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I Just Took a DNA Test—Turns Out, I'm 100% Breaching My Donor Anonymity Contract: Direct-to-Consumer DNA Testing and Parental Medical-Decision-Making

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I Just Took a DNA Test—Turns Out, I'm 100% Breaching My Donor Anonymity Contract: Direct-to-Consumer DNA Testing and Parental Medical-Decision-Making

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INTRODUCTION

The holiday season of 2018 was frightful for Danielle Teuscher. Like some parents, Danielle decided to genetically test her five-year-old daughter, Zoe.[1] Unlike some parents, however, Danielle used a sperm donor to conceive Zoe.[2] Danielle opted to test her donor-conceived daughter with 23andMe's health and ancestry kit[3] to learn more about Zoe's heritage and health risks, but she faced serious legal repercussions from NW Cryobank, the sperm bank that provided the

* J.D. Candidate, Indiana University Maurer School of Law, 2021. This note and the supporting research would not have been possible without the knowledge and support of Professor Jody Lyneé Madeira. Lectures in her course "Reproduction, Childhood, and the Law" sparked my interest in this area, but her enthusiasm and expertise helped me develop this note. I am also grateful to the entire staff of the Indiana Journal of Global Legal Studies for their assistance and feedback throughout the revision process. Finally, I owe a deep gratitude to Emily Baert and Zachary Peifer for looking over numerous drafts of my work and encouraging me throughout many late nights. Any remaining errors are my own.

1. Nila Bala, *Why Are You Publicly Sharing Your Child's DNA Information?*, N.Y. TIMES (Jan. 2, 2020), https://www.nytimes.com/2020/01/02/opinion/dna-test-privacy-children.html.

2. Zoe was conceived with sperm donated by Donor #2744, who was registered as an "Open ID" donor–a donor who is open to contact when his donor-conceived offspring reaches eighteen years of age. *See* Ellen Trachman, *Beware of the Home DNA Test! Mom Strikes Back Against Sperm Bank*, ABOVE THE LAW (Oct. 23, 2019, 1:42 PM), https://abovethelaw.com/2019/10/beware-of-the-home-dna-test-mom-strikes-back-against-sperm-bank/. Danielle's choice of Donor #2744 was largely in part because he was an "Open ID" donor and was "Retired," meaning he had stopped donating and that there was only a limited supply of his gametes available. Complaint para. 26, Teuscher v. CCB-NWB, LLC, 437 F.Supp. 3d 849 (E.D. Wash. 2020) (No. 19-CV-00204).

3. *Test Info*, 23ANDME, https://www.23andme.com/test-info/ (last visited Mar. 12, 2021).

sperm.[4] Zoe's 23andMe results included a match to her paternal grandmother on 23andMe's database.[5] Zoe's paternal grandmother was listed as "receptive to contact" on the site, so Danielle sent a short message through 23andMe's portal[6] indicating Zoe's relatedness and an openness to connect. Despite the paternal grandmother's listing as open to contact, Danielle received a cease and desist letter from NW Cryobank due to her alleged breaches of contract.[7] Further, NW Cryobank sought financial penalties amounting to $20,000.[8] Tis the season?

Specifically, Danielle's alleged breaches included (1) seeking the identity of the donor and (2) contacting the donor's mother.[9] In addition to financial penalties, NW Cryobank stated it would deny her access to four vials of sperm (for which she paid) that she had hoped to use to conceive another child who would be a genetic match to Zoe.[10] Further,

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4. *See* Trachman, *supra* note 2.

5. Gregory Loy, *Taking a Stand Against an Unregulated Industry*, SEVERANCE MAG. (Jan. 21, 2020), https://severancemag.com/taking-a-stand-against-an-unregulated-industry/.

6. *Id.*

7. Jacqueline Mroz, *A Mother Learns the Identity of Her Child's Grandmother. A Sperm Bank Threatens to Sue.*, N.Y. TIMES (Feb. 16, 2019), https://www.nytimes.com/2019/02/16/health/sperm-donation-dna-testing.html (stating that Ms. Teuscher breached her contract by using the results from the ancestry portion of 23andMe to contact the mother of donor used for Ms. Teuscher's child).

8. *Id.*; *see also* Complaint, *supra* note 2, para. 70.

9. On January 12, 2019, Danielle Teuscher received a Cease and Desist Letter from general counsel at NW Cryobank. The letter stated:

> Your attempt to seek the identity of the Donor and then to contact the Donor's mother through 23andMe is, in each case, a flagrant violation of the Agreement (the Customer Agreement). Under Section VIII of the Agreement (Customer Agreement), NWCryobank (sic) is entitled to liquidated damages in the amount of $10,000 for each act in violation of Section VIII. At this point, we are entitled to seek $20,000 in liquidated damages from you $10,000 for seeking the identity, $10,000 for initiating contact).
>
> Upon further investigation, we may be entitled to addtional [sic] monetary damages if you have used other ancestry DNA programs, facial recognition tools on the internet or any other means, directly or indirectly, to contact or seek the identity of the Donor. We will seek a restraining order or injunction if you continue with this course of action in any maner [sic] . . . .
>
> Moreover, we hereby notify you that as a direct result of your flagrant and material breach of the Agreement we are revoking your right to receive the four (4) [sic] additional vials of Donor's sperm that you purchased. No refund will be given.

Complaint, *supra* note 2, para. 70.

10. The cease and desist letter was wrong; Danielle Teuscher had five vials of purchased sperm stored at NW Cryobank. Trachman, *supra* note 2; *see also* Mroz, *supra* note 7.

the company redesignated the status of Zoe's donor from "open ID" to "anonymous,"[11] effectively denying Danielle access to medical information updates from both the donor and parents of other children conceived from that donor's sperm.[12]

Danielle is not the only NW Cryobank consumer impacted by this particular situation—since NW Cryobank sent the cease and desist letter, the company has disabled access to its donor sibling registry,[13] an action that harms all NW Cryobank consumers and conceived children "by preventing them from being able to connect with relatives and make other important connections for the children's wellbeing [sic]."[14]

Though few may consider this to be a justified consequence for Danielle's alleged breach, it is important to note that the *click-wrap* agreement Danielle signed did not include a provision giving NW Cryobank the right to take away Danielle's purchased gametes; the agreement only permitted NW Cryobank to cease storing gametes and to destroy them if payment was not received.[15] Further, the agreement included other provisions biased towards NW Cryobank, like one specifying that any attorneys' fees spent by NW Cryobank on any court action shall be paid by the customer, which is against Washington law.[16] Another issue at the forefront of Danielle's legal issues with NW Cryobank is whether she—and other parents of donor-conceived children—had adequate informed consent before she signed this click-wrap agreement.[17]

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11. Complaint, *supra* note 2, para. 3. NW Cryobank's website lists three types of sperm donor options: (1) Anonymous Sperm Donors–who have been promised that "[p]arents, recipients, or donors cannot initiate any communication"; (2) Open to Communication Sperm Donors–who "have agreed to a minimum of one communication with offspring who are at least 18 years old," and NW Cryobank "will not break anonymity unless both parties request it"; and (3) ID Disclosure Sperm Donors–who have agreed to provide identifying information to donor-conceived adults when they turn 18 years old. *Sperm Donor Types*, NW CRYOBANK, https://www.nwcryobank.com/sperm-donor-types/ (last visited Mar. 12, 2021). However, NW Cryobank requires donor-conceived adults to sign a non-disclosure agreement where they agree not to share this information with other offspring, on message boards, social media, etc. *Id.* Refusal to sign the agreement results in no release of information at all. *Id.*

12. Loy, *supra* note 5; *see also* Trachman, *supra* note 2.

13. Loy, *supra* note 5.

14. *Id.*

15. The agreement contained a space for Danielle Teuscher "to 'click the box' and, when she electronically clicks on the box, the computer program will insert a check mark under each section of the Customer Agreement." Complaint *supra* note 2, paras. 37, 39.

16. Loy, *supra* note 5.

17. *See* Margaret Jane Radin, *Boilerplate Today: The Rise of Modularity and the Waning of Consent*, 104 MICH. L. REV. 1223, 1231 (2006) ("Consent is fictional when almost all of us click on-screen boxes affirming that we have read and understood things we have not read and would not understand if we did.").

Now, with an increased interplay between direct-to-consumer DNA testing and advanced reproductive methods, the position in which Danielle finds herself is seemingly becoming more common. Following the cease and desist letter, parents of donor-conceived children have reason to fear—the investigation of one's donor-conceived child's genetic history may result in similar cease and desist letters, large financial penalties, denials of access to donor medical updates and community forums concerning related children, and denials of future access to gametes.[18]

In the era of widespread availability of direct-to-consumer DNA testing, some facilities in the industry of fertility medicine have acknowledged that the promise of anonymity may inevitably be short-lived.[19] Cryos International, one of the largest sperm and egg banks in the world, has acknowledged that gamete donors can be identified through direct-to-consumer DNA testing.[20] While Cryos International still offers sperm donors the option of being an "ID Release" or a "Non-ID Release" sperm donor, the company makes direct statements regarding the possibility of all donors being found with DNA analysis and genetic testing services.[21] NW Cryobank, on the other hand, has chosen to retaliate against its consumers instead of accepting that advances in technology have reshaped the capacity of accessible health information. Further, NW Cryobank still offers the sperm donors the

18. Loy, *supra* note 5.

19. *ID Release or Non-ID Release Sperm Donor?*, CRYOS INT'L, https://www.cryosinternational.com/en-US/us-shop/become-a-donor/become-a-sperm-donor/how-to-become-a-sperm-donor/id-release-or-non-id-release-sperm-donor/ (last visited Mar. 12, 2021).

20. *Id.* Cryos International website states:

> While Cryos will never release your information, there is a chance of being identified through familial DNA testing. Sperm contains DNA and therefore, there will always be a chance that donors, clients and donor children can be found via a DNA analysis or genetic testing service. As a Non-Id Release sperm donor, we are unable to protect you from being found in this manner. You and all donors should be aware that they could be found in the future through genetic testing. As a Non-Id Release donor, Cryos guarantees that we will never disclose your personal information to anyone.

Id.

21. *Id.* Donor anonymity can also be an issue for egg donors, but less so. "Eggs harvested from women are typically done in a more open manner, with recipients given identifying information about the donors from the outset, or when the child turns 18." Meghana Keshavan, *'There's No Such Thing as Anonymity': With Consumer DNA Tests, Sperm Banks Reconsider Long-held Promises to Donors*, STAT (Sept. 11, 2019), https://www.statnews.com/2019/09/11/consumer-dna-tests-sperm-donor-anonymity/.

option to be "anonymous," despite its current predicament with Danielle Teuscher.[22]

Since the 1800s, donors of reproductive materials have been afforded the right to remain anonymous, largely because of the stigma attached to infertility and the lack of advanced technology to gain access to the information.[23] Additionally, many parents were told there would be "irreparable harm" to their marriages and to their donor-conceived children if this information was given to them.[24] Several countries still offer donor anonymity, while others have dispelled this notion.[25] Anonymity regulations serve as barriers to accessing a donor-conceived child's genetic information because a child's genetic information is often used to trace genetic relatives, including donors.[26] It seems that parents in many countries struggle to gain access to their donor-conceived child's genetic information unless the donor specifically consents. With the rise of direct-to-consumer DNA testing, however, companies like 23andMe have forced a reckoning on the fertility industry as parents circumvent various anonymity regulations to seek health information about their child.[27]

Recently, access to a person's genetic information has become almost mainstream due to the availability and affordability of direct-to-consumer DNA testing in nearly every country.[28] The Center for Genetics and Society found that, as of 2019, more than twenty-six million people throughout the world have taken some kind of direct-to-

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22. *See Sperm Donor Policies*, NW CRYOBANK, https://nwsperm.com/about/sperm-donor-policies (last visited May 8, 2020).

23. *See Sperm Donors Have Been Promised Anonymity for a Century. Then Came 23andMe.*, ADVISORY BD. (Sept. 16, 2019), https://www.advisory.com/daily-briefing/2019/09/16/sperm-donor [hereinafter *Sperm Donors Promised Anonymity*].

24. *Id.*

25. Glenn Cohen et al., *Sperm Donor Anonymity and Compensation: An Experiment with American Sperm Donors*, 3 J.L. & BIOSCIENCES, 468, 469-73 (2016). Countries that currently allow donor anonymity include Canada, Cyprus, France, Japan, Spain, Belgium, Denmark, and the United States. *Sperm Donation Laws by Country*, WIKIPEDIA, http://en.wikipedia.org/w/index.php?title=Sperm_donation_laws_by_country&oldid=654148051 (last visited May 21, 2020). Countries that do not allow donor anonymity include Australia, Austria, Germany, Netherlands, New Zealand, Norway, Sweden, Switzerland, and the United Kingdom. *Id.*

26. *Understanding the Pros and Cons of Genetic Testing,* UNIV. ILL. CHI., https://healthinformatics.uic.edu/blog/pros-and-cons-of-genetic-testing/ (last visited Mar. 12, 2021).

27. *See Sperm Donors Promised Anonymity, supra* note 23.

28. *See* Antonio Regalado, *More Than 26 Million People Have Taken an At-home Ancestry Test*, CTR. FOR GENETICS AND SOC'Y, https://www.geneticsandsociety.org/article/more-26-million-people-have-taken-home-ancestry-test [hereinafter *26 Million People*]; LIZZO, *Truth Hurts*, *on* CUZ I LOVE YOU (Atlantic Records 2017) (including lyrics in which popular singer and rapper, Lizzo, mentions DNA testing).

consumer DNA test; further, "[a]s many people purchased consumer DNA tests in 2018 as in all previous years combined."[29] Each year around the holidays, the price of popular DNA testing kits are marked down, which allows greater access to genetic information.[30] Due to the accessibility and increased popularity of direct-to-consumer DNA testing kits, promises of donor anonymity are disingenuous and possibly fraudulent. Parents of a donor-conceived child can receive information about their child's genes by using direct-to-consumer DNA testing and entirely circumvent (or breach) anonymity provisions that protect the identity of the donor.

As a matter of public policy, numerous countries have expressed their recognition of the importance of genetic testing as it relates to health. The National Human Genome Research Institute, in connection with the U.S. Office of the Surgeon General, stated that, "[t]racing the illnesses suffered by your parents, grandparents and other blood relatives can help your doctor predict the disorders to which you may be at risk, and help you take action to keep you and your family healthy."[31] Further, officials from the United Kingdom's Medicines and Healthcare Products Regulatory Agency say "they support the use of commercial genomic testing to help patients become better informed about their health and future medical decisions."[32]

To add a level of complexity, the United States FDA now regulates certain kits distributed by 23andMe as "medical devices,"[33] seemingly placing DNA testing in the realm of healthcare. This classification suggests that DNA testing is akin to a medical procedure and choosing to take a DNA test is a medical choice. In many countries, like the United States, parents maintain the right to make medical decisions for their minor children, including when to opt in or opt out of a medical procedure.[34] As a result, the regulation of certain 23andMe kits as medical devices introduces a new question: can parents bypass their

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29. *See 26 Million People*, *supra* note 28.

30. *See* Justin Jaffe, *Best DNA Tests for 2021: AncestryDNA vs. 23andMe and More,* CNET (Jan. 11, 2021, 5:15 PM) https://www.cnet.com/health/best-dna-test-for-2021-ancestrydna-vs-23andme-and-more/.

31. *Family Health History for Patients and Family*, NAT'L HUM. GENOME RES. INST., https://www.genome.gov/es/node/82056 (last updated Oct. 6, 2020).

32. Jessica Firger, *U.K. Approves Sales of 23andMe Genetic Test Banned in U.S.*, CBS NEWS (Dec. 3, 2014, 5:50 AM), https://www.cbsnews.com/news/23-and-me-genetic-test-uk-approves-sale-banned-in-us/.

33. *FDA Authorizes First Direct-to-Consumer Test for Detecting Genetic Variants That May Be Associated with Medication Metabolism*, FDA (Oct. 31, 2018), http://www.fda.gov/news-events/press-announcements/fda-authorizes-first-direct-consumer-test-detecting-genetic-variants-may-be-associated-medication.

34. *See generally* Parham v. J.R., 442 U.S. 584 (1979) (holding that parents retain a substantial role in decision-making and act in the best interest of the child).

jurisdiction's regulations on donor anonymity by categorizing the DNA test as a "medical decision" for their child and thus within their parental purview?

The answer to this increasingly common question depends on numerous factors, including the jurisdiction, the rationale for testing the donor-conceived child, the donor's classification, the anonymity agreement, public policy, and more. Though the interplay between direct-to-consumer DNA testing and reproductive regulations concerning donor anonymity is complex, this note advocates for parents' rights to test their donor-conceived minor children by classifying this act as a medical decision.

Part I of this note provides a brief history of assisted reproductive technology and its increased use throughout the world, illustrating the growing number of donor-conceived children and the related importance of knowing genetic information. Part I also surveys regulations concerning donor anonymity in the United States and the United Kingdom to illustrate different jurisdictions' approaches to the regulation of donor anonymity. This note uses the United Kingdom as a model of countries that have prohibited sperm donor anonymity. Part II of this note discusses direct-to-consumer DNA testing, specifically 23andMe's products. This note selects 23andMe as the direct-to-consumer company for its analysis because of the company's dominance in the global market and the regulation of certain kits as "medical devices," [35] which suggests parents' rights to have this test performed on their minor children. Part III of this note explores parental decision-making abilities as they relate to medical decisions concerning minors. Part IV of this note discusses the interplay between donor anonymity and DNA testing, both in the United States and the United Kingdom.

The conclusion of this note discusses possible solutions for the issues presented by regulations concerning donor-conceived genetic information. It also highlights the benefits of allowing access to genetic information of donor-conceived individuals, specifically by allowing parents to genetically test their donor-conceived children. Ultimately, the analysis concludes that donor anonymity is no longer feasible. Instead, this note suggests countries continue to adopt and amend regulations that enable donor-conceived individuals to have access to their own genetic information without fear of redress against them, or their parents.

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35. *See* Justin Jaffe, *Best DNA Test in 2020: 23andMe vs. AncestryDNA and More*, CNET, https://www.cnet.com/health/best-dna-test-in-2020-23andme-vs-ancestrydna-and-more/ (last updated Dec. 19, 2020, 13:37 PM); *Lists of Direct-To-Consumer Tests with Marketing Authorization*, FDA, http://www.fda.gov/medical-devices/vitro-diagnostics/direct-consumer-tests#list (last visited Dec. 15, 2019).

I. BACKGROUND INFORMATION

Part I of this note begins with background information about assisted reproductive technology (ART)—namely, the types of procedures and their increasing usage across the world. Next, it outlines various global regulations that impact how reproductive materials are sent to receiving countries and which individuals may receive those reproductive materials. Collectively, this information supports the claim that ART is increasing in usage across the world and impacting more people as time progresses. Finally, Part I discusses the basic approaches taken to regulate donor anonymity. Part I concludes with an overview of donor anonymity regulations in the United States and United Kingdom.

Assisted Reproductive & Donor Anonymity

Assisted Reproduction Technology

ART refers to medical technology that aims to result in pregnancy through means other than sexual intercourse.[36] ART involves a variety of different medical procedures where the egg, sperm, or embryo are handled outside the body.[37] ART does not include instances where only sperm is handled or procedures in which women take medication solely to stimulate reproductive functions, however.[38] The most common reproductive procedures currently utilized include artificial insemination[39] and in vitro fertilization (IVF).[40] ART has the ability to "promote new forms of equality for people who can't conceive or gestate due to age, health, sexual orientation, the trauma of past pregnancy, or the risk of transmitting disease."[41] Others are able to use their own

36. Model Act Governing Assisted Reproductive Technology § 102(2) (2008). Examples of ART include intrauterine insemination, egg donation, embryo donation, *in vitro* fertilization, embryo transfer, and intracytoplasmic sperm injection. *See generally* CHARLES P. KINDREGAN, JR. & MAUREEN MCBRIEN, ASSISTED REPRODUCTIVE TECHNOLOGY: A LAWYER'S GUIDE TO EMERGING LAW AND SCIENCE (1st ed. 2006) (listing examples of assisted reproductive technologies).

37. *See* JUDITH DAAR, REPRODUCTIVE TECHNOLOGIES AND THE LAW 7 (2d ed. 2013). ART involves the handling of both sperm and egg–it takes two to tango.

38. *What is Assisted Reproductive Technology?*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 8, 2019), https://www.cdc.gov/art/whatis.html.

39. DAAR, *supra* note 37, at 7. This procedure involves introducing sperm into the woman's reproductive tract using an injection device. *Id.*

40. *Id.* This procedure involves surgically removing eggs from a woman's ovaries and combining them with sperm in a controlled setting. *Id.* The resulting product, the embryo, is placed in the woman's uterus. *See id.*

41. DOV FOX, BIRTH RIGHTS AND WRONGS: HOW MEDICINE AND TECHNOLOGY ARE REMAKING REPRODUCTION AND THE LAW 16 (2019).

healthy reproductive materials at a later date with technology that enables cryopreserving gametes.[42]

The advancement of reproductive technology has benefitted individuals throughout the world. Nearly forty years after the birth of Louise Brown, the world's first "test-tube baby," the European Society of Human Reproduction and Embryology estimates that more than eight million babies have been born with the assistance of ART.[43] The number of donor-conceived individuals in the world continues to increase as more people opt to use reproductive technology and ART's success rates continue to stabilize.[44]

Global Nature of Reproductive Technology

With current reproductive technology, "making a baby can be a global affair."[45] Advancements in technology have enabled global interaction with reproductive material used in these services—perhaps most noticeably with the ability to ship sperm, eggs, ovarian tissue, and embryos to fertility clinics and medical laboratories internationally.[46] The egg could come from a woman in Mexico, the sperm from a man in Canada, and the surrogate herself might live in Denmark—the prospects are infinite.[47]

The varying laws and costs applicable to reproductive procedures and technologies in countries create incentives for taking advantage of porous international borders.[48] For instance, surrogacy for pay is legal in certain jurisdictions within the United States,[49] but the process can

42. Cryopreservation refers to a process by which gametes or embryos are treated and then frozen for potential future use. *See generally* KINDREGRAN & MCBRIEN, *supra* note 36 (describing commonly used ART terminology).

43. European Soc'y of Human Reprod. and Embryology, *More Than 8 Million Babies Born from IVF Since the World's First in 1978*, SCI. DAILY (July 3, 2018), https://www.sciencedaily.com/releases/2018/07/180703084127.htm.

44. *See* Vitaly A. Kushnir et al., *Systematic Review of Worldwide Trends in Assisted Reproductive Technology 2004–2013*, 15 REPROD. BIOLOGY AND ENDOCRINOLOGY 1, fig.1, fig.3 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5223447/.

45. Sarah Zhang, *Inside the Hidden Global Supply Chain for Frozen Sperm, Eggs, and Embryos*, WIRED (Apr. 25, 2016 7:00 AM), https://www.wired.com/2016/04/inside-hidden-global-supply-chain-frozen-sperm-eggs-embryos/.

46. *Worldwide Courier Providing Specialist Service in Cryogenically Frozen Transfer of Sperm, Eggs, Embryos and Cells*, IVF COURIERS, https://www.ivfcouriers.com (last visited Mar. 12, 2021); *see also* Peter Nagy, *Is It Safe to Ship Cryopreserved Eggs (and Embryos)?*, FERTILITY IQ, https://www.fertilityiq.com/topics/egg-freezing/is-it-safe-to-ship-cryopreserved-eggs-and-embryos (last visited Dec. 12, 2019).

47. Zhang, *supra* note 45.

48. *See id.*

49. *Id.* New York is restrictive with surrogacy, whereas California is permissive. *Id.*

be prohibitively expensive.[50] Instead, some people look abroad for cheaper alternatives, with less expensive reproductive materials found in "South Africa, Cyprus, Spain, or Ukraine."[51]

Varying reproductive regulations also limit the potential recipients of reproductive materials and procedures. After utilizing IVF, a woman in northern Italy was recently denied the ability to register her donor-conceived son at the public records office due to strict Italian laws that limit fertility treatments to "stable heterosexual couples."[52] This mother's story illustrates yet another reason individuals participate in the global market in furtherance of their goals to become parents: opposition to same-sex couples and singles.[53] Like Italy, France does not recognize children born to same-sex couples through reproductive technology, specifically artificial insemination.[54]

The regulations for shipping reproductive materials depend on the shipping origin and destination. For instance, when shipping sperm internationally, receiving countries may require different kinds of documentation about the nature of the sperm they receive.[55] When shipping sperm internationally, it is common for some regions to charge import and export fees, which adds expense.[56] These fees are commonly used to finance a medical examination of the sperm to verify that it is free from disease.[57] Additionally, some countries restrict sperm imports to a few allotted countries.[58] Kathryn Kaycoff, the president of the Agency for Surrogacy Solutions, describes a case she is currently working on:

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50. *See, e.g.*, *Costs of Surrogacy in the USA*, AM. FERTILITY SERVS., https://americanfertility.com/costs-surrogacy-usa/ (last visited Mar. 12, 2021).

51. *Id.*

52. *Lesbian Mums Can't Register Baby in Italy*, BBC (Apr. 19, 2018), https://www.bbc.com/news/world-europe-43823692.

53. *Id.* In 2016, Italy passed a law that recognizes civil unions between same-sex couples; however, fertility treatments are still only provided for "stable heterosexual couples" that can prove clinical infertility, rather than social infertility due to sexual orientation. *Id.*; *see also* John A. Robertson, *Gay and Lesbian Access to Assisted Reproductive Technology*, 55 CASE W. RES. L. REV. 323 (2004) (exploring reproductive technology and same-sex accessibility).

54. Matt Baume, *France Is Running Out of Sperm*, OUT (Sept. 24, 2019 12:09 PM), https://www.out.com/news/2019/9/24/france-running-out-sperm.

55. Alex Tree, *What Are the Regulations for Shipping Sperm?*, WISEGEEK, https://www.wisegeek.com/what-are-the-regulations-for-shipping-sperm.htm (last updated Dec. 1, 2020).

56. *Id.*

57. *Id.*

58. *Id.*

> [H]er client is trying to export frozen embryos to the US for surrogacy. Surrogacy for pay is illegal in Australia, and the clinic with the current embryos objects to transporting them to the US for paid surrogacy. So now, they're trying to get it shipped to a second Australian clinic that will in turn ship it to the US.[59]

When shipping reproductive materials, the frozen cells need to be cryogenically cold, minus 240 degrees Fahrenheit to be exact.[60] Kimball Pomeroy, an embryologist with the World Egg Bank, explains that if reproductive material reaches above even minus 184 degrees Fahrenheit, it can restart some of the cellular processes, destroying viability. Further, if the eggs warm under the wrong conditions, razor-like ice crystals can form and ruin the prospects of using the egg.[61] Frozen reproductive material can be removed from liquid nitrogen tanks and placed in *shipping dewars*, or frozen containers, to stabilize a freezing temperature.[62] To bypass international aircraft regulations concerning liquid nitrogen, the dewars contain retention foam that acts like a sponge, absorbing liquid nitrogen while releasing only vapor nitrogen during flight.[63] Throughout transport, this dewar can maintain a stable, low temperature for over a week,[64] enabling frozen reproductive materials to survive the longest flight in the world—the United States to Singapore—at nearly nineteen hours.[65]

Recent statistics highlight the popularity of outsourcing various elements in reproductive technology. For example, "[i]n the UK, approximately one-third of licensed sperm donation uses donor sperm imported from abroad, principally from Denmark and the USA."[66] As donor sperm, eggs, and embryos are imported into different countries

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59. Zhang, *supra* note 45.

60. *See id.*

61. *Id.*; *see also* Tree, *supra* note 55. ("When shipping sperm with liquid nitrogen, the sperm is good for more than a week. On the other hand, dry ice is not nearly as cool as liquid nitrogen and should be used to ship sperm only to a nearby location. Dry ice can safely store sperm for up to one day, in which case it cannot be transferred to a liquid nitrogen container, but instead used by a medical professional the same day. If the sperm thaws during shipment, it is no longer usable for insemination purposes.").

62. *See* Nagy, *supra* note 46.

63. *Id.*

64. *Id.*

65. Eric Rosen, *The 2019 List of the Longest Flights in the World*, FORBES (Jan. 2, 2019), https://www.forbes.com/sites/ericrosen/2019/01/02/the-2019-list-of-the-longest-flights-in-the-world/#76a335cc550b.

66. Joyce C. Harper et al., *The End of Donor Anonymity: How Genetic Testing is Likely to Drive Anonymous Gamete Donation Out of Business*, 31 HUM. REPROD. 1135, 1136 (2016).

for use, the donations technically must follow the laws and regulations of the country where the donations are received,[67] but this is easily complicated. For example, in the United Kingdom, donors must follow regulations restricting anonymity, but these regulations only apply to donors as they give reproductive materials to fertility clinics, not to reproductive material sold for self-insemination.[68] Further, there are reports of individuals smuggling reproductive materials over borders, entirely circumventing their jurisdiction's regulations and the standards enforced by the fertility industry.[69]

Without stepping foot outside one's city, an individual can obtain reproductive materials from nearly anywhere in the world. An individual could also ship reproductive materials to a location with more advantageous regulations.[70] In addition to the growing technical capabilities of ART, this globalization introduces a number of issues, including a lack of global standards for testing reproductive material prior to use, monitoring the number of allowed offspring from a single donor, and maintaining anonymity obligations, to name only a few.

Donor Anonymity Regulations

Before discussing the details of various reproductive regulations within the United States and the United Kingdom, it is useful to understand the basic approaches taken to regulate donor anonymity. In a recent study, it was found that most countries banning donor anonymity require all donors to list their identifying information within a registry that becomes available to donor-conceived children at eighteen years old.[71] Donor-conceived persons and their parents could potentially never receive identifying information of their donor in countries that continue to allow donor anonymity. Surveying the practices in the United States and the United Kingdom illustrates the differences among countries' regulations for the fertility industry, including for donor anonymity. Both countries represent contrasting models of how donor anonymity is handled, offering key insights. The

67. *Id.*

68. *See id.* (implying men can still sell their sperm privately on online forums to bypass testing standards).

69. *See generally* Mohammed Hamdan, *"Every Sperm Is Sacred": Palestinian Prisoners, Smuggled Semen, and Derrida's Prophecy*, 51 INT'L J. MIDDLE EAST STUD., 525 (2019) (describing the contemporary phenomenon of smuggling sperm from within Israeli jails, which is treated as a biopolitical act of resistance).

70. *See* Harper et al., *supra* note 66, at 1136.

71. Cohen et al., *supra* note 25, at 470.

differences in reproductive regulation largely stem from each country's values.[72]

United States

The United States often treats healthcare as a market commodity.[73] While the United States generally regulates quality control—such as the licensing of providers and clinics as well as the oversight of drugs, devices, and research—state and federal governments oversee regulation of reproductive medicine.[74] Similar to other medical practices, reproductive medicine also involves "professional self-regulation that includes facility accreditation and practitioner certification."[75] ART development is monitored by the American Society for Reproductive Medicine (ASRM) and its affiliate, the Society for Assisted Reproductive Technology (SART).[76] The members of these societies include reproductive specialists, "patient advocates, congressional and federal agency representatives, legal experts, and consumers."[77]

State regulation of the fertility industry is crucial within the United States because states are responsible for exercising their police powers to grant medical licenses to "practitioners who meet minimum standards of education and skill."[78] States exercise control over the industry by "defin[ing] grounds for misconduct, such as negligence, deceit, fraud, or exploitation of the physician-patient relationship."[79] State legislatures pass medical practice acts and the acts are enforced by states' medical licensing boards.[80] A medical license is often broad and not limited to certain types of medicine.[81] Instead, states' medical

72. *See* Alicia Ouellette et al., *Lessons Across the Pond: Assisted Reproductive Technology in the United Kingdom and the United States*, 31 AM. J.L. & MED. 419, 435–46 (2005) (discussing the difference in ART regulation between the United States and the United Kingdom).

73. *Id.* at 444.

74. AM. SOC'Y FOR REPROD. MED., OVERSIGHT OF ASSISTED REPRODUCTIVE TECHNOLOGY 3 (2010).

75. *Id.* at 4.

76. *Id.*

77. *See id.*

78. *Id.* at 5.

79. *Id.*

80. *Id.* The regulations "define a scope of practice for licensees, require ongoing educational training through approved continuing medical education, and authorize discipline for those who break the law or fail to uphold certain professional standards." *Id.*

81. *Id.*

boards define a scope of practice and practitioners can become board certified.[82]

The United States federal government also has a role in the oversight of ART, specifically through the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and Centers for Medicare and Medicaid Services.[83] These organizations each have their own regulatory responsibilities.[84]

In 1992, the United States passed federal legislation relating to ART: Public Law 102-493, the Fertility Clinic Success Rate and Certification Act.[85] This act requires annual reporting of ART cycle data to the CDC.[86] The CDC reports the data to the public, providing consumers access to ART data and success rates nationwide.[87] The annual reports submitted to the CDC include information ranging from data about individual clinics to national data on infertility treatment success rates.[88] The act "does not regulate the safety or uses of sperm or eggs or embryos but, instead, is designed simply to provide access to information about the success rates of fertility clinics."[89] Also, the act aims to prevent clinics from advertising false pregnancy success rates.[90]

In an effort to avoid poor outcomes, the act establishes a model program for the certification of embryology laboratories, which outlines the "administration of a continuing certification program by the states, quality assurance and control standards, an inspection system, and conditions under which certification can be suspended or revoked."[91] Critically, the adoption of such a laboratory certification program is left entirely up to the states.[92]

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82. *Id.*
83. *Id.*
84. *Id.*
85. *Id.*
86. *Id.*
87. *Id.* at 6.
88. *Id.*
89. NAOMI R. CAHN, TEST TUBE FAMILIES: WHY THE FERTILITY MARKET NEEDS LEGAL REGULATION 54 (2009) (explaining the setbacks with ART regulation).
90. *Id.* at 53-54. *See also* AM. SOC'Y FOR REPROD. MED., *supra* note 74, at 6 ("The data collected include the patients' infertility diagnoses, clinical information pertaining to the ART procedure, and statistics on resulting pregnancies and births.").
91. AM. SOC'Y FOR REPROD. MED., *supra* note 74, at 6.
92. The first set of data on success rates was not published until five years after Congress enacted the Act. If fertility clinics do not provide data about their programs, there are no sanctions beyond being listed as "nonreporting." Further, this Act does not apply to sperm banks or to clinics that only involve artificial insemination—it only covers programs that provide treatments involving embryos or eggs. *See generally* CAHN, *supra* note 89 (explaining the setbacks with ART regulation).

In the United States, the FDA protects "public health by assuring the safety, efficacy, and security of drugs, biological products, and medical devices."[93] With this responsibility "[t]he FDA also has jurisdiction over the screening and testing of reproductive tissues, such as . . . eggs and sperm."[94] The FDA's "good tissue practices" as codified list the requirements for egg and sperm donors, identification controls, the prevention of the spread of infectious diseases, and inspection of facilities that handle reproductive services.[95]

The Centers for Medicare and Medicaid Services (CMS) regulate the diagnostic testing of humans and reproductive specimen under the Clinical Laboratory Improvement Act (CLIA).[96] The CLIA program ensures "quality laboratory testing by establishing standards for accuracy, reliability, and timeliness of patient test results."[97] Only lab tests that make a diagnosis, however, are covered by the CLIA.[98] Thus, blood and semen analysis that diagnose infertility would be covered by the CLIA, but the other procedures in embryology labs that are not diagnostic are not covered by the CLIA.[99]

In addition to federal and state level regulations, the United States also relies heavily on professional self-regulation within the fertility industry.[100] Examples of professional self-regulation include laboratory accreditation, physician board certification, and professional guidance.[101] For laboratory accreditation, the College of American Pathologists and ASRM developed standards "specific as to the education, certification, and expertise of laboratory personnel," and require that "[t]he laboratory must have a performance improvement plan and a quality control program to anticipate and prevent errors."[102] Further, there is a laboratory testing program that assures testing reliability.[103] To maintain accreditation, laboratories are subject to CMS inspections and "must perform periodic self-evaluations and document any necessary corrective actions between site visits."[104]

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93. AM. SOC'Y FOR REPROD. MED., *supra* note 74, at 6.
94. *Id.*
95. *Id.*; 21 C.F.R. § 1271 (2019),
96. AM. SOC'Y FOR REPROD. MED., *supra* note 74, at 6.
97. *Id.* at 7.
98. *Id.*
99. *Id.*
100. *Id.*
101. *Id.*
102. *Id.* at 8.
103. *Id.*
104. *Id.*

Physician board certification in the area of fertility and obstetrics is necessary because of the specialty of this area of medicine.[105] In the United States, "[t]he American Board of Medical Specialties establishes criteria for its member organizations . . . ."[106] To become a board certified obstetrician / gynecologist, practitioners must undergo "four years of training, plus two years in clinical practice . . . followed by training in reproductive endocrinology and infertility . . . ."[107] The board sets standards for the training and performance of physicians.[108] After becoming board certified, physicians continue to keep their skills and knowledge current through participation in a maintenance of certification program.[109]

Lastly, ASRM and SART act as sources of professional guidance. ASRM "is the specialty society for physicians that focus on infertility."[110] It has a Practice Committee that creates "regular reports, including guidelines on minimal standards for providing ART, informed consent, and on the number of embryos to be transferred in IVF procedures."[111] Additionally, the SART is an affiliate of ASRM and has strict membership requirements, including compliance with the reporting standards for clinics, the accreditation of embryology laboratories, adherence to the ethics and practice committee guidelines, and employment of appropriately trained staff.[112]

Before discussing the United Kingdom's fertility regulations, it is important to note a few gray areas in the United States fertility industry. Recent scholarship has noted that there is no law in the United States that requires ART programs to have licensing or accreditation.[113] Though section 3(a) of the Fertility Clinic Success Rate and Certification Act specifies that the CDC should develop a laboratory certification program, the CDC has not been able to require clinics to meet these standards in practice, largely because of states' responsibilities to adopt their own regulations for clinics.[114] Further, failure to adhere to ASRM and SART criteria does not impact the ability

105. *See id.*
106. *Id.*
107. *Id.*
108. *Id.*
109. *Id.*
110. *Id.* at 9.
111. *Id.* ("The guidelines are distributed to all members of ASRM, are published in the Society's journal, *Fertility and Sterility*, and are available to the public on ASRM's website.").
112. *Id.*
113. Ouellette et al., *supra* note 72, at 429.
114. *Id.* at 430.

of clinics to continue operating.[115] Membership in ASRM and SART is completely voluntary, which makes their detailed guidelines also essentially voluntary.[116]

Research into the United States' approach to fertility regulation highlights the lack of incentive among donors, recipients, banks, clinics, and physicians "to push for public regulation" because it "might result in additional restrictions on their activities,"[117] or increased cost in procedures. Further, restrictions accompanying new fertility regulations might negatively impact research studies and trials of reproductive technology. With the quickly advancing reproductive industry and the resulting increased demand for donor reproductive materials, research and trials are critical to ensure safety and good practice.

Additionally, the economic forces of the industry support the lack of regulation.[118] The reproductive industry earns approximately $3–4 billion annually.[119] Individuals using ART technologies, especially donor reproductive material, are often characterized as having elastic budgets to create or expand their families.[120] Donors want to sell, recipients want to buy, and clinics want to profit—ART regulation may not easily fit into this equation.[121]

United Kingdom

The United Kingdom's regulation of the reproductive industry is seemingly more expansive and more enforceable than the regulations in the United States. The government regulates virtually every kind of healthcare in the United Kingdom, including the fertility industry under the Human Fertilization and Embryology Act of 1990 (HFE).[122] This act outlines the functions and procedures of the Human Fertilization and Embryology Authority (HFEA).[123] The HFEA has

115. AM. SOC'Y FOR REPROD. MED., *supra* note 74, at 9.

116. *See id.* at 10.

117. CAHN, *supra* note 89, at 20.

118. *See generally* DAAR, *supra* note 37 (explaining the conflict of interest physicians often face with maximizing opportunities of pregnancy and receiving profits from infertile couples); Mary Lyndon Shanley, *Collaboration and Commodification in Assisted Procreation: Reflections on an Open Market and Anonymous Donation in Human Sperm and Eggs*, 36 L. & SOC'Y REV. 257, 259 (2002) (stating that the transfer of gametes has taken a market analogy, which becomes difficult to argue against once established).

119. DAAR, *supra* note 37, at 183.

120. *Id.*

121. *See generally* David Adamson, *Regulation of Assisted Reproductive Technologies in the United States*, 39 FAM. L.Q. 727, 728 (2005) (arguing that the United States does have an effective regulating system of ART practices).

122. Human Fertilization and Embryology Act, 1990, c. 37 (Eng.).

123. Ouellette et al., *supra* note 72, at 420-21.

complete authority over fertility clinics and fertility research centers; all clinics using reproductive material must receive a license and "follow guidelines for data reporting, advertising, confidentiality, and clinic practices."[124] These guidelines are enforced through powers granted to the HFEA by the British Parliament.[125] Breaches of the Code of Practice put clinics and research centers at risk of losing their licenses, thus not being able to operate.[126] Regulation through the HFEA is broken into three categories: licensing, inspections, and setting standards,[127] which ensure fertility clinics and research centers comply with current law, rules, and standards to promote high-quality care and research.

All fertility clinics and human embryo research centers in the United Kingdom must comply with the 1990 and 2008 versions of the HFE and a number of related pieces of legislation.[128] To provide guidance to clinics and research centers, the HFEA published and routinely updates a Code of Practice that informs clinics and research centers how to meet legal requirements.[129]

In the United Kingdom, all fertility clinics and human embryo research centers are required by law to apply for a license to perform any related work.[130] The HFEA grants licenses for a maximum of four years, with all new clinics automatically receiving a license to operate for two years.[131] The HFEA conducts periodic inspections to make sure services meet the standards in the Code of Practice.[132] The findings are presented to a license committee, which decides whether to grant a license, refuse a license, or put conditions on a license to ensure improvements are made.[133] If it grants a license, the committee also decides how long that license will last.[134]

Before the HFEA grants a new license, or renews an existing one, it conducts an inspection of the facility.[135] For existing clinics and centers, the HFEA conducts inspections every two years to ensure clinics and research centers are abiding by the Code of Practice,[136] though the

124. *Id.* at 421.
125. *Id.*
126. *Compliance and Enforcement Policy*, HUM. FERTILISATION & EMBRYOLOGY AUTH. (Mar. 09, 2016), https://www.hfea.gov.uk/media/1494/compliance-and-enforcement-policy.pdf.
127. *How We Regulate*, HUM. FERTILISATION & EMBRYOLOGY AUTH., https://www.hfea.gov.uk/about-us/how-we-regulate/ (last visited Oct. 15, 2020).
128. *Id.*
129. *See id.*
130. *Id.*
131. *Id.*
132. *Id.*
133. *Id.*
134. *Id.*
135. *Id.*
136. *Id.*

HFEA also inspects clinics and centers more frequently if needed—for example, if it receives a report about something that is a cause for concern.[137] Further, depending on the type of inspection, the HFEA can decide whether to notify the clinic of an upcoming inspection.[138] The inspection includes verifying whether the clinic implemented the HFEA's requested improvements and monitoring how those improvements have progressed based on criteria established by key standards set by the board.[139] The inspectors put all findings into a public report, "identifying any areas which they are concerned about [clinics' noncompliance] and recommending how they can improve."[140]

As previously mentioned, the HFEA sets standards by publishing and routinely updating a document called the Code of Practice.[141] The Code includes directions to ensure all clinics and centers carry out the latest procedures and practices properly.[142] The HFEA also produces consent forms that are used in all clinics to ensure national uniformity, as clinics in the United Kingdom must receive written consent to perform services such as fertility treatments; storage of sperm, eggs, and embryos; donation; surrogacy; and disclosure of information.[143]

In an effort to provide donor-conceived individuals with more information about their origins, the United Kingdom enacted the Human Fertilization and Embryology Authority (Disclosure of Donor Information) Regulations 2004, effective beginning April 2005, that banned donor anonymity.[144] This law requires donors to enter personal information into a registry when donating reproductive material, including both non-identifying and identifying information.[145] A donor-

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137. *Id.*

138. *Id.*

139. *Id.*

140. *Id.*

141. *Code of Practice,* HUM. FERTILISATION & EMBRYOLOGY AUTH. (2018), https://www.hfea.gov.uk/media/2565/hfea-draft-code-of-practice-9th-edition-consultation-version.pdf.

142. *How We Regulate, supra* note 127.

143. *Id.* The HFEA has also created forms using gender-neutral language to accommodate trans and nonbinary patients. To view these forms, see *Consent Forms*, HUM. FERTILISATION & EMBRYOLOGY AUTH., https://portal.hfea.gov.uk/knowledge-base/consent-forms (last visited Dec. 9, 2019).

144. The Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004, SI 2004/1511, art. 2 (Eng.).

145. Andrew Hellman & Glenn Cohen, *Prohibiting Sperm Donor Anonymity in the US and Possible Effects on Recruitment and Compensation*, BIONEWS (Apr. 3, 2017), https://www.bionews.org.uk/page_95954. Non-identifying information includes factors such as physical characteristics and medical background while identifying information includes factors such as full name and date of birth. *Why Donate,* LONDON SPERM BANK, https://www.londonspermbank.com/donor/why-donate/ (last visited Mar. 12, 2021).

conceived child could obtain "a donor's non-identifying information at age sixteen and . . . their identifying information at age eighteen."[146] This registry includes "patient and partner names, patient reference numbers, treatment dates, and details of sperm and egg donors."[147] Because the ban on anonymity is not retroactive, the HFEA also provides information and resources to donors, donor-conceived individuals, and parents of donor-conceived children who fall into the time period predating the new ban on anonymity.[148] Parents of donor-conceived children in the United Kingdom do not have the right to access any of this information; the right to access this register is granted solely to donor-conceived children who have reached the appropriate age as prescribed by the HFEA.[149]

Further illustrating the elaborate fertility regulations in the United Kingdom, the HFEA has collected information about all fertility treatments involving a donor since August 1, 1991.[150] This data is now the largest data collection of its type in the world.[151] These records track every person who receives ART treatments in licensed clinics, donors of embryos, and individuals born through ART in licensed clinics.[152]Additionally, the gathered data is maintained in a national registry, which attempts to avoid situations where two donor-conceived individuals might be involved in an intimate relationship.[153]

The United Kingdom has also taken a substantial step in fertility regulation by acknowledging the capabilities of current technologies

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146. *Id.*

147. Ouellette et al., *supra* note 72, at 424.

148. *See Finding Out About Your Donor and Genetic Siblings*, HUM. FERTILISATION & EMBRYOLOGY AUTH., https://www.hfea.gov.uk/donation/donor-conceived-people-and-their-parents/finding-out-about-your-donor-and-genetic-siblings (last visited Dec. 9, 2019). The type of information held by the HFEA depends on when the individual was conceived, as the information donors are required to provide has changed over the years. *Id.* If a donor-conceived person living in the United Kingdom was born prior to August 1, 1991 (when data collection began), she can contact the Donor Conceived Register, run by the Hewitt Fertility Centre. *Id.* If a donor-conceived person was conceived between August 1, 1991, and March 31, 2005, she can request the HFEA to provide her donor's physical description, the year and country of their birth, their ethnicity, whether they had any children at the time of donation, and any additional information the donor chose to supply. *Id.*

149. *Rules Around Releasing Donor Information*, HUM. FERTILISATION & EMBRYOLOGY AUTH., https://www.hfea.gov.uk/donation/donors/rules-around-releasing-donor-information (last visited Dec. 9, 2019).

150. *Donor-Conceived People and Their Parents*, HUM. FERTILISATION & EMBRYOLOGY AUTH. (Apr. 28, 2020), https://www.hfea.gov.uk/i-am/donor-conceived-people-and-their-parents.

151. Ouellette et al., *supra* note 72, at 423.

152. *Id.*

153. *Id.* at 424.

used by the public. The HFEA released a statement on its site, warning individuals of the consequences of direct-to-consumer DNA testing services:

> [I]t's important to know that it's also possible for home DNA testing and matching services, available online, to result in you being identified, regardless of when you donated. People use these sites to find out about ancestry, health and/or identify their genetic relatives. Many of the sites also allow users to "match" and make contact with other users on their database with whom they are genetically related, often using their real names. Even if you don't use one of these sites yourself, if one of your close genetic relatives and someone conceived from your donation are both signed up to it, you could potentially become identifiable. Your identity could be inferred, if information about genetic "matches" is combined with other publicly-available information about you.[154]

This statement, coming directly from the government, rather than fertility clinics that choose to accept this new reality, ensures consistency of expectations relating to donor anonymity.

The HFEA is seemingly successful in the United Kingdom because of the country's "tradition of national control over health care."[155] Healthcare in the United Kingdom is seen as a public commodity.[156] The regulations tend to balance the private and public interests, though some view them as having a paternalistic impact on the industry.[157] The United Kingdom's system of fertility regulations appears to be more expansive, monitored, and followed.

II. DIRECT-TO-CONSUMER DNA TESTING & 23ANDME

A growing number of companies now offer direct-to-consumer DNA tests that provide consumers with information ranging from their ancestry to the existence of genetic risks for certain medical diseases or

154. *Rules Around Releasing Donor Information, supra* note 149.
155. Ouellette et al., *supra* note 72, at 444.
156. *Id.*
157. *Id.* at 445.

conditions.[158] Direct-to-consumer DNA tests generally only require a small fee and a specimen, usually saliva.[159] Then, the company analyzes the DNA and reports information to the consumer.[160] By the start of 2019, more than twenty-six million consumers had added their DNA to four leading direct-to-consumer DNA testing companies,[161] one giant being 23andMe, which currently ships DNA kits to fifty different countries.[162]

These tests have gained popularity with users around the world.[163] Rationales for direct-to-consumer DNA testing include genealogical curiosity and avoidance of costly insurance plans and appointments with physicians.[164] Internationally, 23andMe is widely known for the service of connecting biologically related individuals through DNA analysis.[165] But recently, 23andMe has expanded from an ancestry test to a test that screens for genetic-risk information.[166] The goal of the health portion of the test is to "give individuals a deeper understanding of their health risks" and to encourage consumers to share their results with healthcare providers for a more complete diagnosis and treatment.[167]

As early as December of 2014, the United Kingdom's Medicines and Healthcare Products Regulatory Agency had given approval for

158. Sarah Schmidt, *9 Leading Companies in Direct-to-Consumer Genetic Testing,* MARKETRESEARCH.COM BLOG (Apr. 6, 2016) https://blog.marketresearch.com/9-leading-companies-in-direct-to-consumer-genetic-testing.

159. *Compare Our DNA Tests*, 23ANDME, http://www.23andme.com/compare-dna-tests/ (last visited Aug. 6, 2020). One can purchase a 23andMe Ancestry test for $99, or a Health & Ancestry test for $199. *Id.*

160. A person's genome "is made up of thousands of genes that carry the hereditary information about your traits . . . This information is based on the arrangement of distinct molecules that make up genes. Some of these arrangements, or variants, can be used to diagnose a rare disease" and to "provide information about a person's risk of developing disease." *Direct-to-Consumer Tests,* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/vitro-diagnostics/direct-consumer-tests (last visited Mar. 12, 2021).

161. Antonio Regalado, *More Than 26 Million People Have Taken an At-Home Ancestry Test*, MIT TECH. REV. (Feb. 11, 2019), https://www.technologyreview.com/s/612880/more-than-26-million-people-have-taken-an-at-home-ancestry-test/.

162. *What Countries Do You Ship To?*, 23ANDME, https://int.customercare.23andme.com/hc/en-us/articles/214806628-What-countries-do-you-ship-to- (last visited Dec. 16, 2019).

163. Regalado, *supra* note 161.

164. Schmidt, *supra* note 158.

165. *Id.*

166. *Genetic Health Risks*, 23ANDME, https://www.23andme.com/test-info/ (last visited Oct. 5, 2020).

167. Jeff Martin, Keith Mong & James Sanchez, *Genetic Testing May Be Tax Deductible*, GRANT THORNTON (Aug. 13, 2019), https://www.grantthornton.com/library/newsletters/tax/2019/hot-topics/aug-13/genetic-testing-tax-deductible.aspx.

23andMe to market and sell its direct-to-consumer DNA health tests in the country.[168] An agency spokesperson stated that the agency had tested the company's kits and ensured they met minimum standards.[169] Additionally, the UK Department of Health and Social Care supported using gene tests to guide patient care.[170]

Several years later, in 2018, the United States FDA authorized 23andMe to market one of its testing kits.[171] The FDA regulates this kit as a medical device[172] as it reports medical information directly to consumers.[173] 23andMe is currently the only direct-to-consumer DNA testing entity that can advertise and screen for important medical information in the United States.[174]

The test screens for certain genetic health risks including Alzheimer's, Parkinson's, and certain variants of genes associated with a higher risk of breast and ovarian cancer (also known as BCRA genes).[175] Further, as of October 2018, the FDA concluded that the test may also be used to inform a patient of her ability to metabolize certain medications.[176] The FDA's review of 23andMe's test found that the company provided accurate data to consumers and that consumers could correctly understand the results of the test.[177] This will undoubtedly change the medical industry, as results from a direct-to-consumer DNA test can now be used to help inform discussions with healthcare providers.

In addition to the United States regulating 23andMe's test as a medical device, a recent IRS ruling[178] issued to 23andMe "clarified that

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168. Michelle Roberts & Paul Rincon, *Controversial DNA Test Comes to UK*, BBC NEWS (Dec. 2, 2014), https://www.bbc.com/news/science-environment-30285581.

169. *Id.*

170. *Id.*

171. Press Release, U.S. Food & Drug Administration, FDA Authorizes First Direct-to-Consumer Test for Detecting Genertic Variants that May be Associated with Medication Metabolism (Oct. 31, 2018) (on file with author) [hereinafter FDA Press Release].

172. *Id.*

173. *Id.*

174. Anna Almendrala, *Home Genetic Tests May Be Riddled With Errors, And Companies Aren't Keeping Track,* Huffpost (Apr. 3, 2018, 5:45 AM), https://www.huffpost.com/entry/home-genetic-test-false-positives_n_5ac27188e4b04646b6451c42.

175. *Lists of Direct-To-Consumer Tests*, FDA (Dec. 20, 2019), https://www.fda.gov/medical-devices/vitro-diagnostics/direct-consumer-tests#list. The following 23andMe tests have received marketing authorization by the FDA: 23andMe PGS Carrier Screening Test for Bloom Syndrome, 23andMe PGS Genetic Health Risk Test, 23andMe PGS Genetic Health Risk Report for BRCA1/BRCA2, and 23andMe PGS Pharmacogenetic Reports. *Id.*

176. FDA Press Release, *supra* note 171.

177. *Id.*

178. A private letter ruling (PLR) is a written statement issued by the IRS to "establish with certainty the federal tax consequences of a particular transaction before the transaction is consummated or before the taxpayers return is filed . . . . A PLR may not be

certain genetic testing services may constitute medical care for purposes of Section 213(d) of the Internal Revenue Code."[179] This ruling indicates that expenses used for qualifying genetic testing services can be submitted for reimbursement to healthcare flexible spending accounts and health savings accounts or, alternatively, deducted as expenses paid for medical care.[180] Though the ancestry portion of 23andMe will not receive tax deductions, consumers can claim a deduction for the health portion at a maximum $177.74 of the $199.00 cost of a health-and-ancestry kit.[181] Such a substantial deduction increases the access to 23andMe's DNA tests, meeting the high and rising testing demands.

23andMe has stated that its services "are not designed for, intended to attract, or directed toward" minors.[182] A parent or guardian, however, "may collect a saliva sample from, create an account for, and provide information related to his or her child who is under the age of [eighteen]."[183] Interestingly, 23andMe released a holiday commercial in 2018 in which the Grinch receives the company's DNA kit as a gift and signs on to 23andMe's site to discover his results.[184] This clever

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relied on as precedent by other taxpayers or IRS personnel." *Understanding IRS Guidance: A Brief Primer*, IRS (last updated Nov. 6, 2019), https://www.irs.gov/newsroom/understanding-irs-guidance-a-brief-primer.

179. Susan M. Nash & Susan P. Schaefer, *Recent IRS Ruling Clarifies Tax Treatment of Genetic Testing Services*, WINSTON & STRAWN LLP (Aug. 16, 2019), https://www.winston.com/en/benefits-blast/recent-irs-ruling-clarifies-tax-treatment-of-genetic-testing-services.html#!/closed_state. To note, IRS PLRs may only be relied upon by the taxpayer who requested the ruling, but they are informative about the IRS's viewpoint. *Understanding IRS Guidance: A Brief Primer*, *supra* note 178.

180. Nash & Schaefer, *supra* note 179 ("Because the genetic testing services included items that are considered medical care (such as genotyping and laboratory services), and items that are not considered medical care (such as general informational reports for purposes of determining ancestry), the IRS required an allocation of the price paid for the DNA collection kit and health services . . . to determine the portion that constitutes Section 213(d) medical expenses.").

181. Richard Rubin & Amy Dockser Marcus, *IRS Greenlights Tax Breaks for Buyers of 23andMe Genetic Tests*, WALL ST. J. (July 22, 2019), https://www.wsj.com/articles/irs-greenlights-tax-breaks-for-buyers-of-23andme-genetic-tests-11563800520. *See also* Nash & Schaefer, *supra* note 179 ("Because the genetic testing services included items that are considered medical care (such as genotyping and laboratory services), and items that are not considered medical care (such as general informational reports for purposes of determining ancestry), the IRS required an allocation of the price paid for the DNA collection kit and health services . . . to determine the portion that constitutes Section 213(d) medical expenses.").

182. *Privacy Highlights*, 23ANDME, https://www.23andme.com/about/privacy/ (last visited Mar. 12, 2021).

183. *Id.*

184. Emily Mullin, *Should You Send Your Kid's DNA to 23andMe?*, WASH. POST (Dec. 19, 2018, 9:00 AM), https://www.washingtonpost.com/lifestyle/2018/12/19/should-you-send-your-kids-dna-andme/.

marketing seems to be aimed at kids and families generally, despite the company's statement that the tests are not designed for children.[185] 23andMe is not alone, either. One study suggested that nearly one-third of direct-to-consumer DNA testing companies have provided results to minors upon parental request.[186] Whether 23andMe intends to test minors' DNA, the company has not disallowed the practice and continues to analyze kits belonging to minors.[187]

In sum, the United Kingdom's early approval of using 23andMe for specific genetic-risk testing demonstrates the country's support of providing individuals access to important health information. Further, the United States' FDA approval and IRS tax deduction for specific 23andMe tests suggests that the federal government considers this service valuable and important for its nation's consumers. Learning about genetic risks associated with one's characteristics enables individuals to prepare for the possibility of abnormality or disease. Knowledge of genetic risks also promotes increased medical knowledge about oneself, which is useful for healthcare providers.

III. PARENTAL MEDICAL-DECISION-MAKING IN THE UNITED STATES AND UNITED KINGDOM

Parental autonomy over minor children is not an absolute right,[188] neither in the United States nor in the United Kingdom. A court in the United States stated that "the essential element of preserving the integrity of the family is maintaining the autonomy of the parent-child relationship."[189] Therefore, the government can intrude on a parent's right to care for a child only for the most compelling reasons.[190] Additionally, United States common law recognizes parental authority to make fundamental decisions for minor children, specifically in

185. *Privacy Highlights, supra* note 182.

186. Heidi Carmen Howard et al., *Are the Kids Really All Right? Direct-to-Consumer Genetic Testing in Children: Are Company Policies Clashing with Professional Norms?* 19 EUR. J. HUM. GENETICS 1122, 1122–23 (2011) (describing different direct-to-consumer DNA testing companies' protocol when testing minors).

187. *See Privacy Highlights, supra* note 182 ("The parent or guardian assumes full responsibility for ensuring that the information that he/she provides to 23andMe about his or her child is kept secure and that the information submitted is accurate.").

188. Newmark v. Williams, 588 A.2d 1108, 1116 (Del. 1991) (explaining that a child diagnosed with Burkett's lymphoma and was given a forty percent chance of survival if he obtained chemotherapy treatments. The court held that the parents were within their rights to forgo treatment).

189. *Id.* at 1115.

190. *See id.* at 1117.

instances involving medical treatment for a minor.[191] Thus, a state may intervene in the parent-child relationship only where the health and safety of the child or the public at large is in jeopardy.[192] A brief analysis of parental medical-decision-making rights in the United States and the United Kingdom follows.

United States

Most jurisprudence in the United States has recognized the family as a protected unit, which gives parents broad authority over minor children.[193] Courts interpreting the Constitution have "rejected any notion that a child is 'the mere creature of the State' and, on the contrary, asserted that parents generally 'have the right coupled with the high duty, to recognize and prepare [the children] for additional obligations.'"[194] The bond between a parent and child typically leads parents to act in the best interests of the child.[195] Because of this bond, courts have given deference to parental decisions regarding the care of minor children.[196]

In light of this deference, courts undoubtedly recognize a parental duty to recognize symptoms of illness and to seek medical treatment, if available.[197] This is because a minor generally lacks the capacity to consent to medical treatment herself.[198] It follows that parents also have

191. *Id.* at 1115-16.

192. *Id.* at 1116.

193. *See generally, e.g.*, Wisconsin v. Yoder, 406 U.S. 205 (1972) (holding that a state law mandating school attendance by children under age sixteen is unconstitutional as applied to Amish children); Prince v. Massachusetts, 321 U.S. 158 (1944) (holding that it is constitutional for the state to step in during situations of child labor); Pierce v. Soc'y of Sisters, 268 U.S. 510 (1925) (requiring children to be educated only in public schools violates the Fourteenth Amendment of the U.S. Constitution); Meyer v. Nebraska, 262 U.S. 390 (1923) (invalidating as unconstitutional a Nebraska law banning the teaching of foreign languages to schoolchildren).

194. *Parham*, 442 U.S. at 602 (internal citations omitted).

195. *Id.* (citing 1 W. Blackstone, Commentaries 447; 2 J. Kent, Commentaries on American Law 190).

196. *See generally, e.g.*, *Yoder*, 406 U.S. 205 (holding that a state law mandating school attendance by children under 16 is unconstitutional as applied to Amish children) *Prince*, 321 U.S. 158 (holding that it is constitutional for the state to step in during situations of child labor); *Pierce*, 268 U.S. 510 (requiring children to be educated only in public schools violates the Fourteenth Amendment of the U.S. Constitution); *Meyer*, 262 U.S. 390 (invalidating a Nebraska law banning the teaching of foreign languages to schoolchildren).

197. *Parham*, 442 U.S. at 602.

198. *See generally* EVALUATION AND TREATMENT OF MINORS, AM. COLL. EMERGENCY PHYSICIANS (2017) (examining "current federal and state legal implications of providing emergency care to minors, as well as guidance in obtaining consent, maintaining confidentiality, and addressing refusal of care").

the ability to seek preventative care for their children, including genetically testing a child to discover allergies to certain medications, food intolerances, and dispositions to fatal diseases. This seems especially important for children who were conceived with donor reproductive materials because at least half of their genetic history remains unknown to them. In this way, it is arguable that parents could use direct-to-consumer DNA testing as an informative tool to better educate them about their donor-conceived child's genetic information.

United Kingdom

The jurisprudence in the United Kingdom involving parental medical-decision-making capacity is similar to that of the United States. Aside from extreme circumstances, the United Kingdom generally recognizes that

> the parents are the best people to make decisions about a child and the State—whether it be the court, or any other public authority—has no business interfering with the exercise of parental responsibility unless the child is suffering or is likely to suffer significant harm as a result of the care given to the child not being what it would be reasonable to expect a parent to give.[199]

In this way, there is a recognized parental right to control a minor's medical treatment in the United Kingdom.[200] It follows that a parent of a donor-conceived child could have a legitimate interest in gaining insight into the genetic information of the minor child through a direct-to-consumer DNA test, like 23andMe. Though the test is not regulated as a medical device in the United Kingdom, the country has emphasized the test's importance with respect to the allowance of genetic testing throughout the country.[201] The results from the test provide genetic and medical information about an individual, here a donor-conceived child, which seems to support the doctrine of acting in the best interest of a child.

In a typical medical setting, minor children are not routinely screened for many of the specific health risks for which direct-to-

199. Jo Bridgeman, *Innovative Therapy and the Law: The Novel Issues Raised by the Case of Charlie Gard*, 34 PROF. NEGL. 5, 5-20 (2018), citing *In the Matter of Ashya King* [2014] EWHC (Fam.) 2964, [31].

200. *Re C (children)* [2016] EWCA (Civ) 374, [43] (Lady Justice King) (appeal taken from the Swansea Family Court) (quoting Sharpe J in the Family Court).

201. Roberts & Rincon, *supra* note 168.

consumer DNA companies test.[202] Additionally, some fertility clinics do not screen donors for certain genetic abnormalities when collecting reproductive material and using reproductive material in assisted reproductive procedures.[203] As a result, many parents may turn to direct-to-consumer DNA tests to seek answers to questions that are not easily answerable due to anonymity regulations.

IV. INTERPLAY BETWEEN DONOR ANONYMITY AND DIRECT-TO-CONSUMER DNA TESTING

Globally, there is still variability with donor anonymity regulations.[204] Children born with donor reproductive material will often face different setbacks to learning their genetic information depending on the jurisdiction in which they are born. One similarity among nearly all countries, though, is the position of the parents. Unless a donor consents to identification, minor, donor-conceived children may: (1) wait for nearly two decades to learn of important genetic information on their own (in places with regulations banning complete anonymity), or (2) never have the ability to learn about the genetic information, including harmful genetic dispositions. Both positions essentially leave parents without the power to make decisions in the best interests of their donor-conceived children.

The issue some fertility clinics have faced with parents using direct-to-consumer DNA testing on minor, donor-conceived children is the adherence to the donor anonymity contract.[205] Generally, it is unlikely that clinics intend to act as a barrier to parents' rights to make medical decisions for their donor-conceived children. It is more likely that clinics fear that parents of donor-conceived, minor children will use direct-to-consumer DNA testing as a mechanism to learn the identity of the donor and attempt to connect with the donor. This could substantially decrease the number of individuals who would be willing to donate reproductive materials if they wish to remain anonymous.[206] This would

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202. Megan Freedman, *Health Screening Milestones for School-Aged Children,* HEALTHGRADES, https://www.healthgrades.com/right-care/childrens-health/health-screening-milestones-for-school-aged-children (last updated Jan. 10, 2020).

203. *See Information Packet for Use of Donor Sperm,* SHADY GROVE FERTILITY (Apr. 2017), https://www.shadygrovefertility.com/application/files/7614/9426/4295/11CPD2.01.01_Donor_Sperm_Info_Packet.revApr17.pdf.

204. Cohen et al., *supra* note 25, at 469.

205. Teuscher v. CCB-NWB, LLC, 437 F. Supp. 3d 849 (E.D. Wash. 2020) (No. 19-CV-00204).

206. *See generally* Meghana Keshavan, *'There's No Such Thing as Anonymity': With Consumer DNA Tests, Sperm Banks Reconsider Long-Held Promises to Donors*, STAT

also subject the clinics to virtually limitless liability for donors to whom they promised anonymity.[207]

At first glance, it seems that parents of donor-conceived children in the United States and the United Kingdom have the potential to bypass various anonymity regulations by using direct-to-consumer DNA testing provided by companies such as 23andMe. In the United States, with 23andMe's health test receiving FDA marketing authorization,[208] parents may have an easier time, as courts generally defer to a parent's decision about the care of a minor child—especially medical decisions.[209] In the United Kingdom, this argument is similar because of the Department of Health's support of using the test.[210] The United Kingdom has indicated an interest in allowing individuals to use direct-to-consumer DNA testing to better inform themselves about their genetic risks.[211] Parents in the United Kingdom may face difficulty advancing this argument because donor-conceived children can now receive information relating to their donor as early as sixteen years of age,[212] unlike donor-conceived children in the United States. Parents in both jurisdictions, however, could argue that waiting this long for important health information is unreasonable.

Courts in the United States and United Kingdom should consider the fact-specific situation of the donor-conceived child's health when the parents pursue direct-to-consumer DNA testing. This approach would turn on the difference between symptomatic and asymptomatic minors. With symptomatic minors, genetic information can be a useful tool in the diagnosis and treatment of a health condition.[213] On the other hand, for asymptomatic minors, access to genetic information and the corresponding results could be postponed until the minor could participate in the decision-making process.[214] Without the presence of symptoms of illness, parental medical-decision-making abilities may not be as strong as when a minor child is experiencing abnormalities or illness.

Finally, courts in the United States and the United Kingdom may also consider the relative ease of direct-to-consumer DNA testing when determining whether parents should be authorized to genetically test

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(Sept. 11, 2019), https://www.statnews.com/2019/09/11/consumer-dna-tests-sperm-donor-anonymity/ (explaining how anonymity plays a role in the number of sperm donors).

207. *See id.*
208. FDA Press Release, *supra* note 171.
209. *See Newmark*, 588 A.2d at 1116.
210. Roberts & Rincon, *supra* note 168.
211. *Id.*
212. Hellman & Cohen, *supra* note 145.
213. Howard et al., *supra* note 186, at 1122.
214. *Id.*

their donor-conceived children despite the anonymity regulations in place. Here, parents of donor-conceived, minor children could argue that this type of testing is noninvasive, often only requiring a sample of saliva.[215] Courts have often factored in the difficulty of the medical procedure when deciding whether to allow or discontinue medical treatment for minor children.[216] Direct-to-consumer DNA testing is not a cure or treatment for a medical issue, but it is a painless procedure that allows parents to obtain important medical information about their donor-conceived child in furtherance of the care and rearing of that child.[217]

Though regulations within the fertility industry are more expansive in the United Kingdom than in the United States, no system is perfect. As recently as the summer of 2018, warnings circulated in the United Kingdom concerning seventeen British sperm donors who had fathered more than five hundred children and likely had been passing on defective DNA.[218] Currently, clinics are not mandated to screen donors for genes such as BRCA1/2, genes which increase the risk of ovarian and breast cancer.[219] In the United States, the use of direct-to-consumer DNA tests exposed a number of doctors who used their own sperm to impregnate patients without the patients' consent.[220] To add insult to injury, NW Cryobank is facing another issue regarding a donor. On September 1, 2020, NW Cryobank issued an email to its consumers that donors 518 and 901A were the same person, resulting in thirty-six births worldwide.[221] These realities illustrate the vast amount of information genetic testing provides and exposes to the public without interference from traditional healthcare regulations, and how genetic testing can help keep the international fertility industry more accountable. The transparency of direct-to-consumer DNA tests enables

215. *Direct-to-Consumer Tests, supra* note 160.

216. *Parham*, 442 U.S. at 602.

217. *See What are the Benefits and Risks of Direct-to-Consumer Genetic Testing?*, MEDLINEPLUS, https://medlineplus.gov/genetics/understanding/dtcgenetictesting/dtcrisksbenefits/ (last visited Mar. 12, 2021).

218. Sarah Knapton, *500 Children Born to Just 17 Sperm Donors*, TELEGRAPH (May 7, 2018), https://www.telegraph.co.uk/science/2018/05/06/17-british-sperm-donors-have-fathered-500-children-figures-show/.

219. *Id.*

220. Jody L. Madeira et al., *Against Seminal Principles: Ethics, Hubris, and Lessons to Learn from Illicit Inseminations,* 110 FERTILITY & STERILITY 1003, 1003 (2018); *see also* Lauren Bavis, *Conceived Through 'Fertility Fraud,' She Now Needs Fertility Treatment*, LANCASTERONLINE (Jan. 28, 2020, 10:00 PM), https://lancasteronline.com/news/health/conceived-through-fertility-fraud-she-now-needs-fertility-treatment/article_3422fc18-41d5-11ea-853e-8b54a883c726.html.

221. Letter from Leora Westbrook, General Manager, NW Cryobank, to NW Cryobank Clients (Sept. 1, 2020) (on file with author).

families to get answers to questions they may not even have asked and may never have been able to discover on their own.

CONCLUSION

While weighing the privacy concerns of donors, the benefits resulting from allowing parents to use DNA testing seemingly outweigh the costs. Despite anonymity agreements that promise donors privacy, the way technology has advanced has dispelled any belief in remaining a completely anonymous individual for donor purposes. Further, without consistent international fertility regulations relating to the testing of donor reproductive material, parents should be authorized to conduct genetic testing in the best interest of the health of their minor child. The low cost and convenience of direct-to-consumer DNA testing allow parents and individuals of varying socioeconomic classes to learn important information about themselves and their loved ones. The United States does not have a national registry that tracks children born through ART treatment, nor does it have a federal registry containing donor information.[222] Though other countries, like the United Kingdom, have more structured regulations, there are still issues.

Regardless of the regulatory regime in place, it is unlikely that parents will ever be free of fears and health issues related to the procedures used to conceive. Therefore, it is necessary to allow parents to exercise their right to make decisions in the best interests of their children. This includes deciding whether their donor-conceived child should undergo genetic testing.

Additionally, continued adherence to anonymity contracts set in place by fertility clinics may enable misconduct to continue to occur and could subject children and families to unnecessary harm. These are public interest concerns that courts should acknowledge when considering redress against parents of donor-conceived children who breach clinic anonymity agreements.

If parents are authorized to send their donor-conceived child's DNA to direct-to-consumer DNA testing companies like 23andMe, it will be important to establish and implement a new standard of privacy for donors who do not wish to be contacted. The fear of losing a significant number of potential donors due to the loss of anonymity is legitimate.[223] Currently, there is no internationally recognized forum where donors

222. Rene Almeling, *The Unregulated Sperm Industry,* N.Y. TIMES (Nov. 30, 2013), https://www.nytimes.com/2013/12/01/opinion/sunday/the-unregulated-sperm-industry.html.

223. Knapton, *supra* note 218.

and donor-conceived children connect, despite the potentially global nature of baby-making.

I suggest creating an international forum to enable donors and donor-conceived children and siblings to connect, *if* they choose to do so. In this forum, a donor would register and could select an option to be contacted. If a parent or donor-conceived child identifies the donor within the international forum and notes an openness to connect, there would be an opportunity for contact. If the donor registered in the forum as not open to contact, parents and donor-conceived individuals would clearly know that contact was not welcome. In doing so, donors and potential future donors would not live in fear of having forced contact with any resulting children born from their reproductive material. Nonetheless, the donor-conceived children and their parents could always have access to the genetic information.

The furtherance of international fertility regulation through global registries could also enhance the transparency of fertility clinics. Direct-to-consumer DNA testing has exposed fertility fraud, an increasingly known phenomenon appearing globally,[224] with cases ranging from Indiana to the Netherlands.[225] An international registry to track all types of fertility treatments and donor-conceived children would assist with the exposure of fertility misconduct—especially with clinics or individuals who choose to transport reproductive material to different jurisdictions in lieu of abiding by the regulations of their jurisdiction. Individuals would have the ability to track half-siblings or donors who reside in other areas of the world, further advancing the ability for individuals to know more about themselves and others who share their genetic information.

There is plenty of room for improvement in the fertility industry. Countries, like the United Kingdom, that allow donor-conceived children to access their donor's identifying information at an earlier age have made significant regulation advancements in comparison to countries like the United States, which currently still allows clinics to promise life-long anonymity to the detriment of many donors and donor-conceived individuals. The United States could consider implementing fertility regulations that eliminate anonymity provisions once a donor-conceived child reaches a certain age, but regulators are unlikely to

224. *See generally* Madeira et al., *supra* note 220, at 1004 ("[G]enetic testing could still reveal other unethical negligent or intentional conduct, such as the use of nonconsenting patients' gametes or embryos to impregnate others. This misconduct occurred in 1995 at the Center for Reproductive Health at the University of California, Irvine, costing the university tens of millions of dollars in settlements and legal fees.").

225. *Id.* ("Netherlands media reported that a physician allegedly engaged in such conduct as recently as 2010 or 2011 . . . .").

implement this kind of regulation due to the drastic impact it would have on the profit-turning fertility industry.[226] Instead, for now, I suggest that reproductive healthcare professionals, parents, and donors in all countries be made aware of the current limits of privacy with the growth of the direct-to-consumer DNA testing market.[227] I also suggest that clinics not be given the option to seek redress against consumers of direct-to-consumer DNA tests. The increased use of DNA tests that identify ancestry and genetic information is not likely to waiver, and clinics that continue to promise donor anonymity seemingly do so in bad faith.

Lastly, I suggest that countries' fertility regulations recognize the interest of parental, medical decision-making. After a child is born with the assistance of donor reproductive material, it seems inequitable for fertility clinics to maintain control over decisions parents make related to the health of their donor-conceived children. This is especially true for children who were not signed parties to the agreements between the clinics, donors, and future parents. Fit parents are presumed to be acting in the best interests of their children; choosing to be informed about the genetic information of a child who was conceived in a quickly advancing industry seems to be the very embodiment of acting in the child's best interest.

More research is needed in the area of direct-to-consumer DNA testing of donor-conceived children. One additional area of research that would build on the topic of this note is a minor's right to obtain or refuse genetic testing herself.[228] This would likely involve the mature minor doctrine,[229] and could implicate the tension between fertility clinics' anonymity agreements and donors' privacy. In this instance, the minor wanting (or refusing) genetic testing was not a party to the anonymity agreement signed by her parents, though the agreement undoubtedly involves the minor. Some United States jurisdictions have enacted

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226. *See generally* Ouellette et al., *supra* note 72 (explaining the difference in government structure of the United States and United Kingdom that would likely prevent the United States from implementing a system similar to the United Kingdom).

227. An important aspect of this involves informed consent, a topic not addressed by this paper. *See generally* Madeira et al., *supra* note 220 (explaining aspects of informed consent).

228. *See generally* Ellen W. Clayton, *How Much Control Do Children and Adolescents Have Over Genomic Testing, Parental Access to Their Results, and Parental Communication of Those Results to Others?*, 43 J.L. MED. ETHICS 538 (2016) (discussing implications of minors and DTC DNA testing).

229. The mature minor doctrine refers to an American rule of law allowing a minor to opt in or out of a medical treatment if she has the necessary. *The Mature Minor Doctrine,* USLEGAL.COM, https://healthcare.uslegal.com/treatment-of-minors/the-mature-minor-doctrine/ (last visited Mar. 12, 2021).

legislation that requires parental consent for a minor to have genetic testing.[230]

Another area for additional research relates to the various direct-to-consumer DNA testing regulations in countries worldwide.[231] As some countries have banned direct-to-consumer DNA testing,[232] parents of donor-conceived children in these countries may face more setbacks when they are trying to discover their minor child's genetic information. It would be useful to know the legal setbacks involved in the pursuit of that genetic information. Additionally, it would be useful to study the legal ramifications of individuals who travel to other jurisdictions to use direct-to-consumer DNA testing.

For better or worse, direct-to-consumer DNA testing is available throughout most of the world and is likely here to stay. As more individuals utilize fertility assistance and other technological advances, the lack of uniformity regarding donor anonymity has become extremely problematic. Clinics should not have the ability to hide from the reality that technological advancements have dispelled the illusion of donor anonymity. It is time to face the truth, no matter how hard it hurts profits. Parents like Danielle Teuscher should not be faced with retribution when acting in the best interests of their donor-conceived children. Instead, fertility clinics should openly and definitively declare that donor anonymity is no longer feasible and make amendments to current practices. Though difficult, it is possible to rethink and restructure the fertility industry as it relates to the rights of donor-conceived children and their parents.

230. ARIZ. REV. STAT. ANN. §§ 1-602(A)(5), (8), 12-2803 (2020); OKLA. STAT. ANN. tit. 25, § 2002 (2020); *see also* 16 DEL. CODE § 1226 (2014).

231. *See generally* L. Kalokairinou et al., *Legislation of Direct-to-Consumer Genetic Testing in Europe: A Fragmented Regulatory Landscape*, 9 J. COMMUNITY GENETICS 117 (2017) (analyzing DTC genetic testing regulations in Europe).

232. *Id.* at 117.