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# Sperm You Can Bank on; a Proposed Federal Regulatory Scheme to Increase Consumer Protection in the Sperm Donation Industry

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# SPERM YOU CAN BANK ON; A PROPOSED FEDERAL REGULATORY SCHEME TO INCREASE CONSUMER PROTECTION IN THE SPERM DONATION INDUSTRY

Jessica Stookey

## I. INTRODUCTION

Sperm donation is a well-accepted practice in the 21st century. It provides a comedic plot line for more than a few popular movies where some mishap occurs in the sperm donation process. In The Switch Jennifer Anniston unknowingly inseminates herself with her friend's sperm instead of her selected donor's sperm; in Delivery Man Vince Vaughn discovers that an error at a sperm bank led his sperm donations to conceive 533 children. In each of these movies all parties involved—donor, parents, and children—get a happy ending and learn some lesson about the meaning of family and love. However, incidents such as these do not just exist in feel-good comedies. Mishaps involving sperm donation are not uncommon. Recent trends with direct to consumer testing, social media, and openness about the topic of sperm donation have brought the incidents surrounding sperm donation into the public eye.

Sperm banks have given mothers the wrong sperm.[1] Donors have lied about critical pieces of medical and personal history.[2] Sperm banks have failed to disclose information about donors that any parent would want to know about the biological father of their child.[3] In almost any other industry these incidents would result in lawsuits. In the medical industry, such mistakes would result in malpractice claims. In typical commerce, these "product" mix ups would constitute a breach of contract or the basis of a products liability claim. But in the unique

[1] *See infra* at 49
[2] *See infra* at 42
[3] *See infra* at 43

industry of sperm donation the alleged injury in these cases is ultimately the existence of a child—a child genetically different than the child the parents had wanted. There are huge ethical concerns with recognizing this child as a legal injury.

The reality is that the sperm donation industry operates largely without regulation to prevent or deter these kinds of incidents. Existing Food and Drug Administration (FDA) regulation offers little protection to consumers, and potential legal remedies are limited at best. For decades the sperm banking industry, and the assisted reproductive technology (ART) industry as a whole, was considered by many to be the "wild west" of the healthcare field. But the prominence of sperm donation in modern family planning demands the enactment of a new regulatory scheme that protects parents and children from trying to squeeze their unique "injury" into the existing parameters of common law remedies. This comment will discuss the current state of the sperm donation industry from a legal standpoint and the issues within it, and then recommend a regulatory scheme that could help protect the people who rely on the industry to start their families.

## II. BACKGROUND

### A. Increased Reliance on Sperm Donors

The increased use of and discussion surrounding sperm donation is largely linked to increased infertility rates, both medical and "social" infertility. Couples are medically infertile if they are unable to conceive after trying for one year.[4] One in six couples experiences infertility.[5] Male infertility—where the problem in conceiving is due to the male partner—is the sole cause

[4] World Health Organization, *Infertility*, https://www.who.int/reproductivehealth/topics/infertility/definitions/en/ (last visited Fall 2019).
[5] American Pregnancy Association, *Male Infertility*, https://americanpregnancy.org/infertility/male-infertility/ (last visited Fall 2019).

of infertility in about 20% of all infertility cases and is a contributing factor in about 30% of cases.[6] Male infertility usually occurs because of sperm abnormalities, inadequate numbers of sperm, or ejaculation problems.[7] These issues can be a result of a number of different disorders, but the exact cause of these issues is unknown in almost half of all male infertility cases.[8] Studies indicate that rates of male infertility are increasing,[9] and with it the need for heterosexual couples to rely on sperm donation to begin their families.[10]

"Social" infertility, sometimes called "circumstantial" infertility, is a term used to describe couples or individuals who must rely on assisted reproductive technology (ART) to reproduce because of their lifestyle as opposed to a medical condition.[11] Changing social norms, values, and lifestyles have caused more single women to procreate without a partner.[12] Improved social acceptance and recognition of legal rights has led more same-sex couples to have biological children.[13] Single women and same-sex female couples will, of course, have to rely on sperm donation to conceive a child. Heterosexual couples may also choose to use a sperm donor when genetic testing or family background indicates that the male has a high probability of passing on an unwanted genetic disease or defect to a child.[14]

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[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] Researchers disagree over whether this increase is actually attributable to some environmental factor, or just an increase in reporting as more men consult with their doctors about infertility.
[10] Ashley Fetters, *Sperm Count Continues to Fall*, The Atlantic (Oct. 12, 2018), https://www.theatlantic.com/family/archive/2018/10/sperm-counts-continue-to-fall/572794/
[11] Your Fertility Friend, *Social Infertility*, https://yourfertilityfriend.com/social-infertility/ (last visited Fall 2019).
[12] *Id.*
[13] *Id.*
[14] Mayo Clinic, *Sperm Donation*, https://www.mayoclinic.org/tests-procedures/sperm-donation/about/pac-20395032 (last visited Fall 2019).

It is difficult to find exact and accurate statistics reporting the number of children born through sperm donation.[15] The most reliable and commonly used statistic is from 2010, showing that 30,000-60,000 of the 4 million babies born in the US that year were born through sperm donation.[16] However, social stigmas and the lack of nationalized reporting system mean that many births from sperm donation likely go unreported indicating that the true number is likely much higher.

## B. The Sperm Donation Process

### i. Donor Perspective

In order to apply to be a sperm donor, a man must be: (1) between 19 and 38 years old, (2) currently attending or having graduated from college, (3) in good health, and (4) legally allowed to work in the United States.[17] First, a man interested in becoming a donor must fill out an initial screening application online detailing his personal information, family background, and education.[18] Second, after passing the initial screening, the man must provide a semen sample.[19] Third, if he passes the lab tests, the man must have a physical examination, meet with a genetic counselor, complete a donor profile, and provide three photographs of the donor as a child.[20] If the potential donor completes these steps without issue, then the man becomes a qualified sperm

[15] Wendy K.R. blog post "How Many Donor Offspring Are Really Out There Donor Sibling Registry https://www.donorsiblingregistry.com/blog/how-many-donor-offspring-are-really-out-there/ (discussing the lack of reporting and accurate numbers in the sperm donation industry and how outdated the "30,000-60,000 per year" is.
[16] Ashley Fetters, *The Overlooked Emotions of Sperm Donation*, The Atlantic (Jul. 9, 2019), https://www.theatlantic.com/family/archive/2018/07/sperm-donations-emotional-consequences/564587/.
[17] Sperm Bank, *Donor Requirements*, https://www.spermbank.com/how-it-works/sperm-donor-requirements (last visited Fall 2019).
[18] Sperm Bank, *Donor Screening Process*, https://www.spermbank.com/how-it-works/donor-screening-process (Last accessed Fall 2019).
[19] *Id.* The semen must be screened for infectious disease. Some sperm banks screen semen for certain genetic issues at this stage, too. This screening is a topic that will be discussed further in a later section
[20] *Id.*

donor.[21] Most facilities request that each donor donate two to three times per week for at least a year and require the donor to be tested every three months for infectious disease.[22]

Sperm banks cannot pay donors for sperm itself; the actual specimen must be legally considered a donation. However, sperm banks pay donors up to $1500 monthly for their "time and expenses" to get around the restriction on purchasing sperm.[23] One sperm bank explains on their website, "Sperm donors also receive periodic incentives such as movie tickets or gift certificates for extra time and effort expended." [24]

At some point during this process the donor signs a contract legally giving up all parental rights and responsibilities for any children resulting from their donation.[25]

**ii. Parent Perspective**

After parents decide to use a sperm donor, they must begin the process of choosing the donor. Many fertility clinics maintain lists of preferred sperm banks.[26] Parents use the sperm bank website to view donor profiles.[27] The design of these websites is quite similar to any online retail website where shoppers can narrow down their search by specific criteria. Parents can search based on a variety of characteristics: age, ethnicity, hair color, eye color, blood type, height, educational degree, etc.[28] Profiles include these basic traits and known family history of heritable disease. Sperm banks usually offer "different tiers of information for more money."[29]

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[21] *Id.*
[22] *Id.*
[23] Sperm Bank, *Sperm Donor Pay*, https://www.spermbank.com/why-donate/sperm-donor-pay (Last Accessed Fall 2019).
[24] *Id.*
[25] Sperm Bank, *Donor Screening Process*, https://www.spermbank.com/how-it-works/donor-screening-process (Last accessed Fall 2019).
[26] Emily Shiffer, *How to Find A Sperm Donor And Get A Good One*, Parents, (No Date?) (https://www.parents.com/getting-pregnant/how-to-find-a-sperm-donor-and-choose-a-good-one/.
[27] *Id.*
[28] *Id.*
[29] *Id.*

Parents can pay the sperm bank extra to get donor childhood photos, voice recordings, answers to questionnaires, personality types, and sometimes even adult photos.[30]

After choosing a donor the parents order the sperm, usually to their fertility clinic.[31] The sperm bank delivers sperm in a special temperature-controlled container.[32] At the clinic a doctor either directly inseminates the mother with the sperm, or introduces the sperm to the egg in a laboratory before transferring the fertilized egg into the uterus.[33]

### iii. Costs

Each vial of "washed" sperm costs $800-$1000 and fertility clinics recommend ordering three to six vials per cycle.[34] Many women do not get pregnant from one cycle so parents must pay this amount for as many cycles as it takes to get pregnant. This price also does not include shipping, storage, and browsing fees.[35] As mentioned above, there can be additional costs for additional information about each sperm donor the parents are considering.[36] These numbers do not include any of the medical costs for consultations, inseminations, or any additional fertility treatments the mother may need. Insurance companies may or may not cover some of these costs depending on the state and particular insurance plan.[37]

## C. Recent Cases and Controversies In The Sperm Donation Industry

### i. *Zelt v. Xytex Corp.*

[30] *Id.*
[31] Emily Shiffer, *How to Find A Sperm Donor And Get A Good One,* Parents, (No Date?) (https://www.parents.com/getting-pregnant/how-to-find-a-sperm-donor-and-choose-a-good-one/.
[32] *Id.*
[33] *Id.*
[34] "Washed" sperm is a specimen of sperm that has gone through several laboratory procedures to eliminate dead, deformed, or immotile sperm to maximize the likelihood of successful fertilization.
[35] https://www.vice.com/en_us/article/53nvex/why-is-sperm-so-damn-expensive
[36] *Id.*
[37] *Id.*

In an 11th Circuit case decided in February, 2019, the Zelts sued a sperm bank, Xytex.[38] The Zelts had two children both conceived through insemination with the sperm of Donor #9623 which they purchased through Xytex.[39] Xytex's website promised they would screen potential sperm donors through interviews and physical examinations.[40] The Zelts decided on this particular donor because Xytex stated that the donor was a Ph.D. candidate, had an IQ of 160, a "nearly perfect" medical and mental health history, and no criminal background.[41] Years after their children were born the Zelts discovered that many of the representations about Donor #9623—James Aggeles—were untrue: Aggles was diagnosed with schizophrenia and had been repeatedly hospitalized for mental health reasons and drug use; he was considered disabled by social security; had a felony conviction; was never enrolled in a Ph.D. program, and had only finished college years after the Zelts purchased the sperm; and he had lied about his IQ.[42] Aggles claimed that he had been encouraged to lie by a Xytex employee so that he would be more successful in selling his sperm.[43] Xytex never requested or verified his medical records with health care providers, nor had they looked into his criminal and educational background which would have been publicly available or easily accessible.[44]

The Federal District Court dismissed the complaint for failure to state claims for which relief could be granted.[45] The district court held that the claims were ultimately for wrongful birth, which Georgia law does not recognize.[46] The 11th Circuit affirmed this dismissal after

[38] *Zelt v. Xytex Corp.*, 766 F. App'x 735 (11th Cir. 2019).
[39] *Id.* at 736.
[40] *Id.*
[41] *Id.*at 737.
[42] *Id.*
[43] *Id.*
[44] Zelt v. Xytex Corp., 766 F. App'x 735, 738 (11th Cir. 2019).
[45] *Id.*
[46] *Id.*

analyzing possible claims and agreeing that wrongful birth—unrecognized in Georgia—was the only appropriate complaint for the matter.[47] The Court stated that while they found the acts of Xytex reprehensible, "We must affirm the dismissal of all of the Zelt's claims that necessarily entail pleading an injury equal to the difference in the value of a child's life with Aggeles as the sperm donor and the value of the child's life with a different donor."[48] The Court took moral issue with labeling this controversy as "unjust enrichment."[49]

### ii. *Cramblett v. Midwest Sperm Bank*

Jennifer Cramblett sued Midwest Sperm Bank in 2014 after discovering that the facility provided her with sperm from the wrong donor.[50] Jennifer and her wife, both white themselves, selected a white donor but some mix-up caused them to receive sperm from a donor other than the one they selected.[51] The sperm they received was from a black donor and the couple's child was "clearly biracial."[52] Cramblett sued under a wrongful birth claim.[53] The complaint claimed that sperm bank numbered the vials for identification with "pen and ink," and that the records were not computerized.[54] The judge dismissed the case holding that it was not a wrongful birth because the child has no health problems; courts maintain that there is no injury if the child is healthy.[55] As the comment will discuss in a later section, wrongful birth actions are dependent on the child having some defect.[56]

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[47] *Id.*
[48] *Id.*
[49] Zelt v. Xytex Corp., 766 F. App'x 735, 738 (11th Cir. 2019). ("Although the amount by which Xytex was enriched is easy to calculate, calling this enrichment "unjust" necessarily implies that the Zelts' children somehow are worth less than they would have been worth had they been conceived using a different donor's sperm.")
[50] Jaqueline Mroz, *Their Children Were Conceieved With Donated Sperm. It Was the Wront Sperm.,* (June 3, 2019) https://www.nytimes.com/2019/06/03/health/sperm-banks-fertility-artificial-insemination.html.
[51] *Id.*
[52] *Id.*
[53] *Id.*
[54] *Id.*
[55] *Id.*
[56] *See infra* at 95

### iii. Doctors Using Own Sperm

There has been a great deal of press and discussion surrounding a recent string of incidents where families have discovered—often through direct to consumer DNA testing—that the sperm they received was not from their selected donor, but rather from their fertility doctor himself.[57] The most publicized recent story has been that surrounding Dr. Cline, an Indiana fertility doctor who used his own sperm instead of sperm form anonymous young doctors in the hospital as he had told the women.[58] The women who were inseminated with Dr. Cline's sperm filed a complaint against him.[59] Under Indiana law, however, such "infertility fraud" is not legally cognizable.[60] More than fifty people have discovered that they are his biological children since the first accusation was made in 2014.[61] Ongoing lawsuits in Idaho, Vermont, California, Canada, and the Netherlands all have similar facts: former patients or their children bringing suit against doctors accused of using their own sperm instead of donor sperm.[62]

## D. Categorization of Incidents in the Sperm Donation Industry

Most of the cases and controversies surrounding sperm donation fall into one of four categories: (1) "Unintentional False Profile"; (2) "Intentional False Profile"; (3) "Unintentional Switch"; or (4) "Intentional Use of Wrong Sperm."

Category (1), "Unintentional False Profile," includes incidents where a sperm donor has deliberately or mistakenly provided false information to the sperm bank, the sperm bank is unaware of the falsity of the information, this information is entered into the donor profile,

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[57] Mihir Zaveri, *A Fertility Doctor Used His Sperm On Unwitting Women*, N.Y. Times, *(Aug. 30, 2018) https*://www.nytimes.com/2018/08/30/us/fertility-doctor-pregnant-women.html.
[58] *Id.*
[59] *Id.*
[60] *Id.*
[61] Sarah Zhang, A Decades-Old Doctor's Secret Leads to New Fertility-Fraud Law, The Atlantic, (May 7, 2019), https://www.theatlantic.com/science/archive/2019/05/cline-fertility-fraud-law/588877/.
[62] https://www.theatlantic.com/science/archive/2019/05/cline-fertility-fraud-law/588877/

parents select the specific donor, and the mother is inseminated with the sperm of the selected donor—the selected donor just has different traits than the profile described.[63]

Category (2), "Intentional False Profile," includes incidents where a sperm donor provides false information to the sperm bank and the sperm bank is aware of the falsity and publishes the false information to a donor profile anyway, or where the sperm bank itself encourages or creates the false information entered into the donor profile.[64] As with the first category, the parents then choose the donor profile representing this false information and are inseminated with that donor's sperm.

Category (3), "Unintentional Switch," includes incidents where there is not an issue of false donor information, but where parents select one donor, and the sperm bank mistakenly provides the wrong donor's sperm.[65]

Category (4), "Intentional Use of Wrong Sperm," includes incidents where someone—whether it be a sperm bank employee or a medical professional performing the insemination procedure—intentionally provides sperm other than the selected donor sperm.[66] This final category presents a number of interesting and complex legal questions because the most publicized stories have involved doctors using their own sperm instead of donor sperm. When a doctor or other medical professional engages this kind of malicious deception malpractice seems like the most appropriate course of action. This comment will discuss the limitations of malpractice actions against the sperm banking industry as a whole in a later section. The legal

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[63] FOODNOTE NEEDED (that case where everyone had the same genetic disease? Fragile X)

[64] *See, e.g.,* Zelt v. Xytex Corp., 766 F. App'x 735 (11th Cir. 2019). (Where an employee of the sperm bank new the donor's IQ was not 160, but encouraged him to list his IQ as 160 and then published this information on his donor profile which the Zelts later selected).

[65] *See, e.g.,* Jaqueline Mroz, *Their Children Were Conceieved With Donated Sperm. It Was the Wront Sperm.,* (June 3, 2019) https://www.nytimes.com/2019/06/03/health/sperm-banks-fertility-artificial-insemination.html. (Where the Crambletts selected a white sperm donor and were inseminated by the sperm of a black donor).

[66] *See, e.g.,* Mihir Zaveri, *A Fertility Doctor Used His Sperm On Unwitting Women,* N.Y. Times, *(Aug. 30, 2018) https*://www.nytimes.com/2018/08/30/us/fertility-doctor-pregnant-women.html.

issues surrounding malpractice actions against solely medical professionals who intentionally use the wrong sperm are outside the scope of this comment.

## III. EXISTING REGULATION

### A. Federal Regulation

#### i. Current FDA Regulation

Current federal regulation of sperm donation is minimal. The FDA classifies sperm under the umbrella category of "human cell, tissue, and cellular and tissue-based product" (HCT/Ps).[67] In 2004, the FDA published three rules to regulate HCT/Ps: (1) Registration and listing requirements, (2) donor eligibility requirements, and (3) good tissue practices.[68] The registration and listing rule states that "all establishments that recover, process, store, label, package, or distribute HCT/Ps must register with the FDA and list their HCT/Ps."[69] The donor eligibility requires all establishments to "screen and test cell and tissue donors for risk factors for, and clinical evidence of, relevant communicable disease agents or disease."[70] The good tissue practice rule sets forth practices that establishments should follow to prevent the spread of communicable disease from infected donors and HCT/Ps within the facility.[71] The practices concern maintenance of collection practices, storage, labeling, packaging, distribution, etc.[72] As applied to sperm donation, these FDA regulations require sperm banks to register with the

[67] FDA, *Donor Eligibility Final Rule and Guidance Q&A*, https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/donor-eligibility-final-rule-and-guidance-questions-and-answers (last accessed Fall 2019).
[68] *Id.*
[69] 21 C.F.R. § 1271.21
[70] 21 C.F.R. § 1271.45
[71] 21 C.F.R. § 1271.145
[72] *Id.*

FDA,[73] screen semen samples for communicable diseases,[74] and implement practices that prevent the spread of communicable disease through the semen.[75]

### ii. Holes in Existing FDA Regulation

The eligibility rule is the only rule relevant to the testing and screening of sperm donors. The rule currently only requires testing for communicable disease, like HIV. There are no additional testing, examination, or interviewing requirements for sperm donors; the regulations covering sperm donation are the same as those for blood and organ donation. The current FDA regulations do not take into account the unique genetic importance of gametes—sperm and eggs.

## B. State Regulations

New York State Department of Health has the strictest regulations in the country regarding reproductive tissue banks. In addition to the FDA-required screenings for communicable diseases, New York requires sperm banks to evaluate the genetic health of donors for specific types of heritable diseases and disorders.[76] The code states, "A complete medical history, both individual and family, including first-degree and second-degree relatives, shall be obtained from each reproductive tissue donor prior to any collection of tissues for clinical use. . ." and continues to list a variety of malformations, genetic disorders, and behavioral factors that may be inheritable by a child conceived from the sperm of the donor.[77] The code states that, except for those factors posing an increased risk for a communicable disease infection, the aforementioned factors do not exclude a man from being a donor, but the reproductive tissue bank's medical director or attending physician shall counsel the recipient about potential risks of

[73] 21 C.F.R. § 1271.21
[74] 21 C.F.R. § 1271.45
[75] 21 C.F.R. § 1271.145
[76] N.Y. Comp. Codes R. & Regs. titl. 10, § 52-8.5
[77] *Id.*

using such a donor's sperm.[78] The New York code also implements a system for inspection of reproductive tissue bank facilities.[79]

## C. Industry Self-Regulation

### i. American Association of Tissue Banks

The American Association of Tissue Banks (AATB) is the highest-level standard-setting body for tissue banks in the US.[80] Tissue banks receive AATB accreditation after submitting to onsite inspections to ensure the bank is managed by professional and appropriate staff, and has quality-assurance policies and procedures in place.[81] There have been issues with some sperm banks claiming to "meet or exceed" AATB standards without having been inspected or accredited.[82]

### ii. American Society for Reproductive Medicine

The American Society for Reproductive Medicine (ASRM) periodically issues recommended guidelines for screening donors.[83] The ASRM is an organization of physicians and professionals in the industry who use their experiences and research to make recommendations for best practices in the sperm donation industry. [84] These recommendations are only "industry standards" and compliance is voluntary. [85]

## D. Foreign Regulations: United Kingdom

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[78] *Id.*
[79] *Id.*
[80] American Association of Tissue Banks, *Accreditation*, https://www.aatb.org/accreditation (last accessed Fall 2019).
[81] *Id.*
[82] Sperm Bank, *Sperm Bank Registration*, https://www.spermbank.com/about/sperm-bank-registration (last accessed Fall 2019).
[83] *Id.*
[84] American Society of Reproductive Medicine, *Vision of ASRM*, https://www.reproductivefacts.org/about-asrm/vision-of-asrm/ (last accessed Fall 2019).
[85] *Id.*

Regulation of sperm donation varies globally based on social views, healthcare systems, and medical technology. While the US government and regulators have taken a largely "hands off" approach to sperm donation, the UK has taken the opposite approach; sperm donation in the UK is heavily regulated.[86] The Human Fertilisation and Embryology Authority (HFEA) regulates all gamete (sperm and egg) donation in the UK.[87] HFEA is the UK's independent regulator responsible for overseeing the use of gametes and embryos in fertility treatment and research.[88] All donors must register with HFEA prior to donating and HFEA enters all of the donors into a national registry.[89] Since 2005, all donors in the UK must agree to be identifiable to any persons conceived from their donation once the person reaches the age of 18.[90] The national registry allows the HFEA to enforce a limit on the number of children a single sperm donor may father to minimize the likelihood of "accidental incest."[91] A sperm donor in the UK may not create more than ten families, but the donor himself may choose to further limit this number.[92]

## IV. APPLICATION OF PRIVATE LEGAL REMEDIES

### A. Existing Legal Theories

#### i. Wrongful Conception

[86] National Gamete Donation Trust, *Donation and the Law*, http://www.ngdt.co.uk/sperm-donor/donation-the-law/ (last accessed Fall 2019).
[87] *Id.*
[88] *Id.*
[89] Human Fertilisation and Embryology Authority, *Donating Your Sperm*, https://www.hfea.gov.uk/donation/donors/donating-your-sperm/ (last accessed Fall 2019).
[90] *Id.*
[91] *Id.*
[92] *Id.* Sperm donors are limited to a number of families rather than a number of children because many parents using donor sperm may want to use the same donor to conceive multiple children. Ten families may be created by a single sperm donor, but each family may have multiple children from that donor.

In a wrongful conception action, the argument is that the plaintiff never wanted to become pregnant in the first place; the legal harm is the pregnancy itself.[93] In these actions, pregnancy-related damages are allowed, but child-rearing damages are not allowed as child-rearing is not a legally cognizable injury.[94] Some states do not allow wrongful conception claims for moral and policy reasons.[95] Most states do allow wrongful conception actions, but claims alleging the use of the wrong or substandard donor sperm do not fit into the parameters of the action.[96] In cases involving the use of a sperm donor the plaintiff clearly intended to become pregnant, which undermines the basic theory of "wrongful conception" claims.[97]

**ii. Wrongful Birth**

In a wrongful birth action, plaintiff alleges that they wanted to become pregnant, but did not want to give birth to a child with defects.[98] A claim for wrongful birth arises from the argument that the parents would have opted not to conceive or would have terminated the pregnancy had the doctor properly advised them of the child's risk for defects.[99] Damages for wrongful birth actions are commonly the difference between the cost of raising a healthy child and the cost of raising the existing unhealthy child.[100] As with wrongful conception, some states refuse to recognize this cause of action for moral and policy reasons.[101] Even in states that do recognize wrongful birth, the use of the wrong sperm or less desirable sperm does not always

[93] *Fulton-DeKalb Hosp. Auth. v. Graves*, 252 Ga. 441, 314 S.E.2d 653 (1984).
[94] *Id.*
[95] NOTE: Malpractice Claims Resulting from Negligent Preconception Genetic Testing: Do These Claims Present a Strain of Wrongful Birth or Wrongful Conception, and Does the Categorization Even Matter?, 39 Suffolk U. L. Rev. 773
[96] *Id.*
[97] *Id.*
[98] *Id.*
[99] *Id.*
[100] *Id.*
[101] NOTE: Whose Sperm Is It Anyways In The Wild, Wild West Of The Fertility Industry?,34 Ga. St. U.L. Rev. 847.

produce an unhealthy child.[102] The resulting child is most often perfectly healthy, just having different superficial attributes than the parents had desired.[103] The issue becomes more complex if the donor has heritable physical or mental health problems, but the child has not yet manifested any problems and only has a certain probability of developing the problem. Courts have grappled with how to properly award damages in these scenarios. Courts are also unwilling to make any damage calculations based on the theory that a child born from one sperm donor is worth less than one born from another donor.[104]

### iii. Malpractice

Sperm banks primarily operate independently from fertility clinics or other medical practices.[105] After the parents select the sperm through the bank, the sperm bank delivers the donor sperm to the medical practice for insemination.[106] The doctor has no more of a way to know whether or not the delivered vials contain the correct sperm than do the parents. Plaintiffs can only bring malpractice suits against medical professionals, so if it was the sperm bank that caused a mix-up of sperm the plaintiff cannot bring a malpractice claim because sperm banks and their employees are not medical professionals.[107]

Malpractice suits could be appropriate in the cases of doctors using their own sperm to inseminate patients since the doctor is the party committing the deception.[108] While plaintiffs could easily prove the duty and breach aspect of a malpractice claim in these cases against

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[102] *Id.*
[103] *Id.*
[104] See Zelt v. Xytex Corp., 766 F. App'x 735, 738 (11th Cir. 2019). See also Jaqueline Mroz, *Their Children Were Conceived With Donated Sperm. It Was the Wrong Sperm.,* (June 3, 2019) https://www.nytimes.com/2019/06/03/health/sperm-banks-fertility-artificial-insemination.html.
[105] NOTE: Whose Sperm Is It Anyways In The Wild, Wild West Of The Fertility Industry?,34 Ga. St. U.L. Rev. 847. (Many fertility clinics will have a "preferred list" of sperm banks they recommend, but normally the clinic and sperm banks are entirely seperate entities)
[106] *Id.*
[107] *Id.*
[108] FOOTNOTE NEEDED (need to find which Law Review article this came from)

doctors, the same issues as discussed above will arise with characterizing the injury and calculating damages. The feasibility of malpractice claims in this context, and the lack of legal recourse against doctors specifically is largely outside the scope of this comment.

### iv. Contract

Contract claims are of minimal use to parents in cases where they receive the incorrect or "lower quality" sperm. Even if the parents prove that the sperm bank breached their contract, the sperm bank can often avoid legal liability by relying on the doctrine of excuse, which applies when the breaching party's failure to perform "causes little material harm."[109] Where incorrect or "lower quality" sperm is used, parents might be required to prove that the resulting genetic qualities of the resulting child differ *materially* from the agreed upon terms of the contract.[110] Parents will have to prove that these unwanted genetic qualities "are not merely incidental to the contract they signed but that go to its very purpose."[111] If argued correctly, parents potentially stand some chance of recovery if the resulting child has inherited a genetic disease or deformity as a result of the sperm bank's actions. Parents in these situations may be able to successfully argue that they contracted for a healthy child free of genetic diseases, and that it was a material breach for the sperm bank to furnish an unhealthy child. However, this legal theory would be inapplicable to the types of incidents that are more likely to occur where the child is healthy but possesses a different genetic makeup than the parents intended. In cases where the child is healthy but having undesirable superficial genetic qualities the parents must argue that they did not just contract for sperm to produce a healthy child, but for sperm to produce a healthy child

[109] ESSAY: REPRODUCTIVE NEGLIGENCE, 117 Colum. L. Rev. 149, 174 (January, 2017).
[110] *Id.*
[111] *Id*. (citing *Jacob & Youngs, Inc. v. Kent*, 129 N.E. 889, 890 (N.Y. 1921). (holding that where builders had used a different brand of pipes than the one specified in the agreement, and the pipes used were of the same quality, contract law afforded the property owner no protection.)

with specific genetic qualities: sperm to produce a child with no inherited predisposition for mental illness, sperm to produce a white child, sperm that is likely to produce a child with a specific physical attributes. These types of arguments will likely be quashed by the materiality doctrine.[112]

Looking to another aspect of contract law, courts will not typically award damages to compensate for mental distress or emotional trauma resulting from a breach of contract.[113] However, most jurisdictions recognize special circumstances in which damages for emotional distress are recoverable.[114] These circumstances arise where the defendant knew or should have known of the special circumstances at the time the defendant entered into the contract. These contracts are those that are "related to matters which concern directly the comfort, happiness, or personal welfare of one of the parties, or the subject matter of which is such as directly to affect or move the affections, self-esteem, or tender feelings of that party." Courts have held that such mental or emotional distress claims are appropriate for cases of contracts for mortuary and crematorium services, or contracts for childcare.[115] Mental or emotional distress contract claims are arguably appropriate in cases involving wrongdoing on the part of a sperm bank. It is undoubtedly upsetting for parents to discover that the father of their biological child is not the person they selected. This selection of donor is a deeply personal choice. The mother in particular may have emotional distress claims because of the violation she may feel after she was inseminated with sperm other than the sperm she chose.[116] It is possible that emotional and

[112] ESSAY: REPRODUCTIVE NEGLIGENCE, 117 Colum. L. Rev. 149, 174 (January, 2017).
All major sperm banks have parents sign a boilerplate contract stating that any specific genetic characteristics are not a guaranteed "term" of the contract.
[113] CONTRACTS TEXTBOOK
[114] CONTRACTS TEXTBOOK
[115] CONTRACTS TEXTBOOK
[116] Elaine S. Povich. *Fighting Fertility Fraud: New State Laws Go After Misuse of Sperm.* Pew, July 3, 2019, https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2019/07/03/fighting-fertility-fraud-newsstate-

mental distress claims could be recoverable here. However, damage calculations for these types of claims are still difficult, and as a matter of public policy courts may be opposed to allowing parents to claim that their child has brought them emotional or mental distress.

### B. Public Policy Concerns

Any private legal action against sperm banks in these incidents is going to necessitate a finding of an injury and calculation of damages. The ultimate "injury" in these cases is a child with a different genetic makeup than the parents had intended. As a matter of public policy, courts are reluctant to conclude that the existence of a child is an "injury" or to make calculations that one child is worth less than another.[117] What is the dollar value of a healthy child? How much less is an unhealthy child worth? How much less is a child with the "wrong" physical appearance worth? How much less is the biological child of a man with a criminal record and average IQ worth than the child of a Ph.D. candidate with an IQ of 160?[118] It is easy to see why courts fail to recognize these claims as legally cognizable. Courts do not want to stretch common law or statutory rights of actions past their outer limits to encompass this class of controversies that is impossible to ethically fit within the confines of existing doctrines. The court is best to defer to the legislature on these legal questions that encompass such profound public policy concerns.

### C. Creation of New Statutory Rights of Action

#### i. Emerging Concept of "Fertility Fraud"

laws-go-after-misuse-of-sperm. (A woman who was inseminated by her doctor's own sperm instead of her selected donor sperm commented "I felt like I was raped 15 times and didn't know it.")

[117] *See generally,* Zelt v. Xytex Corp., 766 F. App'x 735 (11th Cir. 2019).
[118] *See, e.g.,* Zelt v. Xytex Corp., 766 F. App'x 735 (11th Cir. 2019).

As stories surface of doctors intentionally using their own sperm instead of the promised donor sperm, or instead of the patient's husband's sperm, outrage at the limited legal recourse has led some states to push for new legislation that would criminalize what has been labeled as "fertility fraud."[119] This is a step in the right direction indicating that legislators understand the severity of this act, but this criminalization would only apply in the category of "Intentional Use Of Incorrect Sperm" and perhaps extending to severe misrepresentations in the category of "Intentional False Donor Profile." Many of the incidents that occur in the sperm donation industry seem to result from negligence: sperm banks are negligent in delivering the correct sperm to the correct parents, or in verifying the representations made by the donor. These "fertility fraud" laws would offer no protection to parents who were victims of mere negligence rather than malicious misrepresentations.

**ii. Public Policy Concerns with Creating a Statutory Right**

Legislators should be hesitant to create a statutory right of action that would give people a right of action based on the "undesirable" genetic makeup of a child. It seems appropriate that doctors and sperm banks that make intentional misrepresentations face some type of punitive action. As the comment will later discuss, a stricter regulatory scheme should exist with a punitive system for failure to comply with certain standards. However, giving parents a private right of action against sperm banks raises some major and unavoidable policy concerns. First, as discussed throughout the preceding section, the issue of damages will always raise ethical concerns in this context. More importantly, perhaps, is the concern of how such litigation would affect the child in question. It would be emotionally and psychologically devastating for a child to discover that his or her parents sued because they were unhappy with his or her genetic

[119] Sarah Zhang, *A Decades-Old Doctor's Secret Leads to New Fertility-Fraud Law*, The Atlantic, (May 7, 2019), https://www.theatlantic.com/science/archive/2019/05/cline-fertility-fraud-law/588877/.

characteristics. It is troubling to consider how the children at issue in cases like *Zelt* and *Cramblett* will feel when they are old enough to search their name online and read the claims of alleged damages their own parents made. Sperm banks should certainly be held to a higher standard. Parents who have been victims of misrepresentation or negligence by sperm banks are right to be upset. Nonetheless, the emotional and psychological well-being of the children in these cases seems to be too high a cost to pay for a statutory right of action.

## V. PROPOSED REGULATORY SCHEME

As demonstrated by the preceding sections, traditional legal remedies offer little recourse to parents. Existing private remedies cannot comfortably encompass the type of injury alleged in complaints brought by parents against sperm banks, and there are major public policy issues involved with legislators creating statutory rights of action. Sperm banks have been getting away with egregious acts of negligence and misrepresentation for decades, confident in their lack of legal accountability and shielded by the reluctance of customers to publicize any incidents because of the intensely private nature of sperm donation. The emphasis on donor privacy and anonymity makes transparency impossible: the very nature of sperm donation allows the industry to operate under the strictest secrecy.

Regulation is crucial where the nature of the industry prevents people from protecting themselves. Regulation becomes even more crucial where it is the only line of defense. Regulation is most important where, as here, there is minimal threat of civil liability, no criminal action, and little to otherwise deter actors in the industry from taking advantage of people.

Current FDA regulation of the industry is minimal at best. As discussed above, applicable FDA regulations focus on preventing the spread of communicable disease.[120] There

[120] FDA, *Donor Eligibility Final Rule and Guidance Q&A*, https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/donor-eligibility-final-rule-and-guidance-questions-and-answers (last accessed Fall 2019).

are no regulations unique to sperm banking; the FDA regulates sperm no differently than blood and organs.[121] The current regulations do not account for the unique genetic quality of sperm.[122] These regulations do not account for the fact that sperm banks are selling sperm online like a retail item on websites formatted similarly to online dating sites.[123] The FDA should implement a new regulatory scheme that is specific to gametes.

This section of the comment will propose a regulatory scheme intended to increase protections for parents by increasing accountability in, and oversight of the sperm donation industry.

## A. Who Should Regulate The Sperm Donation Industry

The FDA has broad regulatory authority and has responsibilities "closely related to those of several other government agencies." [124] Among other things, the FDA regulates biologics including blood and blood products, and tissue and tissue products. [125] The FDA considers human reproductive tissue, sperm and eggs, tissue products and, thus, sperm is currently regulated by the FDA. [126] It seems appropriate that the FDA continues to remain the regulating authority of sperm. One might argue that the Federal Trade Commission (FTC) would be an appropriate regulatory authority. The FTC regulates advertising and "protects consumers by stopping unfair, deceptive, or fraudulent practices in the marketplace.[127] There are clearly pervasive issues of misrepresentation and deception in the sperm donation industry, and the

[121] *Id.*
[122] *Id.*
[123] *Id.*
[124] FDA, *What Does the FDA Regulate*, https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate (last accessed Fall 2019).
[125] *Id.*
[126] FDA, *Reproductive Tissue Donation*, https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/what-you-should-know-reproductive-tissue-donation (last accessed Fall 2019).
[127] FDA, *What Does the FDA Regulate*, https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate (last accessed Fall 2019).

sperm donation industry operates much like any other distributor of a consumer good. Consumers of donor sperm could potentially stand to benefit if the FTC applied its standards and regulations to the sperm donation industry. However, the creation of human life is far more complex and important than almost any other consumer transaction. Being that the FDA is already involved in the regulation of sperm, albeit only minimally, it seems most appropriate that the FDA continue to be the regulatory authority overseeing the sperm banking industry.

An alternative option would be to create an independent regulatory agency, like the UK's HFEA, to oversee and regulate all embryo and gamete operations.[128] This is a compelling option given the unique characteristics of gametes, but this would be a huge leap to go from no regulation unique to gametes, to an entirely new regulatory agency devoted specifically to the industry. Making such a drastic jump in degree of regulation is just unrealistic at this time. As scientific advancements increase the number of ART options, and as gene editing of embryos looms on the horizon, the feasibility and necessity of creating such an independent regulatory agency to specifically oversee gametes and embryos may increase.[129]

## B. Recommended Regulation

### i. Goals

The overarching goal of the recommended regulatory scheme is to increase protection for consumers of donor sperm. New regulation would achieve this goal by increasing oversight of and accountability in the sperm donation industry. Before articulating a regulatory recommendation, it is important to consider the specific aims of the regulation. What is the

[128] *See infra* 86
[129] Emre Selli, *Scientific Priorities for Assisted Reproduction in the 21st Century*, (Feb. 20, 2019), https://www.ivi-rmainnovation.com/science-priorities-assisted-reproduction-21st-century/

regulation trying to prevent and require? What restrictions and requirements would protect consumers from the harm they currently face in the industry?

It is helpful to consider each of the previously articulated categories of incidents resulting from sperm banks' conduct to determine what types of regulatory measures could prevent or minimize each type of incident. First, "Unintentional False Profile" incidents are a result of an omission by the sperm bank—a result of the sperm bank's failure to adequately confirm the background information the donor has provided about himself.[130] Regulations that set a standard for how sperm banks confirm donor information could help prevent this type of incident.

The second category of incidents, "Intentional False Information," is the result of an affirmative act by the sperm bank. The sperm bank is either publishing donor information it knows to be false, or the sperm bank itself is encouraging the donor to provide false information, or the sperm bank is just unilaterally publishing false information onto donor profiles.[131] Since this is an affirmative act by the sperm bank regulators cannot prevent it by implementing more stringent confirmation checks of donor information; this type of conduct must be deterred by the threat of some punitive action. Without much threat of legal remedy, there is currently little to deter sperm banks from exaggerating or outright lying on donor profiles to increase profits by listing more "desirable" donors.

The third category of incidents, "Unintentional Switch," is a result of negligence by the sperm banks. Some error in recording, labeling, storage, shipping, or the like results in a doctor inseminating the mother with sperm from someone other than the donor selected.[132]

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[130] See, e.g. Ariana Eunjung Cha, *The Children of Donor H898*, WASH. POST (Sept. 18, 2019)
[131] See, e.g., Zelt v. Xytex Corp., 766 F. App'x 735 (11th Cir. 2019).
[132] See, e.g., Jaqueline Mroz, *Their Children Were Conceived With Donated Sperm. It Was the Wrong Sperm.,* (June 3, 2019) https://www.nytimes.com/2019/06/03/health/sperm-banks-fertility-artificial-insemination.html. (describing an incident where a mother was inseminated with sperm other than that of the donor she and her partner selected).

Unfortunately, accidents like these are sometimes just the result of unavoidable human error that would be unpreventable even with extensive regulation. However, some regulatory standards should require that sperm banks be using modern and effective systems to minimize the likelihood of error.

The fourth category, "Intentional Use of Wrong Sperm" can only be prevented by creating a punitive system within the regulatory scheme to deter such behavior. As discussed throughout the preceding sections, there is no existing legal remedies to hold doctors or sperm banks accountable for these actions. The same punitive system that would effectively deter intentional misrepresentations would be used to deter intentional use of wrong sperm.

In all categories of incidents, the secrecy that necessarily surrounds sperm donation allows the sperm banks to continue to get away with this type of conduct. Sperm donors and parents rely on and expect anonymity; the privacy of the donor and of the parents and their resulting children are at the core of the entire process. Sperm banks can easily blame the secrecy and lack of transparency on the need to protect these privacies, but it instead offers cover for sperm banks to continue to get away with practices that would not likely be tolerated in any other industry. Some implementation of facility inspection is essential to ensure that sperm banks are operating in accordance with regulations since consumers have no way of overseeing this themselves.

There are four overall objectives for increased FDA regulation for sperm banks. First, to implement a system of confirming information provided by donors. Second, to enact punitive actions to punish and deter intentional misrepresentations or intentional use of incorrect sperm. Third, to require certain standards for labeling, organization, and distribution practices. Fourth, to establish a system for the inspection of facilities and practices at those facilities.

### ii. Donor Profile Verification Requirement

Sperm banks must verify any donor information represented on the donor's profile. Regulations need not require that specific types of documents or other type of proof be produced. However, verification must involve getting tangible proof from either official documentation or confirmation by an appropriate third party. Regulations would ideally list examples of appropriate verification practices: requiring official transcripts from claimed educational institutions to prove degree, GPA, or honors; requiring W-2s to prove employment in a specific field; requiring official reports from testing organizations to prove SAT scores or IQ; requiring medical files with no gaps greater than eighteen months to verify medical background. Sperm banks would not need to use these exact methods of verification to comply with regulations. For example, perhaps the sperm bank could receive a list of all pertinent medical history from the donor's doctor,[133] so the sperm bank need not comb through the donor's medical history itself. [134]

Under this proposed regulatory scheme Xytex of the Xytex v. Zelt case would have violated the requirement to verify donor profile information.[135] Xytex failed to verify degrees, current educational program, and testing scores of the donor.[136] Xytex could have asked for a number of different types of easily accessible proof—transcripts, bills, official score reports, etc.—to verify the claims made by the donor.

[133] The donor would have to give permission for his doctor to release this information to sperm banks as not to violate HIPPA.
[134] Not all of a donor's medical history would be relevant to sperm banks, only history pertaining to heritable issues. For example, if a potential donor had a severe knee injury it would be unnecessary for the sperm bank employees to read through pages and pages of medical reports pertaining to this injury because this would have no effect on donor's potential offspring.
[135] See, e.g., Zelt v. Xytex Corp., 766 F. App'x 735 (11th Cir. 2019).
[136] *Id.*

The regulations should also state that donors may rely on any documents or other form of proof provided per the bank's requirements so long as it is not unreasonable for the sperm bank to do so. If a donor had somehow provided falsified documents, the sperm bank should only be found to have violated FDA regulation for publishing this information to a donor profile if it was unreasonable for the sperm bank to rely on the document or form of proof. For example, it would be unreasonable for a sperm bank to rely on an "unofficial" transcript as proof of enrollment in an educational program. However, a sperm bank would have fulfilled their duty to reasonably verify the information if an official transcript with the seal of the institution or delivered by the institution was found to be falsified; it would not be unreasonable for a sperm bank to rely on such documentation.

In addition to requiring sperm banks to verify donor information, the proposed FDA regulation would further require sperm banks to disclose its method of verification to parents. The flexibility in the regulatory scheme would allow each sperm bank to decide what specific forms of proof it wants to require donors to present. Some banks will likely do the bare minimum to comply with this verification requirement while other banks go above and beyond this requirement. Regardless, sperm banks must indicate what it means for information to have been "verified" means at their facility. Does verifying a donor's educational status mean obtaining three separate types of documentation confirming the degree, or does it just mean getting a single transcript? Either method would be in compliance with regulation, but parents have a right to know what method was used in screening the biological father of their child. Some parents may be comfortable relying on just the minimum regulatory requirement while other parents may want—and be willing to pay more for—additional assurance. FDA

regulations would require the sperm bank to make its donor verification procedures clearly known on each donor profile.

The regulations would also require that the sperm bank disclose its method of verification for each piece of information with sufficient detail so that parents are not confused or mislead. For example, many sperm banks make claims that donors have undergone genetic testing. The general public may not understand what "genetic testing" means in this context. Sperm banks will almost certainly be testing for specific known, high-risk traits; banks will not be running a full genome test on every donor. This means that sperm banks can confirm whether or not the donor has a high likelihood of passing on the certain heritable diseases that it specifically tests donors for. However, the donor could still have a high likelihood of passing on a heritable gene for some trait that was not being tested for. Full genome testing is not necessary or practicable. It *is* necessary for parents to understand that when a sperm bank indicates that a donor's genetic testing did not indicate any heritable diseases, or only had a low risk of some disease, that it does not mean that the donor has been tested for every possible heritable disease.[137]

If a sperm bank is unable to verify certain claims made by the donor, this donor need not automatically be excluded from becoming a donor. The sperm bank may still allow the man to donate sperm, but the donor profile must not reflect any information that is not verified. However, family medical history is a piece of information that most parents want to know but is impossible to verify. Verifying this information would require privacy waivers from not just the donor, but his parents, siblings, and grandparents; obtaining medical history verification from all of these people is just not feasible.[138] Therefore, sperm banks may disclose the donor's reported

[137] What are Whole Exome Sequencing and Whole Genome Sequencing, NIH, https://ghr.nlm.nih.gov/primer/testing/sequencing (last accessed Fall 2019).
[138] Men likely do not share their decision to become a sperm donor with many people in their lives. These relatives of the donor may also be unwilling to share their full medical histories for this purpose.

family medical history on the donor profile—otherwise this information could never be included on donor profiles. However, sperm banks must make it clear on the profile that the family medical history is only reported by the donor and not able to be verified.

### ii. Specimen Storage and Maintenance Requirement

New FDA regulation should require that all sperm banks utilize a computerized system to organize, maintain, and distribute specimen. All specimen containers should be labeled with a barcode—or an equivalent—and an alphanumeric code. Anytime a specimen is collected, stored, moved, or distributed the barcode should be scanned for verification by a computer program, and the alpha-numeric number should be checked by the human employee. This would also create a computerized record of any date and time the specimen was moved. Each time parents select a donor the donor profile should be linked to the alphanumeric code and barcode which should be fixated automatically on the parents' order or profile. This computer-dependent system would help to prevent mix-ups like the one in *Cramblett v. Midwest Sperm Bank* where the plaintiff claimed that sperm bank labeled specimen with pen and paper. With the advanced state of computer technology there is no excuse for sperm banks to not use a computer program to ensure accurate specimen handling.

### iii. Punitive Action for Intentional Misrepresentations

FDA regulation should outline a punitive cause of action for sperm banks and employees who knowingly or intentionally advertise false information about donors on the donor profiles.[139] Regulations should classify such acts as "misbranding."[140] Fines and/or criminal action should be determined based on the nature of the misrepresentation such that misrepresentations about

[139] 21 U.S.C. § 331. Prohibited Acts.
[140] *Id.*

something more superficial, like educational degree, are punished less severely than misrepresentations about medical or mental health background.

These punitive actions should also apply against any medical professionals—doctors, nurses, etc.—that are responsible for inseminating women with donor sperm. If a doctor were to knowingly or intentionally inseminate a woman with the incorrect sperm, the doctor would also be subject to any fines or criminal action. This addition to the regulations would provide parents with some opportunity for punitive action against the doctors who used their own sperm to inseminate unknowing women. Perhaps future legislation will allow parents to bring more severe "fertility fraud" criminal action or malpractice actions against doctors who take these deliberate deceptive actions. For now, including this venue for punitive action against medical professionals will give parents at least some method of recourse.

**iv. Enforcement Action**

Failure to comply with FDA standards should result in enforcement action.[141] The level of the enforcement action by the FDA should be aligned with the nature and seriousness of the violation.[142] A first instance of failure to comply with standards where there was no resulting harm (harm being a parent conceiving a child with misrepresented or incorrect sperm) would result in a warning letter.[143] Instances where harm did occur as a result of negligence—inadequate steps to confirm background, or inadequate specimen management resulting in a switch—but not an intentional misrepresentation would result in a fine.[144] Incidents where harm

[141] FDA, *Enforcement Action*, https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act (last accessed Fall 2019).
[142] *Id.*
[143] *Id.*
[144] *Id.*

occurred as a result of misrepresentation would result in a higher fine.[145] The FDA could file injunctions against sperm banks to cease noncomplying actions.[146] Seizures and destruction of specimens could occur if the FDA believed specimens to be mislabeled or misbranded.[147] Sperm banks could lose FDA licensing all together after repeat violations.[148]

### v. Inspection

Currently, only New York State requires inspections of sperm donation facilities. Ongoing inspection of facilities and practices is the best way to ensure compliance with standards. Inspection is especially important in an industry such as the sperm donation industry where the emphasis on anonymity and privacy allows the industry to operate with effectively no transparency.

Under the proposed regulatory scheme sperm banks would be subject to biennial inspections as well as unannounced inspections. During inspections, an FDA inspector would be ensuring compliance with both donor profile verification requirements and specimen maintenance requirements. To inspect specimen maintenance programs the inspector would observe employee practices in collection, storage, and distribution. The inspector would ensure that the sperm bank was using an appropriate computer program, employees were being trained in proper specimen-handling procedures, and that employees were actually adhering to these procedures.

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[145] *Id.*
[146] *Id.*
[147] FDA, *Enforcement Action*, https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act
[148] *Id.*

Inspections for compliance with donor profile verification requirements would be a bit more tedious. Overall, the inspector would be looking to confirm that the information on donor profiles was actually verified by the sperm bank and that the verification process was accurately represented to the parents viewing donor profiles. This would require the inspector to observe three different aspects of the sperm banks operations. First, the inspector would observe donor interview procedures to see that employees are asking donors the right questions and gathering the correct preliminary information. Second, the inspector would review randomly selected confidential donor files and compare them to the donor profiles on the sperm bank's website. The inspector would be looking to see that every piece of information on the donor profile was corroborated by some compliant verification document. Third, the inspector would review the website and profiles to ensure that the method of verification the sperm bank has promised parents is the method the sperm bank actually used; if the sperm bank says educational background was verified by a transcript and a diploma photocopy then the inspector needs to find both of those documents in the sperm bank's file on the donor. If a sperm bank is found to be in violation of any of the regulation requirements, then an appropriate enforcement or punitive action would be taken.

### C. Potential Limitations of Proposed Regulation

#### i. Over-regulation

It is important to strike a balance between too little and too much regulation over an industry. Too little regulation and consumer safety and protection are at risk, but too much regulation also has serious economic costs, the brunt of which falls on the lowest income

consumers.[149] Assisted reproductive technologies in their loosely regulated state are already quite expensive, and many commentators note that assisted reproductive technology is a luxury only available to the wealthy.[150] Lower income Americans facing medical or social infertility already struggle to access ART. Enforcing regulatory requirements in the sperm banking industry will unavoidably raise expenses for sperm banks which they will pass off to consumers in increased prices. While the wealthy will be unaffected by the increase, this increased expense will make donor sperm even more burdensome or entirely unaffordable to lower income parents.

### ii. Under Regulation

When compared to the UK's HFEA, this proposed regulation seems under inclusive.[151] As discussed above, the UK has an independent regulatory agency, a national sperm donor registry, and a limit on the number of families that a donor may create.[152] This comment has already discussed the infeasibility of jumping from no unique regulation for the sperm banking industry to establishing an entire independent regulatory agency. A limit on the number of families that a donor may create is important.[153] There are concerns about accidental consanguinity from a population-genetics perspective.[154] The American Society for Reproductive Medicine recommends a limit of 25 births per a population of 800,000 but, of

[149] Adam Millsap, *Too Much Regulation Hurts America's Poor,* (July 23, 2019) https://www.forbes.com/sites/adammillsap/2019/07/23/how-too-much-regulation-hurts-americas-poor/#3a2411bf271f
[150] Ada Dieke, et al., *Disparities in Assisted Reproductive Technology Utilization by Race and Ethnicity* (June 2017), accessed at, https://www.liebertpub.com/doi/abs/10.1089/jwh.2017.6467?journalCode=jwh
[151] Supra (talk about HFEA stuff)
[152] National Gamete Donation Trust, *Donation and the Law,* http://www.ngdt.co.uk/sperm-donor/donation-the-law/ (last accessed Fall 2019).
[153] American Society for Reproductive Medicine and Society for Assisted Reproductive Technology, *Recommendations for Gamete and Embryo Donation: A Committee Opinion* (2012), accessed at https://www.reproductivefacts.org/globalassets/asrm/asrm-content/news-and-publications/practice-guidelines/for-non-members/recommendations_for_gamete_and_embryo_donation-noprint.pdf
[154] *Id.*

course, there is no assurance that this recommendation will be followed.[155] Tracking the number of children born from a donor requires parents to report if insemination is successful, but there is no assurance that parents report births resulting from purchased sperm.[156] The biggest obstacle to complying with this recommended limit, however, is the reality that each sperm bank operates entirety independently.[157] There is no national donor registry, so a donor's sperm may result in however may births at one sperm bank, but then the donor can go to another sperm bank, say he has never donated before, and there would be no way for the sperm banks to know of the other donations and conceived children.[158]

Implementing a national sperm donor registry system has its pros, including allowing an enforced limit on births per donor.[159] A national registry would also increase regulatory oversight and would arguably be a good addition to the proposed regulations above.[160] However, national registries tend to decrease the number of men willing to donate sperm.[161] Donating to a private, independent clinic seems to make men feel more comfortable with the anonymity of the whole process.[162] As with creating an independent regulatory agency, creating a national donor registry would also be a fairly big leap from virtually no regulation of the sperm industry. Creating a national registry should be a long-term goal for improving regulation of the

[155] *Id.*
[156] *Id.*
[157] *Id.*
[158] *Id.*
[159] National Gamete Donation Trust, *Donation and the Law*, http://www.ngdt.co.uk/sperm-donor/donation-the-law/ (last accessed Fall 2019).
[160] National Gamete Donation Trust, *Donation and the Law*, http://www.ngdt.co.uk/sperm-donor/donation-the-law/ (last accessed Fall 2019).
[161] ARTICLE: THE CASE FOR AN UNREGULATED PRIVATE SPERM DONATION MARKET, 20 UCLA Women's L.J. 1
[162] *Id.* For a discussion on how direct-to-consumer genetic testing has effectively eliminated the possibility of total donor anonymity, *see* NOTE: DIRECT-TO-CONSUMER GENETIC TESTING, GAMETE DONATION, AND THE LAW, 55 Fam. Ct. Review 472

sperm donation industry but implementing a basic system of standards and enforcement is a more realistic primary goal for the time being.

## VI. CONCLUSION

An increasing number of same-sex couples, single women, and infertile couples are relying on sperm donation to grow their families. The current FDA regulation does nothing to deter negligence and misrepresentation, and the harm parents suffer does not align with existing common law legal remedies. These deficiencies undermine the parents' control and autonomy in a field where parents have no choice but to place total trust in sperm banks and their employees. Since creating legal remedies that classify the birth of a child as an injury raises substantial ethical and policy concerns, regulation is the best way to protect parents. A regulatory scheme that increases oversight and accountability in the sperm banking industry will be a major step towards taming the "wild west" of assisted reproductive technologies, and making the sperm donation process more reliable for the parents who must rely on it to grow their families.