customers who have adverse predictive genetic test result less favourably than others, without a reasonable justification. Technical, clinical and actuarial relevance of test results should be subject to independent supervision and customers should receive clear explanation of their rights. Moreover, insurers and customers should have equal access to information that is material and relevant for insurance underwriting, taking into account exceptions as provided for in the concordat.

<sup>143</sup> Press release of the *Gesamtverband der Deutschen Versicherungswirtschaft*, 7 October 2004.

indicating a restriction of the use of genetic tests.<sup>144</sup> Under that ceiling it is no longer the industry but the legislator that determines the ceiling.<sup>145</sup> In Belgian, Norwegian and Austrian legislation there is no space left for self-regulation or for co-regulation since they explicitly prohibit the use of genetic testing under any circumstance in insurance or employment.

#### 4.4.3 *United States*

For the United States it is relatively clear that existing legislation offers insufficient protection against the misuse of predictive health information by non-medical actors. There is currently no general federal legislation in place that expressly and adequately protects individual rights in the relevant area. The US Constitution offers protection only against state action, not against discrimination by private employers or insurers. To some extent this gap is filled by the Civil Rights Act of 1964 and the Americans with Disabilities Act, but these Acts do not expressly refer to discrimination based on genetic or personal health information.<sup>146</sup> The interpretation thus far given to both Acts by the Supreme Court does not seem to leave much room for protection against such discrimination either.<sup>147</sup>

This might seem different for specific health insurance legislation. Such legislation as the Employee Retirement Income Security Act (ERISA),<sup>148</sup> the Health Insurance Portability and Accountability Act (HIPAA)<sup>149</sup> and the Genetic

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<sup>144</sup> The Dutch Medical Examinations Act has set limits for disability insurance (€30.901 for the first year of disability benefits and €21.267 for consecutive years) and for life-insurance (€159.505). See Art. 5 (2) of the Act.

<sup>145</sup> The Dutch Act on Medical Examinations also prescribes stakeholders such as representative employers' organisations and employers, consumers, patients and insurers to enter into agreements by self-regulation on the further application of the legal norms that are laid down in the Act and on the establishment of an independent commission where complaints can be filed. Should the parties not be able to reach an agreement, the legislature will take over again after three years. See art. 9 and 14 of the Act.

<sup>146</sup> For a recent overview of the protection offered by the ADA and the Civil Rights Act 1964 against genetic discrimination and violations of genetic privacy, see J.H. Gerards, *supra* (footnote 84), p. 153ff and 168ff. Cf. also S. Mezoﬀ, *supra* (footnote 10) and J. Chorpénning, *supra* (footnote 105), p. 1451ff.

<sup>147</sup> Cf. e.g. S. Mezoﬀ, *supra* (footnote 10), p. 354.

<sup>148</sup> See 29 U.S.C. Chapter 18 (as amended by HIPAA); see in particular § 1140.

<sup>149</sup> Pub. L. 104-191. The amendments made by HIPAA are included in ERISA; see 29 U.S.C. Chapter 18. Highly relevant is also a regulation pertaining to privacy and confidentiality of health information (not limited to genetic information!) that has been adopted on basis of HIPAA: the Privacy Regulation of 2001 (45 C.F.R. Part 160, 162 and 164 (2004)). For an overview and critique see M.C. Pollio, 'The Inadequacy of HIPAA's Privacy Rule: The Plain Language Notice of Privacy Practices and Patient Understanding', 60 *New York*

Executive Order<sup>150</sup> contain various clauses safeguarding genetic privacy and non-discrimination interests.<sup>151</sup> Most commentators agree, however, that this protection is fragmentary and insufficient and that it will be difficult to answer to the risks posed by the availability of predictive personal health information by amending existing legislation alone.<sup>152</sup>

For this reason it is often stressed that new, specific legislation is needed to fill up existing gaps. The introduction of a general non-discrimination or privacy clause in the Constitution or in a general non-discrimination act such as the Civil Rights Act does not seem to be regarded as a serious option.<sup>153</sup> Instead, both state legislation and federal legislative proposals focus on the inclusion of non-discrimination and privacy clauses in sectoral legislation, such as legislation aiming at the health insurance industry or employers in general. Such an approach is considered desirable to meet the different demands and needs of each field and to strike an appropriate balance between the interests involved.<sup>154</sup>

In our study, we did not investigate all regulative instruments that the American states have adopted to combat genetic discrimination, but it is evident that a wide

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*University Annual Survey of American Law* 579 (2004).

<sup>150</sup> Exec. Order No. 13145, 65 Fed. Reg. 6877 (2000); this Order only covers federal employees and does not have any binding force. See also the EEOC Policy Guidance on Executive Order 13145, <[www.eeoc.gov/policy/docs/guidance-genetic.html](http://www.eeoc.gov/policy/docs/guidance-genetic.html)> (last accessed 23 August 2006).

<sup>151</sup> See further J.H. Gerards, *supra* (footnote 84), p. 171ff.

<sup>152</sup> This criticism is widely held, particularly with respect to privacy and non-discrimination protection in health insurance; see e.g. J.A. Colby, *supra* (footnote 6), p. 468, C.S. Diver and J.M. Cohen, *supra* (footnote 13), p. 1450, J. Hustead and J. Goldman, *supra* (footnote 83), p. 292, K.L. Pickens, *supra* (footnote 83), p. 174 and N.E. Kass, *supra* (footnote 57), p. 313. In the field of employment law, similar criticism has been leveled (in particular by M.S. Dichter and S.E. Sutor, 'The New Genetic Age: Who is 'An Individual with a Disability'? Do Our Genes make us Disabled Individuals under the ADA?' 42 *Villanova Law Review* 613 (1997), p. 626 and K.A. Steinforth, 'Bringing your DNA to Work: Employers' Use of Genetic Testing Under the Americans with Disabilities Act', 43 *Arizona Law Review* 965 (2001), p. 969), although Gridley and Gostin have submitted that the present legislation offers sufficient possibilities for the prevention of genetic discrimination; see D. Gridley, *supra* (footnote 101), p. 998 and L. Gostin, *supra* (footnote 102), p. 143.

<sup>153</sup> Such a proposal is only rarely made. See e.g. A. Silvers and M.A. Stein 2003, *supra* (footnote 19), p. 382, proposing an amendment to Title VII of the Civil Rights Act to include discrimination based on genetic identity.

<sup>154</sup> Cf. M. Powers, *supra* (footnote 6), p. 371/372.

range of instruments is used.<sup>155</sup> The state governments seem to make little use of two instruments that are commonly employed in the European states, *i.e.* the introduction of moratoria and the setting of financial ceilings above which the use of genetic information by insurers is allowed.<sup>156</sup> An explanation for this may be that both instruments have been severely criticised in American academic literature and by specialists in the field of insurance. Moratoria are objected to because of their absolute character (they constitute a complete prohibition on all use of genetic information, albeit temporarily) and because of the fear that, once a moratorium is imposed, it may be difficult to remove.<sup>157</sup> Ceiling setting would be a better solution from this perspective, but it is criticised for the fact that it does not solve the problems related to the proper definition of genetic information. Moreover, the method of ceiling setting would lead to an undesired need for price adjustments.<sup>158</sup> Finally, the industry has opposed the introduction of restrictive measures or moratoria, even by means of self-regulation, as it would be difficult to police such measures effectively against non-conforming insurers or employers. This would be undesirable from the perspective of competition.<sup>159</sup>

Little serious consideration has further been given to solutions in the sphere of reforming the American health insurance system into a more publicly organised system based on solidarity.<sup>160</sup> The same is true for the suggestion that a fund could be created to subsidise insurers for accepting high risks against an affordable

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<sup>155</sup> The legislation would seem to show less variety than in Europe, however. At least in the life insurance branch, no use is currently made of moratoria or ceiling setting. For a critical overview of regulative possibilities see M.A. Rothstein, 'Policy Recommendations', in: M.A. Rothstein, *Genetics and Life Insurance. Medical Underwriting and Social Policy*, Cambridge, Mass./London: MIT Press 2004, p. 254ff.

<sup>156</sup> For an explanation of the use of these instruments in Europe, see T. McGleenan and U. Wiesing, *supra* (footnote 137), p. 374 and 375.

<sup>157</sup> See M.A. Rothstein 2004, *supra* (footnote 155), p. 255.

<sup>158</sup> *Id.*, p. 257.

<sup>159</sup> See R.H. Jerry II, 'Antitrust Implications of Insurers' Collaborative Standard Setting', in: M.A. Rothstein, *Genetics and Life Insurance. Medical Underwriting and Social Policy*, Cambridge, Mass./London: MIT Press 2004, p. 214.

<sup>160</sup> See E. Draper, *supra* (footnote 73), p. 318.

rate.<sup>161</sup> Both solutions would demand complete restructuring of the health insurance market, which seems to be politically unfeasible at present.<sup>162</sup>

Instead, other solutions have been chosen. Most common are the introduction of requirements of informed consent; restrictions on access to information; and prohibitions of unfair use of genetic information.<sup>163</sup> These solutions will be discussed in section 4.5.3 below.

## 4.5 *Privacy or non-discrimination approach; or both?*

### 4.5.1 *Introduction*

Several approaches can be adopted to prevent employers and insurers from collecting, using and disclosing genetic and other predictive health information, regardless of the regulatory instrument that is chosen. In the first place, it is possible to opt for a privacy approach, which is specifically used to protect aspects of informational privacy, confidentiality of information, and, as a concrete aspect of the notion of self-determination, the right “not to know”. The choice for a privacy approach would imply that employers and insurers or other actors are explicitly prohibited from having access to genetic information and are prevented from requiring and requesting individuals to undergo a genetic test and to learn about the results. It may also mean that specific measures are introduced to safeguard the confidentiality of genetic information which has become available as a result of medical examinations.

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<sup>161</sup> See e.g. M.M.R. Radetzki and N. Juth, *Genes and Insurance (Ethical, Legal and Economic Issues)*, Cambridge: Cambridge University Press 2003, pp. 73-75. See also R.A. Epstein, ‘The Legal Regulation of Genetic Discrimination: Old Responses to New Technology’, 74 *Boston University Law Review* 1 (1994), p. 20/21.

<sup>162</sup> See M.A. Rothstein, *supra* (footnote 15), p. 456, J. Chorpening, (footnote 103), p. 1471 and cf. T. McGleenan and U. Wiesing, *supra* (footnote 137), p. 371. Interestingly, however, the American Academy of Actuaries has suggested to strengthen the safety nets of Medicare and Medicaid to insure universal access to a minimum level of disability insurance and long term care coverage (American Academy of Actuaries, *The Use of Genetic Information in Disability Income and Long-Term Care Insurance*, Issue Brief Spring 2002, p. 9). Such a system would surely, at least to some extent, diminish the risk of having no access to important social goods because of genetic information, although it would not solve all questions of informational privacy – after all, such information would still be required in the private market supplementing the safety net.

<sup>163</sup> For an overview see National Conference of State Legislatures 2003, <[www.ncsl.org/programs/health/genetics/ndislife.htm](http://www.ncsl.org/programs/health/genetics/ndislife.htm)> (last accessed 23 August 2006).

In the alternative, a non-discrimination approach can be chosen, not so much to protect individuals from *disclosure* of genetic information, as well as to protect them from the *use* of such information. This approach would imply that employers and insurers are prevented from distinguishing between (candidate) employees and potential insurance-takers on the basis of genetic information. By using this approach, unjustified disadvantage based on unalterable personal characteristics is prohibited.

Finally, it is possible to use both approaches in combination. Indeed, this approach seems to be favoured in academic literature, as neither the privacy nor the non-discrimination approach does provide adequate protection against misuse of genetic and other types of predictive health information. The privacy approach would not, after all, protect individuals against misuse of knowledge which an insurer or employer may eventually acquire. The adoption of a non-discrimination approach, on the other hand, does not in itself prevent non-medical actors from collecting or acquiring personal health information. Even if he would not be allowed to use such information, the interests of privacy and self-determination might thus be seriously impaired.

In deciding about the regulative approach to be taken, it is therefore important to guarantee that both the aspect of confidentiality and privacy and the aspect of misuse are covered. It is interesting to investigate if current legislation in the US and in Europe indeed offers such comprehensive protection, or, alternatively, starts from either a privacy or a discrimination centred approach.

#### 4.5.2 Europe

In European legal systems, genetic information is primarily protected by means of privacy legislation and seems rather generous. The regulations cover not only the confidentiality of sensitive health information, but also prohibit in a number of legal systems the collection, use and processing of such information. It may be argued that such an overall prohibition of access to genetic information in the sphere of privacy comes close to a general prohibition on the use of genetic information, offering strong indirect protection against genetic discrimination. But there may be undesirable consequences of a total ban on the use of genetic information in all circumstances. Interests of insurers cannot not taken on board, which may well lead, as has been shown in a study on Belgium and Austria, to adverse selection.<sup>164</sup> Some European legal systems allow the use of genetic information.

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<sup>164</sup> See also H. Nys, I. Dreezen, I. Vinck and K. Dierickx, *Genetic Testing. Patients' rights, insurance and employment. A survey of regulations in the European Union*, European Commission: Brussels 2002, p. 141.

Once this is allowed, a prohibition of discrimination on the basis of genetic information becomes more urgent. But so far, only the Swiss law refers explicitly to the prohibition of discrimination.<sup>165</sup> With regard to discrimination prohibitions at EU-level, Art. 13 EC-Treaty may provide a sound basis for the development of legal norms protecting against genetic discrimination. But Art. 13 contains a limitative list of discrimination grounds, and genetic information is not one of them. It may however find protection in an indirect manner, e.g. through the prohibition of discrimination on the basis of race, ethnic origin or sex.

The choice for the protection of genetic information by privacy-oriented regulations may be explained by the wish to grant individuals more power over their genetic information by stressing the concept of informed consent.<sup>166</sup> It is not clear, however, whether this approach will offer sufficient protection. Especially in situations where the individual gets involved in a relationship of dependence – clearly visible in the underwriting process of an insurance policy or in underwriting a contract with an employer – the concept of power over one's own genetic information may become relative. At the same time there are situations where it is to the benefit of the individual to undergo a genetic test in an employment relationship, for example where it concerns workplace conditions that may affect the individuals' health. A prohibition of discrimination may have added value here.

#### 4.5.3 *United States*

American legislation generally shows a two-pronged approach towards protecting individuals against misuse of genetic information.<sup>167</sup> Firstly, legislation is in place to safeguard individual medical privacy by controlling the disclosure of information and by preventing insurers and employers from having easy access to private information.<sup>168</sup> To this end employers and insurers are, with some exceptions,

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<sup>165</sup> See Art. 4 of the *Bundesgesetz über genetische Untersuchungen beim Menschen*. The Belgian Bill on a prohibition of discrimination on the basis of genetic traits has not entered into force yet (see *Voorstel tot instelling van een verbod op discriminatie op grond van genetische kenmerken*, 11 September 2002), <[www.dekamer.be/FLWB/PDF/50/2018/50K2018001.pdf](http://www.dekamer.be/FLWB/PDF/50/2018/50K2018001.pdf)> (last accessed 23 August 2006).

<sup>166</sup> J.H. Gerards, 'Conclusions', in: *Genetic Discrimination and Genetic Privacy in a Comparative Perspective*, *supra* (footnote 2), p. 235/236.

<sup>167</sup> Such an approach is also favoured by most commentators, who argue that either a pure privacy-based model or a pure non-discrimination based model would offer insufficient protection. See e.g. J. Chorpening, *supra* (footnote 103), p. 1469.

<sup>168</sup> This is of particular interest for those employers that happen to possess medical information about an employee, for instance because they also act as health insurance agents; see on the confidentiality of medical and genetic data in particular S. 306 SE, § 206.

prohibited from requesting or collecting genetic information and from requiring individuals to undergo a genetic test and disclose the results.<sup>169</sup> Such prohibitions also diminish the risk for discrimination on the basis of genetic information. After all, the opportunities for employers and insurers to make use of personal health information are reduced by restricting the possibilities for having access to such information. Still, the need is felt to reduce the possibility that employers or insurers misuse any information they eventually acquire.<sup>170</sup> Academic commentators have therefore proposed that legislation should also contain restrictions on the use of genetic information, which suggestion has been followed in several bills introduced during the last decade.<sup>171</sup> The most recent bills on the issue, S. 306 SE and H.R. 1227, contain provisions that explicitly prohibit any employment practice that would disadvantage an employee or job applicant because of his or her genetic information,<sup>172</sup> or prohibit insurers from using genetic information in determining an individual's eligibility or in premium setting.<sup>173</sup> It is then not so much genetic *discrimination* that is prohibited (which would imply a comparative element: the individual would need to show that he has been treated differently from someone else), as well as the unjustifiable *use* of genetic information. The result of this approach is a relatively light burden of proof for victims of genetic discrimination, who only need to show that the employer or insurer has used genetic information in taking a disadvantageous employment or insurance decision.

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<sup>169</sup> With respect to insurance see in particular S. 306 SE, § 101(c)(1) and § 104(c). Interestingly, this prohibition on the collection of genetic information is rather absolute: no room is left for voluntary and informed disclosure by the individual insured or employee himself, such as has been proposed by some commentators (see e.g. T. Sorell, 'The Insurance Market and Discriminatory Practices', in: J. Burley and J. Harris, *A Companion to Genetics*, Malden: Blackwell 2002, p. 402 and R.J. Pokorski, *supra* (footnote 37), p. 103/104).

<sup>170</sup> See A. Silvers and M.A. Stein 2003, *supra* (footnote 19), p. 378.

<sup>171</sup> See J. Hustead and J. Goldman, *supra* (footnote 82), p. 287 and M.A. Rothstein 1997, *supra* (footnote 15), p. 471. Recommendations to this effect are also made by ELSI (the Ethical, Legal and Social Implications Working Group of the National Human Genome Research Institute) (ELSI et al., *Genetic Information and the Workplace: Implications for Employment, Insurance and Privacy*, 1996, <[www.genome.gov/10001746](http://www.genome.gov/10001746)> (last accessed 23 August 2006)) and by the US Department of Labor, in cooperation with the Department of Health and Human Services, the Equal Employment Opportunities Commission and the Department of Justice (*Genetic Information and the Workplace*, 1998, ([www.genome.gov/10001732](http://www.genome.gov/10001732)) (last accessed 23 August 2006).

<sup>172</sup> See S. 306 SE § 202(a).

<sup>173</sup> See e.g. S. 306 SE § 101(a)(2) and (3) (no discrimination in group premiums based on genetic information) and § 102(b) (prohibition on genetic information as a condition of eligibility).

## ***4.6 Flexible of rigid approach; wide or narrow exceptions?***

### *4.6.1 Introduction*

If it has been decided that it is desirable to restrict the use and collection of genetic information, it is necessary to consider how the relevant measures should be designed. Such design will depend on the definition of genetic information (source-based or content-based), the character of the measures (constitutional protection, statutory regulation, self-regulation with or without moratoria, guidelines) and on the choice for a privacy or for a non-discrimination approach (or a combination of both). As argued before, genetics legislation moreover requires a complicated balance of interests, which may have great influence on the final design of the regulatory instruments. The balance that is struck between these interests may be reflected by the introduction of restrictive measures providing for a number of exceptions to accommodate for the legitimate interests of employers and insurers. Such measures can be designed in a variety of ways. It is possible, for instance, to introduce general, broadly formulated legislation, containing loosely defined exceptions. The application of such provisions is then primarily left to administrative bodies and to the courts, which will have to decide about their correct interpretation. Such broadly defined provisions have the advantage of flexibility and adaptability to new scientific insights and social developments. Alternatively, it is possible to opt for carefully defined provisions and strictly formulated exception clauses, which are less flexible in character, but provide for much legal certainty and clarity, which is beneficial to both market actors and individuals.

Below, our findings with respect to the choices made in the legal systems under study are described and discussed: do they adopt a flexible or rigid approach, and do they allow for widely or narrowly formulated exceptions, and for which reasons?

### *4.6.2 Europe*

The approaches which have been taken in the regulatory arrangements in the European states show a large variation. They may be strict, as in Austria, Belgium, France and Norway, where the collection and use of genetic information for all commercial purposes is prohibited. Austria and Belgium are even stricter than this: their laws not only prohibit insurers from asking for genetic testing, but also prohibit insurance takers from submitting favourable test results to get lower premiums or more interesting insurance contracts. In addition, Austria and Belgium have not formulated exceptions in their legislation. A more flexible approach can be found in the legislation in the Netherlands. Section 5 (2) of the Medical Ex-

aminations Act in principle prohibits medical checks connected to the conclusion of insurance contracts. It provides that no such medical test shall involve questioning the applicant's blood relatives – not even if the illness has already manifested itself or the blood relative has died from it – or, unless the condition is manifest, the applicant himself about hereditary conditions, or about genetic tests undergone by the applicant or his blood relatives. But when the sum insured exceeds financial enquiry limits, this information can be asked for.<sup>174</sup> The evaluation of the Act identified two problems relating to this provision.<sup>175</sup> First, a rather innocent hereditary disease does not have to be announced if the knowledge results from former examinations. However, it has to be announced if the carrier knows about the disease from other sources. Secondly, article 5 refers to 'serious and untreatable diseases' in art. 3 of the Act. Moreover, it refers to diseases that are not yet manifest. There is no exhaustive list of serious and untreatable diseases, and it is not clear when exactly a disease becomes manifest. The United Kingdom and German legislatures have not regulated the protection of genetic information at any level yet. The discussions in the United Kingdom about forthcoming legislation, however, do not give the impression that a strict approach will be chosen. Both legal systems seem to rely on protection by the courts (especially Germany) and on codes of good practice (see the aforementioned concordat of the Association of British Insurers).

With respect to employment, exception clauses do exist in many states. In particular, employers are often allowed to request genetic information from the individual (directly or through a medical practitioner), provided that such information is necessary for or directly related to the employee's professional activities. In the Netherlands, medical examinations for the appointment of a job have to serve the medical requirements of the particular job.<sup>176</sup>

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<sup>174</sup> The following limits were determined: disability insurance €30.901 for the first year of disability benefits and €21.267 for consecutive years and life insurance €159.505. See Art. 5 (2) of the Act.

<sup>175</sup> M. Westerveld and M. Aerts, 'Nieuwe regels voor het verzekeringskeuren: Evaluatie van drie jaar wetstoepassing', *Nederlands Juristenblad* 2002, p. 118-126.

<sup>176</sup> If medical information is necessary, the following conditions apply to the examination: 1) the medical requirements and the execution of the examination must be described before the selection procedure starts; 2) at the start of the selection procedure, the applicants have to be informed about the medical requirements and about the medical examination; the examination has to be performed at the end of the selection procedure, when the candidate is chosen for the job if he is medically eligible and 4) no one is allowed to get information from third parties such as the family doctor or the former employer about the health condition of an applicant without the consent of the applicant. See art. 4 (1) of the Act.

Flexible laws have the advantage of leaving more room for (judicial) interpretation. This can be considered an asset since genetic information is still a developing concept and judicial interpretation may accommodate for future developments. The disadvantage of such formulations is that they can create legal uncertainty until the moment of application for individuals, insurers and employers as to the exact consequences of access to and use of genetic information. There seems to exist consensus about the point of view that the health of the individual and access to health protection prevails over other purposes that can be served by genetic information. In some legal systems there is explicit room for exceptions, albeit that the exception must meet the demands of proportionality and necessity. For example, ceilings of insurance sums determine the extent to which individuals should have access to health insurance or to life insurance.

An absolute prohibition may at first sight be most protective for individuals, but not take sufficient account of the interests of the insurance industry. A ban could expose the insurers to the danger of adverse selection and selective withdrawal which, if experienced on a large scale, could harm the viability of the industry. Early reviews of the operation of the Austrian legislation suggest for instance that there is a divergence between the informal practice of insurance and the strong prohibitions in the law.<sup>177</sup> Here, the attraction of a ceiling system may become clear: it reduces the effects of adverse selection by permitting the insured to seek a bargain or to transfer risks but only within well-defined financial limits. Moratoria and self-regulation are not sufficient in themselves, especially when a sanction system is lacking. They were and have been used as a response of the insurance industry because there are very few relevant and accurate predictive genetic tests available.

#### 4.6.3 *United States*

The present US legislation that is relevant to genetic non-discrimination and privacy interests is, over all, characterised by rather wide and flexible exemptions. Both

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<sup>177</sup> H. Nys, I. Dreezen, I. Vinck and K. Dierickx, *supra* (footnote 163), p. 18. Inquiries made with applicants to the private insurance companies indicate that the insurer cannot force applicants to have genetic tests, and will therefore not pay for such tests. However, those at risk and therefore already on a higher premium often undergo tests at their own expense and some applicants have had their premium reduced as a consequence of negative test results. The existence of a law prohibiting insurers from using genetic test results does not necessarily prevent an applicant for insurance from using that information at his own advantage. See also G. Hauser and A. Jenisch, 'Laws regarding insurance companies', in *Journal of Medical Genetics* 1998, p. 526.

the Americans with Disabilities Act (ADA) and the Civil Rights Act of 1964 contain broadly formulated exception clauses which allow, for example, for the use of protected information if the information discloses an 'inability to perform essential job-functions'.<sup>178</sup> In the course of time these clauses have become somewhat less flexible and open as a result of interpretation and refinement by the American courts. It is questionable, however, if this has led to more adequate protection of the right to privacy and non-discrimination, as the federal courts have applied the relevant clauses of the ADA often (though not always) in favour of employers.<sup>179</sup> In addition, it is doubtful if a genetic predisposition to a disease or disorder would be considered a disability under the ADA at all.<sup>180</sup>

Possibly in reaction to the judicial interpretation of both the scope and the exception clauses of the ADA, the genetic information bills presently under debate in Congress contain much more narrowly formulated exception clauses.<sup>181</sup> The

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<sup>178</sup> See for a discussion of these and other exception clauses J.H. Gerards, *supra* (footnote 84), p. 160ff. See specifically on the ADA also B. Kauffman, 'Genetic Discrimination in the Workplace. An Overview of Existing Protections', 30 *Loyola University of Chicago Law Journal* 393 (1999), p. 415, D. Gridley, *supra* (footnote 152) and K.A. Steinforth, *supra* (footnote 152).

<sup>179</sup> Some courts have accepted, for instance, that screening out of (potentially!) disabled workers may be necessary to improve employee efficiency and productivity. A negative employment decision may be justified on this basis. See e.g. *Milton v. Scrivner*, 53 F.3d 1118, at 1121; see also K.A. Steinforth, *supra* (footnote 152), p. 983. Other commentators conclude, however, on the basis of other case-law that purely economic or financial considerations cannot be held sufficient justifications under the ADA; e.g. L. Gostin, *supra* (footnote 102), p. 134 and D. Gridley, *supra* (footnote 152), p. 995. Interesting is further that the courts have allowed employers under the ADA to require a comprehensive medical examination, including genetic testing, and even to condition the job offer on the results of such examination (*Norman Bloodsaw v. Lawrence Berkeley Laboratory*, 135 F.3d 1260 (9<sup>th</sup> Cir. 1998), at 1273). Critical on this case law are D. Gridley, *supra* (footnote 152), p. 998 and S.M. Suter, *supra* (footnote 11), p. 728.

<sup>180</sup> For an overview of the case law see J.H. Gerards, *supra* (footnote 84), p. 154ff and R.B. Lanman, *supra* (footnote 101), p. 13ff.

<sup>181</sup> With respect to insurance see e.g. S. 306 SE, § 101(c)(2) and § 104(c)(2) and (3). With respect to employment the bill only contains exceptions regarding the acquisition of genetic information; see in particular S. 306 SE, § 202(b)(1)-(5). The prohibition on the use of genetic information in employment decisions seems to be formulated in an absolute manner: the bill contains no express exceptions to the rule. Only negative employment decisions are prohibited, however. If genetic information is used in a positive manner, for instance in the context of accommodating employees whose test results disclose a particular genetic workplace risk or offering genetic services, this will probably not constitute an unlawful employment practice. To this extent, however, the bill is not formulated very clearly. For further details see J.H. Gerards, *supra* (footnote 84), p. 196ff, discussing the predecessor

various legislative provisions offer clear standards to the targeted industries and their narrow formulation might stand in the way of unfavourable interpretations by the courts. It is not easy to predict whether narrowly defined exception clauses will indeed offer more protection to individual interests. In addition, it is open to doubt if such narrow clauses are sufficiently adaptable to continuous scientific developments and unpredictable market reactions.<sup>182</sup> It is difficult to answer such questions until the moment the proposed legislation has entered into force and courts have been confronted with cases arising from its application in practice. Interestingly, the drafters of the present genetic non-discrimination bills seem to have presaged that problems will arise and have provided for the establishment of a committee six years after enactment of the Act to review the developing science of genetics and to make recommendations for legislation.<sup>183</sup> This solution enables the legislature to accommodate for developments in genetic science without necessitating the inclusion of wide exception clauses in the present legislation.

## 5. Conclusions

The increasing availability of predictive health information, in particular genetic information, forms a blessing and a threat at the same time. It is valuable to have information about health risks at one's disposal, but it is also clear that predictive health information is highly sensitive in character and should be carefully handled by all actors who have a legitimate interest in collecting and using such information. This is true in particular for non-medical actors, such as insurers and employers. If such actors do obtain access to predictive health information and use such information as a basis for decision making, they may harm a number of important individual and social interests, varying from individual privacy and non-discrimination interests to the interest in having adequate access to important social goods such as health care and disability pensions.

Thus, the availability of genetic and other predictive health information has caused highly complex dilemmas, which national and federal/supranational governments have found difficult to solve. It is clear to most governments that some form of regulation of the access to genetic and other (predictive) health information by

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of S. 306 SE (S. 1053 SE).

182 Cf. H.T. Greely, *supra* (footnote 3), p. 1504, C.S. Diver and J.M. Cohen, *supra* (footnote 12), p. 1453 and D. Hellman, *supra* (footnote 13), p. 83.

183 See S. 306 SE § 208(b)-(e) and H.R. 1227 § 208(b)-(e), providing for the establishment of a Genetic Nondiscrimination Study Commission.

non-medical actors is called for, but there is much less consensus as to the design of such regulation. It is particularly for this reason that we have endeavoured to distinguish a number of different aspects pertinent to regulation of predictive health information. One of the most important of these relates to the question whether regulation should focus on genetic information alone, or should rather be directed at a wider category of health information. Although there seems to be little consensus on this issue in practice, we have concluded that the latter option is to be preferred (§ 2), not in the least because of the difficulties related to the definition of genetic information.

Whatever definition of the relevant information is chosen, however, it is clear that regulation will also require a balance to be struck between a variety of conflicting interests of equal importance and value. Although it is possible to reach tentative theoretical conclusions as to where such a balance could be found, the comparative analysis has shown that the outcomes of balancing exercise may be different in various legal systems. Any choice to be made in this regard does not only depend on theoretical or political views on the reasonableness of a certain outcome, but also on the political, social and historical backgrounds and the internal organisation of a particular legal system. Decisions as to specific forms of regulation may be influenced by the need for such forms of regulation in the legal system at hand. Hence, it would seem to be impossible to indicate with any precision how the various relevant interests should be weighed and balanced in general. Still, the comparative analysis presented in Section 4 shows that the main line of the conclusions reached in Section 3 is reflected in most of the national measures and proposals we have studied. The conclusions reached in that section may thus legitimately be regarded as a base line for further regulation in the area.

An issue that we did find little consensus on in the comparative review is the proper level of regulation. In theory, legislation adopted at the federal or supranational level might seem to be most effective because of the legal certainty and equality created by such legislation. The patchworks of protection which currently exist in both the United States and in Europe would be removed by such uniform legislation, which would have great advantages for employers and insurance businesses operating across the national borders. On the other hand, it is clear that such legislation would conflict with the desire to take account of national particularities and differences. Especially if the differences between the states concern fundamental characteristics of health insurance systems, as in the European Union, it would not seem to be desirable to impose harmonising legislation which would deeply intrude in the national health organisation systems. This is different for the United States, where the differences in health organisation and insurance regulation between the states seem to be less pronounced. For that reason it might

be easier to introduce uniform legislation in the US than in Europe. For other areas, such as that of life insurance, the differences seem to be less distinct and harmonisation would be less out of place. It is clear, however, that this is only one part of the issue. Of even more practical importance is the fact that harmonising, federal or supranational measures may only be introduced if the constitutional division of competence allows for such measures to be taken. Indeed, there is much uncertainty as to this both in the European Union and in the United States. As long as the division of competence remains unaltered, it is probable that future regulatory efforts will mainly take place on the national level.

Much more congruity is visible as to the areas of regulation. The comparative study has shown that regulatory efforts are currently limited to the areas of employment and health insurance and, to a lesser extent, life insurance, disability insurance and long term care insurance. Indeed, the collection and use of genetic information by employers and insurers currently seems to be most problematic. These actors have already shown concrete interest in acquiring predictive health information and they may use it in a way which may hamper individual access to such important goods as health care or employment. In due time, it may be possible to widen the scope of legislation or other measures to other areas, but for the time being, it is reasonable to limit regulatory efforts to employment and insurance.

Some European states appear to have included general non-discrimination and privacy provisions in their national constitutions, mainly because of the expressive and symbolic value of such provisions. It is clear, however, that a constitutional prohibition is seldom sufficient to strike an effective balance between the various interests concerned. As far as the choice between regulatory instruments is concerned, the introduction of statutory legislation may be favoured over purely constitutional protection and, as far as relevant, over wide (judicial) interpretation of existing legislation. Newly introduced, specific legislation (or specific additions to existing legislation) may contain clear exception clauses which accommodate for the conflicting interests of employers and insurers and which may contain provisions that allow for adaptation to future scientific and social developments. The advantage of this approach is that legal certainty and clarity are created and that more specific protection is offered to all interests concerned. In that respect it does not seem to matter much if specific statutory legislation is sectoral in character (which means that it is specifically designed for the area of employment or for a certain type of insurance) or more general (*e.g.* in the shape of amendment of a general non-discrimination law so to include the ground of genetic information), as long as the legislation strikes a clear and reasonable balance between the various interests described in Section 3.

The comparative analysis has further shown that the protection of privacy and non-discrimination interests and the access to health care, employment and other social goods may be realised to some extent by self-regulation. The imposition of moratoria and ceiling setting are examples of useful instruments that the industry may rely on – the example of the UK has shown that these instruments are working in a rather satisfactory way. In particular, self-regulation would appear to be useful if statutory legislation is not likely to be introduced on the short term and if interpretation of existing legislation would not seem to offer adequate protection of the various interests at risk. The American example of the life insurance industry shows, however, that not all industries will be willing to impose self-regulatory measures. The industry has voiced some relevant objections to such instruments as ceiling setting which may make them less effective. For that reason, we would submit that self-regulation should not be considered as a definitive solution to the dilemmas surrounding the access to predictive health information by insurers. In the end, clear statutory legislation provides a more effective means to reconcile the various conflicting interests.

As far as the content of such statutory legislation is concerned, we stress that such legislation is meant to protect individuals against unwarranted disclosure and use of their personal health information. In order to do so, lawmakers may rely on either a privacy approach – guaranteeing the confidentiality of genetic information by prohibitions on disclosure – or a non-discrimination approach – prohibiting discriminatory use of predictive health information. Although the choice between these approaches may stem from the particularities of a certain legal system, we would submit that a combination of both approaches is to be preferred. To be effective, national legislation should (and to a large extent already does) restrict both access to genetic information and the use of such information to the disadvantage of the individual.

The last issue to be discussed is whether it is more desirable to introduce statutory legislation that is formulated in a broad and flexible way, or, alternatively, in a highly detailed manner. The choice between these alternatives will to some extent depend on legal tradition, but some middle ground may be found. In many legal systems there seems to be a preference for exception clauses that leave some room for interpretation, yet still contain well-described standards and criteria to make clear under which conditions the use of genetic information is allowed. Specific aims may be formulated (e.g. protection of the health of employees) and high standards may be set with respect to the suitability, necessity and proportionality of the use of predictive health information as a means to reach this aim, or with respect to the circumstances under which such information may be collected. Finally, a specific measure provided for in the American genetic non-discrimination

bills seems to be worth copying by other lawmakers. The bills provide for a five year cycle of revision of the relevant provisions, thus creating a possibility to adapt the regulations to new scientific developments and the discovery of new techniques and remedies, but also to the effects of the legislation for the employment sector and the insurance industry. Thus, the legislation remains rather flexible and adaptable, which is a valuable asset in a fast-changing area such as that of genetic medicine.