Washington University Global Studies Law Review

Volume 19 | Issue 1

2020

DIRECT-TO-CONSUMER GENETIC TESTING: EMPOWERING EU CONSUMERS AND GIVING MEANING TO THE INFORMED CONSENT PROCESS WITHIN THE IVDR AND GDPR FRAMEWORKS

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VOLUME 19 NUMBER 1 2020

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SARA A. MAHMOUD-DAVIS*

ABSTRACT

Consumer genomics is an industry that is undergoing exponential growth. Although consumers in the United States (U.S.) currently purchase the bulk of online direct-to-consumer (DTC) genetic tests, the DTC industry's business model depends on exploiting markets worldwide. DTC genetic testing companies increasingly seek to market and sell their services throughout the European Union (EU), which is one of the world's largest economies and is home to a digital, educated, and wealthy consumer base. Since May 2018, the EU General Data Protection

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I dedicate this article to my three daughters, Leila, Eva, and Serena, who have opened my heart, transformed my life for the better, and each day inspire me and teach me something new. My husband Charles deserves special recognition for tirelessly supporting my dreams and aspirations. I am grateful for my dear friend Michaela Golfinopoulos for her unwavering encouragement and support in all aspects of my life. I am thankful for the guidance of my advisor Dr. Maria Sturm, and Program Director Dr. Siegfried Fina, LLM Program in European and International Business Law, the University of Vienna, Austria.

Regulation (GDPR) provides EU consumers with enhanced data privacy protections and places stricter controls on genetic data. When EU consumers purchase online DTC genetic tests, they exercise two distinct fundamental rights—the right to data privacy and the right to informed medical consent. The article explores the intersection of these rights by examining relevant EU and other legislation, mainly the GDPR, the In Vitro Diagnostic Medical Devices Regulation, and the Council of Europe's Oviedo Convention on Human Rights and Biomedicine. Additionally, the discussion highlights the challenges associated with protecting consumers' autonomy and freedom to purchase online DTC genetic tests, while also safeguarding the bioethical standards of informed consent.

The analysis explains that the online purchase of a DTC genetic test involves two distinct consent processes—one for data processing and the other for informed consent. These two consent processes are highly dependent upon each other to protect consumers adequately. Yet, the status quo reveals that informed consent is severely lacking in the purchase of online DTC genetic tests. This results in consumers' loss of control over health and medical decisions, as well as over personal data. Consequently, as the DTC genetic testing industry continues to grow, there is a critical need for more robust online informed consent procedures. The article concludes that current EU regulations fail to sufficiently address the issues specific to online DTC genetic tests. Furthermore, an EU regulation on informed consent, in general, is not feasible. Thus, the article considers opportunities for the EU and its Member States, consumers, and industry to work together to both empower and protect consumers who purchase online DTC genetic tests. Finally, the article discusses methods for industry to improve the online informed consent process.

ABSTRACT DEUTSCH

Der Markt für Verbraucherprodukte im Bereich Genomik wächst rapide. Während derzeit die überwiegende Mehrheit der online direkt an VerbraucherInnen vermarkteten (Direct-to-Consumers, DTC) Gentests in den USA gekauft wird, ist der Erfolg des DTC-Geschäftsmodells vom Zugang zum weltweiten Markt abhängig. Unternehmen, welche DTC-Gentests anbieten, vermarkten und verkaufen ihre Dienste zunehmend auch in der Europäischen Union (EU), einer der größten Volkswirtschaften der Welt mit einer durchwegs digitalisierten, gebildeten und kaufkräftigen Bevölkerung. Seit Mai 2018 genießen europäische KonsumentInnen durch die europäische Datenschutz-Grundverordnung (DSGVO) erhöhten

Datenschutz und einen nun strenger regulierten Umgang mit genetischen Informationen. Erstehen KonsumentInnen in der EU DTC-Gentests online, machen sie von zwei verschiedenen Grundrechten Gebrauch: dem Recht auf Datenschutz und dem Recht auf Aufklärung vor der Einwilligung im Medizinbereich. Basierend auf einer Analyse relevanter EU- und anderer Gesetzgebung, darunter insbesondere der DSGVO, der In-vitro-Diagnostika-Verordnung und des Oviedo-Übereinkommens über Menschenrechte und Biomedizin des Europarats, untersucht die vorliegende Arbeit die Schnittstellen dieser beiden Rechte. Zudem wird die Herausforderung thematisiert, die Autonomie und Freiheit von KonsumentInnen, online DTC-Gentests zu erwerben, zu schützen und gleichzeitig die bioethischen Standards der informierten Einwilligung zu wahren.

Die Analyse zeigt, dass der Online-Erwerb eines DTC-Gentests zwei unterschiedliche Einwilligungsprozesse umfasst: einerseits hinsichtlich der Datenverarbeitung, andererseits in Bezug auf die informierte Einwilligung. Für den ausreichenden Schutz von KonsumentInnen ist eine enge Interdependenz dieser beiden Einwilligungsprozesse erforderlich. Die informierte Einwilligung im Rahmen des Online-Kaufes eines DTC-Gentests ist in der Praxis jedoch hochgradig mangelhaft. Als Folge verlieren KonsumentInnen die Kontrolle über Entscheidungen hinsichtlich ihrer Gesundheit und medizinischer Verfahren wie auch in Bezug auf ihre persönlichen Daten. Angesichts des anhaltenden Wachstums des Marktes für DTC-Gentests besteht dringender Bedarf an robusten Online-Verfahren zur Einholung einer informierten Einwilligung. Die Arbeit zieht die Schlussfolgerung, dass die bestehenden EU-Verordnungen in Hinblick auf die spezifischen Problemstellungen bei Online-DTC-Gentests unzureichend sind. Gleichzeitig wäre aber eine EU-Verordnung zur informierten Einwilligung grundsätzlich nicht umsetzbar. Die Arbeit beleuchtet daher die Chancen der Kollaboration von EU, Mitgliedstaaten, KonsumentInnen und Anbietern mit dem Ziel, KonsumentInnen von online erworbenen DTC-Gentests zu stärken und zu schützen. Abschließend werden für Anbieter intendierte Methoden zur Verbesserung von Online-Verfahren zur Einholung einer informierten Einwilligung vorgestellt.

LIST OF ABBREVIATIONS

CJEU	*Court of Justice of the European Union*
DPO	*Data Protection Officer*
DoH	*Declaration of Helsinki*
DSM	*Digital Single Market*
DNA	*Deoxyribonucleic Acid*
DTC	*Direct-to-Consumer*
DTCGT	*Direct-to-Consumer Genetic Testting*
ENVI	*Environment, Public Health, Food and Safety*
ECtHR	*European Court of Human Rights*
EU	*European Union*
ESHG	*European Society of Human Genetics*
FDA	*United States' Food and Drug Adminiistration*
GDPR	*General Data Protection Regulation*
GSK	*GlaxoSmithKline*
HGP	*Human Genome Project*
ICO	*Informed Consent Officer*
IVDD	*In Vitro Medical Devices Directive*
IVDR	*In Vitro Diagnostice Medical Devices Regulation*
MDCG	*Medical Device Coordination Group*
SDM	*Shared Decision-Making*
TFEU	*Treaty on the Functioning of the European Union*
U.S.	*United States of America*
WMA	*World Medical Association*

I. INTRODUCTION

> Being European means the right to have your personal data protected by strong, European laws. Because Europeans do not like drones overhead recording their every move, or companies stockpiling their every mouse click. This is why Parliament, Council and Commission agreed…this year [to] a common European data protection regulation. This is a strong European law that applies to companies wherever they are based and whenever they are processing your data. Because in Europe, privacy matters. This is a question of human dignity.[1]
>
> President of the European Commission Jean-Claude Juncker

President Juncker's speech references the General Data Protection Regulation (GDPR).[2] In April 2016, the European Union (EU or Union) enacted the GDPR with the goal of protecting EU residents with respect to the processing of their personal data.[3] The regulation went into direct effect throughout the EU on May 25, 2018, and is far-reaching, affecting anyone who processes the personal data of natural persons located within the EU, regardless of their nationality or place of residence.[4] It is a "strong European law"[5] because it applies to U.S. and other foreign companies that do business in the EU, notably capturing those businesses that conduct operations solely through e-commerce without having a brick-and-mortar place of business within the Union.

In that same State of the EU speech, Commission President Juncker underscored that people's lives and the economy depend on digital technology, and he emphasized the need to create a "Europe that empowers [its] citizens and [its] economy" in this digital age.[6] The GDPR is a primary component of the EU Data protection framework and also of the EU's Digital Single Market (DSM) initiative. The DSM works to

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1 Jean-Claude Juncker, *State of the Union 2016*, PUBS. OFF. EUR. UNION 10 (Sept. 14, 2016), https://publications.europa.eu/de/publication-detail/-/publication/c9ff4ff6-9a81-11e6-9bca-01aa75ed71a1/language-en (last visited July 18, 2019) (emphasis added).

2 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), Apr. 27, 2016, 2016 O.J. (L 119) 1 [hereinafter GDPR].

3 *Id.* art. 4(1). The GDPR defines "personal data" as "any information relating to an identified or identifiable natural person ('data subject')." *Id.*

4 *Id.* art. 99(2).

5 Juncker, *supra* note 1, at 10.

6 *Id*. at 13.

ensure the free movement of persons, services and capital, and where individuals and businesses can "seamlessly access and engage in online activities under conditions of fair competition, and a high level of consumer and personal data protection, irrespective of their nationality or place of residence."[7] The GDPR offers EU residents the opportunity and legal mandate to gain greater control over their data, especially over the proliferation of personal data that is available online.

It has been more than a year since the GDPR came into force. This article discusses the GDPR in the context of online Direct-to-Consumer (DTC) genetic tests sold to consumers within the EU. Typically, DTC genetic tests, including test results and interpretations, are sold directly to the consumer without the involvement of a healthcare provider.[8] This common definition of DTC genetic tests is used throughout the article.

The GDPR specifically addresses genetic data, but only within the limited context of data processing and the protection of sensitive information. Yet, as the discussion illustrates, the online DTC genetic testing industry faces the challenge of protecting consumers on two fronts—informed consent and data privacy. These two issues are inextricably linked for consumers purchasing online genetic tests.

Given the growing trend towards DTC genetic testing and the scientific research derived from consumers' participation, there is an increasing need for more robust online informed consent that adequately protects and empowers the consumer.

This analysis begins with the recent EU Regulation on In Vitro Diagnostic Medical Devices (IVDR). The evolution of the IVDR demonstrates the EU's authority and willingness, if any, to impose informed consent requirements on genetic testing. This article discusses how, if at all, the IVDR and GDPR empower and protect EU consumers who directly purchase the online services of DTC genetic testing companies. Additionally, the analysis focuses on the dual challenge of empowering and protecting consumers of DTC genetic tests and makes recommendations to improve the online informed consent process.

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7 *Shaping the Digital Single Market Strategy*, EUR. COMM., https://ec.europa.eu/digital-single-market/en/policies/shaping-digital-single-market (last visited July 18, 2019). The Digital Single Market (DSM) strategy was adopted on May 6, 2015.

8 H. Skirton, et al., *Direct to consumer genetic testing: a systematic review of position statements, policies and recommendations*, 82 CLIN. GENET. 1, 1 (2012).

II. OVERVIEW OF DIRECT-TO-CONSUMER (DTC) GENETIC TESTING COMPANIES AND ONLINES SALES IN THE EU

In June 2019, Top10.com listed the five following deoxyribonucleic acid (DNA) testing companies as the best of 2019: MyHeritage, LivingDNA, AncestryDNA, 23andMe and Vitagene.[9] PCWorld also ranked the best DNA kits by category, citing 23andMe as the best DNA kit overall for its comprehensive coverage of ancestry and genetic health information.[10] AncestryDNA ranked in second place mainly due to it having the largest DNA database with tests from more than 10 million people and regular updates made to its ethnicity estimates.[11] MyHeritage ranked as the most affordable testing service, but it has only 1.5 million people in its database and a greater percentage of them located in Europe. Family Tree DNA, the oldest U.S.-based DNA testing company, ranked as the best for privacy protections. However, the company faced a significant privacy scandal in early 2019. Despite an earlier proclamation from Family Tree DNA founder and president Bennett Greenspan stating, "We don't believe [user data] should be sold, traded, or bartered,"[12] the company acknowledged in February 2019 that it had failed to disclose its sharing of genetic information with the Federal Bureau of Investigation to help solve violent crimes.[13] Still, unlike most of the DTC genetic testing companies, such as 23andMe and AncestryDNA, Family Tree DNA does not ask consumers to consent to agreements that may result in companies and researchers acquiring their data.

23andMe has been at the center of several debates about the ethics of for-profit DTC genetic tests. For example, between 2007 and 2012, the company enticed consumers and research participants by offering genetic tests at low prices (e.g., starting at $299 and now lowered to $99) and even free saliva collection kits in return for saliva samples. The company also launched the "23andWe" project in 2008, asking consumers to collaborate with the company in prioritizing its disease research efforts. Participants voted on a list of diseases, and the company developed numerous surveys

9 *The Best DNA Testing Kits 2019 - Trace Your Ancestry and Genetic Heritage*, TOP10.COM (June 10, 2019), https://www.top10.com/dna-testing/top-reads/best-dna-testing-kits.

10 Dieter Holger, *Best DNA testing kits: Discover the secrets stored in your genes*, PCWORLD (Feb. 12, 2019), https://www.pcworld.com/article/3317567/best-dna-kits.html.

11 *Id.* PCWorld also awarded AncestryDNA the best-in-category for adoptees and genealogy. *Id.*

12 *Id. See* FamilyTreeDNA, *The FamilyTreeDNA Promise*, YOUTUBE (Feb. 5, 2018), https://www.youtube.com/watch?v=0zGdJuBY0k0&feature=youtu.be (last visited July 18, 2019).

13 Matthew Haag, *FamilyTreeDNA Admits to Sharing Genetic Data With F.B.I.*, N.Y. Times (Feb. 4, 2019), https://www.nytimes.com/2019/02/04/business/family-tree-dna-fbi.html.

for participants to share their personal health, lifestyle and other information with the company.[14] In fact, the 23andMeBlog described the project's goal as to "help bring the dream of personalized medicine a few steps closer to reality."[15] At the same time, it pleaded, "all we need you to do is take some surveys."[16] By 2012, the information derived from the 23andWe project led to a "patent for a method of determining predisposition to Parkinson['s] disease."[17] Many consumers and research participants felt betrayed when they learned that 23andMe had secured a patent based on their genetic and personal data.

As New York University Professor Charles Seife said in 2013, the "[p]ersonal genome service . . . is a mechanism meant to be a front end for a massive information-gathering operation against an unwitting public."[18] While there is truth in his statement, the company 23andMe has not hidden its agenda. Patrick Chung, a 23andMe board member, acknowledged, in a 2013 interview:

> The long game here is not to make money selling kits, although the kits are essential to get the base level data. . . Once you have the data, [23andMe] does actually become the Google of personalized health care.[19]

A recent study predicts that the DTC genetic testing market will exceed 2.5 billion U.S. dollars by the year 2025.[20] The same study assesses the main factor to drive industry growth will be the increasing demand for "service personalization in developed regions" such as North America and Europe.[21] As of March 2020, 23andMe's Europe website ships both

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14 Joyce, *23andWe: The First Annual Update*, 23ANDMEBLOG (Jan. 5, 2009), https://blog.23andme.com/23andme-and-you/23andwe-the-first-annual-update/.

15 *Id*.

16 *Id*.

17 Megan Allyse, *23 and Me, We and You: direct-to-consumer genetics, intellectual property and informed consent*, 31 Trends Biotechnol 68, 68-9 (2013).

18 Charles Seife, *23andMe Is Terrifying, but Not for the Reasons the FDA thinks – The genetic-testing company's real goals is to hoard your personal data*, SCIENTIFIC AM. (Nov. 27, 2013), https://www.scientificamerican.com/article/23andme-is-terrifying-but-not-for-the-reasons-the-fda-thinks/.

19 *Id.*

20 Sumant Ugalmugle & Rupali Swain, *DTC Genetic Testing Market to exceed US $2.5 Bn by 2025*, GLOB. MKT. INSIGHTS (June 18, 2019), https://www.gminsights.com/pressrelease/direct-to-consumer-dtc-genetic-testing-market (last visited July 18, 2019).

21 Global Market Insights, Inc., *Direct-to-Consumer Genetic Testing Market to hit $2.5Bn by 2024: Global Market Insights, Inc.*, PR NEWSWIRE (Dec. 11, 2018), https://www.prnewswire.com/news-releases/direct-to-consumer-genetic-testing-market-to-hit-2-5-bn-by-2024-global-market-insights-inc--830436085.html (last visited July 18, 2019).

ancestry and health tests to only five EU countries—Denmark, Finland, Ireland, Sweden, and the Netherlands. However, the company's international website ships ancestry tests to the remaining twenty-two EU countries. Even though the company currently does not sell health tests to all EU countries, citing shipping restrictions "due to the applicable regulations,"[22] it still asks consumers who order only ancestry tests from the international website to participate in research.[23] The company encourages consumers to participate in research, claiming they are "becoming part of something"[24] that is bigger than themselves. The genetic and personal data obtained from selling ancestry tests alone is a treasure trove of data. As the 23andMe website explains, once participants choose to "[a]nswer online survey questions, researchers link their genetic data to study topics from ancestry, to traits, to disease. These contributions help drive scientific discoveries."[25] The growth of European customers is evident by MyHeritage opening in 2018 its first European distribution center for DNA kits in the Netherlands.[26] MyHeritage ships its ancestry DNA kits to most countries in Europe, including those in the EU, and claims it saw a 450 percent increase in sales in Europe in the first five months of 2018.[27] Some of the other principal companies providing DTC genetic tests to the European market include Dante Labs,[28] 24Genetics,[29] Athgene,[30] Genyuss,[31] cerascreen[32] and tellmeGen[33]—all of

22 *Change Location*, 23ANDME, INC., https://www.23andme.com/en-int/?myg=true (last visited Mar. 22, 2020).

23 *Becoming Part of Something bigger.,* 23ANDME, INC., https://www.23andme.com/en-int/research/ (last visited July 22, 2019).

24 *Id.*

25 *Id.*

26 Esther, *MyHeritage Opens European Distribution Center for DNA Kits*, MYHERITAGE BLOG (June 29, 2018), https://blog.myheritage.com/2018/06/myheritage-opens-european-distribution-center-for-dna-kits/.

27 *Id.*

28 *About*, DANTE LABS, INC., https://www.dantelabs.com/pages/about (last visited July 18, 2019). Dante Labs is specialized in whole genome sequencing and offers its tests throughout the EU.

29 *Life is DNA*, 24GENETICS, https://24genetics.com/en/team (last visited July 18, 2019). 24Genetics is based in Europe and claims to be the largest European DTC provider of ancestry and wellness DNA tests.

30 *Register*, ATHGENE, https://athgene.nordicvms.com/Register.aspx?rtn=c (last visited July 18, 2019); *Discover What Makes You Unique*, ATHGENE, http://www.athgene.com/ (last visited July 18, 2019). Athgene offers fitness, lifestyle, and nutrition DNA tests to consumers throughout the EU.

31 *Home*, GENYUSS, https://www.testgeneticoonline.com/en/home/ (last visited July 18, 2019). Genysuss offers health, nutrition, sport nutrition, and dermatological tests to consumers throughout the EU.

32 *About Us*, CERASCREEN, https://www.cerascreen.co.uk/pages/about-us (last visited July 18, 2019); *Zahlung & Versand*, CERASCREEN, https://www.cerascreen.de/pages/versand-zahlung (last visited July 18, 2019). Cerascreen offers consumers health DNA tests, as well as follow-up products and services. The company delivers to fifteen EU countries, plus Norway and Switzerland.

33 *Genetic Test*, TELLMEGEN, https://www.tellmegen.com/en/home/genetic-test/ (last visited

which can be purchased from the companies' websites or on some of Amazon's European websites.[34] In 2019, Dante Labs established a new, highly automated DNA sequencing center in Italy.[35] To recognize this milestone, on Amazon's Prime Day in July 2019, Dante Labs offered to consumers worldwide whole genome sequencing with a new Artificial Intelligence-powered personalized report for 299 Euro—a fraction of the normal price.[36]

The DTC genetic testing landscape is changing rapidly as genomic technology advances and consumer interest increases with a growing variety of DNA tests on the market. In the process of acquiring this big data, the DTC genomic industry must be accountable to consumers and research participants. Such accountability requires robust informed consent procedures. As University of Hong Kong Professor Annie Cheung underscores, there must be a commitment to the values that underpin consent, which are "[a]utonomy, fairness and propriety in the name of research."[37] According to the Stanford Encyclopedia of Philosophy:

> Informed consent is currently treated as the core of bioethics. In clinical practice, the doctrine of informed consent rose to dominance during the course of the 20th century. It replaced a medical ethos founded on trust in physicians' decisions, often on the assumption that "doctor knows best," with an ethos that sought to put patients in charge of their own care.[38]

Our present understanding of the ethical and legal doctrine of informed

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July 18, 2019). TellmeGen, headquartered in Spain, offers a comprehensive DNA test throughout the EU that includes, health, individual traits, and ancestry information. The company also offers various post-test medical and nutritional personalized counseling (i.e., with physicians, geneticist, or nutritionists) options for a fee.

34 *See* www.amazon.de, www.amazon.it, www.amazon.es, www.amazon.co.uk. As of July 18, 2019, the France and Netherlands' Amazon sites did not offer DNA test kits.

35 Dante Labs, Inc., *Dante Labs Announces New Special Offering for Prime Day 2019, in Celebration of Its New AI-Powered Reports and Sequencing Center*, PR Newswire (July 15, 2019), https://www.prnewswire.com/news-releases/dante-labs-announces-new-special-offering-for-prime-day-2019-in-celebration-of-its-new-ai-powered-reports-and-sequencing-center-300884751.html.

36 Dante Labs, Inc., *Dante Labs Launches GenomeL, the First Commercial Long Reads Human Whole Genome Sequencing*, PR NEWSWIRE (Apr. 8, 2019), https://www.prnewswire.com/news-releases/dante-labs-launches-genomel-the-first-commercial-long-reads-human-whole-genome-sequencing-300826213.html.

37 Annie Cheung, *Moving beyond Consent for Citizen Science in Big Data Health and Medical Research*, 16 NW. J. TECH. & INTELL. PROP. 15, 17 (2018).

38 Nir Eyal, *Informed Consent*, *in* THE STAN. ENCYCLOPEDIA OF PHIL (Edward N. Zalta, ed., 2019), https://plato.stanford.edu/archives/spr2019/entries/informed-consent/.

consent, particularly that involving human research, traces its roots to the post-World War II period. The discovery of barbaric human experiments carried out by the German and Japanese forces led in part to such influential developments as the Nuremberg Code[39] and the Declaration of Helsinki (DoH),[40] which served as early models for governments to develop informed consent guidelines, laws and regulations.[41] Section VI further discusses the impact of the Nuremberg Code and the DoH on the development of informed consent principles in Europe. Sorin Hostiuc explains that the legal doctrine of informed consent evolved differently in Europe from that in the United States and in Britain.[42] This divergence is primarily due to key differences between the American and British common law tradition (i.e., based on legal precedent) and that of Europe's civil law tradition (i.e., based on Roman law and its moral principles).[43] Hostiuc provides examples from certain European countries, like in France and Germany, where informed consent was either rooted in the moral behavior of physicians (i.e., in France and Germany primarily in the 19th century) or in terms of the relationship between the investigator and his subject with respect to research (i.e., in Germany in the early 20th century).[44]

39 Library Congr., Trials of War Criminals before the Nuernberg Military Tribunals under Control Council Law No. 10, Vol. II 181-83 (1949) [hereinafter Nuremberg Code].

40 World Med. Ass'n, World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (2013) [hereinafter DoH].

41 Ruth R. Faden & Tom L. Beauchamp, A HISTORY AND THEORY OF INFORMED CONSENT 151, 156, 186 (1986) (explaining that following the end of World War II and the conclusion of the Nuremberg Trials there was a dramatic shift from there being "virtually no noteworthy formal guidelines or codes governing research with human subjects;" to there being more than 20 guidelines and codes designed to protect human subjects, which were adopted between 1948 and 1968 by major organizations. Also, noting that "although Nazi atrocities appear to have been the single most important causal factor in this chain [of events], the full explanation is multi-causal.").

42 Sorin Hostiuc, *A Short Introduction to the History of Informed Consent in Great Britain and the United States*, *in* THE AGE OF INFORMED CONSENT: A EUROPEAN HISTORY 15, 34 (Sorin Hostiuc & Octavian Buda, eds., 2018) (citing Jessica W. Berg et al., INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE 11-12 (2001)) (drawing a contrast to Professor Jessica Berg's characterization of the origins of the legal doctrine of informed consent in the United States).

43 *Id.* at 35.

44 *Id*. at 34.

III. ANALYSIS OF EU LEGISLATION: THE DEBATE SURROUNDING GENETIC TESTING, GENETIC COUNSELING[45] AND INFORMED CONSENT

In April 2017, the European Parliament and the Council of the European Union approved the IVDR,[46] allowing for a transition period of five years and repealing its 1998 predecessor, the In Vitro Medical Devices Directive (IVDD),[47] as well as a related European Commission Decision.[48] The IVDR takes effect May 26, 2022, and, because it is an EU regulation, is binding in its entirety and directly applicable in all EU Member States (Member States) without being transposed into national legislation (unlike the 1998 IVDD).[49]

The final version of the IVDR was built on years of legislative debate that included the expert opinions of various healthcare and medical organizations and industry-related stakeholders. The EU Commission first submitted proposed legislation in September 2012. The explanatory memorandum that accompanied the draft legislation explained:

> The existing regulatory framework for in vitro diagnostic medical devices has demonstrated its merits but has also come under criticism in recent years. In an internal market with 32 participating countries and subject to constant scientific and technological progress, substantial divergences in the interpretation and application of the rules have emerged, thus undermining the main objectives of the Directive, *i.e.* the safety and performance of [in vitro diagnostic medical devices] IVDs and their free movement.[50]

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45 Anna Middleton et al., *Direct-to-consumer genetic testing: where and how does genetic counseling fit?*, 14 PERSONALIZED MED. 249, 250 (2017) (explaining that 'genetic counseling' is defined generally by "professional bodies around the world as a client-centered communication process, designed to help people understand and adapt to the medical and psycho-social consequences of either having, being at-risk from or passing on a genetic condition.").

46 *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU*, Apr. 5, 2017, 2017 O.J. (L 117) 176 [hereinafter IVDR].

47 *Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices*, Oct. 27, 1998, 1998 O.J. (L 331) 1 [hereinafter IVDD].

48 *Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices, adopted in implementation of Directives 90/385/EEC, 93/42/EEC and 98/79/EC*, Apr. 19, 2010, 2010 O.J. (L 102) 45.

49 EUR. UNION, *Regulations, Directives and other acts* (Mar. 7, 2019), https://europa.eu/european-union/eu-law/legal-acts_en.

50 *Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices*, COM (2012) 541 final (Sept. 26, 2012).

In April 2013, rapporteur Dr. Peter Liese of the EU Parliament's Environment, Public Health, Food and Safety (ENVI) Committee submitted a draft report responding to the Commission's suggested regulatory changes.[51] Rapporteur Dr. Liese, as a member of the EU Parliament's European People's Party (EPP), commissioned a paper from the Centre for European Law at the University of Passau that attempted to provide legal justification for broader and deeper regulation of genetic testing. This paper is commonly known as the "Passau Opinion."[52] In October 2013, the EU Parliament initially adopted the amendments endorsed by the ENVI draft report, including the so-called "Liese Amendments," which were based on the analysis presented in the Passau Opinion.[53]

The amended definition of "medical device" sparked controversy because it included devices with a "direct or indirect medical purpose" that "provid[ed] information concerning direct or indirect impacts on health."[54] Such a broad mandate likely would have regulated all types of genetic testing, including all types of DTC genetic testing. Furthermore, a Joint Statement issued by four key stakeholders—the PHG Foundation, the European Genetic Alliances' Network, the European Alliance for Personalised Medicine and the Wellcome Trust—explained that such a long regulatory arm could cause confusion over the types of devices covered (e.g., "lifestyle apps" such as Fitbit), and potentially jeopardize the competitiveness of EU Member States by "stifl[ing] innovation."[55] As a result, consumers would likely experience a "delay in access to

51 *Draft Report on the proposal for a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices*, COM (2012) 0541 (Apr. 3, 2013) [hereinafter Liese Report]. Separately, the version of the ENVI report from the Plenary sitting is dated October 10, 2013. *Draft Report on the proposal for a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices*, COM (2012) 0541 (Oct. 10, 2013).

52 *See Options for Action of the European Union in the Area of Human Genetics and Reproductive Medicine in the Light of the Proposal for a Regulation on In Vitro Diagnostic Devices*, CENTRUM FÜR EUROPARECHT AN DER UNIVERSITÄT PASSAU (2013) [hereinafter PASSAU OPINION].

53 Lawford Davies Denoon & Axon Lawyers, *Opinion: The Competence of the European Union to Legislate in Relation to Certain Amendments Endorsed by the European Parliament in Connection with a Commission Proposal for an In Vitro Diagnostic Device Regulation*, ALLIANCE OF EUROPEAN LIFE SCIENCES LAW FIRMS 1, 12 (FEB. 19, 2014), https://www.eshg.org/fileadmin/eshg/documents/IVD/ESHG_Opinion_19_February_2014_final.pdf [hereinafter ALLIANCE OPINION].

54 *Amendments adopted by the European Parliament on 22 October 2013 on the proposal for a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices*, amend. 42, proposed art. 2.1(1), COM (2012) 541 (Oct. 22, 2013) [hereinafter Adopted Amendments].

55 PHG Foundation et al., *Joint statement on amendments tabled in the report of the Committee on the Environment, Public Health and Food Safety on the proposal for a regulation on in vitro diagnostic medical devices*, PHG FOUNDATION 2 (Oct. 2013), http://www.phgfoundation.org/documents/338_1382516791.pdf [hereinafter Joint Statement].

healthcare products" without a measurable benefit to patient safety.[56]

The contentious Liese Amendments, with a focus on genetic medicine, defined "device for genetic testing" as "an in vitro diagnostic medical device the purpose of which is to identify a genetic characteristic of a person which is inherited or acquired during prenatal development."[57] Again, this is an overly broad definition that, according to the stakeholder's Joint Statement, attempted to cover "any test that seeks to identify a genetic variant regardless of whether it is found commonly in populations or is causally linked to illness or disease."[58] Finally, the proposed Article 4a, entitled "Genetic information, counselling and informed consent," caused the most controversy because it tried to regulate "the practice of genetic medicine," listing very specific requirements for who may order a test (i.e., only a medical doctor),[59] the type of information provided to patients, how patients are counseled before and after testing, and how patient consent is granted (i.e., expressly and in writing only) and revoked (i.e., in writing or orally).[60]

Speaking on behalf of the European Society of Human Genetics (ESHG)—a non-profit organization based in Vienna, Austria—Dr. David Barton, from the Department of Clinical Genetics at Our Lady's Children's Hospital in Ireland, explained that the proposed Article 4a was unrealistic because "it is common practice for genetic tests to be ordered by other healthcare professionals such as genetic counsellors."[61] Furthermore, Dr. Barton expressed concern that:

> [T]hese proposals, as they stand, restrict legitimate, ethically-acceptable genetic testing activities such as the screening of newborn babies. They infringe on accepted and acceptable clinical practice when [the EU] should simply be regulating IVDs, effectively hijacking a sound and important Regulation to interfere with carefully regulated clinical practice, and infringing on patients'

56 *Id.*

57 Adopted Amendments, *supra* note 54, amend. 49, proposed art. 2.12(b).

58 Joint Statement, *supra* note 55, at 2.

59 For example, this restriction would prohibit accredited genetic counselors and trained midwives from engaging in their professional duties of genetic counseling and routine prenatal screening tests. *See* Joint Statement, *supra* note 55, at 3.

60 Adopted Amendments, *supra* note 54, at amend. 271, proposed art. 4a new.

61 Antony Blackburn-Starza, ESHG says EU medical devices regulation could pose a risk to patients' interests, 825 BIONEWS (Oct. 26, 2015), https://www.bionews.org.uk/page_95253 (last visited July 18, 2019).

autonomy.[62]

The organization EuroGentest echoed a similar concern that the measures proposed in Article 4a constituted an attempt "to regulate medical practice via device regulation."[63] ESHG's 2013 Position Statement explained that Article 4a places an unfair burden on the medical device user (e.g., the laboratory staff conducting a genetic test analysis) to ensure that medical professionals who care for the patient meet the regulatory requirements.[64] Accordingly, ESHG concluded that the proposed Article 4a is "unworkable in the daily practice of genetic medicine."[65]

Despite the widespread criticism of the Liese Amendments, on October 22, 2013, the EU Parliament adopted an amended version of the EU Commission's proposal,[66] voting for the Liese Amendments. While the Liese Amendments are impractical to implement from a medical device user and clinical perspective, they also lack legal authority.[67] In February 2014, in the wake of Parliament's acceptance of the Liese Amendments, the members of the Alliance of European Life Sciences Law Firms issued a legal opinion (hereinafter the Alliance Opinion[68]), concluding that Parliament acted beyond the scope of its "legislative competence" and that the Passau Opinion "seriously misrepresent[ed] this competence."[69]

First, the Alliance Opinion reasons that the Treaty on the Functioning of the European Union (TFEU) Article 168(4)[70] limits the scope of any EU

62 *Id.*

63 *New legal opinion finds EU does not have the power to enact radical genetic counselling laws*, EUROGENTEST 1 (Apr. 2014), http://www.eurogentest.org/fileadmin/templates/eugt/pdf/IVDLegalOpinionExecutiveSummaryApril2014.pdf (EuroGentest was formerly a project funded by the European Commission to harmonize the process of genetic testing, from sampling to counseling, across Europe. As of January 2014, the EU funding for EuroGentest ended and the organization continued its activities as an integrated part of the ESHG).

64 *ESHG Position Statement on the Inclusion of an Article on Genetic Testing in the Proposed Regulation on In Vitro Diagnostic Devices*, ESHG 1 (May 2013), https://www.eshg.org/fileadmin/www.eshg.org/NHGS2013/ESHG_Position_Statement_on_IVD_Regulation.pdf [hereinafter ESHG POSITION STATEMENT].

65 *Id.* at 1.

66 Adopted Amendments, *supra* note 54.

67 EUROGENTEST, *supra* note 63, at 2-3.

68 ALLIANCE OPINION, *supra* note 53, at 1, 12.

69 *Id.* at 1, 9 (referencing the Consolidated Version of the Treaty on the Functioning of the European Union art. 168(4), June 7, 2016, 2016 O.J. (C 202) 1). The Passau Opinion argued that the EU could adopt the Liese Amendments based on general internal market competence (i.e., TFEU art. 114), and on health competence (i.e., TFEU art. 168(4)), and based on EU case law and several EU and other international treaties. *See id.* at 15-16, 21-24, 33-34. As background, the ESHG requested the 2014 Alliance legal opinion to provide an assessment of the competence of the EU to legislate certain issues raised by the proposed Liese Amendments.

70 Consolidated Version of the Treaty on the Functioning of the European Union art. 168(4),

regulation only to the public health concerns related to the "quality and safety for . . . devices for medical use."[71] The Alliance Opinion elaborates that any EU measures undertaken on this issue can only address the "quality and safety of the devices themselves," and "cannot be prescriptive as to how to practice medicine with medical devices, for example by prescribing mandatory patient counselling," associated with the use of a medical device.[72]

Second, the Alliance Opinion explains that because the EU does not have exclusive competence to act in this area, the principles of subsidiarity and proportionality govern the circumstances in which the Union is permitted to take action, rather than the Member States.[73] Specifically, the Alliance Opinion claims that the Union competence to legislate on in vitro diagnostic medical devices does not extend to the practice of medicine in relation to these medical devices, in part, because the "[E]uropean Commission already stated that matters of informed consent are better dealt with at [the] national level."[74] Accordingly, the principle of subsidiarity mandates that the decision to impose any such informed consent rules should be left up to the Member States. The EU Parliament website explains:

> [t]he principle of subsidiarity seeks to safeguard the ability of the Member States to take decisions and action and authorises intervention by the Union when the objectives of an action cannot be sufficiently achieved by the Member States, but can be better achieved at Union level, 'by reason of the scale and effects of the proposed action.'[75]

Furthermore, with respect to the principle of proportionality, the "content

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June 7, 2016, 2016 O.J. (C 202) 1 [hereinafter TFEU].

71 ALLIANCE OPINION, *supra* note 53, at 11 (quoting TFEU art. 168(4)(c): "[the EU] shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet *common safety concerns*: (c) measures setting high standards of *quality and safety* for medicinal products and devices for medical use.") (emphasis added).

72 ALLIANCE OPINION, *supra* note 53, at 6, 11-13 (explaining that "[A]rticle 168(4) is very specific in that Article 168 TFEU can only be relied on as a legal basis for adopting measures to (1) meet common safety concerns and (2) set high standards for quality and safety of medical devices.").

73 *Id.* at 13 (referencing TFEU art. 5(3) and Protocol (No 2) on the application of the principles of subsidiarity and proportionality).

74 *Id.* at 2.

75 Roberta Panizza**,** *Fact Sheets on the European Union: The principle of subsidiarity*, EUROPEAN PARLIAMENT (Apr. 2019), http://www.europarl.europa.eu/factsheets/en/sheet/7/the-principle-of-subsidiarity (last visited July 18, 2019).

and form" of any Union action must not "exceed what is necessary" to achieve the goal.[76]

The Alliance Opinion demonstrates that the clear objective of the Liese Amendments is to "regulate [the] modalities of genetic counselling"[77] and informed consent in the Member States.[78] As Dr. Barton explained, on behalf of the ESHG, "Medical practice, including genetic medicine, is organized and delivered in many different ways in different Member States" of the EU, and the Liese Amendments "[e]ncroach[] on this diversity and seek[] to dictate in detail the arrangements for every clinic where a genetic test may be ordered."[79] Yet, any differences that exist throughout the EU in genetic counseling and informed consent practices do not pose any significant barriers to trade that would require EU-level intervention.[80] For this reason, the Alliance Opinion underscores that Member States hold the legislative power in this area, and are better equipped to address the issues of genetic counseling and informed consent at the national level where they can properly "account [for] the differences in the field of practice of medicine" in their respective country.[81]

In fact, the EU ultimately agreed with this reasoning and asserted in Recital 9 of the enacted IVDR that:

> It appears that it is possible that divergent national rules regarding the provision of information and counselling in relation to genetic testing might only have an impact on the smooth functioning of the internal market to a limited extent. Therefore, it is appropriate to lay down only limited requirements in this regard in this Regulation,

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76 ALLIANCE OPINION, *supra* note 53, at 2 (citing TFEU art. 5(4)).

77 *Id.* at 13.

78 *Id.* at 7 (citing TFEU Protocol (No 2) art. 8 on the application of the principles of subsidiarity and proportionality). Accordingly, the Alliance Opinion concluded that if a regulation were enacted incorporating the Liese Amendments, pursuant to TFEU Protocol (No 2) on the application of the principles of subsidiarity and proportionality and TFEU art. 263, those directly affected could initiate proceedings against the regulation in the Court of Justice of the European Union (CJEU) on "grounds of infringement of the principle of subsidiarity by a legislative act." *Id.*

79 Blackburn-Starza, *supra* note 61.

80 ALLIANCE OPINION, *supra* note 53, at 13.

81 *Id. See* European Patients' Forum, *Patient's Rights in the European Union*, HEALTH RIGHTS (2009), http://health-rights.org/index.php/cop/item/patients%E2%80%99-rights-in-the-european-union-2009 (providing an overview of patients' rights legislation and policies, including the right to informed consent, in EU member states). The European Patients' Forum (EPF) is an umbrella organization founded in 2003 and works with many European patients' rights groups in support of public health and health advocacy. *See also* Pre-Max Consortium, *Patients' Rights in the European Union Mapping eXercise Final Report*, European Commission (2016), https://ec.europa.eu/health/sites/health/files/cross_border_care/docs/2018_mapping_patientsrights_frep_en.pdf (discussing the legislation, policy, and enforcement of patients' rights, including the right to informed consent, in EU Member States).

> having regard to the need to ensure constant respect of the principles of proportionality and subsidiarity.[82]

IV. THE IVDR'S SCOPE AND IMPACT RELATED TO GENETIC TESTING

If the Liese Amendments to the IVDD on genetic testing had been adopted into the new IVDR, Kalokairinou et al. point out that they "[w]ould have effectively signaled a ban on most types of DTC genetic testing" throughout the EU.[83] However, ultimately the EU legislative bodies recognized that such amendments exceeded their authority and voted instead on a more balanced version of the proposal. Kalokairinou et al. describe the final Regulation text as "pragmatic" because it manages to focus on the main goal of the safety and performance of in vitro diagnostic medical devices, while "plac[ing] more emphasis on genetic counselling and informed consent compared to the [IVDD]," but also "leaving Member States leeway to adapt those requirements in their clinical practice."[84]

The IVDR, as it goes into effect in 2022, establishes rules for "placing," "making available," or "putting into service" in vitro diagnostic medical devices for human use on the EU market[85] and sets considerably more stringent scientific and technical requirements than the IVDD. Mainly, clinical evidence must demonstrate the intended benefit(s) and safety of the device, and a post-market surveillance system must ensure ongoing conformity with the Regulation.[86] The aim is to provide for greater harmonization[87] of in vitro diagnostic medical devices throughout the EU, by "establish[ing] a robust, transparent, predictable and sustainable regulatory framework . . . which ensures a high level of safety and health whilst supporting innovation."[88]

The IVDR *does* apply to genetic testing, and includes DTC genetic testing, but only those tests that are health or medical-related—as will be explained below.[89] Understanding the parameters of the IVDR requires a

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82 IVDR, *supra* note 46, recital 9.

83 Louiza Kalokairinou et al., *Legislation of direct-to-consumer genetic testing in Europe: A fragmented regulatory landscape*, 9 J. COMMUNITY GENET. 117, 128 (2018).

84 *Id.* at 129.

85 IVDR, *supra* note 46, at art. 1(1).

86 *See id.* at Ch. VI: "Clinical Evidence, Performance Evaluation and Performance Studies," and Ch. VII: "Post-Market Surveillance, Vigilance and Market Surveillance."

87 *See* TFEU, *supra* note 70, at art. 114.

88 IVDR, *supra* note 46, recitals 1-2. *See* TFEU, *supra* note 70, art. 168(4).

89 Technically, the 1998 IVDD did not cover genetic testing. However, as EMERGO, a UL Company, specialized in global regulatory consulting explains, "with some rule bending" the IVDD

close-reading of the definitions of "in vitro diagnostic medical device" and "companion diagnostic." Article 2(2) defines "in vitro diagnostic medical device" as:

> [A]ny medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:
> (a) concerning a physiological or pathological process or state;
> (b) concerning congenital physical or mental impairments;
> (c) *concerning the predisposition to a medical condition or a disease;*
> (d) to determine the safety and compatibility with potential recipients;
> (e) *to predict treatment response or reactions;*
> (f) to define or monitoring therapeutic measures. Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices.[90]

Article 2(7) defines "companion diagnostic"[91] as:

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informally oversaw genetic tests. Now, under the new IVDR, genetic testing is formally defined as an in vitro diagnostic medical device. Ronald Boumans, *Understanding Europe's New Invitro Diagnostic Medical Devices Regulation: What manufacturers need to know ahead of IVDR implementation*, EMERGO (2016), https://www.emergobyul.com/resources/articles/white-paper-eu-ivdr; *See also European Commission Staff Working Document Impact Assessment on the Revision of the Regulatory Framework for Medical Devices, Accompanying the documents Proposals for Regulations of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and on in vitro diagnostic medical devices,* at 13-14, SWD (2012) 274 final (Sept. 26, 2012), https://op.europa.eu/en/publication-detail/-/publication/487acc33-213b-4fdf-bdbb-8840209a8807/language-en (explaining that despite the IVDD not formally regulating genetic testing, out of 200 responses that included mainly industry, healthcare professionals and academics, and regulatory bodies, the consensus was that the IVDD covered "[o]nly genetic tests that have a medical purpose").

90 IVDR, *supra* note 46, at art. 2(2) (emphasis added).

91 Companion diagnostics are DNA tests and a subset of the field of study of pharmacogenomics, which is "[t]he use of a person's genomic makeup to predict a drug response, or to tailor therapy specifically for that patient." Frost & Sullivan, *Companion Diagnostics for Oncology*, ALLIANCE OF ADVANCED BIOMEDICAL ENGINEERING (2017), https://aabme.asme.org/posts/companion-diagnostics-for-oncology (last visited July 21, 2019). For example, in 1998, the U.S. Food and Drug Administration (FDA) approved the first targeted medicine Herceptin. Herceptin shuts off the Human epidermal growth factor receptor 2 (HER2 or HER2/neu) protein, expressed by the gene ERBB2, present in abnormally high amounts in about one-quarter to one-third of breast cancers. The companion diagnostic test looks for excessive levels of HER2 in a

> [A] device which is essential for the safe and effective use of a corresponding *medicinal product* to[92]
> identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or
> identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product."[93]

In Article 2(2), clauses (c) and (e) are entirely new additions to the definition of in vitro diagnostic medical device, as compared to the definition provided in the 1998 IVDD. These new clauses specifically address the growing trend of gene-based medicine. As the IVDR Recital 10 emphatically states, in vitro diagnostic medical devices include "all tests that provide information on the predisposition to a medical condition or a disease, *such as genetic tests*," a reference to clause (2)(c), and "tests that provide information to predict treatment response or reactions, *such as companion diagnostics*," a reference to clause 2(e).[94]

Considering the use of the terms "medical condition," "disease," and "treatment" in clauses 2(c) and (e), the scope of these clauses appears limited to health or medical-related genetic tests and companion diagnostics and would apparently exclude the other so-called "recreational"[95] genetic tests related to ancestry, ethnicity, identity (i.e., familial ties, to include paternity) and race, as well as those related to personality or character traits[96] and physical traits (e.g., bitter taste sense,

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patient's tumor or for extra copies of the HER2 gene in a patient's tumor, indicating that Herceptin could be an effective treatment for that patient's breast cancer. U.S. FOOD & DRUG ADMIN., *Personalized Medicine and Companion Diagnostics Go Hand-in-Hand*, https://www.fda.gov/consumers/consumer-updates/personalized-medicine-and-companion-diagnostics-go-hand-hand (last visited July 21, 2019).

92 *Directive 2001/83/EC, of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use*, art. 1(2), 2001 O.J. (L 311) 67 (defining "Medicinal product") (emphasis added).

93 IVDR, *supra* note 46, at art. 2(2).

94 *Id*. recital 10 (emphasis added).

95 Heike Felzmann, *'Just a Bit of Fun': How Recreational is Direct-to-Customer Genetic Testing?*, 21 THE NEW BIOETHICS 20, 30-31 (2015) (citing J. P. Evans, *Recreational genomics; what's in it for you?*, 10 GENET. MED. 709 (2008) (using for the first time the term 'recreational genomics')) (explaining that the term is often used to describe "genetic testing for ancestry or other non-health concerns from genetic testing for health factors," or to describe "any testing that does not have clear diagnostic and health management targets.").

96 Online dating companies, U.S.-based GenePartner, Instant Chemistry, DNA Romance, and Pheramor to name just a few, have entered the DTC genetic testing market, trading saliva for the chance of finding your perfect match. Spareroom is a United Kingdom-based company that is piloting a similar genetic matching service to help renters find their ideal roommate based on a DNA sample

earwax type, eye color, salty versus sweet preference, and sleep movement).[97] GeneWatch UK similarly concludes in its regulatory summary of the IVDR that "[g]enetic tests which claim to predict disease risk or drug response, or diagnose a medical condition, clearly fall within the scope of the Regulation, whilst genetic ancestry or paternity tests do not."[98] Slokenberga also asserts that the entire definition, Article 2(2), refers only to "health related" in vitro diagnostic medical devices.[99] Additionally, with respect to Article 2(7) "companion diagnostics," GeneWatch UK finds that, "[g]enetic tests . . . used to make recommendations regarding supplements, functional foods, or further medical testing may be classed as 'companion diagnostics.'"[100] This is because the EU prefers to take a stricter view in cases of doubt about such "borderline products," labeling them as a "medicinal product" so as to err on the side of protecting the consumer.[101] For these reasons, it is clear that the IVDR is applicable to all health or medical-related genetic tests and companion diagnostics, including all such DTC tests.

Yet, there remains some ambiguity as to what types of DTC genetic tests are categorized as health or medical-related. For example, Slokenberga questions whether the IVDR applies to tests that identify gene responses to nutrition, referred to as nutrigenetics.[102] GeneWatch UK recently echoed this concern, unsure of whether the IVDR definition, specifically Article (2)(2)(e), would encompass so-called "lifestyle" genetic tests, which try "[t]o predict the body's response to diet or exercise."[103] The obvious argument is that genetic-based individual diet

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and a personality test. Jackie Mansky, *The Dubious Science of Genetics-Based Dating*, SMITHSONIAN (Feb. 14, 2018), https://www.smithsonianmag.com/science-nature/dubious-science-genetics-based-dating-180968151/; Emily Mullin, *These DNA testing companies are mainly trying to sell you other stuff*, MIT TECH. REV. (Apr. 26, 2018), https://www.technologyreview.com/s/611002/these-dna-testing-companies-are-mainly-trying-to-sell-you-other-stuff/.

97 *Dna Reports List*, 23ANDME, INC., https://www.23andme.com/dna-reports-list/ (last visited July 21, 2019).

98 *The EU's In Vitro Diagnostics (IVD) Regulation: a summary of the regulatory requirements for software and genetic tests,* GENEWATCH UK 2 (Dec. 2017), http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/IVDReg_GWbrief_fin.pdf.

99 Santa Slokenberga, *Direct-to-consumer Genetic Testing: Changes in the EU Regulatory Landscape*, 22 EUR. J. HEALTH LAW 463, 473 (2015) (discussing the scope of the proposed IVDR provisions).

100 GENEWATCH UK, *supra* note 98, at 3.

101 Nicole Scholz, *Medicinal products in the European Union: The legal framework for medicines for human use*, EUR. PARL. 5 (2015), https://www.europarl.europa.eu/RegData/etudes/IDAN/2015/554174/EPRS_IDA%282015%29554174_EN.pdf.

102 Slokenberga, *supra* note 99, at 474.

103 GENEWATCH UK, *supra* note 98, at 2. *See* Mullin, *supra* note 96 (explaining that in 2018, the well-known U.S.-based creator of frozen low-calorie/low-fat meals, Lean Cuisine, launched on a trial basis a DNA-based meal-plan, claiming that "genetic markers help determine your customized nutrient

and exercise advice do have a health-related or medical purpose and could reasonably be viewed as falling under the IVDR provisions.[104] Ultimately, in the lead up to and after the 2022 IVDR effective date, the EU Member States and the EU Commission will need to determine if these types of "lifestyle" tests fall into either the recreational or the health or medical category.[105]

Having established the application of the IVDR to health or medical-related genetic tests, including such DTC genetic tests, it is imperative to consider the territorial scope and application of the Regulation. The IVDR territorial scope is broad because it introduces in Article 6 the concept of "distance sales." Article 6(1) states: "A device offered by means of information society services, as defined in point (b) of Article 1(1) of Directive 2015/1535, to a natural or legal person established in the Union shall comply with this Regulation." The referenced 2015 Directive defines "information society services" as "any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services."[106] Article 6(2) also addresses the situation where a device may not be "placed on the market," but is used within a commercial context—either in return for payment or free of charge—to provide a "diagnostic or therapeutic service."[107] These IVDR provisions mark the EU's first regulatory attempt to capture the e-commerce sector as it relates specifically to the offering of genetic tests originating in third countries, like the U.S, which are then made available to EU residents.

While it is a valiant effort to impose the IVDR technical and scientific requirements on non-EU online DTC genetic testing companies, the regulation lacks specifics about its enforcement mechanism and possible

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intake;" and other companies Nutrigene and LifeDNA sell vitamin supplements based on your DNA sample).

104 Liese Report, *supra* note 51, at 59 (stating that "[t]hese tests may have at least indirectly very severe consequences to people's health," providing the example of a patient who needs to lose weight for health reasons but uses a low-quality nutrigenetic or lifestyle test that does not deliver the promised results); GENEWATCH UK, *supra* note 98, at 2.

105 *See* IVDR, *supra* note 46, recital 8, art. 3 (explaining that to maintain consistency among the EU Member States, especially in "borderline cases," the EU Commission either upon request by a Member State or by its own initiative, after consulting with the Medical Device Coordination Group (MDCG), shall "determine whether or not a specific product, or category or group of products, falls within the definitions of 'in vitro diagnostic medical device' or 'accessory for an in vitro diagnostic medical device.'").

106 *Council Directive 2015/1535, 2015 O.J. (L 241) 1 (EU) of the European Parliament and of the Council of 9 September 2015* (laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services)., 2015 O.J. (L 241) 1.

107 IVDR, *supra* note 46, art. 6(2).

action to be taken against violators.[108] Rather, IVDR Article 106 requires the Member States to devise and implement the penalties for infringement of the rules.[109] As Slokenberga reminds us, the EU consumer will expect that all tests available for purchase within the EU meet the same rigorous standards, regardless of origination.[110] For now, consumers and industry must wait and see what happens when the IVDR becomes effective in May 2022.

Lastly, the provision in the IVDR that demonstrates how far the EU is able and willing to legislate on the issue of informed consent is Article 4, entitled "Genetic information, counselling and informed consent."[111] This is a new provision that did not exist in the 1998 IVDD. Moreover, it is drastically different from the 2013 proposed Article 4a, which was discussed earlier in connection with the Liese Amendments.

This final enacted version requires "Member States" to ensure the provision of "relevant information on the nature, the significance and the implications of the genetic test, as appropriate," to an individual (or her legal representative) who is being genetically tested for "medical purposes" only, and strictly in a "healthcare" setting.[112] "Healthcare" is defined as "health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices[.]"[113] Furthermore, the requirement is limited to genetic tests used for the medical purposes of "diagnostics, improvement of treatment, predictive or prenatal testing."[114] Under these specific circumstances, "Member States" must ensure that there is "appropriate access to counselling" for genetic tests that "provide information on the genetic predisposition for medical conditions and/or diseases which are generally considered to be untreatable"[115] (unless a diagnosis is merely being confirmed by a genetic test or a companion diagnostic is being used).[116] Finally, Article 4 expressly states that Member States have the latitude to adopt or maintain measures at a national level that are "more protective of patients, more specific or which deal with informed consent." Notably,

108 *See id.* recital (34), art. 10(15), art. 11, Annex VII 1.4 (Liability).

109 *Id.* art. 106.

110 Slokenberga, *supra* note 99, at 478 (discussing the scope of the proposed IVDR provisions).

111 IVDR, *supra* note 46, art. 4.

112 *Id.* art. 4(1).

113 *Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare*, art. 3(a), 2011 O.J. (L 88) 45.

114 IVDR, *supra* note 46, art. 4(11).

115 *Id*. art. 4(2).

116 *Id*. art. 4(3).

Article 4 specifically places the burden on Member States to ensure its requirements are met, allowing them to craft the necessary measures at the national level.[117] This is a clear response to the earlier criticism of the 2013 amendments that the EU was interfering with the day-to-day practice of medicine under the guise of a regulation on in vitro diagnostic medical devices.

With respect to Member States' rights, Article 1(8) also makes clear that the IVDR in no way affects the right of a Member State to "restrict the use of any specific type of device in relation to aspects not covered by [the IVDR]."[118] Additionally, Article 1(9) underscores that the Member States retain the right to impose national laws "concerning the organisation, delivery or financing of health services and medical care" to include, but not limited to, requiring a medical prescription for certain devices, permitting only certain health professionals or health care institutions to dispense or use certain devices, and mandating specific professional counseling to accompany the use of certain devices.[119] Consequently, in the context of DTC genetic tests, these IVDR provisions will not affect the current bans in place in some EU countries, like Germany and France,[120] on DTC sales of genetic tests; nor do they prevent other EU countries from imposing certain restrictions or bans on DTC genetic tests sold within their jurisdiction.[121]

V. THE GDPR AND LESSONS LEARNED FROM THE IVDR: THE STATUS OF INFORMED CONSENT IN THE DATA PRIVACY REGULATION

Since the IVDR debate concluded that national legislatures were better positioned to craft informed consent requirements and that any informed consent mandate by the EU would be an overreach of the Union's authority, it is no surprise that only a few years later the GDPR refrained from broaching the specific issue of "informed consent" within the context of genetic data processing. For these well-founded reasons, among others, the phrase "informed consent" is nowhere to be found in the Regulation's text. While the GDPR does have specific provisions on "consent" in

117 *Id*. arts. 4(4), 2(58) (defining "informed consent" as "a subject's free and voluntary expression of his or her willingness to participate in a particular performance study, after having been informed of all aspects of the performance study that are relevant to the subject's decision to participate. . .").

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

119 *Id*. art. 1(9).

120 Kalokairinou et al., *supra* note 83, at 126.

121 GENEWATCH UK, *supra* note 98, at 10.

general, and for special data categories (i.e., sensitive data), including genetic data, where "explicit consent," is required, any mention of the informed consent process is obviously absent from the Regulation's text.[122]

Article 9.1 of the GDPR specifies that the processing of data related to sensitive categories (i.e., race, ethnicity, sexual orientation, political opinions, trade union membership, religious and philosophical beliefs, genetics, biometrics, and health) are prohibited unless one of the ten exceptions of Article 9.2 applies. Exception 9.2(a) permits the data subject to provide "explicit consent" to the processing of such sensitive data. When it comes to genetic and health-related data, this requirement of *explicit* consent blurs the distinction for the layman between "explicit consent" and "informed consent." Let us be clear, "explicit consent" is no substitute for "informed consent."

Furthermore, even though the GDPR carves out a separate category for the processing of sensitive personal data and imposes a stricter consent requirement for this category, it fails to define "explicit consent." This is problematic for consumers, particularly when considering the business model of online DTC genetic testing companies. The companies remain at liberty to define for themselves "explicit consent." Moreover, consumers are likely to misinterpret the stricter consent requirement as an equal replacement for "informed consent"—which it is not.

While the focus of the GDPR is no doubt the protection of one's data, the health sphere and data privacy world collide when online DTC genetic testing companies acquire and analyze biospecimens (e.g., saliva, hair, or cheek cell samples, etc.) that are considered some of the most sensitive, revealing, and unique identifying information that humans possess.[123] Before discussing any further the topic of informed consent within the context of DTC genetic testing and the GDPR, it is necessary to understand the relevant Regulation's definitions (presented in order of appearance in the Definitions section).

"personal data" means:
any information relating to an identified or identifiable natural

122 *See* GDPR, *supra* note 2, recitals 51, 71, 111, arts. 9, 22.

123 *See* Jorge N. Lafferriere, *Protecting Privacy and Family Life in the Era of Recreational Genetics and Big Data*, 7 INT'L J. JURIS. FAM. 11, 33 (2016) (describing genetic information as a "valuable" asset, and discussing the risks for the individual and family members who participate in DTC genetic testing); James W. Hazel & Christopher Slobogin, *Who Knows What, and When?: A Survey of the Privacy Policies Proffered by U.S. Direct-to-Consumer Genetic Testing Companies*, 28 CORNELL J. L. & PUB. POL'Y 35, 49-50 (2018) (explaining the various policies of DTC, genetic testing companies, to destroy or store one's physical DNA sample).

> person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person[.][124]
>
> "'consent' of the data subject" means:
> any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her[.][125]
>
> "genetic data" means:
> personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question[.][126]

Although the "consent" definition includes the term "informed," the required provision of information only relates to the processing of personal data. The GDPR's consent requirement solely deals with the data subject's agreement to the specified data processing. Furthermore, the Article 9 requirement for "explicit consent" is limited solely to the processing of sensitive data, such as genetic data. To reiterate, "informed consent" as a doctrine and healthcare standard is absent from the text of the GDPR.[127]

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124 GDPR, *supra* note 2, art. 4(1).

125 *Id.* art. 4(11).

126 *Id.* art. 4(13).

127 *See* Kärt Pormeister, *Informed consent to sensitive personal data processing for the performance of digital consumer contracts on the example of "23andMe"*, 6 J. EUR. CONSUMER & MKT. L. 17 (2017) (analyzing a data subject's consent to data processing within the general framework of contract law). However, Pormeister uses the terms "consent" and "informed consent" interchangeably when discussing the GDPR. Pormeister's analysis appears to confuse the two distinct types of consent and fails to acknowledge "informed consent" as a healthcare-related doctrine that is absent from the GDPR. *Id.*

VI. WHY EU CONSUMERS OF DTC GENETIC TESTS SHOULD BE CONCERNED ABOUT THE GDPR'S LACK OF INFORMED CONSENT GUIDELINES

Data processing and genetic testing are two very distinct subject matters, but when the GDPR addresses the processing of genetic data as one of the "special categories" of personal data (i.e., "sensitive data"), these two separate issues intersect.[128] The GDPR affords the data derived from biological samples special consideration, so consequently, a need arises to balance data privacy with bioethical principles, and even healthcare standards within the context of DTC services.

This article focuses on the challenges involving the consent process with respect to DTC genetic testing. Just as consent to data processing is a pillar of the GDPR data privacy regime,[129] similarly informed consent is a core element of healthcare practice and biomedical research on human participants. Before proceeding, it is important to understand the evolution and legal basis of informed consent in healthcare and bioethics[130] within the EU and the international community.

Informed consent is based on the ethical and legal concept of patient autonomy (i.e., "You as the patient have the right to make decisions about your own health and medical conditions.").[131] Concerning modern-day medical research on humans, the Nuremberg Code established that "[t]he voluntary consent of the human subject is absolutely essential."[132] This was the first of ten principles enumerated in the Nuremberg Code.[133] Subsequently, in 1964, the World Medical Association (WMA) drafted the DoH, which furthered the development of international guidelines for

128 GDPR, *supra* note 2, recital 10, art. 9.

129 *Id.* recitals 32, 42-43, arts. 6(1)(a).1(a), 7, 9; Charter of Fundamental Rights of the European Union, 2012 O.J. (C 326) 391 [hereinafter Charter] (deriving from Article 8, "Protection of personal data," which states "(1) Everyone has the right to the protection of personal data concerning him or her. (2) Such data must be processed fairly for specified purposes *and on the basis of the consent of the person concerned* or some other legitimate basis laid down by law.") (emphasis added).

130 For the purposes of this article, the following broad definition of "bioethics" used by the European Court of Human Rights (ECtHR) has been adopted. *See* Research and Library Division, *Research Report: Bioethics and the case-law of the Court*, EUR. CT. H.R. 38 (2016), https://www.echr.coe.int/Documents/Research_report_bioethics_ENG.pdf (stating that "[b]ioethics 'has been understood to encompass the protection of the human being (his/her human rights and in particular human dignity) in the context of the development of biomedical sciences[,]' including consent to medical examination or treatment.").

131 Richard A. Wagner, *Informed Consent*, EMEDICINEHEALTH (Oct. 17, 2018) https://www.emedicinehealth.com/informed_consent/article_em.htm#what_is_informed_consent. *See* Faden & Beauchamp, *supra* note 41, at 8, 235-273 (analyzing the theoretical concept of autonomy in relation to informed consent).

132 Nuremberg Code, *supra* note 39, 181-83.

133 *Id*.

ethical research on humans.[134] The WMA continuously updates the DoH, most recently revising it at the 64th WMA General Assembly in 2013.[135] The DoH has an entire section with several provisions devoted to informed consent.[136]

The Charter of Fundamental Rights of the European Union (Charter),[137] which legally binds EU institutions and EU Member States, echoes the principles of the Nuremberg Code and the DoH. In Article 3 "Right to the integrity of the person," the Charter states that in the areas of medicine and biology, "the free and informed consent of the person concerned" must be respected.[138] Additionally, the Council of Europe's 1997 Oviedo Convention on Human Rights and Biomedicine (Oviedo Convention or Convention),[139] states in Chapter II - Consent, Art. 5:

> An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time.[140]

Vera Lúcia Raposo describes Article 5 on informed consent as "one of the

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134 DoH, *supra* note 40.

135 *Id.*

136 *Id.* at *Informed Consent*, ¶¶ 25-32. Additionally, DoH ¶ 24 addresses the need to protect a research participant's privacy and confidentiality of their information.

137 Charter, *supra* note 129 (legally binding the Union and its Member States since the Treaty of Lisbon entered into force on December 1, 2009). Treaty of Lisbon Amending the Treaty on European Union and the Treaty Establishing the European Community, Dec. 13, 2007, 2007 O.J. (C 306) 1 [hereinafter Treaty of Lisbon]

(stating in Article 6.1 "The Union recognises the rights, freedoms and principles set out in the Charter of Fundamental Rights of the European Union of 7 December 2000, as adapted at Strasbourg, on 12 December 2007, which shall have the same legal value as the Treaties"). *See also* David Anderson & Cian C. Murphy, *The Charter of Fundamental Rights*, *in* ANDREA BIONDI ET AL., EU LAW AFTER LISBON 155 (2012) (discussing the origins, development and current status of the rights protected by the Charter).

138 Charter, *supra* note 129, art. 3. EU citizens are the principal beneficiaries of the Charter's protections, but both EU and non-EU citizens can exercise most of the rights granted by the Charter, to include Article 3 "Right to the integrity of the person." The determining factor is whether the alleged fundamental rights' violation is attributed to the Union itself or to an EU Member State "when implementing EU law." *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*, ETS No. 164 (Apr. 4, 1997) [hereinafter Oviedo Convention],

139 Oviedo Convention.

140 *Id.* art. 5.

cornerstones of the convention."[141]

The Oviedo Convention also addresses in Chapter IV – Human Genome the specific need for genetic counseling when predictive genetic tests are conducted "[t]o identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease."[142] The Convention also mandates that such tests only be done for health purposes or for scientific research linked to health purposes (e.g., other possible discriminatory reasons are prohibited such as employment or health insurance coverage).[143] Raposo hails the prohibition of genetic discrimination as one of the Convention's key achievements, which reinforces the principles declared in the UNESCO Declaration on the Human Genome and Human Rights.[144]

The Oviedo Convention is the first international attempt at a legally binding instrument to address the challenges of biomedicine and bioethics. Yet, as Raposo underscores, it was necessary to craft it in very "broad and generic" terms to reach some degree of consensus.[145] Ultimately, the Convention has little direct legal effect because it fails to sanction any violations of its norms. Furthermore, the Convention only grants the European Court of Human Rights (ECtHR) a limited advisory role, which leaves the Court unable to enforce the Convention.[146] Raposo explains, however, that these constraints have not stopped the ECtHR from increasingly mentioning the Oviedo Convention in its decisions.[147]

To date, twenty-nine countries—a mix of EU Member States and Members of the Council of Europe (e.g., Georgia, Switzerland, Turkey)—have signed and ratified the Convention, albeit several countries with reservations.[148] Notably, the United Kingdom and the EU Member States of Austria, Belgium, Germany, Ireland, and Malta have neither signed nor ratified the Oviedo Convention. The five EU Member States that signed the Convention, but never ratified it are Italy, Luxembourg, Netherlands,

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141 Vera Lúcia Raposo, *The convention of human rights and biomedicine revisited: Critical assessment*, 20 INT'L J. HUM. RTS., 1277, 1280 (2016).

142 Oviedo Convention, *supra* note 138, art. 12.

143 *Id*. art. 11.

144 Raposo, *supra* note 141, at 1281.

145 *Id.*

146 Oviedo Convention, *supra* note 138, art. 29.

147 Raposo, *supra* note 141, at 1281, 1292 n. 32.

148 Treaty Office, *Chart of signatures and ratifications of Treaty 164*, EUR. COUNCIL https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164/signatures?p_auth=XAV5vkhQ (last visited July 21, 2019) (listing seventeen of the twenty-eight EU Member States that have signed and ratified the Oviedo Convention: Bulgaria, Croatia, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Greece, Hungary, Latvia, Lithuania, Portugal, Romania, Slovakia, Slovenia, and Spain).

Poland, and Sweden.

The Council of Europe crafted additional protocols to the Oviedo Convention to address certain biomedical and bioethical issues in more depth. One such protocol is the "Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes," (hereinafter Protocol on Genetic Testing) which opened for signature in 2008 and entered into force on July 1, 2018.[149] To date, five countries have ratified it, including the three EU Member States of Norway, Portugal, and Slovenia.

The Scope of the Protocol on Genetic Testing is limited to tests that are conducted for health reasons and aim to identify the genetic traits of a person that are inherited or acquired during prenatal development.[150] Article 7(1) requires that all these genetic tests for health purposes be performed under individual medical supervision.[151] Chapter IV – Information, genetic counselling, and consent Articles 8 and 9 reaffirm the consent requirements in Article 5 of the Convention on Human Rights and Biomedicine. Specifically, Article 8(1) mandates that the appropriate information be provided to a person prior to him or her undergoing a genetic test, to include the "[t]he purpose and the nature of the test, as well as the implications of its results."[152] Article 8(2) further requires that appropriate genetic counseling be available for a person who undertakes a "predictive genetic test[],"[153] which is defined as a test predicting a monogenic disease, detecting a genetic predisposition or susceptibility to a disease, or identifying the person as a healthy carrier of a gene responsible for a disease.[154] Article 8(2) defines standards for the genetic counseling, explaining that it must be "non-directive," and the "form and extent" of the counseling will depend on the meaning of the test results and their importance for "the person or the members of his or her family, including possible implications concerning procreation choices."[155] Article 9 mandates that an individual give "free and informed consent" prior to any

149 *Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes*, CETS No. 203, art. 2 (Nov. 27, 2008) [hereinafter Protocol for Genetic Testing].

150 *Id*. art 2.

151 *Id.* art. 7(1).

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

153 Oviedo Convention, *supra* note 138, art. 12 (defining predictive genetic tests).

154 Protocol for Genetic Testing, *supra* note 149, art. 8(2).

155 "Non-directive" is a clinical term defined by Oxford Dictionary as: "That does not direct; (Psychology) that does not give or involve instructions on how to proceed." So, under these circumstances the person would make his own choice freely. *Non-directive,* LEXICO, https://www.lexico.com/en/definition/non-directive (last visited July 21, 2019).

genetic test on her, and that consent may be "freely withdrawn" at any time.[156]

The Protocol on Genetic Testing acknowledged in 2008 the continued growth of the DTC genetic testing industry, and that consumers would have direct access to testing outside of the traditional healthcare system.[157] Consequently, Article 7(2) does envisage a scenario where a ratifying government to the Protocol on Genetic Testing permits an exception to the general rule that requires "individualized medical supervision" for health-related genetic tests.[158] It is incumbent upon the government to determine the appropriate circumstances to allow for such an exception, ensuring that the other provisions of the Protocol on Genetic Testing are met (e.g., provision of information pre-test, free and informed consent and genetic counseling). However, the carve-out provision is ambiguous because the final sentence of Article 7(2) prohibits its use if a genetic test has "important implications" for the health of the person, his family members, or for procreation decisions.[159] This final sentence ultimately undermines the utility of the exception. It is unlikely that a government could determine on a broad scale which test results have "important" significance since, arguably, the impact of the results is highly subjective. The extremely personal nature of a test result means that it affects each person and family member differently. Furthermore, it would be extremely burdensome and nearly impossible for a government to apply the exception widely to DTC genetic tests where the services and test results differ extensively among companies. Moreover, a government would be overreaching its authority and encroaching on one's right to private life[160] if it presumed that it could assess the level of importance that each person and their family attribute to a test result.

The Explanatory Report to the Protocol on Genetic Testing explains that each state is left to determine how to best implement the requirement for individualized medical supervision, as well as the exception to it (i.e., no individual medical supervision). The report emphasizes that the goal of the Article 7 provision is the "protection of the person concerned."[161] The report elaborates that the "authorities or bodies" involved in any decision to permit a test to be conducted without individual medical supervision

156 Protocol for Genetic Testing, *supra* note 149, art. 9.

157 *Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes*, CETS No. 203 (Dec. 27, 2008) [hereinafter EXPLANATORY REPORT FOR GENETIC TESTING].

158 *Id*. at 3; Protocol for Genetic Testing, *supra* note 149, art. 7.

159 *Id*. at 3; Protocol for Genetic Testing, *supra* note 149, art. 7.

160 *See* Charter, *supra* note 129, art. 7.

161 EXPLANATORY REPORT FOR GENETIC TESTING, *supra* note 157, at 9.

should consider the following factors:

> [T]he importance of the potential implications of the test considered for the persons on whom it would be carried out or for the members of their family, the ease of interpretation of the results and, if appropriate, the treatment possibilities for the disease or disorder concerned.[162]

Furthermore, the report highlights that the decision could depend on whether a person carries out the test entirely on his or her own by using a mail-order kit, for example, or whether a laboratory conducts the analysis.[163]

Although the Protocol on Genetic Testing envisages a government body making these decisions, I contend that government is not in the best position to effectively craft requirements for DTC genetic testing. As I explained briefly above, the DTC genetic testing industry poses unique challenges to prescribing blanket rules on individual medical supervision. Additionally, I argue that the informed consent process in its entirety is more pertinent to ensuring DTC genetic tests protect consumers—not merely whether a certain type of medical professional is involved.

The second Oviedo Convention protocol that is relevant for this discussion is the "Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research" (hereinafter Protocol on Biomedical Research).[164] Both the Protocol on Biomedical Research and the Protocol on Genetic Testing have the shared goal to "protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms," each within their respective areas—the former biomedical research on human beings and the latter genetic tests for health purposes.[165]

The Protocol on Biomedical Research forms an important part of the discussion on informed consent because DTC genetic testing companies often share (i.e., sell or rent in return for money or other types of remuneration) an individual's biospecimen, the data derived from the

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162 *Id.*

163 *Id.*

164 *Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research*, CETS No. 195 (Jan. 25, 2005) [hereinafter Protocol on Biomedical Research].

165 *Id*. art 1; Protocol for Genetic Testing, *supra* note 149, art. 1.

specimen, or an analysis of the data, with drug manufacturers,[166] start-ups, and biobanks (i.e., "a collection of biological samples that have been taken for the purpose of research"[167]).[168] For example, the widely known DTC genetic testing company 23andMe states on its website that "[o]n average, a customer who chooses to opt into research contributes to over 230 studies on topics that range from Parkinson's disease to lupus to asthma and more."[169] 23andMe reports that it has over ten million customers, and more than eighty percent of them have opted to share their data for research purposes, and as a result, the company has published more than one hundred fifty "peer-reviewed studies in scientific journals."[170]

The impact of DTC genetic testing companies' direct access via online and mail-order to a vast army of research subject volunteers is that the biomedical research process is accelerated exponentially. Haydeh Payami, a neurodegenerative disease researcher at the New York State Department of Health, commented in 2012 that the strides 23andMe made in identifying two genetic variants of Parkinson's disease from the DNA analysis of more than 30,000 people, if done conventionally "[w]ould have taken several decades and tens of millions of dollars" —as opposed to the eighteen months it took 23andMe.[171] DTC genetic testing and the biomedical research that results from it clearly break the traditional mold of recruiting patients to participate in disease studies. As Grunbaum's Discover magazine article notes, it may typically take more than ten years to obtain just a few thousand patients needed to participate in certain disease studies.[172]

23andMe has expanded its global partnerships. In 2015, China's WuXi Healthcare Ventures, the investment arm of WuXi PharmaTech,[173] was

166 For example, in 2011, 23andMe made public its collaboration with pharmaceutical company Genentech to study Alzheimer's disease. It was the first time such a partnership between a DTC genetic testing company and a drug company had been made public. Ewen Callaway, *23andMe teams up with Genentech to tackle Alzheimer's*, NATURE.COM: NEWSBLOG (June 28, 2011), http://blogs.nature.com/news/2011/06/23andme_genentech.html?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+news%2Frss%2Fnewsblog+%28News+Blog+-+Blog+Posts%29.

167 Rachel Thompson & Michael McNamee, *Consent, ethics and genetic biobanks: the case of the Athlome project*, 18 BIOMED CENT. GENOMICS 49, 50 (2017).

168 Kristen Hovet, *Selling yourself? These companies want to pay for your genetic information*, GENETIC LITERACY PROJECT (Oct. 24, 2018), https://geneticliteracyproject.org/2018/10/24/selling-yourself-these-companies-want-to-pay-for-your-genetic-information/ (last visited July 21, 2019).

169 23ANDME, INC., https://www.23andme.com/research/ (last visited Mar. 22, 2020)

170 23ANDME, INC., https://mediacenter.23andme.com/company/about-us/ (last visited Mar. 3, 2020).

171 Mara Grunbaum, *Private DNA Companies Tap Crowds to Speed Disease Research*, DISCOVER MAG. (Jan. 5, 2012), http://discovermagazine.com/2012/jan-feb/56.

172 *Id.*

173 *WuXi Healthcare Invests in US Genomics Testmaker 23andMe*, BIOSPACE (Oct. 21, 2015), https://www.biospace.com/article/releases/-b-wuxi-healthcare-b-invests-in-us-genomics-testmaker-

one of the investors who contributed to raising $115 million for 23andMe.[174] More recently, in 2018, the global pharmaceutical giant GlaxoSmithKline (GSK), headquartered in the United Kingdom, announced its collaboration in a multi-year agreement where it will be 23andMe's "exclusive collaborator" for drug target discovery programs.[175] GSK will have access to 23andMe's extensive database and proprietary statistical analytics to drive its research.[176] The financial benefit to both GSK and 23andMe is significant. The two companies will share proceeds from new treatments and medicines that result from their collaboration. GSK also has made a $300 million equity investment in 23andMe.[177]

The few examples of just one DTC genetic testing company—23andMe—demonstrate the rapid expansion of the DTC genomics industry and the growing need to ensure that consumer participation in "for-profit" research is supported by rigorous informed consent guidelines. It is imperative that these guidelines be specifically designed for DTC genetic research. The Protocol on Biomedical Research serves as a starting point for crafting such guidelines.[178] The following provisions from the protocol are most relevant to the DTC genetic testing companies' business model and describe the type of information that consumers would likely need to make an educated decision to participate in research.

Chapter IV – Information and Consent, Article 13 - Information for research participants, requires that potential participants be given "adequate information in a comprehensible form." It specifies in Article 13(2) that the informed consent requirements should "[c]over the purpose,

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23andme-/.

174 *See also* Steven W. Mosher, *What Will China Do With Your DNA? China's Fourth Magic Weapon, Part III: Bioweapons*, THE EPOCH TIMES (Mar. 24, 2019), https://www.theepochtimes.com/what-will-china-do-with-your-dna_2850925.html (arguing that the Chinese government's access to foreign DNA through its investment in and purchase of biotech companies, collaboration with genomic research centers, and collection and analysis of DNA samples sent to China, results in China having access to our personal genomic data, and may lead to China putting the data of Americans and other foreigners to military use. For example, Mosher hypothesizes that China's aggregation of all this genomic data might help it to create a bioweapon that targets a specific individual or entire ethnic race); Sui-Lee Wee, *China Uses DNA to Track Its People With the Help of American Expertise*, N.Y. TIMES (Feb. 21, 2019), https://www.nytimes.com/2019/02/21/business/china-xinjiang-uighur-dna-thermo-fisher.html.

175 *See GSK and 23andMe sign agreement to leverage genetic insights for the development of novel medicines*, GLAXOSMITHKLINE, PLC., (July 15, 2018),

https://www.gsk.com/en-gb/media/press-releases/gsk-and-23andme-sign-agreement-to-leverage-genetic-insights-for-the-development-of-novel-medicines/ (providing details on the GSK – 23andMe collaboration).

176 *Id*.

177 *Id*.

178 Protocol on Biomedical Research, *supra* 164.

the overall plan and the possible risks and benefits of the research project, and include the opinion of the ethics committee."[179] Article 13(2) explains that before an individual is asked to participate in research, the consent should cover several key issues, which are listed in paragraph (2)(i)-(viii). Article 13(2)(iv) is a provision that intersects with the goals of the GDPR, by addressing the methods for ensuring the confidentiality of personal data and respect for private life. Article 13(2)(v) requires that participants have access to information derived from the research that is of any relevance to them, as well as access to the results. Additionally, Article 13(2)(vii) mandates that any potential further uses, including commercial uses, of the "research results, data or biological materials" be disclosed to the research participant.[180] Article 13(2)(viii) requires the disclosure of the source of the funding of a research project.[181] Finally, Article (13)(3) ensures that a participant is informed of their right to refuse consent and to withdraw consent at any time.

Chapter IV – Information and Consent, Article 14 – Consent, specifically addresses and reaffirms the longstanding international principle that research that involves an intervention on a person requires "the informed, free, express, specific and documented consent of the person."[182] The Explanatory Report to the Protocol on Biomedical Research notes that this informed consent rule "emphasizes the autonomy of research participants in their relationship with researchers and health care professionals."[183] In fact, the concept of individual autonomy is prevalent throughout the Charter, as well as the other EU and international legal instruments already discussed in relation to informed consent. Autonomy is especially relevant to our discussion because it is an essential component of the fundamental rights of informed consent and data protection—two issues that are significant to consumers of DTC genetic testing.

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179 *Id*. art. 13.

180 *Id*.; *Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research*, CETS No. 195 (Jan. 25, 2005) [hereinafter EXPLANATORY REPORT FOR BIOMEDICAL RESEARCH] (highlighting that the "[r]equirement in [Article 13(2)(vii)] does not reflect any endorsement or condemnation of research conducted with commercial applications in mind." But it rather underscores that an individual's "[m]otivation for participation in biomedical research . . . may be out of solidarity, and information on foreseen commercial uses of their contribution to the research may be important to them in making a decision on whether to take part or not.").

181 *See* Protocol on Biomedical Research, *supra* note 164, art. 13(2)(i)-(viii) (providing list of relevant information that should be provided to an individual before being asked to consent to participate in a research project).

182 Protocol on Biomedical Research, *supra* note 164, art. 14(1).

183 EXPLANATORY REPORT FOR BIOMEDICAL RESEARCH, *supra* note 180, at 14.

VII. THE PRINCIPLE OF AUTONOMY: ITS SIGNIFICANCE IN EMPOWERING AND PROTECTING CONSUMERS OF DTC GENETTICS TESTS

Uniquely, the EU Charter of Fundamental Rights addresses both informed consent in a medical context (i.e., Article 3) and the protection of personal data, including consent to its processing (i.e., Article 8). Article 8 is essentially the forerunner of the GDPR's concept of data protection. As Yvonne McDermott explains, Article 8 marked the first time a "stand-alone" right to data protection was declared.[184] McDermott identifies "autonomy" as one of the four "values" that is integral to data protection, citing non-binding Recital 7 of the GDPR.[185] Recital 7 states, "[n]atural persons should have control of their own personal data."[186] Echoing the remarks made by EU Commission President Juncker quoted earlier, she further emphasizes that "[t]he principle of autonomy and the related focus on consent is also clearly linked to the concept of dignity."[187] I. van Ooijen and Helena Vrabec similarly highlight that one of the main intentions of EU legislators in drafting the GDPR was to "strengthen[] individual control," based on early policy discussions and non-binding Recitals 7 and 68.[188] They also reiterate the point made by McDermott and President Juncker that "[i]ndividual control, in particular with regard to one's person, has been described as a reflection of fundamental values such as *autonomy*, *privacy*, and *human dignity*."[189]

While autonomy is critical to an individual's ability to exercise her fundamental right to informed consent (i.e., health and research-related) and data protection, it also poses challenges that put the individual at risk. One of the biggest threats to an individual making an autonomous decision is the individual's lack of a clear understanding of the choices presented, including the potential risks, benefits, and consequences. For example, concerning data processing, McDermott cites a 2012 GDPR proposal where the European Commission stressed that "individuals are often neither aware nor in control of what happens to their personal data and therefore fail to exercise their rights effectively."[190] Van Ooijen and Vrabec

184 Yvonne McDermott, *Conceptualizing the Right to data Data Protection in an Era of Big Data*, 4 BIG DATA & SOC'Y 1, 2 (2017).

185 *Id*. at 3.

186 GDPR, *supra* note 2, recital 7.

187 McDermott, *supra* note 184, at 3.

188 van Ooijen & Helena U. Vrabec, *Does the GDPR Enhance Consumer's Control over Personal Data? An Analysis from a Behavioral Perspective*, 42 J. CONSUMER POL'Y 91, 92 (2018).

189 *Id.* (emphasis added).

190 *Proposal for a Regulation of the European Parliament and of the Council on the protection*

discuss the GDPR from a behavioral perspective and identify both "information overload" and "information complexity" as significant threats to individual control at what they call the "information receiving stage."[191] They explain that the "overload—of information poses a threat to individuals' ability and motivation to scrutinize the key details that are necessary to make informed privacy decisions."[192] Moreover, they cite a Norwegian study that demonstrated it took nearly thirty-two hours to simply read the text of the terms and conditions of thirty-three smartphone applications (i.e., 1,920 minutes or approximately fifty-eight minutes per application), which did not account for understanding the policy or its consequences.[193] They also note that disclosures are only becoming "longer and more complex" as technology progresses, which increasingly places a "strain on individuals' cognitive functioning."[194] They conclude that there are "[i]nformation asymmetries between the individual and the data collector" because of the "black box" nature of data processing and the subsequent "abstract" explanations provided to consumers.[195]

A similar challenge exists with the health and research-related informed consent process, particularly with respect to genetics and DTC genetic testing. In fact, the 2008 Explanatory Report to the Protocol on Genetic Testing warns that "[t]he results of genetic analysis are often complex and a proper understanding of their implications is, in many cases, difficult to understand for the persons concerned."[196] Similarly, Dr. Emilia Niemiec explains that "[g]enetics is a relatively advanced subset of biology, and the task of successfully communicating genetic concepts to a public unfamiliar with the subject can be challenging."[197] Moreover, a study by Amanda Singleton et al. found that consumers may get an inaccurate view of the benefits, risks and limitations of online genetic tests based on the information presented on a DTC genetic testing company website.[198] Singleton and her colleagues reviewed the website content of

of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation), COM (2012) 11 final.

191 van Ooijen & Vrabec, *supra* note 188, at 94-96.

192 *Id.* at 94.

193 *Id.* at 95.

194 *Id.*

195 *Id.* at 96.

196 EXPLANATORY REPORT FOR GENETIC TESTING, *supra* note 157, ¶ 2, at 1.

197 Emilia Niemiec et al., *Readability of informed consent forms for whole-exome and whole-genome sequencing*, 9 J. COMMUNITY GENET. 143, 144 (2018) (citing Colleen McBride et al., *Future health applications of genomics: priorities for communication, behavioral, and social sciences research*, 38 AM. J. PREVENTATIVE MED. 556, 560 (2010)).

198 Amanda Singleton et al., *Informed Choice in Direct-to-Consumer Genetic Testing (DTCGT) Websites: A Content Analysis of Benefits, Risks, and Limitations*, 21 J. GENET. COUNS. 433, 436-438 (2012).

twenty-three health-related DTC genetic testing companies.[199] Their findings indicated that on the main website pages, consumers are "exposed to an average of six times as many benefits as risks and limitations."[200] The study concluded that most companies don't provide a balanced view of the benefits, risks, and limitations, and even presented conflicting information, thus skewing consumers' perspectives and understanding of the genetic testing services.[201] Dr. Renee Sterling evaluated the promotion and sales strategy of online DTC companies offering nutrigenetic testing services in 2006, finding the websites lacked "[a]dequate and transparent information for informed-decision-making and rarely highlighted the importance of consumer consultation with a genetics professional."[202] The asymmetrical situation described earlier by van Ooijen and Vrabec concerning data processing applies here as well because the consumer is at a disadvantage in grasping the complexity of the genetic testing service's characteristics and consequences.[203]

As for-profit companies, it is no surprise that the DTC genetic testing companies' websites slant the information in favor of a company's services to encourage consumers to buy genetic tests.[204] Additionally, DTC genetic testing advertisements frequently appeal to the consumer by portraying the service as one that "provides empowering knowledge about one's body—a clever framing strategy that promotes a sense of personal entitlement to that knowledge," as noted by Rose Geransar and Edna Einsiedel in their 2008 article.[205] Yet, the irony is that this knowledge in and of itself has little utility to a consumer if she lacks the resources and tools to appropriately judge the information both at the pre-test (i.e., pre-purchase) and post-test (i.e., the genetic test results) stages. A significant detrimental consequence is that individual autonomy—the linchpin of informed consent—is severely undermined when a person fails to have a fair and complete understanding of the genetic testing options and information presented. Any consent she provides for genetic testing that is based on unclear or insufficient information has far less meaning and

199 *Id.* at 434 (providing a descriptive content analysis of 23 English-language DTC genetic testing websites offering health-related genetic tests between June 15 and July 1, 2009).

200 *Id.* at 437.

201 *Id.* at 439.

202 Renee Sterling, *The on-line promotion and sale of nutrigenomic services*, 10 GENET. MED. 784, 794 (2008).

203 van Ooijen & Vrabec, *supra* note 188.

204 Singleton et al., *supra* note 198, at 439.

205 Rose Geransar & Edna Einsiedel, *Evaluating Online DTC Marketing of Genetic Tests: Informed Choices or Buyers Beware?*, 12 Genet. Testing 13, 21 (2008).

effect.

Moreover, when informed consent and data processing consent are both essential components of a DTC genetic testing purchase, a lack of transparency in one area reverberates throughout the entire commercial transaction. The consumer's loss of control and weakened autonomy in the informed consent process will diminish their control over their personal data too.

During an online DTC genetic test purchase, the informed consent for the test itself is inherently intertwined with the consent for data processing. Although the two consent processes are different, they each demand the delivery to the consumer of clear, impartial, and adequate information. For example, if a consumer does not satisfactorily understand the health benefits, risks, and consequences of submitting a biospecimen for genetic testing, she likely won't comprehend adequately the type of personal genetic data that is being collected, processed, stored, reused, and sold. Thus, a consumer's degree of understanding in the informed consent process impacts her selection of data protection options. This is one of the key reasons why it is imperative that online DTC genetic testing companies develop robust informed consent procedures. The status quo results in a consumer's loss of individual control over her health and medical decisions, as well as over her personal data.

VIII. MOBILIZING INDUSTRY TO STRENGTHEN INFORMED CONSENT

As the DTC genetic testing industry continues to grow rapidly, there is an increasing need to better protect online consumers and inform their choices. Yet, the discussion on the IVDR and the Oviedo Convention demonstrates the difficulty of reaching EU consensus on specific informed consent rules. Moreover, as explained previously, there is a real legal question as to whether the EU possesses the authority (i.e., limits of competence) to regulate the methods and practice of informed consent. As mentioned earlier, the EU has a mandate to ensure public health safety, according to TFEU Article 168.[206] However, Article 168(7) makes it clear that Member States have the power to define their own health policy, including the manner in which they deliver health services and medical care.[207]

Considering TFEU Article 168 and the recent IVDR controversy, the development of an EU regulation on informed consent is improbable and

206 TFEU, *supra* note 70, art. 168; ALLIANCE OPINION, *supra* note 53, at 11.
207 TFEU, *supra* note 70, art. 168(7).

unlawful. Furthermore, individual EU Member State legislative action in this area is too sporadic. Kalokairinou et al. found fourteen of twenty-six European countries have national legislation on informed consent related to genetic testing.[208] Additionally, the authors found that ten of these fourteen countries, plus six other European countries (i.e., a total of sixteen of twenty-six), require genetic counseling for various types of genetic tests.[209] In most cases, though, European national laws on genetic testing do not directly address DTC tests, only tangentially if at all.[210] Notably, some EU Member States, such as France and Germany, have informed consent and genetic testing laws that are highly restrictive, partly in an attempt to prevent consumer access to certain DTC genetic tests within their jurisdiction.[211] Rachel Thompson and Michael McNamee explain this type of reactive legislation is known as the "whiplash effect,"[212] where the restrictions are "disproportionate" and go beyond what is necessary to protect individuals.[213] Yet, there are other Member States like Luxembourg, Poland, and Romania that have no legislation on genetic testing. Thus, Kalokairinou et al. have called the status quo a "fragmented [regulatory] landscape."[214] Besides, EU and Member State regulators are in a reactive mode, trying to catch up to the rapidly growing science of personalized genomics and the burst of DTC genetic tests on the market. In fact, not only policymakers but researchers in the health field also fell short and failed to mobilize quickly to assess the impact of this new technology and its marketing to consumers.[215]

Although Member State legislation in this area is currently disjointed, there are still possibilities of cooperation between the EU and its Member

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208 Kalokairinou et al., *supra* note 83, at 124 (identifying the fourteen countries as: Austria, Czech Republic, France, Germany, Hungary, Ireland, Italy, Norway, Portugal, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom).

209 *Id.* at 122-123 (identifying the sixteen countries as: Austria, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Norway, Slovakia, Slovenia, and Spain).

210 *See* these articles for an in-depth discussion of the national legislation and policy statements on genetic testing in Europe: Muhammad Rafiq et al., *Direct-to-Consumer Genetic Testing: A Systematic Review of European Guidelines*, 19 GENET. TEST. MOLECULAR BIOMARKERS 1 (2015); Pascal Borry et al., *Legislation on direct-to-consumer genetic testing in seven European countries*, 20 EUR. J. HUM. GENET. 715 (2012).

211 Kalokairinou et al., *supra* note 83, at 126.

212 Thompson & McNamee, *supra* note 167, at 51 (citing J. FLORIDI & B. MITTELSTADT, THE ETHICS OF BIOMEDICAL BIG DATA (Springer 2015)).

213 Thompson & McNamee, *supra* note 167, at 51.

214 Kalokairinou et al., *supra* note 83, at 119.

215 Colleen McBride et al., *Future health applications of genomics: priorities for communication, behavioral, and social sciences research*, 38 AM. J. PREVENTATIVE MED. 556, 560 (2010).

States to improve informed consent for consumers of DTC genetic tests. TFEU Article 168(1) defines the health policy powers of the Union, stating, "Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health." TFEU Article 168(2) grants the EU power to "encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas."[216] Additionally, Article 168(5) provides that the "European Parliament and the Council . . . may also adopt incentive measures designed to protect and improve human health . . . excluding any harmonisation of the laws and regulations of the Member States."[217] These provisions provide the legal authority for the EU to support Member States and assist them in coordinating their efforts to protect consumers' right to informed consent in the purchase of online DTC genetic tests and participation in related research.

Consumers, government, and industry are the three key stakeholders that must work together to ensure that DTC genetic testing is conducted ethically and responsibly. There is a balance that must be sought between the stakeholders' respective interests of personal autonomy, safety and health, and corporate research and innovation. R. E. van Hellemondt et al. contend that "free access to DTC genetic tests strengthens the individuals' autonomy, as protected by the right to private and family life."[218] The authors reference the Charter of Fundamental Rights, Article 7 "Respect for private and family life," and cite several ECtHR cases to support this point.[219] The authors also argue that the companies have "obligations" to obtain informed consent and, in the very least, the EU Member States have a "duty" to safeguard the informed consent process.[220] This point underscores that the burden is shared between the DTC genetic testing companies and the EU Member States to ensure the requirements of informed consent are fulfilled.

The EU and its Member States have a key role to play in motivating industry action. There needs to be an EU-wide coordinated campaign to improve the education of consumers so that they can demand more from

216 TFEU, *supra* note 70, art. 168(2).

217 *Id*. art. 168(5).

218 R.E. van Hellemondt et al., *Regulating the use of genetic tests: Is Dutch law an example for other countries with regard to DTC genetic testing?*, 3 Amsterdam L. F. 13 (2011), http://amsterdamlawforum.org/article/view/194.

219 *Id.* at 17 (citing: Mikulic v. Croatia, 2002-I Eur. Ct. H.R. 141; Pretty v. the United Kingdom, 2002-III Eur. Ct. H.R. 155; Christine Goodwin v. the United Kingdom, 2002-VI Eur. Ct. H.R. 1.; Ternovszky v. Hungary, no. 67545/09 (2010)).

220 *Id*.

industry and are better informed to exercise their personal autonomy and fundamental right to informed consent. As Rose Geransar and Edna Einsiedel explain, there exists a "[s]trong public interest in and perceived right of access" to DTC genetic testing services, which requires devoting more resources to educating doctors and consumers about genetics, disease etiology, and genetic testing issues and concerns.[221]

Additionally, the EU can foster state cooperation to combat a growing cross-border threat to public health from the online sales of DTC genetic testing services that fail to meet the minimum informed consent standards. One option to protect consumers is for Member States either individually or collectively to impose a temporary sales ban on DTC genetic testing companies selling within their territory until they comply with internationally acceptable informed consent standards. Eventually, the Member States, with the assistance of the Union, could establish performance objectives and standards that DTC genetic testing services would have to meet in order to conduct online sales within the EU. This latter option might be in the form of EU guidelines, but most effective would be a regulation applicable to all DTC genetic testing services regardless of the location of their headquarters or the DNA processing lab—in or outside the EU. In fact, in response to the Liese Amendments, the ESHG made a similar proposal, stating:

> The ESHG would strongly support Dr. Liese if he were to propose a stand-alone Regulation or Directive on genetic testing, within the limits of EU competence in healthcare, as we believe that it is only by this means that our shared objectives can be achieved.[222]

Such a regulation would have an extra-territorial application like the GDPR, which would be necessary given the online and global nature of the DTC genetic testing industry.[223]

Lastly, the DTC genetic testing industry should be encouraged to improve its standards and self-regulate. Industry can respond faster and more effectively to create stronger informed consent procedures. Arguably, the industry understands the complexities of genetic testing better than EU and national legislators. Industry also has the added incentive to work hard to gain customer trust, which will expand sales and

221 Geransar & Einsiedel, *supra* note 205, at 21.
222 ESHG POSITION STATEMENT, *supra* note 64, at 2.
223 GDPR, *supra* note 2, art. 3.

cultivate the DTC genetic testing business overall. Furthermore, industry may be better positioned to analyze and assess the interaction between recently implemented GDPR provisions and newly proposed online informed consent procedures.

IX. RECOMMENDATIONS FOR REFORMING ONLINE INFORMED CONSENT

Collectively, several EU and international legal instruments, particularly the Nuremberg Code, DoH, Charter of Fundamental Rights, IVDR, and the Oviedo Convention and its additional protocols, establish a clear framework of informed consent principles and standards. Working within this framework, it is imperative that consumers and government demand from industry an improved commitment to live up to these established values of informed consent.

The earlier discussion highlighted that the current online informed consent process for DTC genetic tests fails to adequately advise consumers of the risks, benefits, consequences, alternatives, and the probability and severity of the risks occurring. Additionally, the pre- and post-test online interactions lack personalized information and care from a certified genetic specialist. Furthermore, in the interest of building their customer base and gaining customer trust, the DTC genetic test companies should dedicate more resources to the informed consent process and place greater importance on the issue within their corporate management.

Consequently, the proposed recommendations focus on three areas where the most effort should be placed to improve the informed consent process—online communication, genetic counseling, and corporate management.

A. Recommendation 1—Improve Online Communication

If ordinary healthcare situations present communication challenges in the informed consent process,[224] an online DTC environment significantly amplifies those challenges. One pitfall of the informed consent process that is especially pertinent to online informed consent is the tendency towards the use of persuasion. As Søren Birkeland points out, obtaining informed consent can "take[] the form of being 'very presumed.'" It may

224 Søren F. Birkeland, *Informed Consent Obtainment, Malpractice Litigation, and the Potential Role of Shared Decision-making Making Approaches*, 24 Eur. J. Health L. 264, 270-271 (2017) (explaining there are various schools of thought on the amount and type of information that should be shared with a patient to sufficiently satisfy informed consent, such as protecting patients from excess information or sharing all available information).

result in a pro forma situation, "these are the pro[s] and those are the possible con[s]—please sign this document!"[225] These persuasive characteristics appear to be inherent to online transactions because they demand that you click 'agree' if you want to use their services (e.g., buy a DNA test).

Moreover, the online informed consent process is buried in the "lengthy and densely worded"[226] contract presented to consumers, and it lacks the qualities necessary to obtain truly free, voluntary, and informed consent. Andelka Philips' study between 2011 and 2014 of seventy-one DTC Genetic Testing companies (i.e., those with terms and conditions publicly available) revealed that all the online contracts were "either clickwrap (click-through) or browsewrap agreements."[227] The consumer provides their consent by clicking on 'I Agree,' typically without fully reading and understanding the contents.[228] As Phillips underscores the "validity of consent provided merely through visiting a website is open to challenge."[229]

Improving online communication with the consumer entails changes to both the content and delivery methods of the information. The DTC genetic testing industry could enhance its objectivity and improve online consent if it relied more on the use of unbiased, third-party material (i.e., written and audio-visual). As objectivity increases and persuasiveness diminishes, the industry must thoroughly integrate into its business model the possibility that a certain portion of prospective customers will choose not to complete their purchase or participate in research based on the information presented to them in the informed consent process.

In order to effectively convey the complex information about DNA testing, the DTC genetic testing companies should employ more diagrams and audio-video technology. Using visual aids and audio-video to present information in a clear, objective manner and engage in a dialogue will significantly contribute to consumers' enhanced understanding of their purchase of genetic test information and participation in research. The 'Your DNA, Your Say'[230] international project serves as a good model for

225 *Id.* at 271.

226 Andelka M. Philips, *Genomic Privacy and Direct-to-Consumer Genetics: Big Consumer Genetic Data – What's in that Contract?*, IEEE CS SECURITY AND PRIVACY WORKSHOPS, 60, 61 (2015), http://www.genopri.org/uploads/3/9/9/9/39999711/9933a060.pdf (last visited July 24, 2019).

227 *Id.*

228 *Id.*

229 *Id.* at 62. *See also* Andelka M Phillips, *BUYING YOUR SELF ON THE INTERNET: WRAP CONTRACTS AND PERSONAL GENOMICS* (2019).

230 Anna Middleton et al., *'Your DNA, Your Say': gathering attitudes toward genomics: design,*

industry. For example, the researchers involved in the project crafted nine films to explain genomic data sharing.[231] They realized that "[t]here is a real need to 'socialize' genomics for publics so that they can make informed choices about how and whether to engage with genomic technologies."[232] Thus, keenly aware that the public's knowledge of genomics is low, the films and associated survey used the term 'DNA information' instead of 'genomics.'[233] The films employed the proven use of metaphor and narrative to more easily convey complex information and connect with participants.[234] The researchers also strived to present the information in an unbiased, neutral manner.[235]

If companies want to compete for market share in the EU (and elsewhere), it is advisable that they move away from a contract-centric view towards a patient-provider perspective, to ensure their customers are well-informed and voluntarily consenting to services and research. Moreover, the consent process needs to be viewed as an ongoing relationship since the data is stored long term, and there will always be new and innovative genetic tests and scientific research opportunities. Thus, companies also must create more effective strategies for re-contacting consumers to seek re-consent for new scientific studies and further sharing of data.[236] These suggested measures will improve the informed consent process.

B. Recommendation 2—Offer Pre-Test Genetic Counseling

Another critical aspect of informed consent is the information exchange and dialogue that exists between the patient and her healthcare provider. Birkeland explains that 'shared decision-making' (SDM) is one method of obtaining informed consent that involves "both parties [the patient and the provider] share information; . . . take steps to build a consensus about the preferred treatment . . . and that an agreement is reached on the treatment to implement."[237] The DTC genetic testing industry could improve online

delivery and methods, 15 PERSONALIZED MED. 311, 314 (2018).

231 *See* Society and Ethics Research Wellcome Genome Campus, *Your DNA, Your Say*, YOUTUBE (Mar. 9, 2016), https://www.youtube.com/watch?v=WZMdkOsLb4Y&list=PLicKqIwYPVo7wWrnlm02CF1snVuoBbWTz.

232 Middleton, *supra* note 230, at 314.

233 *Id.*

234 *Id.*

235 *Id.*

236 *See* Deborah Goodman et al., *Consent Issues in Genetic Research: Views of Research Participants*, 19 PUB. HEALTH GENOMICS 220 (2016).

237 Birkeland, *supra* note 224, at 271 (quoting C. Charles et al., *Shared Decision-making in the*

informed consent if it retained genetic counselors to engage with customers in the informed consent process, emulating the SDM model. Also, it is imperative that the DTC companies provide genetic counseling services free-of-charge for consumers to ensure fairness and uphold the ethical values of the informed consent doctrine. This would be a costly and time-intensive endeavor for the DTC companies, but the rapid growth of the online personal genomics industry warrants this level of commitment.

A key hurdle to overcome for the DTC genetic testing industry is that the current global genomics market outpaces the available genetic counselors and the capacity to educate and train new genetic counseling professionals. As of 2018, it was estimated there were nearly 7,000 genetic counselors worldwide in at least twenty-eight countries—with more than sixty percent of them practicing in North America.[238] Europe clearly appears to lag behind the United States and Canada in the availability of genetic counselor training programs. In fact, Austria, Belgium, Germany, and Portugal are among the EU member states who do not recognize the profession of genetic counseling "due to legal restrictions requiring that genetic counseling is [a] medical act, and therefore conducted by physicians."[239] As of 2018, only about eighteen countries in Europe had licensed genetic counselors working in various roles, and there were only eleven active genetic counselor master's training programs throughout Europe, compared to nearly forty in the United States and five in Canada.[240] Evidently, there are numerous difficulties involved with redirecting the limited number of genetic counselor resources into the rapidly expanding DTC genetic testing industry.[241] Yet, market economics indicate that the supply of genetic

Medical Encounter: What Does It Mean? (or it takes at least two to Tango), 44 SOC. SCI & MED. 681-92 (1997).

238 MaryAnn Abacan et al., *The Global State of the Genetic Counseling Profession*, 27 EUR. J. HUM. GENETICS 183, 195 (2019).

239 *Id.* at 192.

240 *Id.* at 184-85, 188-192 (explaining that the UK's Genetic Counsellor Registration Board grants formal genetic counselor registration, but it remains voluntary despite the fact that most employers require it. In the EU, the European Board of Medical Genetics established standards of practice for genetic counselor registration and started a registration system in 2013, recognizing professionals with a master's degree as well as other relevant training and experience, including internationally-trained genetic counselors from the US, Canada, South Africa, and Australia who work full-time for a minimum of one year in Europe.).

241 *See* Jeanna M. McCuaig et al., *Next-Generation Service Delivery: A Scoping Review of Patient Outcomes Associated with Alternative Models of Genetic Counseling and Genetic Testing for Hereditary Cancer*, 10 CANCERS 435 (2018) (discussing alternative ways to engage genetic counselors via telephone, videoconference, group sessions, etc.).

counselors eventually will rise to meet the demand, without compromising the essential work done by genetic counselors in clinical practice, research, education, and public health.[242]

While some online DTC genetic testing companies provide consumers with access to genetic counselors, very few companies offer pre-test counseling services as part of the informed consent process. For example, a 2010 study identified twenty online DTC companies (i.e., those that explicitly offered genetic testing for mental health conditions), fourteen of which did not provide any genetic counseling services.[243] Five of the twenty companies did provide their own counseling services.[244] Only one company, 23andMe, offered (at least at the time) independent counseling to discuss post-test results.[245] Only three of the six companies that offered counseling services provided them for both pre-and post-test.[246] The remaining three companies' counseling services were post-test only.[247] The genetic counselors were available by various means—such as phone, Skype, or email.[248]

Besides enhancing the informed consent process, pre-test genetic counseling could play a significant role in helping consumers decide to hand over their personal genomic data for research purposes. Once consumers consent online to have their DNA processed and shared for research purposes, spit in the vial, and mail the saliva sample to the laboratory, the data will be shared until consent is withdrawn; and as 23andMe explains on its website, once shared it cannot be "reversed or undone."[249]

23andMe CEO and co-founder Anne Wojcicki advocates for consumers to have the freedom to access their genetic data without

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242 *See* Birkeland, *supra* note 224; *see also* Jennifer M. Hoskovec et al., *Projecting the Supply and Demand for Certified Genetic Counselors: aA Workforce Study*, 27 J. GENET COUNS. 16 (2018) (predicting that the supply of genetic counselors working in the patient care field will reach equilibrium within 5 to 10 years due to the growth of genetic counseling training programs).

243 Anna Harris et al., *Counseling Customers: Emerging Roles for Genetic Counselors in the Direct-to-Consumer Genetic Testing Market*, 22 J. GENET. COUNS. 277, 280 (2013).

244 *Id.*

245 *Id.* In June 2010, 23andMe engaged Informed Medical Decisions, Inc., a U.S.-network of board-certified genetics experts, to offer independent genetic counseling services to new and existing customers to discuss their tests results. The counselors were trained in 23andMe's unique reports and processes. *Press Releases*, 23ANDME, INC. (June 3, 2010), https://mediacenter.23andme.com/press-releases/23andme-enlists-informed-medical-decisions-to-make-independent-genetic-counseling-services-available-to-customers/.

246 Harris et al., *supra* note 243, at 280.

247 *Id.*

248 *Id.*

249 *Individual Data Sharing Consent*, 23ANDME, INC., https://www.23andme.com/about/individual-data-consent/ (last visited July 24, 2019).

obtaining the approval of an insurance company or a physician.[250] However, outside of a traditional healthcare setting, it is arguably more imperative that consumers be given all the necessary objective facts (e.g., to include the test validity, clinical utility, risks, benefits, test consequences, data privacy issues, family concerns, etc.) in an understandable manner, and have the ability to share information and ask questions in the pre-test stage. It is only after being presented with a proper informed consent process that a consumer should have the option to purchase a DTC genetic test or participate in genetic research. To assist the informed consent process, DTC genetic testing companies could develop standardized decision tools "[t]o thoroughly think through [consumer/patient] preferences and risk information without relying only on a [counselor's] memory, skills, and likings."[251] As Birkeland points out, these could be internet-based tools, brochures, or videos on various genetic tests and key issues of concern.[252]

DTC genetic testing companies may offer access to pre-test counseling via several forms of communication, but face-to-face video conferences or web-link would probably result in the most effective informed consent dialogue. In fact, a 2010 study of attitudes of European clinical geneticists underscores the importance of face-to-face counseling.[253] Seventy percent of respondents strongly disagreed with offering a DTC genetic test without a face-to-face medical consultation when preventive or therapeutic measures could be taken based on the test results.[254] The level of strong disagreement decreased considerably to thirty-nine percent when asked about DTC genetic tests of traits or conditions that have no or relatively minor health consequences (e.g., ear lobe shape or gluten insensitivity).[255] However, the level of strong disagreement spiked to ninety-four percent when asked about DTC genetic tests of conditions that are neither treatable nor preventable, and ninety-seven percent for conditions with serious health repercussions (e.g., neurological impairment).[256] These findings

250 Anne Wojcicki, *Consumers don't need experts to interpret 23andMe genetic risk reports*, STAT (Apr. 9, 2018), https://www.statnews.com/2018/04/09/consumers-23andme-genetic-risk-reports/.

251 Birkeland, *supra* note 224, at 271.

252 *Id.* at 272.

253 Heidi C. Howard & Pascal Borry, *Survey of European clinical geneticists on awareness, experiences and attitudes towards direct-to-consumer genetic testing,* 5 GENOME MED. 1, 7 (2013) (analyzing the full and partial responses from 131 clinical geneticists from 28 EU countries—a survey response rate of 44%).

254 *Id.*

255 *Id.*

256 *Id.*

also demonstrate that different types of DTC genetic tests demand different levels of genetic counseling; not all DTC genetic tests necessarily require face-to-face consultations.[257] Finally, the study revealed that most respondents raised the need for genetic counseling "before and/or after" DTC genetic testing to ensure consumers understand the results and their consequences.[258]

23andMe's CEO Wojcicki argues that consumers are empowered when they have access to their genetic test results.[259] But, consumer empowerment is not just about the end result (i.e., access to one's genetic test results). Consumer empowerment is built upon a process, and that process starts way before any testing occurs. As discussed earlier, individual autonomy and personal empowerment depend upon informed choices. Beginning with the pre-market and advertising stage through to the post-test counseling and follow-up research opportunities, DTC genetic testing companies must rethink the content of information they provide to consumers, how the information is communicated, and the counseling services they offer to support consumers' understanding of genetic testing.

C. Recommendation 3—Build Corporate Responsibility in a Digital Age

Finally, senior managers must be integrally involved at all levels of the informed consent process to successfully reform it and give it meaning. This begins with senior managers lending critical support to the development of new information strategies to address the weaknesses in the current online informed consent methods. Senior managers also must insist upon the creation of effective and consumer-oriented genetic counseling programs.

Additionally, there are some elements of the GDPR that serve as a model for online DTC genetic testing companies to develop a stronger informed consent framework. As Claudia Quelle explained, "[t]he GDPR marries the emphasis on autonomy and consent with a parallel focus on

257 *Id.*

258 *Id.* at 5, 11.

259 Wojcicki, *supra* note 250 (speaking about the 23andMe BRCA1 and BRCA2 breast cancer gene mutation test approved by the FDA in 2018). As Melissa Fassbender underscores, the FDA-approved test only reports on 3 out of more than 1,000 known BRCA mutations and a negative result does not rule out increased cancer risk. Melissa Fassbender, *Why patient counseling is an essential component of genetic testing*, OUTSOURCING-PHARMA (Aug. 28, 2018), https://www.outsourcing-pharma.com/Article/2018/08/28/Why-patient-counseling-is-an-essential-component-of-genetic-testing.

the duties of data controllers."[260] The regulation places the burden on the covered entity to appoint a Data Protection Officer (DPO) who reports to the entity's highest level of management.[261] The GDPR mandates where applicable that entities self-evaluate the risks, perform impact assessments, and identify and implement risk mitigation strategies.[262] DTC genetic testing companies could each appoint an officer to perform similar tasks to ensure they are fulfilling informed consent requirements in line with internationally recognized guidelines. This position could be called the 'Informed Consent Officer' (ICO). The ICO, like a DPO, would act independently, but also be knowledgeable about the DTC genetic testing industry and an integral member of the corporation. Although this would be a voluntary initiative, it could help to strengthen the credibility of the informed consent process and enhance consumer confidence in DTC genetic testing. Consumers, health professionals, and government regulators would welcome bold moves by corporate management to self-regulate.

X. CONCLUSION

The international Human Genome Project (HGP) began in 1990 and concluded in 2003, successfully sequencing the three billion DNA base pairs in the human genome and between 20,000 to 25,000 human genes.[263] All the sequence data derived from the HGP is stored in public databases, and scientists worldwide have free and unrestricted access to it.[264] This remarkable achievement continues to have an immense impact on our society. It has transformed our understanding of biological science, genomics, human health and disease, and has created new ethical, legal, and social challenges associated with these scientific advancements. The HGP laid the foundation for the incredible growth of the DTC genetic testing market over the past seventeen years, and the resulting explosion of personal genomic data.

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260 Claudia Quelle, *Not just user control in the General Data Protection Regulation. On controller responsibility and how to evaluate its suitability to achieve fundamental rights protection*, SEMANTIC SCHOLAR (2011), https://pdfs.semanticscholar.org/2eeb/f1efca870fc524b381010c97712f98e89419.pdf?_ga=2.3795120.1467810442.1564020120-15932401.1563209134.

261 *See* GDPR, *supra* note 2, Articles 37-39.

262 GDPR, *supra* note 2, arts. 35-36; recitals 77, 90.

263 *International Consortium Completes Human Genome Project*, NAT'L HUMAN GENOME INST. (Apr. 14, 2003), https://www.genome.gov/11006929/2003-release-international-consortium-completes-hgp.

264 *Id.*

Now, the rapid expansion of the DTC genomic industry and big data brings society to a new crossroads where individual rights to data privacy and informed medical consent intersect with issues of consumer autonomy and access to DTC genetic testing services. There is a delicate balance to achieve between empowering consumers and protecting them.

DTC genetic testing companies hold the enormous power of data, and it is incumbent upon them to act responsibly and ethically in their collection, storage, and sharing of that data. The GDPR has made strides in overall data protection. However, EU consumers of online DTC genetic tests are still at risk of misunderstanding the consequences of their purchase and losing control over their genomic data due to the absence of adequate online informed consent. This industry, like many others operating online internationally and cross-border, is difficult to regulate effectively. Moreover, EU-wide informed consent rules applicable to DTC genetic tests are unlikely to materialize in the near term and probably are beyond the scope of EU authority.

As a result, there is flexibility for the industry to develop its own stringent bioethical and medical standards, including informed consent procedures. Companies that commit to educating and counseling consumers in genomics and developing and implementing measures to ensure compliance with bioethical and medical values will be successful in retaining and growing their consumer base, not only within the EU, but globally. If the industry fails to take advantage of the present opportunity to self-regulate, consumer interest and confidence in personalized health and genomics will likely wane and be written off as having been just another fad.