

Comment, Swimming Free of Regulation: The Need for a National Regulatory System for Sperm Donation

I. Introduction

More than two million births worldwide have been achieved through various assisted reproductive technologies.¹ Assisted reproductive technology (“ART”) is used to help individuals and families conceive a child through “artificial or partially artificial means.”² ART methods are widely utilized, in part because of the growing trend to delay parenthood, which increases chances of infertility.³ ART is also an attractive method of procreation among LGBTQ+ individuals and couples hoping to grow their families. There are multiple methods of achieving pregnancy through ART, some of which can be combined, depending on the circumstances of the client.⁴ Surrogacy, in vitro fertilization (“IVF”), pre-implantation surgeries, and artificial insemination are among the most common methods of ART.⁵ To conceive, a sperm sample is required, but not all partners have fertile sperm or can produce sperm. Infertility impacts 8-12% of couples worldwide, and of those couples, 40-50% of their infertility issues are due to “male factor” infertility (e.g., low sperm concentration, poor sperm motility, and/or abnormal sperm morphology).⁶ Therefore, sperm donation is an attractive solution for families unable to conceive naturally and those with same-sex partners.

¹ Andrea Preisler, *Assisted Reproductive Technology: The Dangers of an Unregulated Market and the Need for Reform*, 15 DEPAUL J. HEALTH CARE L. 213, 214 (2013).

² *Id.* at 215.

³ *Id.* at 215-16.

⁴ *Id.* at 215.

⁵ *Id.*

⁶ Naina Kumar & Amit Kant Singh, *Trends of Male Factor Infertility, An Important Cause of Infertility: A Review of Literature*, 8 J. HUMAN REPRODUCTIVE SCI. 191 (2015).

Sperm donation is a multi-billion-dollar industry, cloaked in secrecy and operating free of federal regulation.⁷ Without federal regulation, the sperm donation industry has resulted in exploitation, fraud, and “commercialization of one of the most valued and personal aspects of our society.”⁸ Increased access to DNA testing through services such as Ancestry and 23andMe has resulted in more than 50 fertility doctors being accused of fraud for implanting their own sperm into patients as opposed to their patient’s selected sperm sample.⁹ Many children born of donor sperm use online ancestry services to connect with half-siblings, and one person found their sperm donor had fathered 150 children total.¹⁰ Sperm bank liability for these problems are almost non-existent, and no duty of care exists to clients.¹¹ A growing movement of reproductive legal scholars are calling for the creation of a National Sperm Donor Registry to better regulate the industry and help establish laws to protect patients, children born of donor sperm, as well as donors themselves.¹²

This comment proceeds in three parts. Part II will address the current lack of regulation in the sperm donor industry and issues that exist as a result. Part III speaks to the creation of a national registry to regulate the sperm donation industry. Part IV will discuss anticipated challenges of enforcing a national sperm donor registry.

⁷ Preisler, *supra* note 1, at 228.

⁸ *Id.* at 214.

⁹ Jacqueline Mroz, *When an Ancestry Search Reveals Fertility Fraud*, N.Y. TIMES (Feb. 28, 2022), <https://www.nytimes.com/2022/02/28/health/fertility-doctors-fraud-rochester.html>.

¹⁰ Jacqueline Mroz, *One Sperm Donor, 150 Offspring*, N. Y. TIMES (Sept. 5, 2011), <https://www.nytimes.com/2011/09/06/health/06donor.html>.

¹¹ Preisler, *supra* note 1, at 231.

¹² *Id.* Naomi Cahn, *Necessary Subjects: The Need for a Mandatory National Donor Gamete Databank*, 12 DEPAUL J. HEALTH CARE L. 203 (2009); see also Naomi Cahn, *The New “ART” of Family: Connecting Assisted Reproductive Technologies & Identity Rights*, 2018 U. ILL. L. REV. 1443.

II. Lack of Industry Regulation and Existing Issues

The U.S. federal government has largely remained uninvolved in regulating reproductive technology.¹³ Since the development of ART by the private sector, the government has been apprehensive about forming a “legal framework of rules and regulations.”¹⁴ There are slim, but existing requirements and guidelines from two entities regarding sperm donation.

The Food and Drug Administration (FDA) provides scant requirements for sperm donation; namely, a medical record review and a screening for “communicable and infectious diseases” such as HIV and Hepatitis C.¹⁵ In addition to the FDA, the American Society for Reproductive Medicine (ASRM) and the Society for Assisted Reproductive Technology (SART) created standards for *voluntary* clinic accreditation, but many clinics choose not to participate.¹⁶ ASRM and SART struggle to objectively review the few clinics that do comply with recommended standards due to their corporate relations. Among SART’s member companies are corporate, pharmaceutical giants such as Bayer, Wyeth (acquired by Pfizer), and Eli Lilly; therefore, these billion-dollar entities exert some control over this “self-regulating” marketplace, free of federal oversight.¹⁷

Outside of the FDA’s few requirements for donors and the ASRM’s recommendations, no other mandated accountability measures exist for the sperm donor industry. Without federal regulation, an array of issues exist in the sperm donation industry, such as limitless donations by donors, lack of extensive, physical and mental donor health testing and screenings, and secrecy about long-term donor health due to anonymity.

¹³ Naomi Cahn, *Do Tell! The Rights of Donor-Conceived Offspring*, 42 HOFSTRA L. REV. 1077, 1088 (2014).

¹⁴ Preisler, *supra* note 1, at 217.

¹⁵ 21 C.F.R. § 1271.5 (2006); Nofar Yakovi Gan-Or, *Reproductive Dreams and Nightmares: Sperm Donation in the Age of At-Home Genetic Testing*, 51 LOY. U. CHI. L.J. 791, 797-78 (2020).

¹⁶ Preisler, *supra* note 1, at 221.

¹⁷ *Id.* at 215, 220.

A. *Limitless Donation*

Five of twenty-six sperm banks supply 75-80% of the total sperm distributed in the United States.¹⁸ These sperm banks do not report how many children are born from each donor and no laws exist limiting the number of children that can be born to each donor.¹⁹ The absence of state and federal laws to regulate the number of children born to each donor has resulted in some sperm banks creating their own regulations to tackle this issue, but without a federal regulatory system to provide a uniform approach, any self-regulation remains at the initiative of the individual sperm bank.²⁰ California Cryobank, a sperm bank, claims to limit the number of *families* to which they give one donor's sperm sample—about 20-25 families, which is consistent with ASRM's recommendations—but the number of children born to those families is still unknown because no tracking system exists.²¹ However, when compared to other countries such as the Netherlands—which allows no more than 10 families per donor—the United States falls dramatically behind on simple protections for families with donor-conceived children.²² Limiting the number of children born of one sperm donor is an important step forward to avoid donors from fathering an exorbitant amount of children, which was the case with one donor who parented 150 children.²³

¹⁸ Pamela Foohey, *Recent Developments in Health Law: Potential Nat'l Voluntary Gamete Donor Registry Discussed at Recent Health Law Symposium*, 36 J.L. MED. & ETHICS 597 (2008).

¹⁹ Robert Klitzman, *The U.S. Needs a Sperm Donor Registry*, SLATE (Oct. 18, 2019, 7:30 AM), <https://slate.com/technology/2019/10/almost-family-fox-sperm-donor-registry.html>; see 42 U.S.C.A. § 263a-1 (2009); see also Denise Grady, *As the Use of Donor Sperm Increases, Secrecy Can Be a Health Hazard*, N.Y. TIMES (June 6, 2006), <https://www.nytimes.com/2006/06/06/health/as-the-use-of-donor-sperm-increases-secrecy-can-be-a-health-hazard.html>.

²⁰ Susan Dominus, *Sperm Donors Can't Stay Secret Anymore. Here's What That Means.*, N.Y. TIMES (June 26, 2019), <https://www.nytimes.com/2019/06/26/magazine/sperm-donor-questions.html>.

²¹ *Id.*

²² Glenda Fauntleroy, *The Big Chill: Do Sperm Banks Need Stricter Regulations?*, ENDOCRINE NEWS (June 2017), <https://endocrinenews.endocrine.org/big-chill-sperm-banks-need-stricter-regulations/>; Grady, *supra* note 19.

²³ Mroz, *supra* note 10.

Public policy against consanguinity demands that the federal government regulate the number of children conceived by a single donor to lower the chances of half-siblings becoming romantically and sexually involved.²⁴ If a donor provided his sample to one or two sperm banks in a concentrated area, multiplied by several donations at each bank, the chance of half-siblings growing up in the same geographic region is entirely probable.²⁵ “Inadvertent consanguinity,” or incest, can have heartbreaking consequences such as relationship dissolution and/or genetic abnormalities if children are born to the half-siblings.²⁶ The rate of severe abnormalities increases 31-44% when siblings reproduce and, though harder to track in humans, genetic mutations can last several generations.²⁷

Other countries such as Sweden, Britain, and France have legal limits on the number of children that can be born from one donor, yet the United States has failed to adopt such a law.²⁸ The creation of a national registry—that parents can opt into—could, ideally, track the number of children born to every donor, and provide a vague geographic summary of where donor-conceived children are located, to avoid concerns about half-siblings becoming intimately involved with one another. A national registry could also mandate and manage existing issues about sperm donors transmitting genetic mutations due to lack of donor health testing and screening, as well as donor-born children inheriting encumbering mental illnesses that have not been reported to the sperm banks.

²⁴ See, e.g., Martina Merten, *Keeping It in the Family: Consanguineous Marriage and Genetic Disorders, from Islamabad to Bradford*, *BMJ* (Apr. 29, 2019), <https://www.bmj.com/content/365/bmj.l1851>.

²⁵ Vanessa L. Pi, *Regulating Sperm Donation: Why Requiring Exposed Donation Is Not the Answer*, 16 *DUKE J. GENDER L. & POL'Y* 379, 389 (2009).

²⁶ Lisa M. Luetkemeyer, *Who's Guarding the Henhouse and What Are They Doing with the Eggs (and Sperm)? A Call for Increased Regulation of Gamete Donation and Long-Term Tracking of Donor Gametes*, 3 *ST. LOUIS U. J. HEALTH L. & POL'Y* 397, 417-18 (2010) (A couple in Britain realized they were twins, separated at birth, shortly after marrying and immediately requested an annulment after discovering their relation to one another.); see also Naomi Cahn, *Accidental Incest: Drawing the Line – or the Curtain? – for Reproductive Technology*, 32 *HARV. J.L. & GENDER* 59, 87 (2009).

²⁷ Cahn, *supra* note 26, at 85.

²⁸ Fauntleroy, *supra* note 22.

B. *Lack of Donor Health Testing and Screening*

The FDA requires adherence to screenings for communicable diseases, as well as infectious ones such as HIV, Hepatitis B & C, and other sexually transmitted diseases.²⁹ However, the ASRM recommends sperm banks adopt a more thorough health testing and screening process that includes a detailed medical history, testing for genetic diseases, and even psychological assessments and counseling.³⁰ Beyond these recommendations, no oversight exists to verify information about a donor's medical history, education status, and/or involvement in the criminal justice system.³¹ Sperm banks are also not required to monitor the long-term health of a donor, so they can only provide information about disorders and diseases up to the point of sperm donation.³² If a donor developed a serious medical condition later in life that could be genetically passed on to the donor-conceived child, which is common for diseases such as schizophrenia, the donor is not required to report the condition to the sperm bank, donor-conceived child, or the child's parents.³³ One study conducted by the Donor Sibling Registry found that 84% of its surveyed sperm donors were never contacted for medical updates and almost 25% said they had significant health updates that would be important for families to know about.³⁴ Without continued health-monitoring of sperm donors, donor-conceived children remain uninformed about potential risks they face and are deprived of opportunities to mitigate future health outcomes.

Sperm donor No. F827 fathered eleven children through his sperm samples and was later found to have passed a serious gene defect to five of those children that increased their risk for leukemia and required expensive, daily shots to prevent the disease.³⁵

²⁹ 21 C.F.R. § 1271 (2007); Fauntleroy, *supra* note 22.

³⁰ Fauntleroy, *supra* note 22.

³¹ Naomi Cahn & Sonia Suter, *Sperm Donation Is Largely Unregulated, but That Could Soon Change as Lawsuits Multiply*, THE CONVERSATION (Jan. 18, 2022, 8:40 AM), <https://theconversation.com/sperm-donation-is-largely-unregulated-but-that-could-soon-change-as-lawsuits-multiply-174389>.

³² Pi, *supra* note 25, at 390.

³³ *Id.*

³⁴ Wendy Kramer, *Sperm Donation Needs Federal Regulation*, TIME (Apr. 25, 2016, 10:20 AM), <https://time.com/4299641/sperm-donation-needs-federal-regulation/>.

³⁵ Grady, *supra* note 19.

Those donor-conceived children have a 50% chance of passing the gene to their future children and will have to make difficult decisions about using their own gametes (i.e., eggs and sperm) in their reproductive journeys.³⁶

Financial incentives exist for sperm banks to opt-out of more thorough health screenings and that should not be the accepted norm.³⁷ Families deserve the opportunity to know about physical and mental health complications of the donor, so they can provide optimal care for their donor-conceived child(ren). Without extensive, mandatory health screenings, more families will continue to suffer difficult and sometimes debilitating outcomes, like the Gunner family endured.³⁸

The Gunners suffered the tragic loss of their son, Steven, to an opioid overdose.³⁹ Steven struggled with mental health issues, opioid abuse, and erratic behavior for more than a decade.⁴⁰ Steven was donor-conceived, and the donor lied to the sperm bank about his mental health and criminal history.⁴¹ The donor suffered from severe schizophrenia which was passed onto the Gunner's son.⁴² The family wished they would have known the donor's history, so they could have done everything possible to support their son's mental health, especially from a young age.⁴³

Creating federal regulations mandating sperm banks to comply with donor health screenings at the time of donation and beyond could save lives or at minimum, provide imperative health knowledge to families, so they can care for their donor-conceived child(ren) and teach them to care for themselves as they age. An expert family law and reproductive technology scholar, Naomi Cahn, proposes prohibiting anonymous sperm donation, so that

³⁶ *Id.*

³⁷ Preisler, *supra* note 1, at 231-32.

³⁸ Fauntleroy, *supra* note 18; Amy Dockser Marcus, *A Grieving Family Wonders: What if They Had Known the Medical History of Sperm Donor 1558?*, WALL ST. J. (Jan. 2, 2022, 5:30 AM), <https://www.wsj.com/articles/a-grieving-family-wonders-what-if-they-had-known-the-medical-history-of-sperm-donor-1558-11641119405>.

³⁹ Marcus, *supra* note 38.

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.*

donor-conceived children and families can seek out the donor's future health information.⁴⁴

C. *Lack of Donor Information*

Sperm donation in the United States is mostly anonymous, reinforcing the nation's historical preference for privacy.⁴⁵ There is a growing movement toward open-identity sperm donation in the interests of donor-conceived children and their families.⁴⁶ Some clinics are now offering "identity release programs" where sperm donor information becomes available to a child once they reach 18 years of age.⁴⁷ However, the majority of sperm donors do not use those programs and no U.S. law or regulation requires clinics to offer them.⁴⁸ Identity-release programs would allow donor-conceived children to learn about their genetic origin and have a fuller understanding of their medical history.⁴⁹ Another benefit to identity-release programs is the increased truthfulness and accountability that is likely to result if donors have to attach their identity to their profile.⁵⁰

Opponents of open-identity donor requirements are concerned that removing donor anonymity will result in fewer people becoming sperm donors.⁵¹ However, financial incentives exist for individuals to continue donate their sperm given that a vial of sperm will earn a donor, on average, between \$30-50; some

⁴⁴ See, e.g., NAOMI R. CAHN, *THE NEW KINSHIP: CONSTRUCTING DONOR-CONCEIVED FAMILIES* (2012); NAOMI R. CAHN, *TEST TUBE FAMILIES: WHY THE FERTILITY MARKET NEEDS LEGAL REGULATIONS* (2009); Cahn, *Necessary Subjects*, *supra* note 12; Naomi R. Cahn, *What's Right About Knowing?*, 4 J. L. & BIOSCIENCES 377 (2017); see also Ivana Saric, *Colorado Becomes First State to Ban Anonymous Sperm and Egg Donations*, AXIOS (June 1, 2022), <https://www.axios.com/2022/06/01/colorado-ban-anonymous-sperm-egg-donation>.

⁴⁵ Foohey, *supra* note 18, at 597.

⁴⁶ *Id.*

⁴⁷ Glenn Cohen, Travis Coan, Michelle Ottey, & Christina Boyd. *Sperm Donor Anonymity and Compensation: An Experiment with American Sperm Donors*. 3 J.L. & BIOSCIENCES 468, 469 (2016).

⁴⁸ *Id.*

⁴⁹ *Id.* at 471-72; Foohey, *supra* note 18, at 597.

⁵⁰ Preisler, *supra* note 1, at 230.

⁵¹ Alexander N. Hecht, *Assisted Reproductive Technology*, 1 Hous. J. HEALTH L. & POL'Y 227, 240 (2001).

sperm banks are willing to pay as much as \$100 per vial.⁵² A group of scholars conducted a study on this exact issue and sampled 393 anonymous and open identity sperm donors to ask whether they would still donate if they were required to put their names in an available registry for donor-conceived children when they reached age 18.⁵³ Roughly 70% of the participants expressed that they would be willing to openly donate with an additional \$40-102 financial incentive.⁵⁴ Other countries, such as the United Kingdom, no longer allow anonymous sperm donation and have continued success in ART methods.⁵⁵ Therefore, an important consideration for a future regulatory system would be to mandate identity release programs, which are common practice in many countries, and already exist at some clinics in the United States, as a health measure for donor-conceived children and their families.⁵⁶

III. Creating a National Sperm Donor Registry

The United States needs a regulatory structure that balances the right to family privacy and autonomy, while also ensuring safe medical care for families trying to conceive through assisted reproduction.⁵⁷ Reproductive scholars are most favorable to the creation of a national, mandatory “databank” or regulatory structure to manage sperm donor information.⁵⁸ A federal approach to sperm bank regulation can address the “patchwork of highly variable laws” that exist among all fifty states.⁵⁹ Fifty sepa-

⁵² Preisler, *supra* note 1, at 231; Luke Winkie, *Odd Job: Can a Man Earn a Living on Sperm Donation Alone? This Guy Did*, Vox (May 1, 2019, 3:30 PM), <https://www.vox.com/the-goods/2019/5/21/18634371/sperm-donor-pay-process-price>.

⁵³ Cohen et al., *supra* note 47, at 488.

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ See the landmark U.S. Supreme Court cases about parents’ constitutional rights to the care, custody, and control of their children: *Meyer v. Nebraska*, 262 U.S. 390 (1923); *Pierce v. Soc’y of Sisters*, 268 U.S. 510 (1925); *Wisconsin v. Yoder*, 406 U.S. 205 (1972); *Troxel v. Granville*, 530 U.S. 57 (2000). Preisler, *supra* note 1, at 233.

⁵⁸ Cahn, *Necessary Subjects*, *supra* note 12, at 217.

⁵⁹ Pi, *supra* note 25, at 398; Naomi Cahn & Sonia M. Suter, *The Art of Regulating ART*, 96 CHI.-KENT L. REV. 29, 42 (2021).

rate registries will result in nationwide duplicative efforts, whereas a federal approach can provide uniform standards to regulating the sperm donation industry.⁶⁰ Regulatory reform is not without its challenges and the perfect system of regulation does not exist, but the creation of a federal structure to approach this issue is necessary.⁶¹ Frameworks currently exist that could be used to shape a national sperm donor registry, and to build on that foundation an online management system would be beneficial for clinics and sperm banks nationwide.⁶² To achieve this system, an existing federal entity—or the creation of a new one—will need to be organized into the new regulatory structure.

A. *Fertility Clinic Success Rate and Certificate Act*

One legal, health scholar proposes using the Fertility Clinic Success Rate and Certificate Act (“FCSRCA”) under the CDC as a starting point to create a federal system of sperm donor regulation.⁶³ The FCSRCA was enacted in 1992 due to public policy concerns about the absence of standards of care in the ART market; it outlines the critical need for ART regulation and promoted a model program for certification of embryo laboratories.⁶⁴ A federal certification system could institute a code of medical ethics to be adopted by all sperm banks with federal oversight to ensure compliance.⁶⁵ Under this system, proper reporting and data collection through an online management system would then be mandated by each clinic on matters such as: the number of children born of each donor, a (voluntary) geographic map of where donor-conceived children live to avoid half-siblings from being romantically involved, as well as comprehensive criminal, physical, and mental health screenings, and the collection of current and long-term donor health information.

B. *Registry Online Management System*

All sperm banks would benefit by using the same online management system to ensure uniformity and to oversee clinic

⁶⁰ Pi, *supra* note 25, at 399.

⁶¹ Preisler, *supra* note 1, at 233.

⁶² *Id.* at 234.

⁶³ *Id.*

⁶⁴ *Id.* at 217.

⁶⁵ *Id.* at 234.

compliance. Encryption protocols should be utilized to protect the security of donor and client information.⁶⁶ To incentivize clinics to expedite the implementation of such a system, financial awards could be given by the federal government to clinics that prioritize this uniform approach to medical care for clients.⁶⁷ The CDC should release annual reports of clinics that complied and fail to comply with the system, so that clients can choose their sperm bank and donor accordingly.⁶⁸ Failure to follow the system's mandates could result in monetary sanctions and/or being banned from the market to incentivize sperm banks to comply.⁶⁹

In addition to provider use, the online system should also include a client log-in portal. Clients can use the program to maintain health records, have recipients (voluntarily) report their location for consanguinity prevention purposes, and update their children's long-term health outcomes. An option to make the client's profile public, so that their children's half-siblings and their families could reach out, if desired, could also be beneficial.⁷⁰

Ultimately, the goal of creating a national sperm donor registry is to provide clients with current and ongoing information about their chosen donor and prevent half-siblings from becoming romantically and sexually involved. Adult children created through sperm donation also have a strong interest in accessing information about their biological origins.⁷¹ This data could be used by federal agencies to ensure "mandatory standards are appropriate and highlight areas that may need more regulation."⁷²

C. Federal Enforcement Entity

An existing or new federal entity will need to be responsible for enforcement of the national registry. An entity with an existing structure and system for overseeing assisted reproduction regulation is the Food and Drug Administration ("FDA").⁷³ The FDA would need to make substantial adjustments to accommo-

⁶⁶ Cahn, *Necessary Subjects*, *supra* note 12, at 222.

⁶⁷ Preisler, *supra* note 1, at 233.

⁶⁸ *Id.* at 234.

⁶⁹ *Id.*

⁷⁰ Cahn, *Necessary Subjects*, *supra* note 12, at 222.

⁷¹ *Id.*

⁷² Preisler, *supra* note 1, at 235.

⁷³ Gan-Or, *supra* note 15, at 796.

date a uniform approach to regulating the sperm donor industry.⁷⁴ First, the FDA's authority to regulate ARTs would need be broadened beyond its current scope.⁷⁵ Second, the FDA would need to improve or create stronger data collection methods to oversee compliance with the new system of regulation.⁷⁶ Third, the FDA would need to deliver complete transparency on regulation compliance for extensive donor health screenings and sensitive issues such as the number of children born to each sperm donor.⁷⁷ Another way forward might be to create a new entity to regulate the sperm donor industry rather than trying to restructure an existing one.⁷⁸

In England, the HFEA "licenses, monitors, and inspects fertility clinics."⁷⁹ The HFEA also collects data and provides free, impartial information about assisted reproduction.⁸⁰ Such an entity could be led and governed by "scientific, clinical, and bioethics experts" who have specialized knowledge in reproductive technologies.⁸¹ Implementing a federal regulatory structure to oversee the sperm donation industry is worth the investment to protect donor-conceived children, families, and donors themselves, but it is not without challenges.

IV. Challenges of Creating a National Sperm Donor Registry

One reproductive scholar acknowledges similarities between regulating abortion, formerly protected by the Constitution through the right to privacy, and regulating assisted reproductive technology.⁸² Specifically, these issues encounter similar disagreement about the appropriateness of federal regulation versus state regulation. Both issues must balance religious considerations, but the sperm donor industry must also consider market-

⁷⁴ Cahn & Suter, *supra* note 59, at 78.

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.* at 80.

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² Preisler, *supra* note 1, at 233.

driven forces concerned with economic benefits.⁸³ It will be critical to balance the interests of the sperm bank industry, donors, recipients, donor-conceived children, interest groups, and religious branches while keeping medical and ethical concerns of ART regulatory reform at the center of this initiative.

A. Economic, Political, and Religious Hurdles

There are significant stakeholders in the sperm donor industry that resist regulatory reform by claiming that adequate self-regulation already exists.⁸⁴ An overhaul of the industry would create federal oversight on sperm banks, penalizing providers that exploit consumers for profit by misrepresenting vital health information to families.⁸⁵ Further, regulation will require sperm banks to spend more money on health screenings and adopt a new operating system, cutting into initial profits, so market forces are likely to “undermine any opportunity to assess the current state of deregulation.”⁸⁶ Economic incentives exist for this industry to avoid substantive regulation, so finding a way to include industry giants, such as the five dominating sperm banks that account for more than three-quarters of donated sperm, in the reform process could prove beneficial since their opposition would be a significant obstacle.⁸⁷

Religious organizations have a range of responses toward the morality of ARTs.⁸⁸ Some religions see ART as a “potential ally” in family formation whereas others struggle with the sanctity of creating children through non-reproductive processes.⁸⁹ However, sperm donation is not as controversial as methods of ART involving female gametes where issues about human embryos arise.⁹⁰ Therefore, many religious organizations might be persuaded to advocate for sperm donor industry regulation be-

⁸³ *Id.*

⁸⁴ Cahn & Suter, *supra* note 59, at 85.

⁸⁵ Preisler, *supra* note 1, at 233.

⁸⁶ *Id.*

⁸⁷ Cahn & Suter, *supra* note 59, at 85.

⁸⁸ Andrew Dutney, *Religion, Infertility, and Assisted Reproductive Technology*, 21 BEST PRAC. & RES. CLINICAL OBSTETRICS & GYNECOLOGY 169, 179 (2007).

⁸⁹ *Id.*

⁹⁰ *Id.*

cause it serves as a potential relief from infertility and procreation is often viewed as a core religious duty.⁹¹

To navigate remaining concerns and create alliances with political groups and religious organizations, scholars at the head of this movement should entrench themselves in public policy against consanguinity. Messaging around regulatory reform should put incest at the center as a public health concern and highlight the increased risk for genetic mutations among children born to half-siblings.⁹² Incest as a social taboo spans across prominent U.S. political ideologies (i.e., Democrat, Republican, and Independent), so bipartisan support for federal oversight could be expected in at least this regard. One poll found that 86% of participants would support abortion in cases involving rape or incest: 94% of Democrats, 88% of Independents, and 76% of Republicans.⁹³ Therefore, even a topic as divisive as abortion can foster common ground among different political groups when incest is involved. Legislatures should consider the tremendous influences that religious organizations and political groups have on social attitudes and remain open to their perspectives in the fight for regulatory reform.

Reform in the sperm donation industry should account for economic, religious, and political concerns while putting at the forefront the medical and ethical issues of an unregulated sperm donation market.⁹⁴ Forward progress and innovation in reproductive science “hinge on the government’s ability to successfully implement ART policy.”⁹⁵

V. Conclusion

The advancement of ARTs has made it possible for individuals and families to conceive who do not have the biological ability to do so. The evolution of the sperm donation industry has

⁹¹ *Id.* at 172.

⁹² Cahn, *supra* note 26, at 85.

⁹³ Stephanie Perry, Marc Trussler, Josh Clinton & John Lapinski, *Vast Majority of Republicans Support Abortion Exceptions for Rape, Incest, and Mother’s Health*, NBC NEWS (Oct. 17, 2022, 7:52 AM), <https://www.nbcnews.com/politics/2022-election/vast-majority-republicans-support-abortion-exceptions-rape-incest-moth-rcna52237>.

⁹⁴ Preisler, *supra* note 1, at 234.

⁹⁵ *Id.*

resulted in a market-driven approach to family creation that prioritizes profits over clients. Without a system of federal regulation, sperm banks will continue operating free from oversight under the guise of “self-regulation.” It is imperative that the United States catches up to other industrialized countries when it comes to laws and regulations about family creation through ARTs. To do so, a national approach to regulating the sperm donation industry is critical to protect families utilizing ART methods of procreation. A national registry for sperm donors can address existing issues such as limitless sperm donation, lack of health screening and testing, as well as donor anonymity concerns. Such a regulatory structure can be overseen by an existing entity such as the FDA or a new enforcement agency can be created. This mission will require the involvement of multiple stakeholders, interest groups, and religious organizations, but together, a national system of regulation can be implemented to protect donor-conceived children, families, and donors themselves.

Ashley Rogers

