

LESSONS FOR GERMANY'S GENDIAGNOSTIKGESETZ FROM EUROPE'S PROTOCOL ON GENETIC TESTING FOR HEALTH PURPOSES

INTRODUCTION

On April 24, 2009, the German *Bundestag* passed the *Gesetz über genetische Untersuchungen bei Menschen* [Human Genetic Examination Act], more commonly known as the *Gendiagnostikgesetz* [Genetic Diagnosis Act] (“GenDG”).¹ The GenDG regulates genetic examinations and the availability of information obtained from such examinations. This Act, enacted one year after the enactment of the United States’ similar Genetic Information Nondiscrimination Act (GINA),² is one of the most extensive of its kind,³ and has been criticized as infringing on the individual's right to control the use of his own genetic information.⁴ The

1. Gesetz über genetische Untersuchungen bei Menschen, Gendiagnostikgesetz [GenDG] [Genetic Diagnosis Act], April 24, 2009, BGBl. I at 2529 (Ger.), translated in Deutsch/Englisch Bundesrat Drucksache 374/09, available at http://www.eurogentest.org/uploads/1247230263295/GenDG_German_English.pdf [hereinafter GenDG]. The Act did not enter the *Bundesgesetzblatt*, a federal law gazette where final federal statutes are made public, until July 31, 2009. BUNDESRAT DRUCKSACHEN (BR) 374/09 (Ger.). Except where otherwise indicated in the Act, the Act took effect on February 1, 2010. *Gendiagnostikgesetz* at 2538, § 27 (1). Within this Note, references to the GenDG in English are to the translation above.

2. Genetic Information Nondiscrimination Act, Pub. L. No. 110-233, 122 Stat. 881 (codified as amended in scattered sections of 26 U.S.C. and 42 U.S.C.) (2008). The Genetic Information Nondiscrimination Act (GINA) regulates primarily the health insurance and employment contexts, while the scope of the *Gendiagnostikgesetz* is much broader.

3. An exhaustive comparison of national laws concerning genetic information is outside the scope of this Note. Heleen Janssen has provided extensive summaries and comparisons of national European genetic information laws (Austria, Belgium, France, Germany, Greece, Ireland, Italy, Norway, Portugal, Switzerland, and the United Kingdom) in her well-researched book *Genetic Information and Genetic Privacy in a Comparative Perspective*. See Heleen L. Janssen, *Genetic Information in European States*, in GENETIC INFORMATION AND GENETIC PRIVACY IN A COMPARATIVE PERSPECTIVE 47, 59–91 (2005). The book, published in 2005, examines the German laws pre-*Gendiagnostikgesetz*. At the end of the book, Janneke Gerards lays out an exhaustive survey of pre-GINA U.S. laws affecting genetic information in multiple contexts, such as the Americans with Disabilities Act, the Civil Rights Act, the Employee Retirement Income Security Act, the Health Insurance Portability and Accountability Act. See Janneke H. Gerards, *Regulation of Genetic Information in the United States*, in GENETIC INFORMATION AND GENETIC PRIVACY IN A COMPARATIVE PERSPECTIVE 105, 153–80 (2005).

4. “One of the laudable purposes of the act, ‘to protect human dignity and to ensure the individual right to self-determination via sufficient information,’ is belied by provisions of the Act that restrict the ability of individuals to access their own genetic information directly.” David Clark, *Genetic Exceptionalism and Paternalism Themes in New German Legislation*, GENOMICS L. REP.,

GenDG has also been recognized either as a long-awaited protection for the increasingly important field⁵ of genetic information,⁶ or alternatively, as an attempt by Germany to foreclose the possibility of a repetition of the horrific eugenics schemes of the Nazi regime.⁷ Regardless of whether one follows the tenets of genetic exceptionalism—“that genetic tests are unique and therefore justify special consideration with regard to informed consent and privacy”⁸—there is certainly a level of understanding and specificity that should be required in any law that tackles the subject.

This Note argues that, in some important respects, the German GenDG and, in fewer respects, the Council of Europe’s conceptually similar Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Genetic Testing for Health Purposes, also called the Protocol on Genetic Testing for Health Purposes (“Protocol”),⁹ do not provide the level of understanding and specificity necessary to provide equity to all parties in situations where its edicts apply.

Part I of this Note summarizes and emphasizes major aspects of the GenDG and the Protocol. Part II addresses the right to know and home genetic testing kits, issues for which the Protocol provides the best alternative with specific exceptions and more flexibility. In Part III, this Note acknowledges that the Protocol provides a better alternative on issues of consent, particularly in situations of lack of capacity to consent, improper refusal to consent, and balancing of interests in paternity testing, but examines ways that both laws could better address the issue.

Sept. 2, 2009, <http://www.genomicslawreport.com/index.php/2009/09/02/genetic-exceptionalism-and-paternalism-themes-in-new-german-legislation/>.

5. “The rapidly evolving science of genetic screening and testing seems likely to be in the forefront of medical development in this century.” Sheila A.M. McLean, *The Genetic Testing of Children*, in *SOCIETY AND GENETIC INFORMATION: CODES AND LAWS IN THE GENETIC ERA* 145, 158 (Judit Sándor ed., 2003).

6. See *Heimliche Vaterschaftstests sind nun verboten* [Secret Paternity Tests are now Forbidden], SPIEGEL ONLINE: POLITIK, Apr. 24, 2009, <http://www.spiegel.de/politik/deutschland/0,1518,620897,00.html>.

7. “[I]t’s clear that this regulation is driven in part by a desire to steer well clear of anything that might stir up memories of eugenics and medical experimentation on unwilling subjects conducted half a century ago.” Daniel MacArthur, *Germany’s Anti-Genetic Testing Legislation Misses the Point*, WIRED (Sept. 3, 2009, 5:15 AM), <http://www.wired.com/wiredscience/2009/09/Germany's-anti-genetic-testing-legislation-misses-the-point>.

8. Michael J. Green & Jeffrey R. Botkin, “Genetic Exceptionalism” in *Medicine: Clarifying the Differences between Genetic and Nongenetic Tests*, 138 ANNALS OF INTERNAL MED. 571, 571 (2003).

9. Council of Europe, Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes, C.E.T.S. No. 203 (2008), available at <http://conventions.coe.int/treaty/Commun/ChercheSig.asp?NT=203&CM=8&DF=30/10/2009&CL=ENG> [hereinafter “Protocol”].

I. THE GENDIAGNOSTIKGESETZ AND THE COUNCIL OF EUROPE'S PROTOCOL ON GENETIC TESTING FOR HEALTH PURPOSES

A. *The Gendiagnostikgesetz, Discrimination, Accreditation, and Test Results*

The GenDG prohibits discrimination based on “genetic characteristics.”¹⁰ Its rigorous quality assurance and accreditation system¹¹ requires that genetic tests be conducted only by medical doctors.¹² In order to test, an institution must obtain “express, written consent of the subject person, both in regard to the respective genetic examination and genetic sample.”¹³ Under the GenDG, a doctor has a pre-exam duty to inform the subject patient about the exam, including: an explanation of the purpose, type, scope, and significance of the exam; health risks associated with the exam; the intended use of the information; and the patient’s right to revoke consent at any time.¹⁴ A patient’s request to not be informed of the results must be granted.¹⁵

Genetic counseling¹⁶ should be offered along with the exam results, including counseling concerning physical or psychological difficulties

10. GenDG § 4(1). Genetic characteristics are defined as “human genetic information inherited upon fertilisation or otherwise gained before birth.” GenDG § 3(4).

11. To perform genetic examinations, an institution must obtain accreditation “from a generally recognized, authorized source.” GenDG § 5(1). It is not clear what this “source” must be. The institution seeking accreditation must “establish internal quality assurance procedures,” employ qualified staff, retain and destroy samples according to Sections 12 and 13, and participate in external quality assurance programs. Furthermore, “[i]nstitutions shall only be accredited for the analysis types and analysis procedures stated in the respective accreditation application. The accreditation period is limited to a maximum of five years.” GenDG § 5(1). The Act also requires in Section 6 that the institution allowed to conduct genetic tests use its supplies itself and only for the authorized purposes.

12. GenDG § 7(1). The Act further requires that “predictive genetic examinations may only be conducted by medical doctors who are certified specialists in human genetics or by other medical doctors who, within the framework of their own area of expertise, were also able to obtain certification, specialization, or additional qualification to conduct genetic examinations.”

13. GenDG § 8(1). “The consent stated in the foregoing sentence includes the decision in regard to the scope of the given genetic examination as well as regarding the decision if, and if so to which extent, the examination results may be disclosed or, as the case may be, destroyed.” The section then provides that subject permission may be revoked at any time, orally or in writing, and such revocation must be immediately documented and reported. GenDG § 8(2).

14. *Id.* § 9.

15. *Id.* § 9(2)(5).

16. The GenDG defines genetic counseling as:

[A] thorough explanation of possible medical, psychological and social issues which might arise in relation to conducting or, as the case may be, not conducting the subject genetic examination and as regards any given or potential examination results, alongside the possibilities of supporting the subject person in the context of any physical or psychological difficulties which have or may occur as a result of such genetic examination or its results. If it can be assumed that genetic relatives of the subject person are also carriers of the subject

which have occurred or may occur as a result of the genetic examination or its results, and such counseling must be offered¹⁷ if a discovered condition is untreatable.¹⁸

Except with the subject's express, written consent, test results may not be disclosed to anyone other than the test subject.¹⁹ Information obtained through genetic testing may only be used for its intended and consented-to purpose. Any test sample must then be destroyed upon request, once the sample is no longer required for those purposes,²⁰ or after ten years.²¹ While genetic examinations of persons lacking the capacity to consent

genetic characteristics with significance for an avoidable or treatable illness or health condition, genetic counselling shall include the recommendation that such relatives also undergo genetic counseling.

GenDG § 10(3). The last sentence quoted here is the closest that the GenDG comes to acknowledging a familial interest in a relative's genetic information. Yet it still does not loosen the strict consent requirements discussed later in this Note—the recommendation here is made to the test subject, who thus has the unfettered choice of whether to disclose the information to family.

17. GenDG § 10(1). The original German Act uses the verb "soll," which the English translation interprets as "shall." While the verb "shall" in American English more often has come to denote a requirement rather than a recommendation, the verb base "sollen" in German more often denotes a recommendation. PONS WÖRTERBUCH FÜR SCHULE UND STUDIUM [PONS DICTIONARY FOR SCHOOL AND UNIVERSITY] 2308 (1st ed. 2005) (translating the German verb "sollen" into the English word "should" in the majority of cases); *see, e.g.*, DEUTSCHES RECHTS-LEXIKON [GERMAN LEGAL ENCYCLOPEDIA] 3684 (3rd ed. 2001); RECHTSWÖRTERBUCH [LEGAL DICTIONARY], DR. CARL CREIFELDS, 1089 (20th ed. 2011) (failing to provide a definition for the word "sollen," leading to the conclusion that the general translation applies in the legal context as well). In order to provide meaning to the juxtaposition in § 10(1) of the "shall" phrasing in the normal case with the "must" phrasing in the untreatable case, readers in the United States should interpret the word "shall" in the EuroGenTest English Translation as "should," denoting recommendation rather than requirement. *See* BLACK'S LAW DICTIONARY 1407 (8th ed. 2004) (providing the first definition of "shall" as "[h]as a duty to; more broadly, is required to," and, "This is the mandatory sense that drafters typically intend and that courts typically uphold.").

18. The Act also provides that the subject may consent to having an additional expert professional consulted. It further provides, "If it can be assumed that genetic relatives of the subject person are also carriers of the subject genetic characteristics with significance for an avoidable or treatable illness or health condition, genetic counseling shall include the recommendation that such relatives also undergo genetic counseling." This applies to testing on a fetus. GenDG § 10(3)-(4).

19. The Act states that the person disclosing the information, whether to the subject or to an authorized third party, must always be the medical doctor responsible for the testing. *Id.* § 11.

20. *Id.* § 13(1). The Act does allow use of the samples for other purposes "to the extent that such use is permitted by other legal regulations" or in cases where the subject has given fully informed, express, and written consent. *Id.* § 13(2).

21.

To the extent that there is reason to believe that such destruction would infringe against the subject person's protected interests, or in cases where the subject person has requested in writing that the subject items be retained for a longer period of time, then instead of destroying the items pursuant to second sentence, No. 1, the responsible medical person must seal the results and must inform the person or institution authorized according to § 7 (2) thereof immediately.

Id. § 12(1).

may be conducted, they must remain within specific guidelines related to the severity of the condition and the awareness of the patient.²²

B. Special Types and Uses of Genetic Information

Prenatal genetic examinations may be conducted only to determine genetic characteristics that might impair the baby's health before or after birth, or to determine how medication necessary for other reasons may affect the fetus because of its genetic characteristics.²³ The baby's gender may also be determined and reported to the mother with her consent.²⁴ In recognition of personal autonomy, genetic tests may not be conducted to detect diseases that do not present themselves until after the age of eighteen.²⁵

Paternity testing is allowed,²⁶ in accordance with existing German privacy laws on the subject.²⁷ Yet no other genetic determinations may be made from such tests, except limited medical determinations with the consent of the mother, unless, per the Criminal Code, there was an illicit act (such as rape or sexual abuse of children) involved in the conception of the baby.²⁸ The GenDG prohibits secret paternity tests by requiring the

22. *Id.* § 14.

23. *Id.* § 15(1).

24. *Id.*

25. *Id.* § 15(2). This provision would seem to effectively promote the future autonomy of the human, because if the disease does not affect the child until the age of eighteen, the child can make the choice after that time whether he will test for it or not. Yet there is a problem with the formulation of this provision. The English version requires that the illness "break out" after the age of eighteen; the language is essentially identical in the original German—"ausbricht"—to break out. This seems to prohibit genetic testing on fetuses and embryos for illnesses for which preventative measures could be taken before the age of eighteen, even though the illness only breaks out after the age of eighteen. While such instances may be rare, no law should prohibit testing that could help prolong the embryo or fetus's future life. The provision could read, "if, according to the generally accepted status of science and technology, *no preventative steps could be taken to fight the illness* before the age of eighteen." This would maintain the substantial scope, but delete the possible life-shortening effect.

26. *Id.* § 17.

27. The Act is made subject to the Criminal Code, the Passport Act, the Personal ID Act, and the Foreigners Act. In general, not as many safeguards need be taken for genetic determinations made using oral cheek swabs under the U.S. laws as must be taken under the German Act. This is especially true in regard to the decision to disclose or destroy results of genetic examinations and the identity of the person who may inform the subject concerning the test. *Id.* § 17(4)-(8). "Should probable cause exist that a criminal act has occurred, then contrary to Subparagraph (5) the results of the genetic exam and the subject genetic sample may be transmitted even after the revocation of consent . . ." *Id.* § 17(8).

28. *Id.* § 17(6), (8), § 15(1); Strafgesetzbuch [StGB] [Criminal Code] §§ 176-179, Nov. 13, 1998, BGBL. I at 3322 (Ger.). Such determinations could include, *inter alia*, testing for genetic diseases.

fully informed consent of the person whose genetic sample is being tested.²⁹

Additionally, the GenDG provides for special rules in the contexts of mass screenings,³⁰ insurance,³¹ and employment.³²

C. Administration and Punishment

The GenDG provides for fees, fines, and sanctions for violating the statute.³³ The Act also establishes the Genetic Diagnostic Commission,³⁴ a

29. The prohibition of secret paternity tests was one of the most stressed aspects of the German Act in media reports surrounding its enactment. *See, e.g., Bundestag stellt heimliche Vaterschaftstests unter Strafe [Bundestag makes secret paternity testing a punishable offense]*, FOCUS ONLINE, Apr. 24, 2009, http://www.focus.de/gesundheit/gesundheits-news/gendiagnostikgesetz-bundestag-stellt-heimliche-vaterschaftstests-unter-strafe_aid_392947.html; *Bundestag schränkt Gentests ein [Bundestag curbs genetic testing]*, ZEIT ONLINE, Apr. 24, 2009, <http://www.zeit.de/online/2009/18/gendiagnostik-gesetz> (“Durch das neue Gendiagnostikgesetz werden unter anderem heimliche Vaterschaftstests verboten und mit bis zu 5000 Euro bestraft” [“Under the new Genetic Diagnosis Act, secret paternity tests, among other things, are forbidden and punishable with a fine of up to 5000 euros”]).

30. “Any mass genetic screening may only be conducted if the objective of such examination is to determine if the subject person possesses genetic traits which, according to the generally accepted status of science and technology, are significant in terms of preventing or avoiding an illness or health problem.” GenDG § 16. Also, any kind of mass genetic screening is subject to approval by the Genetic Diagnostic Commission created by this Act. *Id.*

31. *Id.* § 18. This context is not specifically mentioned in the Council of Europe’s Protocol on the subject. In the insurance setting, the law bans third parties from obtaining any kind of genetic information, except in cases where the contract at issue exceeds 300,000 euros. As the implications of the differences between the German law and the Protocol are vast and this particular field much-analyzed, this difference will not be discussed in this Note. *Id.*; *see, e.g.* Ashley M. Ellis, *Genetic Justice: Discrimination by Employers and Insurance Companies Based on Predictive Genetic Information*, 34 TEX. TECH. L. REV. 1071 (2003); Natalie E. Zindorf, *Discrimination in the 21st Century: Protecting the Privacy of Genetic Information in Employment and Insurance*, 36 TULSA L.J. 703 (2001).

32. GenDG § 19. This context is also not specifically mentioned in the Council of Europe’s Protocol. Genetic privacy in employment has been heavily explored in previous works, and therefore will not be discussed in this Note. *See, e.g.,* Ellis, *supra* note 31; Zindorf, *supra* note 31.

33. All sanctions are criminal, and vary in severity, with the lowest punishment being one year imprisonment or corresponding fines for, among other things, “a genetic examination without the necessary required consent [and] a prenatal genetic examination [that] does not serve medical purposes or is not directed at determining the genetic characteristics named there of the embryo or fetus.” GenDG § 25(3). The maximum punishment is two years imprisonment or corresponding fines for engaging in the activities that lead to the lesser sanction, but doing so “with the intent to enrich themselves or harm others.” GenDG § 25(2). Fines may be levied for misdemeanors including “not destroying or not promptly destroying or not sealing or not promptly sealing the results of any genetic examination or analysis,” and “conducting a genetic examination of a. the father or mother of the child whose descent is to be determined, b. the child seeking to have his or her descent determined, or c. any other person without the necessary consent,” and “disclosing any data or results stated” in a genetic examination analysis. The fines can be as high as 300,000 euros. GenDG § 26(7)–(8).

34. The Act provides:

The Commission will be established at the Robert Koch Institute consisting of 13 experts from the fields of medicine and biology, two experts from the fields of law and ethics, as well

regulatory body with authority to establish guidelines concerning priorities, procedures, and qualifications. Included in this authority is the ability to determine specifically when the “accepted status of science and technology” may present interests that outweigh privacy interests³⁵ as they pertain to other sections of the Act.³⁶ While several groups are represented on the commission’s panel, insurer and employer interests are not.³⁷

D. The Council of Europe’s Protocol on Genetic Testing for Health Purposes

In 1996, the Committee of Ministers of the Council of Europe instructed the Steering Committee on Bioethics to draw up a protocol³⁸ to the Convention on Human Rights and Biomedicine.³⁹ The Convention

as three representatives dedicated to the realization of patient interests, consumer interests and disabled persons’ self help issues to an authoritative federal organization.

GenDG § 23(1).

The Commission is to enact its own bylaws, and its members serve for three-year terms. *Id.* “The Robert Koch Institute (RKI) is the central federal institution responsible for disease control and prevention” in Germany. THE ROBERT KOCH INSTITUTE: TASKS AND AIMS OF THE ROBERT KOCH INSTITUTE, Nov. 10, 2004, http://www.rki.de/cln_091/nn_216780/EN/Content/Institute/General/general__node__en.html?__nnn=true.

35. GenDG § 23 (2).

[T]he Genetic Diagnostic Commission shall establish guidelines for, in particular,

1. the evaluation of genetic characteristics in regard to
 - a) their respective significance in relation to illnesses and health conditions, as well as the possibility of avoiding, treating or prevent illnesses and health conditions
 - b) their significance in terms of the effects of pharmaceutical products during treatment,
 - c) the necessity to conduct a genetic examination according to § 14 (1) Nr. 1 to avoid, prevent or treat any genetically caused illness or health condition or the necessity to conduct a genetic examination according to § 14 (1) Nr. 2 to clarify illness or health condition that can occur in the offspring of a genetically related person,
 - d) their importance in regard to the impairment of the health of an embryo or foetus during pregnancy or after birth § 15 (1) . . .
 - e) their material importance in regard to the preconditions required for issuance of a legal regulation according to § 20 (3)
2. the requirements and qualifications for
 - a) determining genetic counselling according to § 7(3). . .

Id. The Commission also determines who qualifies as an expert in the field, requirements of the duty to inform and counsel, reliability of methods, requirements for prenatal risk assessments, and more. *Id.*

36. *Id.*

37. Such mentioned interests include the fields of medicine and biology, law and ethics, patient interests, consumer interests and disabled persons’ self help issues. *Id.* 23(1).

38. *See supra* note 9.

39. Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being With Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, E.T.S. No. 164 (1997), available at <http://conventions.coe.int/treaty/Commun/ChercheSig.asp?NT=164&CM=8&DF=30/10/2009&CL=ENG> [hereinafter “Convention on Human Rights and Biomedicine”].

entered into force on December 1, 1999,⁴⁰ and has been signed by thirty-five states, twenty-eight of which have further ratified or acceded to it.⁴¹ Yet the Protocol to the Convention, which opened for signatures on November 27, 2008, has not yet obtained the five ratifications—including those of four Council of Europe states—necessary for entry into force.⁴² Rather, the Protocol has been signed by five states, two of which have ratified it.⁴³ Germany has not signed or ratified either the Convention or the Protocol,⁴⁴ although a German doctor chairs the Council of Europe's Working Party on Human Genetics.⁴⁵ While the Protocol is not binding on Germany as a non-party, this Note examines its importance as an instructive guide for the German Act.

40. *Complete List of the Council of Europe's Treaties*, COUNCIL OF EUROPE, <http://conventions.coe.int/treaty/Commun/ListeTraites.asp?CM=8&CL=ENG> (last visited Sept. 19, 2009).

41. Convention on Human Rights and Biomedicine, *supra* note 39.

42. Protocol, *supra* note 9.

43. *Id.*

44. Convention on Human Rights and Biomedicine, *supra* note 41; Protocol, *supra* note 9. While it follows that if a country did not sign the Convention, it would not sign the Protocol to the Convention, it is unclear why Germany has not signed the Convention. The *Bundesministerium der Justiz* [the Federal Ministry of Justice] simply states on its official website:

Bisher hat Deutschland die Biomedizinkonvention noch nicht unterzeichnet. Voraussetzung für die Ratifizierung des Übereinkommens ist, dass das nationale Recht den Standards der Konvention entspricht. Über diese Mindeststandards hinausgehende nationale Schutzvorschriften bleiben selbstverständlich bestehen. Die Bundesrepublik Deutschland würde also bei Ratifizierung des Übereinkommens nicht von ihrem hohen Schutzstandard abrücken müssen. Eine Entscheidung darüber, ob die Bundesrepublik Deutschland das Übereinkommen unterzeichnen wird, ist jedoch noch nicht getroffen worden.

[Germany has not, as of yet, signed the Biomedicine Convention. One requirement for those nations signing the agreement is that national law must meet the standards of the Convention. National protections that go beyond those of the agreement's minimum standard would of course remain in effect. If the Federal Republic of Germany were to ratify the agreement, it would therefore not be required to retreat from its high standard of protection. Nevertheless, no decision has been made as to whether the Federal Republic of Germany will sign the agreement.]

Biomedizinkonvention und Zusatzprotokolle [Biomedicine Convention and Additional Protocols], BUNDESMINISTERIUM [FEDERAL MINISTRY], http://www.bmj.bund.de/enid/Bioethik/Biomedizin/konvention_und_Zusatzprotokolle_19y.html (last visited Feb. 8, 2010).

45. Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes: Explanatory Report, Introduction art. 8, available at <http://conventions.coe.int/Treaty/EN/Reports/Html/203.htm> (last visited Sept. 23, 2010) [hereinafter "Explanatory Report"].

E. Scope of the Protocol

The Protocol does not apply to genetic tests carried out on the human embryo or fetus, or to genetic tests carried out for research purposes.⁴⁶ It stipulates that human interests and welfare will prevail over the sole interest of society or science.⁴⁷ It prohibits any form of discrimination⁴⁸ against a person, either as an individual or as a member of a group,⁴⁹ based on genetic heritage,⁵⁰ and it directs that appropriate measures be taken⁵¹

46. Protocol, *supra* note 9, art. 2(2). The purpose for the exclusion from the Protocol of testing for research or on an embryo or fetus is not clear.

47. Protocol, *supra* note 9, art. 3. This requirement remains somewhat nebulous, even in view of its limited discussion in the Explanatory Report. Explanatory Report, *supra* note 45, ¶¶ 37–38 (“This article affirms the primacy of the human being concerned by genetic tests covered by the Protocol over the sole interest of society or science. . . . The aim of [the Protocol] is to protect human rights and dignity.”).

48. The Explanatory Report specifically states: “Yet not all differences in treatment necessarily amount to discrimination. In particular, positive measures that may be implemented with the aim of re-establishing a certain balance in favour of persons at a disadvantage because of their genetic heritage are not regarded as discrimination.” Explanatory Report, *supra* note 45, ¶ 40.

49. This language does differ slightly from that of the German law. Under the German law, “[n]o one may be discriminated against or disadvantaged on account of his or her genetic characteristics *or the genetic characteristics of a genetically related person*. . . .” GenDG § 4(1) (emphasis added). In the Protocol, the emphasis is on discrimination against the person “either as an individual *or as a member of a group on grounds of his or her genetic heritage*. . . .” Protocol, *supra* note 9, art. 4(1) (emphasis added). The effect of these two statements could be different. For example, a person who is discriminated against because his brother has a genetic condition would be covered under the German law, but might not be covered under the Protocol because it is not his “genetic heritage” that is the basis for the discrimination, but rather that of his brother’s. *See infra* note 50 for the definition of “genetic heritage”. Yet if this interpretation were correct, it would seem to take away the meaning of the phrase in the Protocol “or as a member of a group”—if one can be discriminated against only on the basis of his own chromosomes and genes, discrimination against him solely because he is a member of a group should not matter. It seems, then, that the terms in the same sentence—“as a member of a group” and “his or her genetic heritage” contradict each other, or at least that the term “as a member of a group” adds no extra meaning to the sentence. This may be one reason to believe the definition of “genetic heritage” is not meant to be limited to the individual discriminated against. Protocol, *supra* note 9, art. 4(1); *see infra* note 50.

50. Protocol, *supra* note 9, art. 4(1). The term “Genetic Heritage” seems to be unclear on its face, and is not defined in the Explanatory Report. Yet the language is borrowed from the Convention on Human Rights and Biomedicine, the Explanatory Report for which states that the phrase “genetic heritage” refers to one’s chromosomes and genes. “Genetic testing consists of medical examinations aimed at detecting or ruling out the presence of hereditary illnesses or predisposition to such illnesses in a person by directly or indirectly analysing their genetic heritage (chromosomes, genes).” Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine: Explanatory Report, ¶ 72, available at <http://conventions.coe.int/Treaty/EN/Reports/Html/164.htm> [hereinafter Convention on Human Rights and Biomedicine Explanatory Report].

The term “their” must be interpreted as referring to the singular “person” from earlier in the sentence. Professor Hendriks criticizes the Convention and its Explanatory Report for leaving the definition of “genetic heritage” not particularly clear by failing to elaborate on its meaning. Aart Hendriks, *Protection Against Genetic Discrimination and the Biomedicine Convention*, in HEALTH LAW, HUMAN RIGHTS AND THE BIOMEDICINE CONVENTION: ESSAYS IN HONOUR OF HENRIETTE

“to prevent stigmatization of persons or groups in relation to genetic characteristics.”⁵²

Under the Protocol, all genetic tests must meet quality assurance requirements in programs, monitoring, and qualifications of persons providing the genetic services.⁵³ The tests must also have clinical utility⁵⁴ and be performed under individualized medical supervision.⁵⁵ The subject of the test is to be “provided with prior appropriate information in particular on the purpose and the nature of the test, as well as the implications of its results”⁵⁶ and shall receive “appropriate genetic

ROSCAM ABBING 207, 209 and 215 (J.K.M. Gevers et al. eds., 2005), available at <https://openaccess.leidenuniv.nl/bitstream/1887/13932/2/Protection+against+genetic+discrimination+and+the+biomedicine+convention.pdf>.

51. “Possible measures to prevent stigmatisation include general information campaigns on the human genome and its characteristics and on advances in our knowledge of human genetics, aimed at the general public as well as incorporated into education and training curricula. Parties should encourage such initiatives.” Explanatory Report, *supra* note 45, ¶ 43.

52. Explanatory Report, *supra* note 45, ¶ 41. “A distinction can be drawn between stigmatisation and discrimination, in that ‘stigmatisation’ is not necessarily relevant to the exercise of an individual right. The concept of ‘stigmatisation’ rather relates to the way in which a person or group is perceived on the basis, in this case, of their genetic characteristics, whether these exist or are thought to exist. It takes, in particular, the form of words or acts that negatively label a person or group of persons on account of their known or supposed characteristics.” Explanatory Report, *supra* note 45, ¶ 42. Paragraph 44 of the Explanatory Report provides that particular attention be paid to stigmatization in the context of screening programs. In neither the Protocol itself nor the Explanatory Report is stigmatization outright prohibited (only sought to be prevented), although discrimination clearly is prohibited. *Id.* ¶¶ 39–44.

53. Parties are to ensure that:

genetic tests meet generally accepted criteria of scientific validity and clinical validity; (b) a quality assurance programme is implemented in each laboratory and that laboratories are subject to regular monitoring; (c) persons providing genetic services have appropriate qualifications to enable them to perform their role in accordance with professional obligations and standards.

(a) Protocol, *supra* note 9, art. 5.

54. “Clinical utility of a genetic test shall be an essential criterion for deciding to offer this test to a person or a group of persons.” Protocol, *supra* note 9, art. 6. “‘Clinical utility’ is to be understood by the value of the test results in guiding the person concerned in his or her choices regarding prevention or therapeutic strategies.” Explanatory Report, *supra* note 45, ¶ 57. The Explanatory Report groups criteria for determining clinical utility into two large categories: (1) “criteria concerning the test” (including the value of the test results in terms of prevention or treatment, and the quality and accessibility of the genetic services available) and (2) criteria relating to the situation of the test subject. Explanatory Report, *supra* note 45, ¶ 58.

55. A subject may allow exceptions to this requirement, but “such an exception may not be made with regard to genetic tests with important implications for the health of the persons concerned or members of their family or with important implications concerning procreation choices.” Protocol, *supra* note 9, art. 7.

56. *Id.* art. 8(1).

counseling.”⁵⁷ Free and informed consent must be given for testing, and it can be freely withdrawn.⁵⁸

For persons not able to consent, a genetic test may be carried out only for his or her direct benefit or the benefit of family members, with exceptions.⁵⁹ In addition, prior appropriate information must be given to the entity whose authorization is required, as well as to the subject.⁶⁰ Mass genetic screenings may only be implemented following approval by the competent body, and only subsequent to an independent evaluation of ethical acceptability.⁶¹ Such screenings must also meet further specific conditions.⁶² And unlike the GenDG, the Protocol requires that governments facilitate public access to “objective general information on

57. *Id.* art. 8(2). The definition of “genetic counseling” in the Protocol is more extensive than the definition in the GenDG:

The notion of “genetic counselling” is to be understood here as a communication and support process aiming to enable individuals and, where appropriate, families to make informed choices with regard to a genetic test and its implications. It includes the provision of information prior to consent as required in paragraph 1. It also includes an offer of support before and, if appropriate, after the test, to the person concerned, to help him or her to deal with the implications of the test and its results, including, where appropriate, communication to family members of information relevant to their health, or procreation choices. Genetic counselling is an individualised process taking into account, in particular, the psychological and family context of the person concerned and involving an exchange between him or her and the person providing the counselling. This support process may therefore vary in form and extent depending on the test considered but also on the particular significance of the information that the test is likely to provide for the person concerned or for members of his or her family. In certain cases, the person concerned would also benefit from psychological support provided by persons with appropriate competencies.

Explanatory Report, *supra* note 45, ¶¶ 81–83. The following section, Paragraph 84, clarifies that if there are “important health implications for members of his or her family, one must refer to Article 18.” *Id.* ¶ 84. Article 18 contains the requirement that if there are such implications, the person tested shall be informed. Protocol, *supra* note 9, at Art. 18. Like the GenDG, though, it does not go so far as to require that the family members be informed without the capable test subject’s consent. *Id.*

58. Explanatory Report, *supra* note 45, ¶ 88.

59. *Id.* arts. 13, 14.

60. *Id.* art. 13.

61. *Id.* art. 19.

62. Protocol, *supra* note 9, art. 19. Those conditions are:

(a) the programme is recognised for its health relevance for the whole population or section of population concerned; (b) the scientific validity and effectiveness of the programme have been established; (c) appropriate preventive or treatment measures in respect of the disease or disorder which is the subject of the screening, are available to the persons concerned; (d) appropriate measures are provided to ensure equitable access to the programme; the programme provides measures to adequately inform the population or section of population concerned of the existence, purposes and means of accessing the screening programme as well as the voluntary nature of participation in it.

Id.

genetic tests, including their nature and the potential implications of their results.”⁶³

II. LESSONS FOR THE *GENDIAGNOSTIKGESETZ* FROM THE PROTOCOL

A. *Right Not to Know*

Under the GenDG, pre-test consent must be obtained as to “if, and if so to which extent, the examination results may be disclosed.”⁶⁴ Assumedly, this disclosure would include disclosure to the test subject himself.⁶⁵ This stands in contrast to the Protocol, which simply states that “[e]veryone undergoing a genetic test is entitled to know any information collected about his or her health derived from this test.”⁶⁶ It seems from this phrasing that the default rule in the absence of consent would be opposite in each situation: in Germany, no disclosure to anyone including even the test subject himself, and under the Protocol, disclosure to the subject.

63. *Id.* art. 20.

64. GenDG § 8(1).

65. The German phrasing here is that the test subject can decide “ob und inwieweit das Untersuchungsergebnis zur Kenntnis zu geben oder zu vernichten ist” which has been translated by EuroGenTest as allowing the subject to decide “if, and if so to which extent, the examination results may be disclosed or, as the case may be, destroyed.” *Id.* The critical phrase is “zur Kenntnis zu geben,” or in English, “disclosed.” The verb is somewhat open-ended, in that the person disclosing would be the doctor, and the information would then be disclosed to everyone but the doctor, including the test subject himself. This would seem to be the most logical interpretation of the “disclosure,” as nowhere else in the German law is a subject’s right to know as closely alluded to, and such a law concerning genetic information must be interpreted as including something as fundamental as the subject’s own right to know.

Interestingly, though, is the implication that comes into play if the term “disclose” does not include the subject himself. Then we must look elsewhere in the law to find an indication of the patient’s right to know. The nearest any section comes to this topic is in section nine, on the duty to inform. *Id.* § 9. That section requires that the subject must be informed, before giving his consent to the test, with “clarification as to the intended use of any genetic samples as well as the results of any genetic examinations or analyses.” *Id.* § 9(2)-(3). This phrase can be interpreted in two ways: either clarification applies to the intended use of the results, or clarification applies to the results themselves. The latter possibility, though, cannot be the case, because clarification must be given before consent can be valid, and consent must be given before the test can be performed. Under this interpretation, clarification of the meaning of the results is given before the results are known, which cannot be. The clarification must then pertain to the intended use of the samples, which would be known before testing. Therefore, this section does not create for the subject a right to know the results, but only a right to know the intended use of the results. This section is the only other besides section eight that approaches the subject of the right to know, and both sections give the test subject a right to control disclosure of test results. *Id.* §§ 8(1), 9(5). If disclosure means only disclosure to people other than the test subject, no section of this law explicitly creates a patient’s right to know test results. While “disclosure” may well include the test subject, the fact that the law is so near to ambiguity on this point of the patient’s right to know but at the same time so clear about the right not to know, reveals the legislative attitude that the right not to know is more important than the right to know.

66. Protocol, *supra* note 9, art. 16(2).

Thus, the GenDG assumes the subject does not want to know, and the Protocol assumes the subject does.

The GenDG sets the right not to know test results above the right to know them. While the right to know is only inferred from the requirement of consent before disclosure, the right not to know is explicitly laid out in Section 9.⁶⁷ Furthermore, the right not to know is not qualified in any way.⁶⁸ The Protocol, in contrast, provides that “[t]he wish of a person not to be informed shall be respected,”⁶⁹ but also states that, “[i]n exceptional cases, restrictions may be placed by law on the exercise of the rights” to know and not to know.⁷⁰ These exceptional cases are further laid out in the explanatory report as those in which “the doctor’s duty to provide care, stated in Article 4 of the Convention on Human Rights and Biomedicine, might conflict with the patient’s right not to know.”⁷¹ The Protocol then introduces the duty of care as a factor to be balanced, and the doctor must determine in her own expertise whether this duty outweighs the right not to know.⁷²

67. “Clarification in regard to the right of any subject person to not have to know results, including without limitation the right of the subject person to not have examination results, either partially or entirely, disclosed but to have them destroyed instead. . . .” GenDG §§ 9(2), 9(5).

68. *Id.*

69. Protocol, *supra* note 9, art. 16(3).

70. *Id.* art. 16(4).

71. Explanatory Report, *supra* note 45, ¶ 135. The reference here to Article 4 of the Convention on Human Rights and Biomedicine might be misstated. Articles 3 and 4 of that Convention read:

Article 3 – Equitable access to health care

Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality.

Article 4 – Professional standards

Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards.

Convention on Human Rights and Biomedicine, *supra* note 39, arts. 3, 4. Article 3, with its specific provision for “equitable access to health care of appropriate quality,” seems to be the more logical reference because it much more directly “state[s]” a doctor’s duty to provide care than does Article 4, which deals only generally with “professional obligations and standards.” *Id.*; Explanatory Report, *supra* note 45, ¶ 135.

72.

Both the right to know and the right not to know may, in specific circumstances, be subject to certain restrictions in the interests of the person concerned. Information on the health of a person who has expressed a wish not to know is sometimes particularly important for him or her. For example, knowing that he or she has a predisposition to a disease might be the only way to enable him or her to take measures to prevent that disease or delay its development. In such cases, the doctor’s duty to provide care, stated in Article 4 of the Convention on Human Rights and Biomedicine, might conflict with the patient’s right not to know. It is up to national law to indicate whether, having regard to the circumstances of the particular case, the doctor may make an exception to the right not to know.

Explanatory Report, *supra* note 45, art. 135.

The Protocol makes room for situations in which information about preventable diseases is made known to the unwilling subject, while the GenDG makes no such allowance. Yet a subject should be able to have all necessary information before making a choice. In defense of the individual's right not to know, the GenDG may create situations in which subjects may be harmed or may even die simply because they do not want to know.

While individual autonomy should be supported and paternalism avoided to the extent possible, a subject who may have originally thought that he did not want to know test results might later benefit from knowledge that prevented or delayed the onset of a genetic illness.⁷³ Test results could also greatly affect the lives of test subjects' relatives.⁷⁴ The patient's or relative's interest in avoiding a life-altering or fatal disease⁷⁵ should override his uninformed interest in remaining ignorant of information. In this regard, the Protocol presents the best approach in its allowance of exceptions to the right not to know. It must also be remembered that because the Protocol allows for national laws to prevent

73. Andorno provides an excellent summary of current arguments concerning the right not to know, many of which follow similar lines to the ones set forth in this Note:

The main practical objection is that this right is not feasible because, in order to decide not to receive some information, the person should previously be informed of the possibility of having a particular health risk. Now, this is precisely what the individual wanted to avoid. A most fundamental objection is that, according to a long and well established philosophical tradition, knowledge is always good in itself and therefore a "right to remain in ignorance" appears as a contradiction; that is, as an irrational attitude, which is incompatible with the notion of "right".

R. Andorno, *The Right Not to Know: An Autonomy Based Approach*, 30 J. MED. ETHICS 435, 436 (2004). Andorno also addresses the arguments that not imparting knowledge to patients is paternalistic. *Id.* Andorno makes a well-reasoned argument that "the possibility to choose not to know the results of genetic tests may constitute an *enhancement of autonomy*, because the decision to know or not to know is not taken out of the hands of the patient by the doctor," as long as patient consent is explicit. *Id.* at 436, 439. Andorno concludes, in line with the Protocol, that the right not to know "is a relative right, in the sense that it may be restricted when disclosure to the individual is necessary in order to avoid serious harm to third parties, especially family members, which means that some form of prevention or treatment is available." *Id.* at 439. Andorno's focus on autonomy is criticized in a commentary following his article, in which G. Laurie (whom Andorno often cites) argues that the right to know is a right of privacy that subsumes Andorno's right to autonomy. G. Laurie, *Commentary*, 30 J. MED. ETHICS 439, 439 (2004).

74. Andorno recites the argument put forward by others that refusing knowledge about a genetic test, the results of which could be important to family members' health, is acting against solidarity. Andorno, *supra* note 73, at 436.

75. "In some diseases, as for example in cystic fibrosis, phenylketonuria, and glucose six phosphate dehydrogenase deficiency, — the information is vital for the health (or life) of some family members and allows preventive intervention." Gunter Bruns & Moshe Wolman, *Morality of the Privacy of Genetic Information: Possible Improvements of Procedures*, 19 MED. & L. 127, 134 (2000).

the doctor from making such an exception, Germany would still be able to sign on to the Protocol and retain its current policy on the right to know.⁷⁶

B. Exception to the Medical Supervision Requirement

Both the GenDG and the Protocol contain a general requirement of either supervision or direct administering of genetic testing by a medical doctor.⁷⁷ Yet the Protocol allows for an exception to this requirement.⁷⁸ The Protocol somewhat cryptically states: “Exceptions to the general rule . . . may be allowed by a Party, subject to appropriate measures being provided, taking into account the way the test will be carried out, to give effect to the other provisions of this Protocol,” and goes on to state that “such an exception may not be made with regard to genetic tests with important implications for the health of the persons concerned or members of their family or with important implications concerning procreation choices.”⁷⁹ The “other provisions of this Protocol” mentioned are “the provisions concerning the nature and quality of prior information, free and informed consent and genetic counseling.”⁸⁰ Yet it remains unclear what would qualify as “important implications” or “appropriate measures.”

The Explanatory Report to the Protocol clarifies that home genetic test kits, also called direct-to-consumer (DTC) tests, in which the consumer

76. “In exceptional cases, restrictions *may* be placed by law on the exercise of the rights” to know and not to know. Protocol, *supra* note 9, art. 16(4) (emphasis added).

77. Compare Protocol, *supra* note 9, art. 7(1) with GenDG § 7(1). The interpretation of the two laws could differ slightly on this point. The German law differentiates tests into those which are either diagnostic or predictive in nature. GenDG § 7(1). In the case of diagnostic tests, the tests must be carried out by a medical doctor herself; in the case of predictive tests, such must be carried out by “medical doctors who are certified specialists in human genetics or by other medical doctors who within the framework of their own area of expertise were also able to obtain certification, specialization or additional qualification to conduct genetic examinations.” *Id.* The Protocol, on the other hand, requires only that “a genetic test for health purposes may only be performed under individualised medical supervision.” Protocol, *supra* note 9, art. 7(1). The most reasonable interpretation of this phrase is that the test itself need not be carried out by the doctor—rather only that the doctor must individually supervise the person carrying out the test. What type of supervision this entails may be somewhat open-ended in the Protocol, but the Explanatory Report does clarify what effect the supervision should be to “enable the person concerned to have suitable preliminary information with a view to an informed decision regarding the carrying out of this test and, if appropriate, to have access to an appropriate genetic counseling.” Explanatory Report, *supra* note 45, ¶ 64. The Explanatory Report also specifically directs that a precise evaluation of the situation is a determining element in that respect, and that a telephone conversation between a doctor and subject does not allow for such an evaluation. *Id.* Therefore, if the test is not carried out by the doctor herself, the supervision must be of such quality as to enable the doctor to provide a precise evaluation based on her knowledge of the case.

78. Protocol, *supra* note 9, art. 7(2).

79. *Id.*

80. Explanatory Report, *supra* note 45, ¶ 66.

can both administer and analyze the test, are perfectly acceptable.⁸¹ This is true at least in situations as dictated by a state Party to the Protocol⁸² according to the following factors: the potential implications for the test subject and his family; the ease of interpretation of the results; treatment possibilities for the disease or disorder concerned (if appropriate)⁸³; whether the sample is analyzed by the subject or by a laboratory;⁸⁴ and the ability of the test subject to consent.⁸⁵ Guiding all of these factors is the objective of the “protection of the person concerned”⁸⁶ and the main concern of “[t]he correct interpretation of results and the guarantee of appropriate genetic counseling to understand their implication.”⁸⁷

There is no exception to the requirement of individualized medical supervision “in the case of genetic tests with important implications for the health of the person concerned or of members of his or her family, or for choices concerning procreation.”⁸⁸ The exception available in cases that do not meet those criteria can thus be quite broad,⁸⁹ standing in stark contrast

81. The Protocol accepts many types of direct-to-consumer kits, including those in which the test subject can analyze his own sample:

The exceptions under consideration do not concern the performance of a test on a particular individual but rather readily identifiable test device for which the genetic characteristics it is meant to identify would be specified. The genetic tests concerned may be carried out by a laboratory after the biological material has been removed by a professional or by the person concerned him or herself who then sends it to the laboratory. They may also be tests entirely carried out by the person concerned with a kit enabling him or her to remove the biological sample as well as to carry out the analysis.

Explanatory Report, *supra* note 45, ¶ 67.

82. “It is left to each state to determine how to implement this provision effectively.” *Id.* ¶ 68.

83. *Id.* The reference of the term “if appropriate,” which is taken directly from Article 68 of the Explanatory Report, is not explained further in either the Protocol or the Explanatory Report to it. It seems to simply state that treatment possibilities need only be a factor in allowing direct-to-consumer kits in those situations where treatment could be required, i.e., a “disease or disorder” as stated in the Explanatory Report. *Id.*

84. “The envisaged measures to give effect to the provisions of this Protocol could be different depending on whether the test considered is fully carried out by the person concerned by means of a kit or whether the analysis is carried out by a laboratory.” *Id.*

85. “The performance without individualised medical supervision of genetic tests on persons not able to consent, raises special concerns. States should bear these in mind when authorising, or not, direct access to such tests.” *Id.* ¶ 69.

86. *Id.* ¶ 68.

87. *Id.* ¶ 70.

88. *Id.*

89. At first blush, it is hard to think of genetic tests that would not present such important implications for health or for choices concerning procreation. Yet some could fall under the exception: determination of the nationality of one’s ancestry, or paternity testing. Even these, though, would more often than not be expected to lead to information with such important health or procreation implications. For example, paternity testing intended simply to determine the identity of the father could also reveal that the father has a genetic predisposition to a disease, such as heart disease or alcoholism, which genes have been transmitted to the test subject child, and which would certainly create important health or procreation implications for the child. Ancestry and nationality

to the German law, which *always* requires medical performance of tests and thereby completely bans the use of DTC genetic test kits.⁹⁰

DTC kits can increase individual access to genetic information and thereby increase personal autonomy.⁹¹ Yet some fear that they may easily be misused or misinterpreted by consumers who do not follow directions or who lack the ability to interpret the tests and results.⁹² Thus, a fear of lack of consumer education would support the GenDG's blanket prohibition of DTC kits. While any medical device manufacturer cannot ensure that consumers will, in reality, always follow all directions, the severity of the potential problems of misuse and misinterpretation are greatly alleviated by the Protocol's requirement that only less significant tests and those which are easy to interpret are allowed in DTC kits.⁹³ Yet commentators have also objected to the general idea of DTC kits because such kits cannot require informed consent.⁹⁴ The Protocol also specifically addresses this problem by recognizing the ability of the consumer to make an informed decision as an important concern in determining whether DTC kits should be allowed.⁹⁵ Overall, then, the Protocol provides specific guidelines that make for a workable system governing direct-to-consumer genetic kits.

III. LESSONS FOR THE *GENDIAGNOSTIKGESETZ* AND THE PROTOCOL

A. *Persons Lacking the Capacity to Consent*

In the case of a genetic test on a subject lacking capacity to consent, the GenDG provides first, among other things, that the test may only be conducted if the subject himself has a genetic illness or condition that

determinations could also have similar important implications when that particular nationality or ancestry has a higher incidence of a disease than the general population, as is the case with people of African descent and sickle-cell anemia and Ashkenazi Jews and a wide range of diseases, including Tay-Sachs Disease. Trudo Lemmens, *Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?*, 45 MCGILL L.J. 347, 372–73 (2000).

90. GenDG § 7(1).

91. In fact, the German law is criticized by the Genomics Law Report for purporting to ensure the individual right to self-determination (similar to autonomy) but at the same time restricting the individual's ability to directly access his own genetic information. *See supra* note 4.

92. *See generally* Rebecca Antar Novick, Comment, *One Step at a Time: Ethical Barriers to Home Genetic Testing and Why the U.S. Health Care System is Not Ready*, 11 N.Y.U. J. LEGIS. & PUB. POL'Y 621 (2007–2008).

93. Explanatory Report, *supra* note 45, ¶ 68.

94. Novick, *supra* note 92, at 635.

95. Explanatory Report, *supra* note 45, ¶ 64.

requires the test to be performed as part of treatment.⁹⁶ The law makes a narrow exception only when, “in the case of a planned pregnancy and in regard to a genetically related person,” there is no other way to determine whether the offspring will have a genetic illness or condition.⁹⁷

The Protocol, on the other hand, deviates from its base treaty, the Convention on Human Rights and Biomedicine,⁹⁸ by allowing “a genetic test to be carried out, for the benefit of family members, on a person who does not have capacity to consent,” as long as, among other things, “the purpose of the test is to allow the family member(s) concerned to obtain a preventive, diagnostic or therapeutic benefit that has been independently evaluated as important for their health, or to allow them to make an informed choice with respect to procreation.”⁹⁹

As opposed to the GenDG, the Protocol allows testing for the benefit of family members, not just their unborn offspring, in the case of a subject lacking capacity to consent. The Explanatory Report to the Protocol identifies a situation in which testing for the benefit of living family members would be vital: “[A] person not able to consent [who is] suffering from cancer.”¹⁰⁰ In the example, information from a genetic test

96. In the case of:

any person who does not possess the capacity to recognize the nature, meaning or scope of a genetic examination, and is therefore unable to adjust his or her will accordingly, genetic examinations for medical purposes as well as gaining any genetic samples necessary therefore may only be conducted if

1. according to the generally accepted status of science and technology, doing so is necessary to avoid, prevent or treat a genetically-caused illness or health condition of the subject person, or if treatment with medication, which can affect genetic characteristics.

GenDG § 14(1).

97. *Id.* § 14(2)(1).

98. The original Convention states, “[s]ubject to Articles 17 and 20 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit.” Convention on Human Rights and Biomedicine, *supra* note 39, art. 6(1). Articles 17 and 20 referred to outline requirements in regards to persons lacking the capacity to consent when the purpose of tests is for research and organ removal, respectively. “Intervention” is defined in the Explanatory Report to the Convention as covering “all medical acts, in particular interventions performed for the purpose of preventive care, diagnosis, treatment or rehabilitation or in a research context.” Convention on Human Rights and Biomedicine Explanatory Report, *supra* note 50, art. 29.

99. Protocol, *supra* note 9, art. 13(a).

100. Explanatory Report, *supra* note 45, ¶ 106. The Explanatory Report also lists two other illustrations of the law at work in hypothetical situations:

Another example is that of a child who was diagnosed, on the basis of clinical signs and symptoms and biochemical tests, with cystic fibrosis. This disease can be related to many different genetic mutations. For possible future procreation choices, it can be important to identify the existing mutation in the affected child. This will make it possible to look for the mutation in the child’s parents in order to determine if it is them who transmitted it or if it is a mutation newly appeared in the child having developed the disease. In the latter case, there would be no particular reason to fear for the health of a future child of the couple concerned.

on the subject would not be used for his own benefit, but to save the lives of his living relatives. Those living relatives could be tested for the same mutations that appear in the subject in order to determine their likelihood of developing the same cancer, giving the relatives a chance to take preventive and early detection measures to combat the cancer.¹⁰¹

Under the GenDG, such relatives would not be allowed to obtain this genetic information to save their own lives, unless they requested the test under the pretext that they would use the genetic information in their decision to bear children. The result seems grossly inequitable—in effect, those relatives would lose their chance to take early or preventative measures against the cancer, increasing their likelihood of dying from the disease. This risk to the relatives is not outweighed by an attendant benefit to the test subject.¹⁰²

B. Impossibility of Obtaining Consent from Subject, and Deceased Subjects

The Protocol provides:

When it is not possible, with reasonable efforts,¹⁰³ to contact a person for a genetic test for the benefit of his or her family member(s) on his or her biological material previously removed for another purpose, the law may allow the test to be carried out in accordance with the principle of proportionality, where the expected benefit cannot be otherwise obtained and where the test cannot be deferred.¹⁰⁴ The Protocol also states that provisions shall be made for the subject when he expressly opposes the genetic test.¹⁰⁵

A last example is the case of diseases, especially rare ones, for which the genetic mutation involved has not been identified. In such case, the transmission of the mutation can be traced by studying genetic linkage. In order to determine a genetic risk in a family in which a genetic disease with an unidentified genetic mutation has manifested itself, it is possible that genetic tests on affected but also unaffected children would be necessary, so as to obtain an acceptable degree of diagnostic certainty—for example, for other members of the family, whether of child-bearing age or not.

Explanatory Report, *supra* note 45, ¶¶ 107–108.

101. Explanatory Report, *supra* note 45, ¶ 106.

102. It could be argued in certain situations that there is still a great privacy interest, but a court would be hard-pressed to prove that one's right to privacy outweighed another's right to live.

103. The Explanatory Report does not specify further what "reasonable efforts" to contact the subject would entail. It does, however, provide that those cases of benefit to relatives that are envisaged in the law are generally of a health benefit nature. Explanatory Report, *supra* note 45, ¶¶ 107–108.

104. Protocol, *supra* note 9, art. 14. While the Protocol does not specify "health benefits" as the type at issue, the Explanatory Report identifies situations where "failure to carry out the envisaged

The GenDG provides no exception to the subject consent requirement in the case of a deceased or impossible-to-find subject.¹⁰⁶ This means that in the situation (provided in the Explanatory Report to the Protocol) of a family with a history of ovarian cancer where the genetic mutation had not been identified, the use of the subject's genetic information to identify the mutation would be prohibited.¹⁰⁷ This could increase the difficulty of identifying the mutation,¹⁰⁸ and relatives' ovaries might need to be removed unnecessarily in the fear that they will exhibit the disease, when they may not actually have the genetic mutation that causes the disease. Such an outcome defies reason and is easily avoidable.¹⁰⁹

Similar to the exception for genetic impossibility of subject contact is the exception for deceased subjects under the Protocol.¹¹⁰ The only major

genetic test may have serious consequences for the health of those family members whom it was intended to benefit." Explanatory Report, *supra* note 45, ¶ 118.

105. The Protocol does not state what these Provisions should be, but allows for such Provisions to be made. Protocol, *supra* note 9, art. 14.

106. GenDG § 14.

107.

This applies, for example, to families in which there have been several cases of ovarian cancer, and the genetic mutation involved has not been identified. The genetic test envisaged might help to carry out a family study with a view to identify the mutation, making it unnecessary to remove the ovaries of female family members in whom it would not be identified. In such cases, it may be considered that the benefit for the family members concerned is particularly important and substantially outweighs any risks to the person whose biological material would be used – in particular for his or her private life – if the test were carried out without his or her consent.

Explanatory Report, *supra* note 45, ¶ 118.

108. Identification of the gene would likely be more difficult without genetic information of a relative who has already exhibited the effects of the suspected gene. As Lucassen puts it, in situations where multiple large genes may be associated, the sensitivity of genetic testing in the "at-risk" woman is greatly increased if the familial mutation can first be identified in an "affected" relative. Without this, the negative predictive value of a genetic test is currently low. If the familial mutation is known, however, a highly accurate predictive test can be available for management options such as prophylactic surgery. A. Lucassen & J. Kaye, *Genetic Testing Without Consent: the Implications of the New Human Tissue Act 2004*, 32 J. MED. ETHICS 690, 690 (2006).

109. Lucassen & Kaye do point out some problems for estranged or out-of-touch family members under a similar law in the U.K. that allows for persons to obtain the results of their relatives' genetic tests without that relative's consent. "People may have a legitimate fear that they will be blamed for passing on 'bad' genes, or, alternatively, they may have a genuine reason to believe that such information would harm their relatives and may withhold it to protect them." *Id.* Lucassen & Kaye acknowledge that debates on this subject have tended to justify disclosure of genetic test results to the subject's relatives of an already known test in very rare circumstances. *Id.* at 691. The authors criticize the U.K. act, though, for not differentiating between test results of already-taken tests, and new testing without subject consent for the health of family members. *Id.* The latter, according to Lucassen & Kaye, presents greater problems because it "is contrary to the basis of the original consent." *Id.* The same lack of differentiation is present in the Protocol, and the same criticism could be made. *See generally* Protocol, *supra* note 9.

110. A genetic test for the benefit of other family members may be carried out on biological samples "removed from the body of a deceased person, or "removed, when he or she was alive, from a

difference here is that the Protocol requires, in the case of a deceased subject, that “the consent or authorization required by law has been obtained.”¹¹¹ The GenDG specifies nothing in the case of deceased subjects,¹¹² meaning that would-be recipients of the benefits of genetic information in family health situations seem to be left with no recourse to gain access to it if the deceased gave no express, written consent before he passed.

The Protocol allows no exception to the consent requirement when fully informed consent is obtainable.¹¹³ Family disclosure over the objections or absent the consent of the test subject is a highly contested issue.¹¹⁴ Family members should have an interest in a test subject’s genetic information, but such information can cause psychological trauma rather than a desired benefit,¹¹⁵ or may go against the family member’s interest if that family member does not want to know or does not want others to know.¹¹⁶ Several studies show that those with knowledge of genetic information with adverse health consequences did not make decisions to avoid those outcomes, or worse yet, committed suicide based on the belief that they would exhibit the symptoms of a disease years in the future.¹¹⁷

person now deceased, only if the consent or authorization required by law has been obtained.” Protocol, *supra* note 9, art. 15.

111. *Id.* The law referred to here is national law:

It is left to national law to determine the rules governing consent (e.g. express or presumed) or authorization applicable to genetic tests hence implemented. It is also left to national law to specify the conditions for the evaluation of “the benefit of other family members.” For the evaluation of such a concept, the principles of necessity and proportionality must be taken into account.

Explanatory Report, *supra* note 45, ¶¶ 125–126.

112. The only provision in the GenDG that comes close to addressing the situation of a deceased test subject is section 14, concerning persons lacking the full capacity to consent. That section, though, is meant for living but incapable test subjects. GenDG § 14(1) (“[G]enetic examinations . . . may only be conducted if . . . before proceeding the examination was explained to the person in a manner that was as understandable as possible to the person. . .”).

113. Protocol, *supra* note 9, art. 9.

114. See, e.g., Graeme T. Laurie, *Challenging Medical-Legal Norms: The Role of Autonomy, Confidentiality, and Privacy in Protecting Individual and Familial Group Rights in Genetic Information*, 22 J. LEGAL MED. 1 (2001); Ellen Wright Clayton, *What Should the Law Say About Disclosure of Genetic Information to Relatives?*, 1 J. HEALTH CARE L. & POL’Y 373 (1998); Janet A. Kobrin, Comment, *Confidentiality of Genetic Information*, 30 UCLA L. REV. 1283 (1983); Bruns & Wolman, *supra* note 75.

115. Laurie, *supra* note 114, at 11–12.

116. *Id.* at 10–11.

117. *Id.* at 12–13. In one Swedish study, parents who knew their child had an alpha₁-antitrypsin deficiency exhibited long term psychological consequences and did not show the appreciable reduction in smoking that doctors had advised parents to undertake to avoid exacerbation of the results of the genetic disorder. In the United States, cystic fibrosis screening programs were abandoned early because they created premature psychological distress. And in one study, subjects who became aware that they had a gene for Huntington’s Disease committed suicide at a rate ten times higher than the

Solving the problem of how a family member will react to genetic information involves considerations of autonomy, confidentiality, and privacy so complex that there may not be one best answer for all cases.¹¹⁸ Yet certain reasons for withholding genetic information from family members should be deemed unacceptable. Examples of such reasons from the literature include: strained relationships, lost contact, fear of being blamed for passing bad genes, or a belief that such information would harm relatives.¹¹⁹ Other possible reasons include embarrassment about the genetic disease or the related procedure, distraction because of one's own concerns, fear that the relative might have trouble obtaining insurance because of the information, not wishing to be the bearer of bad news, the unsure nature of the specific genetic test, or even spite.¹²⁰ Under both the GenDG and Protocol, the test subject with capacity and ability to consent to disclosure of genetic information always has the last word, and no reasons for withholding consent are illegal.¹²¹ Therefore, the test subject always has bargaining power against anyone seeking his genetic information, and it is conceivable that a test subject could require payment in exchange for the genetic information. Additionally, a test subject may refuse to consent to disclosure in order to collect life insurance proceeds once a relative dies from a disease the subject could have helped cure.

One commentator argues that “[e]lementary decency requires that the one who obtained genetic information should impart it to his relatives and others to allow them to avoid future damage.”¹²² Another characterizes “autonomy, beneficence, nonmaleficence, and justice” as “the four principles of ethics” [that] have significantly influenced much of Western thinking and action, particularly in the medical-legal sphere.”¹²³ While the GenDG and the Protocol arguably increase patient autonomy, a family member’s autonomy is likely decreased when she is being barred access to

United States average, even though they were years away from exhibiting the effects of the disease. Laurie also points out that those family members who are not affected by the disease can even have the negative psychological effect of survivor guilt. *Id.* at 13–14.

118. Laurie ends his extensive treatise on autonomy, confidentiality, and privacy by acknowledging that his solution is “not without its problems.” *Id.* at 54. Bruns and Wolman acknowledge that their “proposed solution is not a secure panacea for the difficulties [of genetic screening].” Bruns & Wolman, *supra* note 75, at 139.

119. Lucassen & Kaye, *supra* note 108, at 690.

120. Clayton, *supra* note 114, at 374.

121. GenDG § 8; Protocol, *supra* note 9, art. 9.

122. Bruns & Wolman, *supra* note 75, at 137.

123. Laurie, *supra* note 114, at 15. Laurie takes these principles from Thomas Beauchamp & James Childress, *PRINCIPLES OF BIOMEDICAL ETHICS* (4th ed. 1994), but acknowledges that these principles are “not the only model of medical ethics in existence.” *Id.* n.40.

genetic information.¹²⁴ Beneficence, nonmaleficence, and justice would all require that a patient or the patient's doctor divulge relevant genetic information to family members in order for them to receive the greatest benefit, the least harm, and fair treatment for all such relatives. This is especially true in cases where the reasons for withholding information include spite or attempted personal gain.

In view of these foundational principles, both Germany and the Council of Europe should reconsider their stance in light of the basic premise it reveals—that sometimes consent is more important than life. Certainly the lawmakers drafting the GenDG would not have intended such results, but by creating a blanket consent requirement, they may induce them. To correct these defects, a possible clause in the law could read: “A test subject cannot withhold consent for an improper reason. Such improper reasons include—(1) personal pecuniary gain; or (2) animosity toward someone seeking such consent.”

C. Secret Paternity Testing

On the subject of consent and descent determination through secret paternity tests, both the GenDG and the Protocol take the same stance—all such genetic tests require free and informed consent of the test subject.¹²⁵ Yet a previous case from the European Court of Human Rights presents a different possibility. In *Mikulić v. Croatia*,¹²⁶ a daughter born out of wedlock sought to determine whether the defendant was her father.¹²⁷ The Croatian courts, where the case began, had no procedure to compel the defendant to comply with a court order requiring him to undergo DNA testing for paternity.¹²⁸ The ECHR held, *inter alia*,¹²⁹ that this was a

124. Laurie, *supra* note 114, at 21. Laurie points out that “[c]entral to the principle of autonomy is choice,” which requires knowledge and capacity to choose, but a family member unaware of genetic information does not have the knowledge to make a choice. *Id.*

125. GenDG § 17. The Protocol does not address paternity testing specifically. Instead, it makes a blanket consent requirement, and then only makes limited exceptions. The only such exception that could possibly address paternity testing is the exception on persons not able to consent, and only following a creative interpretation of the Protocol so as to include mental health implications under the term “health” in Article 13(a). Protocol, *supra* note 9, art. 13(a). This reading seems unlikely, as all three of the examples given in the Protocol for such an exception involve physical health implications. Explanatory Report, *supra* note 45, ¶¶ 106–108.

126. *Mikulić v. Croatia*, Eur. Ct. H.R. App. No. 53176/99 (2002).

127. *Id.* at 2.

128. *Id.* at 9–10. The first-instance court did, however, decide that the defendant was the father based primarily on the fact that the defendant had been avoiding the DNA testing. *Id.* at 3. This holding was later quashed by the Zagreb County Court. *Id.* The European Court of Human Rights determined that when no procedure to compel DNA testing is present, there must be some “alternative means enabling an independent authority to determine the paternity claim speedily.” *Id.* at 10.

violation of Article 8 of the European Convention on Human Rights,¹³⁰ because the applicant had not obtained the respect for her private life to which she was entitled to under the Convention.¹³¹ The court created and applied a balancing test: there must be a “fair balance between the right of the applicant to have her uncertainty as to her personal identity eliminated without unnecessary delay and that of her supposed father not to undergo DNA tests.”¹³²

A person’s interest in knowing her father’s identity should be considered integral to the person’s mental and emotional health. *Mikulić*’s recognition of that interest as an important factor to be balanced against the possible father’s privacy interest seems more reasonable than the Protocol and the GenDG in their blanket prohibition on paternity testing without consent.¹³³ Such an identity interest of the possible offspring could be limited and qualified so as to override the father’s privacy interest only in cases where, because of the mental, emotional, or physical condition of

129. The applicant-daughter also successfully argued that the delays in the proceedings and the inability of the court to obtain a paternity test result violated Articles 6(1) and 13 of the European Convention on Human Rights, respectively. *Id.* at 6, 11. Article 6(1) states: “In the determination of his civil rights and obligations or of any criminal charge against him, everyone is entitled to a fair and public hearing within a reasonable time by an independent and impartial tribunal established by law.” Council of Europe, Convention for the Protection of Human Rights and Fundamental Freedoms: The European Convention on Human Rights art. 6(1), C.E.T.S. No. 005 (1950) [hereinafter “European Convention on Human Rights”]. The court in *Mikulić* held that the applicant’s “right to have her paternity established or refuted and thus to have her uncertainty as to the identity of her natural father eliminated” related to civil rights and obligations, and that therefore Article 6(1) “ensur[ed] the progress of the proceedings.” *Mikulić*, Eur. Ct. H.R. App. No. 53176/99, at 6.

Article 13 provides: “Everyone whose rights and freedoms as set forth in this Convention are violated shall have an effective remedy before a national authority notwithstanding that the violation has been committed by persons acting in an official capacity.” European Convention on Human Rights, *supra* note 129, art. 13. The court stated that the violation of Article 13 flowed from the violation of Article 6(1) “in so far as the applicant has no domestic remedy whereby she may enforce her right to a ‘hearing within a reasonable time’ as guaranteed by Article 6 § 1 of the Convention.” *Mikulić*, Eur. Ct. H.R. App. No. 53176/99, at 11.

130. The Article provides:

1. Everyone has the right to respect for his private and family life, his home and his correspondence.
2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

European Convention on Human Rights, *supra* note 129, art. 8.

131. “[T]he inefficiency of the courts has left the applicant in a state of prolonged uncertainty as to her personal identity. The Croatian authorities have therefore failed to secure to the applicant the ‘respect’ for her private life to which she is entitled under the Convention.” *Mikulić*, Eur. Ct. H.R. App. No. 53176/99, at 10.

132. *Id.*

133. GenDG § 8; Protocol, *supra* note 9, art. 9.

the possible offspring, it would be most inequitable for her to remain without knowledge of her father.¹³⁴

CONCLUSION

The strict consent requirement of the GenDG, and even the looser consent requirement of the Protocol, could often leave families scrambling to find answers that are easily accessible through other family members' genetic tests, including information about possible future health problems and paternity. In regard to the right not to know and direct-to-consumer genetic tests, the Protocol hits the mark by allowing for health interest exceptions in the former case and limited exceptions creating greater accessibility to non-crucial genetic information in the latter. The difficulties for the GenDG, and sometimes the Protocol, come in areas where it seems the legislators did not consider individual situations in which it may be inequitable to the test subject or his family to allow the test subject unrestricted control over genetic information.¹³⁵ The study of medical genetics seems to hold the secrets of not just what one has done in the past, but what will come in one's future.¹³⁶ Greater individual autonomy and control in this rapidly evolving area of medicine and science is a laudable and reassuring goal. Yet blanket consent requirements go past the point of equity and reasonableness and ignore the important competing interests of family members whose health, or even lives, may be at stake.

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134. Factors that could show a possible offspring's interest in paternity testing could include identifiable psychological trauma undergone by the child and diagnosed by a psychiatric professional that appear as a result of, or are greatly intensified by, the child's lack of knowledge as to the identity of her father. Or, externally measurable factors such as stability of the childhood home could be used.

135. In general, the German genetic law follows an "individualist" approach, placing the test subject's individual autonomy and privacy above almost all else. The Protocol, on the other hand, provides exceptions that are "communitarian," and recognizes the interests of family members and society in certain genetic information. For an exposition of these two classifications, see Sirkuu Kristiina Hellsten, *Biotechnology, Genetic Information, and Community: From Individual Rights to Social Duties?*, in *GENETIC INFORMATION: ACQUISITION, ACCESS, AND CONTROL* 297, 297 (Alison K. Thompson & Ruth F. Chadwick eds., 1999).

136. Laurie, *supra* note 114, at 9.

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