

Citizen Petition

January 1, 2017

The undersigned submits this petition under 10.20 and 10.30 of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs to request the Commissioner of Food and Drugs to issue regulations.

A. Action Requested

Because the FDA currently mandates minimal medical testing of sperm and egg donors (no other regulation exists), we request that the commissioner of the FDA look into the state of affairs surrounding the sperm donation industry, and then develop the appropriate and much needed regulation/oversight.

B. Statement of Grounds

Challenges Faced by Donor Conceived People and Their Families Show Need for National Regulation of Cryobanks

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Introduction:

Cryobanks give women and couples who were once not able to have a child, the opportunity to conceive - the ability to start or grow their own family. The great majority of sperm bank customers are LGBT people and single women procuring donor* gametes as a way to build their families [3], while a smaller percentage of sperm bank customers are infertile couples. According to the Center of Disease Control, impaired fecundity (the inability to have a child) affects 18% of men who have sought help for fertility (594,000- 846,000 men) [14]. Although not all want or require donor gametes, the need and desire for cryobanks continues to grow, and challenges in the field are becoming more apparent.

The infertility industry is a multibillion-dollar, largely unregulated industry [9]. This lack of regulation has led to many issues for donor conceived people, their families, and their donors [4,6]. The wide variety of practices and procedures and the loose interpretation of "recommended" policies have led to many issues at a psychological, medical, and community level. These issues arise due to lack of consistency with medical testing, health history follow-up, sharing and updating urgent medical information,

openness and transparency, and record keeping and communication.

1. Medical Testing and Health Follow-Up:

Currently there are few or no regulations in the donor conception industry governing genetic and medical testing and the follow-up of health issues. According to the Donor Sibling Registry (DSR), 60% of the issues reported to their organization are medical in nature [12]. These medical issues can be categorized by time of medical necessity: (1) pre-conception, and (2) post-conception.

Pre-Conception:

Pre-conception medical and genetic examinations allow for more informed decisions and reduced unexpected health problems with donor-conceived offspring. The Food and Drug Administration requires donors to be tested for eight types of “communicable disease agents and diseases” and the American Society of Reproductive Medicine (ASRM) has genetic testing “guidelines” for cryobanks [1,16], as adhering to the ASRM is voluntary. In a survey of seven US cryobanks, all of the banks reported that they perform blood tests, “genetic tests” and a medical screen on each donor [12]. Although they responded to a survey saying that they “completed the tests”, all banks do not perform the same tests nor do they keep records consistently.

There are also no standards related to the communication of the test results for the donor or the recipient. This has become apparent through reports and testimonials collected by the Donor Sibling Registry [6].

In the statement below, a customer relates frustrations that her donor conceived child suffers from a disease that could have been prevented with proper pre-conception medical testing of the donor. This statement is one of thousands on file with the Donor Sibling Registry and one that also resulted in a lawsuit. [19]

*Although sperm donors are referred to as “donors” they are compensated for each sperm donation.

"I have had numerous health problems since birth with my NECC conceived daughters. The doctors suspected cystic fibrosis, which is a hereditary condition and can only be found if both parents are carriers. I knew that I was a cystic fibrosis carrier and that was the primary reason I had looked to a sperm bank in order to get a screened donor. Before buying the sperm I had asked very carefully about their cystic fibrosis screening; I was assured that every donor was screened.

After the doctor had raised the issue of cystic fibrosis, I contacted New England Cryogenic Center and asked for the details of the donor's screening. However, they have been unable to produce any proof that they screened for cystic fibrosis. Did they forget to screen? Deliberately lie about the screening? Or did they mislay the results? Any of those scenarios is very scary."

-New England Cryogenic Center Parent, 2005

For 16 years on the Donor Sibling Registry (DSR) families have shared their personal testimonies showing the need for policy change regarding shared medical information in the cryobank industry. For more than a decade, beginning with the Polycystic Kidney Disease case of Johnson v. California Cryobank in 2002^[8], several lawsuits pertaining to medical issues have also been filed. In 2016 Collins vs. Xytex^[11] claims Xytex's negligence in properly representing the medical and social history of a donor. The common donor for the Xytex lawsuit was said to have been screened and checked, but was later found out to have schizophrenia, which may have been caught by genome sequencing. Currently, there are 23 known donor conceived children from this donor^[2].

Cryobanks may attribute both excessive cost and assumed privacy concerns for donors as rationale for not providing full genome sequencing as a standard benefit to consumers. Whether or not there is evidence to support this claim, 84% of 1700 surveyed recipients said that they would be willing to pay more for sperm that had undergone comprehensive genetic testing. Furthermore, 94% of 164 surveyed sperm donors would have accepted an offer for genetic testing, had it been offered by their sperm banks^[1]. The reality is that cryobanking is becoming somewhat of a retail service: in order to protect customers, prevent health issues, and improve health standards, full genome sequencing for donors should be mandated protocol.

In the donor conception industry, there needs to be more comprehensive standardized testing and regulated sharing of medical information with donor recipients. The DSR recommends that The American Society of Reproductive Medicine amend its stance on full genomic testing, which is not currently recommended^[1]. Mandating genomic testing would allow recipients to make the most informed decisions when choosing a donor.

Post-Conception:

Along with medical and genetic testing pre-conception, it is important to have requirements regarding medical updates from both the donor conceived child and the donor. Currently, out of seven major cryobanks in the U.S. none require medical updates^[12]. From a group of 164 surveyed sperm donors, 84% have never been contacted by their clinic(s) for medical updates^[3]. Many

cryobanks recruit donors from universities, a relatively young age demographic [12]. The self-reported health history is no more than a snapshot of one day in the life of a healthy college-age donor. Because many major health irregularities are adult onset and do not present themselves until later in life, this poses a great risk to the recipients of sperm-donations, who are likely receiving incomplete medical histories for their future children, if they are receiving any at all. In the instances that a donor learns more about his or her health after donating, it is important that there are systems in place to update and share necessary information with their biological children.

DSR testimonials report that oftentimes cryobanks do not contact families when an illness is reported by a donor or by other recipient families. Sometimes this is because the cryobanks do not have accurate records about the children born from any one donor, so contacting families to alert them is therefore impossible. For example, a recipient learns that her sperm donor has a genetic predisposition for a genetic disease:

"California Cryobank did not act in a morally responsible manner regarding my donor. When a genetic link was discovered in a disease that was in the donor's family, the donor disclosed this information to the sperm bank. I only found out about this when I went to order more sperm and was told that the donor was no longer available. California Cryobank did not contact me, or the one other donor parent that I'm in contact with. When I asked why they didn't contact me, I was told that they didn't know who had conceived with the sperm. It would have been responsible to notify all purchasers of the sperm, it's an important piece of our children's health history"

California Cryobank Parent, 2007

There are also circumstances where the donor conceived child may need critical health information about their family history to improve their quality of life or medical outcomes. For instance, this Xytex customer was unable to receive the family health information desired for medical care:

"At age 5, my daughter was diagnosed with a brain cyst. During the process the neurosurgeon needed critical medical information on the donor we used at Xytex. Xytex was adamant that they would not help unless my child was in medical life threatening danger, with proof that genetics was the cause. Imagine knowing that your child has to be on the brink of death, with proof of a genetic problem, for them to help."

Xytex Cryobank Parent, 2009

"Our donor passed on a potentially deadly genetic disease to two children (twins) and sadly one of them passed away at 15 months old. Fairfax did not notify the families of this disease and has only notified those who are storing sperm at their facility, or who has called to find out why the donor has been terminated (no longer listed on their website). It's unclear if any other kids (we've found 10 so far) will get this disease. It's worrisome that if a child was born ill to a family who wasn't notified about this disease, they could die because swift treatment is essential and it isn't a disease that would immediately be suspected because it's rare. "

Fairfax Cryobank Parent, 2004

In 2004, the Surgeon General along with additional agencies from the U.S. Department of Human Health and Services, launched the Family Health History Initiative, a national public health campaign to encourage all families to learn more about their family health history^[16]. This campaign exemplifies that at a national level, family health history is an important screening tool.

Donors should be required to regularly update their current medical, genetic and social information in a donor data bank. Information in this donor data bank would then be available to share with families and the information would be available quickly and reliably.

In the medical field there has been an increasing demand for the standardization and efficiency of health records through patient rights acts and the transition to electronic record keeping. It would serve useful for cryobanks to model their care off of the pre-existing framework in the medical field. One of the key features implemented with the Affordable Care Act is a Patient Bill of Rights. The Bill of Rights standardizes information provided to patients so they can make more informed choices about their health plans and care along with setting a requirement for minimum care^[15]. If cryobanks were to implement a "Bill of Rights" it would allow for recipients to ensure that they are given any valuable health information (pre and post-conception) and that the information received is both accurate and standardized.

Additional pre-existing framework from the medical field which cryobanks should also model off of is the requirement of electronic records. In the medical industry, the Health Information Technology for Economic and Clinical Health (HITECH) Act was passed in 2009, "to improve health care quality, safety, and efficiency through the promotion of health IT, including electronic health records (EHRs) and private and secure electronic health information exchange"^[18]. When HITECH was passed, medical industries were given financial incentives from the government when they transitioned to electronic records before the deadline. After the deadline, medical industries were charged for not adhering to the standardization. Because many cryobanks still operate with paper records, implementing regulation with record keeping would allow for better tracking, quality and safety of donors, and ultimately, healthier children.

In order to make cryobanks safer and more reliable for the next generation, the DSR recommends policy that would: (1) standardize and expand preconception testing, (2) standardize protocol to ensure that consumers are informed about test results and the source of the data, (3) mandate full genome sequencing, (4) require medical, genetic and social updates, and (5) require electronic record keeping

2. Openness and Transparency

Currently, cryobanks in the U.S. offer gamete recipients the options of using an anonymous donor or an open donor^[12]. An open donor is a donor who is willing to be known once the donor conceived child turns 18 years old. An anonymous donor is guaranteed (by the cryobank) anonymity after donating; the gamete recipient and the donor will not know the identity of each other. However, with DNA testing, social media and Google, no donor should ever be guaranteed anonymity. It is now common for donors to be found via commercial DNA testing websites (donors do not need to DNA test themselves in order to be found) and with the Internet. While preliminary research has shown that open donor contracts are more successful for the psychological development and well-being of donor conceived children, we are now hearing that "open" donation policies and effectiveness varies from sperm bank to sperm bank^[12]. Many people who bought "open" donors are finding out that their

donor has changed their mind, their donor refuses to reply to contact, or that the sperm bank can't locate the man 18 years after donating.

Anonymous Donors:

There are several reasons that recipients and donors may choose anonymity rather than open donors. One of the reasons is the additional financial burden for recipients to use an open donor. All seven cryobanks surveyed charge recipients more to have an open donor [12]. Some banks also charge for additional information about the donor such as a personal statement or a recent photo.

Another potential reason for recipients and donors to choose anonymity is that banks lead them to believe it is truly confidential. However, with modern technology and access to DNA tests, true anonymity is virtually impossible to maintain. Ryan Kramer, Co-Founder of the Donor Sibling Registry was conceived using an anonymous donor, but through DNA testing was able to find his biological father in 2005, so this is not recent news. JLH Evers, the Editor-In-Chief of the journal *Human Reproduction*, just this year acknowledged the end of donor anonymity, "Due to genetic testing donor anonymity does no longer exist" [7].

The Donor Sibling Registry membership currently includes more than 52,500 parents, donors and offspring. This 501©3 organization has helped to facilitate mutual-consent contact for more than 13,825 donor offspring with their half-siblings and/or their donors on the DSR website.[13] Additionally, offspring who have located donors through Internet searches or DNA testing are sharing this information with all contacts made on the DSR. A false guarantee of anonymity and confidentiality can lead to situations where families and donors can feel unprepared and overwhelmed.

The umbrella of perceived anonymity also limits the amount of oversight required of the cryobank. This lack of policy effectively lets the cryobank industry off the hook for a myriad of issues and complex challenges being experienced by donors, recipients and offspring. The below testimony is just one example of the side-effects of this 'don't ask don't tell' policy in the cryobank industry:

"Not only do they "not check", but California Cryobank actually falsified my donor's education in order to make him more appealing to me. He in fact had no college, but they (not he) wrote in 1 year. They also changed the check box from curly to wavy hair because they knew that was what I was looking for. Those are only the things I've been able to verify, so who knows what else they lied about. Yes, getting rid of the screen of anonymity they've been able to hide behind can only be a good thing for the consumers and for our kids."

- California Cryobank Parent, 2008

Along with donor fraud, perceived anonymity makes it easier for cryobanks to create false impressions of donors. For example, California Cryobank has compared donors to celebrities. Arbitrarily comparing donors to celebrities distracts recipients from the lack of information being provided about their donor. Though it is exciting to imagine that your child could look like Brad Pitt, the information being provided is inaccurate, and gives false hope of what a conceived child will look like.

In 2010, California Cryobank commented on their celebrity comparisons: "They are judged to be the best of our subjective abilities... It could be that the donor's eyes

resemble one look-a-like, his chin resembles the other and his mouth is shaped like the third's."

"Our donor has celebrity matches on the California Cryobank site. He's a good-looking guy, but not a movie star, and it made me angry, to see that they're using professional beautiful people to sell "normal" people. At first, I didn't really see any resemblance, but then I sat down with pictures side by side, and after looking for a bit could say "Oh, they chose this celebrity for a match on this specific feature." If you don't have all the information (recipients and kids), you'd never figure out which features from which celebrities were a match to the donor's."

-California Cryobank Parent, 2010

Overall, the promise of anonymity limits the capability to regulate the accuracy of donor information.

Open Donors:

The alternative to an anonymous donor is an open or "willing-to-be-known" donor. Open donor policies are supposed to allow the child to learn the identity of their biological parent at the age of 18 [10]. Open donor agreements should hold both banks and donors to a higher level of accountability, which should be the standard for all donors and donor banks. If both the donor conceived child and the donor are able to talk, it is less likely that there would be donor fraud or inaccurate information on the donor profile. Currently, open donor processes may allow, only many years later, for communication about medical issues or questions that may occur.

Open donor contracts could require that there is a structure in place to facilitate communication at any time. Simply put, this extra element of regulation in the industry would benefit donors, recipients, and the 'unwilling' and voiceless participants, that are the children born through a cryobank system. Examples of this pre-existing framework can be found in open donor contracts. Many egg clinics are already writing the Donor Sibling Registry into their contracts so that parents and donors are connected (anonymously) right from pregnancy or birth. Medical information, photos and private messages can be shared right from the start, as the need for a middleman is removed. Sperm banks can follow the same framework, 18 is an arbitrary age, (not based on any study results on the psychological needs or best interests of the offspring), as many donor offspring have questions and desire to connect long before the age of 18 [3].

In addition to increased accountability, there are also psychological advantages to having an open donor. Survey results show that 83% of offspring who are not in contact with their donors, wish to be [3]. The average age of posted donor conceived people on the DSR is currently 15 years old. Currently, sperm bank policies mandate that donor conceived children are unable to contact their donor before the age of 18, likely due to the claimed legal responsibilities and liabilities of banks. [12]. However, Kramer et al. show that identity formation happens long before a child reaches the age of 18 [4]. Open donations not only allow for necessary communication, but also for healthier identity development of donor conceived children; it would be beneficial to allow contact before the age of 18.

One of the concerns for removing the option of anonymous donors is that some cryobanks claim that this will decrease the number of donors. However, Human Fertilisation and Embryology Authority

(HFEA) numbers in the UK have shown an increase in sperm donors since identity disclosure went into effect [5]. Furthermore, the Donor Sibling Registry has found 11 countries that have successfully banned anonymous gamete donation, and supplies this as evidence to the contrary. This includes an increase in donors also reported in Australia [5]. Further evidence will be required to effectively make the claim that the industry would suffer from this type of regulation. Even if donor numbers drop, do the ends always justify the means? Is anonymous sperm donation harmful, unethical and violating the rights of the children? If so, a drop in the numbers of donors as a trade off to ending an anonymous practice that has been harmful to donor conceived people around the world might be an appropriate consequence.

The national regulation that would end anonymous gamete donation would benefit all stakeholders in the cryobank industry. Until formal policy is implemented, cryobanks would benefit from incentivizing open- donor contracts by removing financial burdens and by properly educating donors about their legal and financial protections. Ultimately, this type of policy will create a system that will support the psychological development and well being of donor conceived children.

3. Record Keeping and Communication

In order to increase the openness and contact between cryobanks and donor families, there needs to be mandated standardized record keeping and communication. Cryobanks should use their records similarly to medical records to track the health of donor conceived children, and donors in their system. Lack of policy regarding record keeping perpetuates issues with communication, medical follow-up, and donor fraud. The current state of record keeping does not allow accurate tracking of donor conceived children, sibling groups, families, or donors.

Lack of standardized record keeping and communication is apparent when facts about the donor are different than what was initially communicated to the family pre-conception:

“Well, I’m in a state of shock and dismay. I went online to Xytex...As I was rereading his information I was stunned to find this: right there in the beginning information on him is the horrible news that he is listed as a NO to being part of the donor identity program. This was the MOST IMPORTANT aspect to us in choosing a donor and we asked our fertility clinic for a listing of ONLY those donors they had on hand from Xytex that were listed as YES donors and took them at their word. This leads me to believe that someone provided incorrect and terribly life altering information for us.”

-Xytex Cryobank Parent, 2005

The number of offspring per donor is not consistently tracked which leads to large groups of half-siblings. 9% of the issues reported to the Donor Sibling Registry are related to large groups of half-siblings. Large groups can be harmful to families because of the possibility of random meetings (consanguinity), because of medical issues and for psycho-social reasons [3]. The max number of children per donor claimed by cryobanks is ever growing, and now ranges from 15-60 [12]. The Association for Reproductive Medicine recommends a max of 25 kids per donor per population of 800,000 [1]. (For a city like NY, this could mean hundreds of children allowed for one single donor.) However, you cannot limit the number of children born to each donor without accurate record keeping and reporting. There are many groups

larger than the maximum recommendation.

"I was pretty overwhelmed when I was pregnant and found your site (the Donor Sibling Registry). There were 50 kids listed for my donor. It is probably getting closer to 200 now."

-Fairfax Cryobank Parent, 2012

The group of 150 reported to the New York Times in 2011 now consists of around 200 half-siblings [13]. There isn't any mandated policy ensuring that banks keep record of how many donor conceived children have been born from their bank, and there is no way for banks to check if a donor has donated at any other banks. Currently, some banks ask on the prospective donor form if they have donated at other banks. If they say they have, they will not be able to donate which would eliminate their financial reward for donating. Banks have no way to check if someone has donated before. In two published studies, surveyed donors reported that between 22-27% of them had donated to more than one clinic. [4]

Donors should be tracked by their social security numbers for easier access and recording of information ie: number of births, medical records. Having a central donor ID database that contains donor's social security numbers would be useful for sperm banks across the world to ensure that a donor hasn't donated at any other clinics.

In order to accurately track the number of donor conceived children, there also needs to be a policy mandating the reporting of donor offspring births. 45% of sperm donor recipients had no request by the sperm bank or clinic to report the birth of their child(ren) [3], and some sperm banks report that only 20% - 40% of recipients report back their live births. This leads to an unknown number of donor-conceived children and more chances for large groups to occur. A central databank should also contain the information on recipients and offspring to accurately track the number of donor conceived children born to any one donor.

In order to limit the number of large group issues and to increase the information and knowledge and ultimately support donor conceived children, there needs to be (1) tracking of all recipients, donors and births and safeguarding of all records in a central data bank indefinitely. The information needs to be accessible by all involved families, (2) mandated reporting of donor-conceived live births from each donor, and (3) limits on the number of births conceived with the sperm from any given donor.

Conclusion

The donor conception industry is a largely unregulated industry with wide variation in donor bank policies and procedure. Issues that arise are due to lack of consistency with medical testing, health history follow-up, sharing and updating medical information, openness and transparency, and record keeping and communication.

Many of these issues are not unique to the donor conception industry. The U.S. Federal Government has already acknowledged the importance of quality medical electronic record keeping (HITECH), Patient Bill of Right (ACA), testing for communicable diseases and agents (testing requirements from the CDC), and screening for family health history (The Surgeon General's Family Health History Initiative).

However, these federal regulations don't address the complexities within the donor conception industry. There is a great need for more oversight and regulation of donor banks.

There are additional international policies that could be used as a model for regulations. For example, the U.K. has the Human Fertilisation and Embryology Authority (HFEA) to regulate the donor conception industry.

In order to improve medical and psychological outcomes of donor conceived children, a regulatory body should be formed in the U.S. to mandate and oversee policy for sperm banks. The current variation in sperm bank policies and procedures leads to issues at a psychological, medical, and community level. It is necessary for both recipients and donors to be fully educated and informed when making the decision to either conceive a child or to donate sperm.

There are many complexities associated with creating a regulatory body, and implementing policy for donor banks. Effective policy change can occur by involving and educating a wider audience, including all stakeholders. Such stakeholders would include the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the Center for Disease Control (CDC), the Donor Sibling Registry (DSR), cryobanks, parents, donors, and donor conceived people.

Proposal for regulation of cryobanks would include:

Medical:

- Standardize and expand preconception testing.
- Standardize protocol to ensure consumers are informed about test results and the source of the data.
- Mandate full genome sequencing.
- Require medical, genetic, and social updates.
- Require electronic record keeping.

Openness and Transparency:

- Ban anonymous gamete donation.

Record keeping and Communication:

- Track all recipients, donors and births and safeguard all records in a central data bank indefinitely. The information needs to be accessible by all involved families.
- Mandate reporting of donor-conceived live births from each donor.
- Limit the number of births conceived with the gametes from any given donor.

It is in the best interests of donor-conceived children that we take action to develop more regulation in the donor conception industry.

Note: We have only addressed sperm donation in this paper, but most of the recommended policy is also relevant for the egg donation industry.

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C. Environmental Impact

We hereby claim a categorical exception from this requirement per 21 C.F.R. 25.30.

D. Economic Impact

We shall provide this information to the Commissioner upon request.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

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