FDA CITIZEN’S PETITION COMMENTS

1. I am strongly in favor of increasing regulation and oversight for the Assisted Reproductive Technology industry.

2. The cryogenic industry is in dire need of regulation. Our cryobank has been unable or unwilling to locate our "identity release" donor for 6 months now, despite all requirements/paperwork being in order, and does not return phone calls or emails regarding the status of our request to contact the donor.
However, with DNA testing we were able to locate the donor ourselves, only to learn that some of the original information we were provided by the cryobank was incorrect, including identity release status, ethnicity/religion, college information, SAT scores, and certain health information. This industry needs to be regulated so that donor information is factually correct and that the cry obanks are being forthright and honest in their dealings with clients.

3. The United States is one of the only developed countries on earth that is lacking crucial regulation and oversight of the artificial reproduction industry. There is ample research supporting the negative effects that this lack of regulation continues to cause. The FDA has a responsibility to put common sense regulations in place to ensure the safe and ethical creation of human lives by donor conception.

4. I work with infertile individuals and couples who desperately seek regulation of the sperm bank industry. They are very vulnerable. They would feel so much more secure moving forward with sperm donation if the industry was regulated.

5. I strongly support additional review of the donor gamete industry. I believe the FDA should engage in further investigation of the business of egg, sperm, and embryo donation as a basis for developing further regulation and oversight. As an academic who has studied and written articles and books about the fertility industry, I strongly urge you to undertake additional review. Thank you.

6. I reported to the sperm bank that my child was diagnosed with cancer (lymphoma/leukemia) the same week of his diagnosis and provided proof, so they could report it back to the donor and to the other families who had used the same donor. Almost two years later, none of the 11 families I am in contact with have been notified about my son's condition.

7. As a donor-conceived person who discovered this shocking fact well into adulthood, I fully support this petition. I consider each of the proposed reforms an immediately pressing step towards recognizing basic rights for this highly neglected yet growing population.
Also, I am grateful to have the active support of prominent diplomats to work towards international legal change. I fully support any change that recognizes that the inherently complex needs of children born via reproductive technology must be addressed first and foremost. This includes removing the several layers of secrecy and recognizing biological identity as a fundamental human right.

8. I strongly support regulation of the cryobank industry, especially limits on the number of births conceived with the sperm from any given donor.

9. I am a parent of donor-conceived children and therefore was a customer of the sperm donor industry. I reviewed a number of sperm banks, in particular looking for 'open donors' who would be willing to be known once the donor-conceived offspring turns 18.
It's shocking to realize that there are no regulations regarding record collection or keeping, or medical updates or medical information sharing, or tracking of offspring, or limits on offspring. It's past due for this to be addressed, and I hope that the FDA can bring some

desperately needed regulation. I fully support this petition.
Sincerely, Melanie B

10. Recent input from families who used California Cryobank. This information illustrates the dishonest manner in which sperm banks (California Cryobank is not unique in this respect) disseminate information about limits on numbers of offspring for any one sperm donor*:
"They told me in 2011 it was limited to 20 family units but they are now saying it has increased to between 25 and 30 family units." "In 2011 CCB also told me that they limit families of open id donors to 20 and anonymous donors to 25. " "Back in 2004 I was told that each donor had 10 vials and that was it. " "When I used CCB in 1999 they told me limited to 30 families- as of right now there are 30 kids. "In about 1990 they told me ten. I guess it just depends on who answers the phone!" "In 1991 they said 1 or 2 births was the limit." "In 2005 we were told the limit per donor was ten families " "In 2010, when we chose our CCB donor, we were told 10 families max." Note: When a prospective donor called CCB last summer and asked this question: "What is the maximum number of children that you allow per donor? California Cryobank told the prospective donor, "12 to 15 family units."

11. As a donor-conceived person, I fully support this petition and all of its recommendations. The sperm/oocyte/embryo donation industry needs more regulation. It's ridiculous to me there is no limit on the number of offspring a "donor" can have. When a single "donor" can have tens, if not hundreds, of offspring, there is a risk that the offspring could meet, be attracted to each other, and unknowingly have sexual relations with each other. It also creates the risk that a "donor's" defective genes could be passed down at a disproportionate rate, increasing the amount of disease in society as a whole. Thus, it is imperative that "donors" be fully screened and the number of their offspring limited.

Moreover, allowing a "donor" to be anonymous is unethical. In the world of adoption, society has acknowledged the benefit of open records for offspring, including their psychological and emotional health; sperm/oocyte/embryo donation is no different. Moreover, prohibiting anonymity will help ensure that the information sperm banks disseminate to customers about "donors" is truthful; they would longer get away with lying about a "donor" or exaggerating benefits to sell a vial of sperm because people would be able to finally verify the information for themselves. As noted in the Citizen Petition, banning anonymity does not automatically result in a shortage of "donors." Even if it did, I believe that is not too high of a price to pay. Anonymity should also be prohibited because, thanks to DNA testing companies like Ancestry, anonymity can no longer be guaranteed. Several of my donor-conceived friends have found their parents this way. I've spent more hours than I care to admit trying to use genetic genealogy to uncover my own roots. I'm appalled that I even have to use it in the first place though; I believe we all have a right to know where we came from, and that this information has been wrongly withheld from me. Also as requested in the Citizen Petition, it is important for records to be kept indefinitely to, inter alia, allow for pertinent health information to be shared. When I met with my mother's OBGYN, who recruited his own sperm donors, I was devastated to learn that he had no records related to my conception because the law did not require him to keep them. As a result, I have no health history whatsoever from my paternal side, which is terrifying. I worry not just for myself but also my own children. Extensive records are required for animal breeding, but when it comes to humans, there is nothing substantial. This must change.

12. We have just learned that our oocyte donor has Bipolar Disorder that could have been caught if she had been properly screened prior to donating in 1997. My 18 year old donor-conceive child just heard the heartbreaking news yesterday through the clinic psychologist where she was conceived. The physiologist said that if our donor had applied to donate now, she would have been denied. Fortunately, this clinic is now very active in pre-screening and is working hard to do post health screening also. No donor-conceived child should have to hear that they have a

genetic predisposition for a serious health problem when it could have been avoided.

13. Yes please! This is important. It's hard enough when families have to turn to a bank that takes a large sum for a single specimen but to not know what we're getting ourselves into, the lack of regulation is scary. It's a gamble many Americans are forced to take because of an inability to conceive between the two of them. There should be more regulation to make sure donors and their offspring are healthy, both mentally and physically.

14. I strongly support additional review of the donor industry. I believe the FDA should engage in further investigation of the business of egg, sperm, and embryo donation as a basis for developing further regulation and oversight. As an academic and practitioner in the health sciences, and a parent, I strongly urge you to undertake additional review. Thank you.

15. We used donor sperm that resulted in the creation of two beautiful children. We have been made aware now that there are over 100 children throughout the world but primarily within North America conceived using the same donor sperm. This is a clear example of the consequences resulting from a lack of oversight and regulation within the industry.

16. We used Idant, which did not do any psychological screening. By the donors own admission when meeting him 20 years later he suffers from bipolar disorder and was hospitalized as a teenager. My daughter suffers from bipolar disorder a highly genetic disorder. One of his other offspring completed suicide when she was eighteen. Another was in residential treatment as a teenager and then prison as an adult. He donated twice a week for two years. Talk shows have a certified mental health professional screen their participants. I think that companies that provide sperm should be held to that minimum standard to help avoid unspeakable harm to offspring.

17. The US is one of the last developed countries to address the need for oversight in the fertility process. I urge you to adopt strong regulations regarding this area.

18. My son had leukemia, my daughter was born with rare genetic anomaly only seen in her across the nation & internationally and my middle son has mental health concerns. The identity release donor
was able to be reached by the sperm bank but refused to get genetic testing when my daughter's doctors requested biological input from both me and sperm donor to identify if the genetic disorder is genetic/hereditary. We have no knowledge of my children could pass on genetic risks due to lack of medical history. Having regulations for sperm donors can increase the knowledge of factual genetic concerns when creating families through assisted reproduction. Please add vital regulations to this field of medicine!!!

19. I can hardly believe this is not being done already! I think it is imperative to have oversight of donors initially and to get updated information over time -- especially health information of the donor and his/her family. I hope the FDA will give this petition its thorough attention.

20. I recently wrote the following in support of this Citizen’s Petition to the FDA, submitted by Wendy Kramer, the founder of the Donor Sibling Registry. The purpose of the Petition is to persuade the FDA “to look into the state of affairs surrounding the sperm donation industry, and then develop the appropriate and much needed regulation/oversight.”
I couldn’t agree more.
As a physician and donor-conceived person, I request that the Cellular, Tissue and Gene Therapies Advisory Committee convene to review the concerns addressed by Ms. Kramer in this Citizen’s Petition. Currently, donated gametes are regulated as human cell, tissue, and cellular and tissue-based products (HCT/P) by the Center for Biologics Evaluation and Research (CBER) under 21 CFR Parts 1270 and 1271.[i]
Donated gametes are fundamentally different from other HCT/Ps in that they are not being used

to treat a disease – they are used to create new people. These individuals cannot possibly consent to the conditions of their own creation. Because of this unique circumstance, gamete donation must be considered separately from other HCT/Ps.

Current FDA requirements focus primarily on protecting the gamete recipients (ie., potential parents) from communicable disease. These requirements have repeatedly failed to protect the most vulnerable population – the children – from preventable adverse health outcomes that I describe below. Similar to Ms. Kramer, I focus primarily on sperm donation, though many of the concerns specified below are applicable to egg donation as well.

Hypertrophic obstructive cardiomyopathy (HOCM) is one of the most common autosomal dominant diseases with an estimated prevalence of 1 in 500.[ii] It typically presents in early to middle adulthood, and the first symptom can be sudden cardiac death in an otherwise healthy individual. Fortunately, early identification through screening of individuals known to be high risk can allow implantation of potentially life-saving automatic internal cardioverter-defibrillators (AICDs). Because there is no requirement that a record of live births be kept, there is no way to alert donor-conceived children whose genetic parent or half-sibling has been diagnosed. Far from speculative, this specific scenario has already happened and was extensively documented.[iii] As of 2009, at least one of these children has died. There is no way of knowing exactly how many children may be affected.

Additional genetic diseases transmitted to children from donor sperm, most likely unknowingly, include Autosomal Dominant Severe Congenital Neutropenia,[iv] Fragile X,[v] Long QT syndrome,[vi] and Lynch Syndrome,[vii] among others.

Excessive financial compensation has long been recognized as coercive in human subjects research. Advertising to prospective sperm and egg donors emphasizes the monetary gain from donating, providing incentive to not disclose medical history that might exclude them. One very recent, highly publicized case involved a former sperm donor who misrepresented himself as having a genius IQ and advanced degrees who was later found to have schizophrenia and a criminal record.[viii]There is currently no independent verification of personal and family medical history.

The true scope of these problems is impossible to know. Because of the following circumstances, we suspect these issues could potentially impact thousands of Americans, if not more:

1. Estimates of how many children are conceived using donor sperm in the US are based on data that is almost 30 years old. In 1988, it was estimated to be 30,000 offspring/year.[ix] We have no way of knowing how many people are created through donor sperm today, but if this number is at all accurate, over one million donor-conceived people have been born since 1980.
2. Frozen human sperm has been used up to 40 years after collection.[x]
3. Shockingly large numbers of offspring may result from a single prolific donor. One donor has been documented as fathering over 150 individuals, but the true number of his offspring is unknown, and may be much higher.[xi]
4. There is no standardized identification system for each donor, therefore one man can donate at multiple banks without disclosing this information.
5. Families are not required to register live births with the sperm bank. All other registries, such as the Donor Sibling Registry, are voluntary.

In recognition of these issues, other countries have changed their policies and increased oversight. For instance, the United Kingdom limits the number of children from a single donor to 10, mandating the identity of the donor be released when children turn 18, screening for genetic disorders, and providing donors with only modest amounts of money to cover expenses.[xii]

The American Society of Reproductive Medicine (ASRM) has published a list of industry recommendations, some of which address the above issues.[xiii] This is far from adequate as the recommendations are not binding, and sperm banks in violation of these recommendations suffer no consequences from either the ASRM or the FDA. **A wolf cannot guard the hen house.**

The FDA must act to protect children created through the use of donor eggs and sperm. A vital first step would be a meeting of the Cellular, Tissue and Gene Therapies Advisory Committee to discuss the issues raised in this document and Ms. Kramer's Petition.

[i] Tissue and Tissue Products, http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm, accessed January 15, 2017.

[ii] Shah, M. Hypertrophic cardiomyopathy. *Cardiology in the Young*(2017), 27(Suppl. 1), S25–S30.

[iii] Maron, B.J., et al. Implications of Hypertrophic Cardiomyopathy Transmitted by Sperm Donation. *JAMA* (2009), 302(15):1681-4.

[iv] Boxer, L.A., et al. Strong evidence for autosomal dominant inheritance of severe congenital neutropenia associated with ELA2 mutations*. J Pediatr* (2006), 148(5):633-6.

[v] Wirojanan J., et al. A girl with fragile X premutation from sperm donation*. Am J Med Genet Part A* (2008), 146A:888–892.

[vi] Heisel, W. *Code Unknown: Trying to connect with sperm donor through online community.* Center for Health Journalism, http://www.centerforhealthjournalism.org/2014/12/18/code-unknown-trying-connect-sperm-donor-through-online-community, accessed January 15, 2017.

[vii] *Sperm donor with genetic illness speaks out*, Copenhagen Post, http://cphpost.dk/news/national/sperm-donor-with-genetic-illness-speaks-out.html, accessed January 15, 2017.

[viii] Hauser, C. *Sperm donor's profile hid mental illness and crime, lawsuits say,* New York Times, https://nyti.ms/1SMA6rx, accessed January 15, 2017.

[ix] U.S. Congress, Office of Technology Assessment, *Artificial Insemination: Practice in the United States: Summary of a 1987 Survey—Background Paper*, OTA-13P-BA-48 (Washington, DC: U.S. Government Printing Office, August 1988). http://www.princeton.edu/~ota/disk2/1988/8804/8804.pdf, accessed January 15, 2017.

[x] Human Fertilisation and Embryology Authority. *Freezing and storing sperm*, http://www.hfea.gov.uk/74.html, accessed January 15, 2017.

[xi] Mroz, J. *One sperm donor, 150 offspring.* New York Times, https://nyti.ms/1Axj4VZ, accessed January 15, 2017.

[xii] Human Fertilisation and Embryology Authority. *HFEA agrees new policies about family donation and the number of families one donor can create,* http://www.hfea.gov.uk/6518.html, accessed January 15, 2017.

[xiii] Ethics Committee of the American Society for Reproductive Medicine. *Interests, obligations, and rights in gamete donation: a committee opinion,*http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Ethics_Committee_Reports_and_Statements/interests_obligations_rights_of_donor.pdf, accessed January 15, 2017

21. Our donor was a carrier of a rare genetic disease that we didn't find out about until I was pregnant. Thankfully our child was fine, but one of the donor children ended up having the disease. The sperm bank did not test for common genetic disorders such as SMA and cystic fibrosis.

22. In the end we are the voices for our children. For me providing both my children who were conceived using a donor with any and all information is best.

23. I notified the spem bank that I used to conceive as soon as I found out that my child had a unique form of epilepsy and mood disorder. Thankfully, the donor had already decided not to participate in the program any longer.

Also, I had chosen my donor for many reasons but one of them was that he, the donor, agreed to be known when my child turned 18. The bank contacted him but he stated he didn't want to be known and the bank supported his decision. My child was deeply saddened. We do know some of the other offspring of this donor. Some have no conditions, one has sever migrains similar to my child. However, some of the offspring decided to do Ancestry DNA and located a brother of the donor but have not opted to contact the "uncle". We may try that for closure.

24. I am a clinical psychotherapist who works with families who have used donors and banks to

conceive children. I am also a parent of a donor conceived now adult child. For thirty years, I have had a front row seat to the shameful consequences that come from Sperm Banks that placed profits over ethics. The Sperm Bank industry continues to be unregulated and has been allowed to flourish without governmental oversight. In a for profit world, where medical procedures, vulnerable parents trying to conceive and children are part of the equation, this seems like a dangerous combination

I have seen blatant deletion of vital medical information withheld from uninformed recipients. I've experienced myself the Banks changing agreements regarding limitations of the number of offspring of a given donor, without consulting with the families that will be affected by the change. These decisions and the many ways the Banks avoid limits on profiteering at the expense of basic ethics clearly benefit the corporation over the consumer.

For those of us directly affected by these decisions, the consequences have been great. Banks not sharing pertinent medical information has meant in some cases, children born with serious and life threatening illnesses and families now facing children with lifetime disabilities. Sperm Banks need oversight and regulation now - before another generation is negatively affected by profit, greed and anonymity. Knowing our biological roots and medical history is not a commodity to be bought and sold but a basic civil right.

25. I used an anonymous donor to conceive my son in 1992. When my son was 15 I was able to locate the donor and made contact, but he never responded. While researching his family tree, his sister made contact to tell me the family suffered from a genetic defect of the aortic root, resulting in aortic aneurysms in her mother and three brothers, including the donor who suffered an aortic dissection in 2007. He survived, but he never reported this genetic defect to the three banks where he donated. It is autosomally inherited, meaning that 50% of all children from this donor will inherit this defect. It is a silent killer. Most people don't know there is a problem until the aorta dissects, resulting in death 80% of the time. After having my son checked out at Johns-Hopkins, he also had an aortic aneurysm growing in his chest at the age of 17. It was surgically repaired, and he has to be followed with annual echocardiograms for the rest of his life. If I hadn't located the donor, and his sister hadn't located me, I would never have known about this potentially deadly genetic defect. I contacted all three sperm banks, but none of them would take my word for it, even though I had the donor's name and my son's doctor records. The sister had given me the donor's medical info, so I contacted his cardiologist and informed him that his patient had been a sperm donor. The doctor wrote a report and sent it to each of the facilities; they forwarded it to the families who purchased the sperm, resulting in seven more births being reported (although all the 34 children were now teenagers). I can only pray that all families are now aware and are taking steps to prevent a tragedy. This industry is all about making money; it does nothing to protect the children or families involved. If not for my own efforts, 34 children and their families would not know about this genetic defect. The banks don't ask for medical updates, and when they receive information, they often don't contact the families involved. This has been going on since the industry began, and it is time for a change!

26. believe the U.S. should implement a federal law limiting each individual donor to a limit of 10 offspring, or the offspring of 10 families. My cryobank told me there was a limit of 30 families when I purchased sperm, but then they subsequently raised the limit on my donor to 60 families. So my child is currently one of 90+ half-brothers and half-sisters, and we expect the final number to be at least 100 or 150 children. This isn't the fault of the donor, but of the sperm banks and the lack of regulation. My child will always have to check that prospective mates aren't her half-sibling before deciding to have children, and, much more likely, she may unknowingly form bonds with classmates, friends, coworkers and then discover they are her siblings. This situation should not be allowed to continue happening to further generations of donor-conceived children.

27. I am the parent of a donor conceived child. I had to report my son's birth three times over the years (I would occasionally call California Cryobank to see if there was any updated medical information from the donor) before it was finally in their records... The California Cryobank refuses to tell me how many other births have been reported. This industry writes its own rules, and some of the rules can change depending on who answers the phone at the cryobank.

28. I am the mother of a sperm donor conceived daughter. We are in contact with multiple of her siblings thanks to the Donor Sibling Registry. We are thankful that we have contact with some of her siblings. We know there are more out there but they do not choose any contact. It's unfortunate that they choose this because we share important health information with each other. Without regulation we will never know how many offspring are out there and what kinds of health information is not being shared. We also have no way to contact our donor without regulation. As our daughter gets older that will be important for us to have access to his ongoing health history to ensure we know about any genetic issues. I am also a social worker who practices the family finding model for state wards. I have heped connect kids with family members who did not know about them and have seen how much good that can do. Please consider regulation and abolishing anonymity.

29. The lack of record keeping by the banks are appalling. I have contacted ours at least yearly and they told me after nearly 6 years that I never reported my child's birth. They were surprised I was in touch with over 35 siblings and knew of at least 50, some within 3 miles of our home. With kids ranging from in utero to 10 years old, this donor is still available and they told me they can't get an updated medical history. The kids deserve to know what genetic issues they may have from their biological relatives. So many diseases are genetic, breast cancer, diabetes, colon cancer all have familial predispositions; it is their right to know. The banks do nothing to facilitate this information at all. Puppy breeding is more regulated than human gametes. As a medical professional I find it shocking and the FDA absolutely needs to regulate this.

30. I was promised an open donor but then when I reported health concerns the sperm bank retaliated by saying that they would never release his identity. So I had to use gentic testing to discover the donor's identity. I found a lot of inconsistent information about my donor once I knew his identity compared with the profile. Thank God my kids are actually healthy now, but the attitude of the sperm bank that I used was awful and concealing donor information ought to be illegal.

31. The egg and sperm industry needs to be regulated in order to protect all people involved, especially the children born of donated gametes. The industry is more about profits than science or health. A basic maximum number of families per donor and number of offspring need to be instated. Known donor or donor release should be made a requirement for all egg and sperm donations as it is proven to be best for the people born from those donations (see all the years of research on adopted individuals and now those conceived via donor. As a parent who chose to have a child via known donor sperm donation, a legal document that protects all parties involved at the onset of home inseminations would be very helpful.

32. I also support this petition. At the age of 31, after randomly taking an AncestryDNA test to gain greater clarity on my ancestry, I quickly realized through my results that my father was not my biological father. Several months later, my parents revealed that they had used a sperm donor to conceive my brothers and I (we are triplets). This has been the shock of my life and an incredible blow to my identity. What has shaken me even more profoundly, however, is the fact that, at this point in time, I have absolutely NO legal rights to information regarding MY OWN biological identity. The fertility doctor used by my parents, Dr. Lorraine Carole King, who had been operating out of Jefferson University Hospital in Philadelphia, PA, not only advised my parents prior to their fertility treatments to NEVER disclose our true method of conception (and, thus, biological parentage), but still to this day refuses to speak to me or provide me with any information regarding my biological identity. Her office, as of July 2016, has maintained that because I was not her direct patient, she cannot disclose ANY information to me whatsoever, and

she refuses to speak with me directly. Her office also maintains that ALL records, even non-identifying information about the procedure and donor (my own biological father), have been destroyed. My parents informed me that she even destroyed all records immediately after the procedure, thus never even maintaining relevant records for the required 10 years. We were born in 1984. Each of us has heritable medical conditions and zero access to our paternal medical records.

Every human should have the right to know their own biological parentage. This right was denied me at my own conception, and my right to know my own paternal biological family has been stolen along with it, all without any possibility of my own consent. This is knowledge that should be fundamentally mine, and at the very least, the manner of my conception should never have been made secret, certainly not after reaching the age of 18. For the medical industry to take part in a.) purposefully and irreparably separating biological family and b.) counseling social parents to keep this fact of separation hidden from their children, and c.) never notify said children once they reach adult age is CERTAINLY not living up to the oath of "Do No Harm". Over time, it is becoming increasingly apparent that open adoptions (and, likewise, open sperm donations) are best practice, resulting in healthier, better adapted offspring. As such, and due to the fact that while sperm donors may make the decision to rescind all natural rights to their offspring, their adult children never gave consent to subsequently have THEIR biological relationships, let alone right to biological family information, severed, I support putting an unequivocal end to the practice of anonymous sperm donation. Furthermore, all my life, I have been silently denied the right to know my own biological half-siblings, of whom there are probably many. I may never get the chance to know them, since I have no access to any information whatsoever regarding my donor (not even non-identifying information). I cannot tell you how much mental anguish this produces. Additionally, my ability to know and have a relationship with my paternal biological grandparents has also been stolen, as by this point, after 31 years of not even being allowed to know that they exist (thanks to the MEDICAL industry), they are likely already deceased. At this point in time, my only recourse for reclaiming my biological identity and salvaging what may remain of my paternal biological relationships rests with commercially available DNA testing platforms and my own research. So far, I have positively identified (through DNA) my paternal great-grandparents (by way of a biological paternal first cousin once removed, via a DNA test), and it is likely only a matter of time before I identify my parents' donor (my biological father). As such, and increasingly, the idea that the fertility industry can guarantee donor anonymity has essentially become a falsehood.

Our generation is quickly discovering the lies that we have been told, and the damage could not be greater. No one should be barred knowledge of how they entered this world, CERTAINLY not by the medical field. This practice needs to end. Please do the right thingthe ART and larger medical field can no longer feign ignorance to the harm done. More of us daily are coming of age and awareness of all that has been taken from us. We are also becoming aware that the medical industry actively colluded to deny us our biological families and identities. Please take action to restore our access to our identities and families, if not for us, then at least for future generations who can be spared this pain. It is within your power, and is the medical community's responsibility, to both right this wrong and find yourselves on the right side of history.

33. Regulation for sperm donation through the word is urgent, I am writting from Argentina where we receive sperm from USA banks

34. I am a sperm donor-conceived adult and I support this petition. Although I believe that progress has been made since the time of my conception over 40 years ago, there are still significant gains to be made so that donor conceived people in the present and future will have access to critical genetic information.

35. I am so grateful that I have a beautiful son through sperm donation. He has many donor siblings (upwards of 25 that we know of) and that is a whole lot! While we are happy for this big family, clearly there need to be limits on the number of offspring. Geography is also an issue;

some of my son's half-siblings live within ten minutes of each other. I also hope that the organization we obtained the sperm from will honor its ID reveal policy when the time comes. And the horror stories about incorrect medical information and inadequate and unchecked information are deeply disturbing. This industry needs regulation and it needs to be sooner rather than later.

36. Better regulations just make sense.

37. As a 21-year-old donor conceived HUMAN, I think it's embarrassing and incredibly unethical on various safety, medical, and humanitarian levels that the United States does not regulate this industry. When my sister got sick, there was no way for her to access potentially life-saving genetic information/history from the sperm bank because--when left to themselves--they act in the interest of money instead of the children they are helping to create.

Donor conception is rapidly becoming something that is no longer taboo or done in secret or shame. It is a legitimate method used by millions of families to have children, and the FDA needs to buck up, acknowledge this, and take some responsibility for the industry.

38. I am a parent of a DC child. I support this petition.

39. In 1992 I was inseminated by ReproLab in New York City. I chose a donor number 03SDO. The lab technician and his wife lived in my neighborhood and were expecting there child the same time and hospital as me. We met after the births of our daughters and I have a photo of all of us together. So Reprolab knew there was a live birth. Years later when DNA testing became common, I found out my daughter was not the offspring of 03SDO. It took an attorney, thousands in DNA tests and ten years for me to find which donor had been used. The upset and cost of there carelessness cannot be underestimated. I filed a complaint with New York State Department of Health who found against Reprolab (that Reprolab had violated New York State protocols of record keeping). But that also measn they may have violated requirements to test for STDs and other genetic anomalies. Reprolab is still in business, still lying to clients and NOTHING IS DONE. The United States has to put an end to commoditizing sale of sperm. Please help us do that. Strengthen penalties against banks that do not verify what they are told by donors, and don't limit the number of offspring.

40. I was an anonymous (as required by the fertility clinic) sperm donor from 1988-1990. Two years ago, I had an epiphany and contacted the fertility clinic and requested my donor number, which I'd long since forgotten. This simple request has been ignored. My intentions were honorable - indeed, an ethical obligation - to avail myself to the children who were conceived by my donations and provide them family medical histories and the opportunity to learn of their paternity and heritage. I submitted to the clinic a notarized release if confidentiality and waited. As I came to realize that the clinic was reluctant to facilitate contact (owing, I surmised, to general concerns over liability), I took a proactive approach.
One year ago, I learned of the Donor Sibling Registry and found a post by a birth mother 8 years prior. Fortuitously, I recognized its detailed description of the donor as my own. I made contact. The exchanges and gatherings that followed have been wonderful. I could not have imagined how important this connection is to my biological daughter! After we confirmed our relationship through DNA testing, I've since learned of two other donor conceived children and hope for a response from them to my AncestryDNA email messages. Surveying the hundreds of online registry posts by DC children and parents, I am shocked to find that there are only four other sperm donors in my home state of Oregon that have connected with their DC child(ren). I've read more than a thousand posts and blogs written by DC children throughout the U.S. and their words powerfully convey an interest in finding a sense of identity and, oftentimes, answers to specific questions. My heart goes out to them. My personal experience informs a heightened awareness of the rights of donor conceived children, of the responsibilities of gamette donors who may have presumed a right to anonymity, and of the compelling need for overdue regulation of an unchecked industry. The rights of DC children of all ages should not rest with lax records keeping,

voluntary disclosure of potentially life-saving medical information, and a passive acceptance of archaic fertility services practice. I urge you to consider this petition and promote higher standards of accountibility.

41. I wish this also included egg donation regulations. There are many young females involved in egg donation that there are no follow up on medically. There is also no way for donor conceived people to find out medical information from their donor. There are no studies of the long term effects of egg donation to the egg donor. DNA testing is the way people find their biological family of donor conceived. They will find cousins, uncles, and their donor.

42. This is a hugely important initiative from the Donor Sibling Registry. As a professional and researcher in this field over many years and based in the UK, I am convinced of the need for regulation, safe storage of the information that donor-conceived people need and for having well resourced systems for releasing such information to them. It is the human right of every person to know the identity of their genetic, gestational and legal parents and this applies just as much to donor-conceived and surrogate-born individuals as to everyone else. Should the US acknowledge these rights in this way it would send a powerful message around the world.

43. I was an anonymous donor at the California Cryobank when I was in graduate school and medical school, as a non-anonymous option was not available. I joined the Donor Sibling Registry when I first heard about it, and I have been fortunate enough to hear from several children and their parents. I have even met some of them, which has been a uniformly positive experience. I have not encountered anyone who had undue expectations of our meeting and our communication. Instead, I have had the privilege to become acquainted with some children who are very much wanted and loved by their families and who are happy with their lives. The children simply want to understand more about their genetics and other medical information as well as about the origin of their personality traits. I support regulation of the industry in order to ensure that the children who result from donation will be able to access information related to their genetics and their heritage.

44. Having families with help of high tech procedures and donor gametes is in desperate need of regulation just like any other industry or business!!! It is unfathomable in this day and age when men, women, and couples use donor sperm, donor egg, or donor embryos to have their families that there is inaccurate or incomplete information about the egg, sperm or embryos donors. The agencies helping these families are doing a disservice to the families when medical and psychological screening is not thorough, donations are not regulated, births are not reported, and serious health problems, psychological disorders, and genetic diseases are not being reported either. Please consider the parents and children who are suffering because there are no regulations!

45. Fiom/ISS, a national Dutch Social work agency, supports the 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.

Fiom is a specialist institution when it comes to search for roots .We provide independent information on and assistance in questions regarding lineage information. In addition, Fiom helps people who are searching for biological family inside and outside the Netherlands and manages a DNA- database which enables matches in case of anonymous donor ship. Fiom shares knowledge with professionals through their website, training courses and consultations. The Dutch Journal of Medicine(Ned Tijdschr Geneeskd. 2016;160:D137) published a Fiom article about five years of experience with the 'Fiom KID-DNA database' and the matches that were achieved. In all our work (in regards to the donor industry and also with adoption cases) we conclude that being given a choice is fundamental for the wellbeing of whom it concerns. Anonymity and bad regulations frustrates free choice and leads to unnecessary grief and incomplete information about genetic diseases, with all its consequences.

46. I was conceived by anonymous sperm provision in 1951. An early one. I have long argued for

openness and an end to anonymity. I made an award-winning film about it.

A proper registry is the minimum that we offspring deserve. We have the right to know who we come from. Secrets and lies kill us -- literally. And anonymity is being defeated by cheap DNA testing, anyway. Create regulatory oversight using the HFEA as a model -- and END ANONYMITY. See this one hour documentary "Offspring", seen in 61 countries, about my search for my donor and my 500 half siblings.
https://vimeo.com/128603400

47. My two children are both donor conceived via donor insemination from the same anonymous donor. They are full siblings. I am their dad and their mom is their mom. We chose donor insemination as I suffer from non-obstructive azoospermia. They have two known half siblings both in single mom households who used the same anonymous sperm donor.

Each of these four children are lucky as to date we have seen no ill effects resulting from hidden health issues not disclosed by their donor on his profile forms. I have met and read many stories of multiple children born from a common donor that have developed various ailments and diseases. My kids are two of four and suffer no ill effects of having to cope with being one of 20. 30, 40 and in a number of cases 50 plus half siblings born from one single sperm donor. For too long the U.S. sperm donor industry has been run and regulated or rather non-regulated as commercial enterprises and not as health related organizations that must be held accountable and subject to oversight under common standards. The issue of anonymity needs to be addressed. The issue needs to be examined with an eye to Identity Release being available to the donor conceived offspring..

48. I was conceived via anonymous sperm donation in Canada in 1986. No medical information about the donor was ever made available to my family, and reportedly, the clinic my parents used destroyed donor records. The destruction of these medical records a set number of years after the mother's last visit to the clinic, well before donor-conceived offspring came of age, was considered legal because only the mother was regarded as a patient of the clinic with any right to that information not the offspring whose very genetic material those records pertained to. This policy was challenged in court, but the clinic's rights to deny donor-conceived offspring any information and even to destroy the relevant records were upheld. It is horrifying to me that the fertility industry was and is permitted to disavow any medical responsibility to the offspring they help produce, and that a paid donor's right to complete privacy is viewed as all-important, whereas my right to vital information about my own health is viewed as irrelevant. It's clear to me that these priorities are not motivated by any reasonable standard of ethics but by a desire to avoid liability for harm.

The harmful implications of this view have become especially clear to me in the last two years. My promising career in science was derailed in 2015 by the abrupt onset of Postural Orthostatic Tachycardia Syndrome (POTS) and Mast Cell Activation Syndrome (MCAS) following a severe allergic reaction. These two conditions have recently been found to co-occur frequently as a "disease cluster" among people with the autosomal-dominant genetic connective tissue disorder Ehlers-Danlos Syndrome (EDS). My doctors suspect that I have EDS as well, but family history is an important part of the diagnostic criteria, and there is nothing suggestive of a history of EDS on my mother's side, so I have been waiting for over a year to see a specialist who hopefully will be able to diagnose this condition without that crucial information. In addition to POTS and MCAS, EDS is associated with many more comorbidities, such as early-onset arthritis, Chiari malformation, heart abnormalities, and retinal detachment. If I did inherit EDS from my donor, as seems very likely to be the case, it's virtually guaranteed that some of the wide range of comorbid conditions would have occurred in his family history, even if he was never diagnosed with EDS himself. It is alarming to me that I have been at risk of so many medical complications for my entire life and had no indication of that because of the deliberate decision of a purported medical

practice to keep this information from me.
It is clear that this industry does not regard donor-conceived offspring as patients they have medical responsibilities toward, but as commercial products they wish to sell and forget with as little administrative hassle and accountability as they can get away with. This medical negligence is unacceptable. And that is to say nothing of the more abstract concept of the individual's right to know their own origins and heritage and the profound psychological implications of being denied that fundamental personal information. I have found that almost no one who wasn't donor-conceived or adopted is able to truly understand that aspect of the deliberate and systematic withholding of donor information, which is why I focus on the medical aspect. In my opinion as a donor-conceived individual, anonymous sperm and egg donation should be abolished. At bare minimum, providing adult donor-conceived individuals with comprehensive and routinely updated medical records, including family background, should be mandatory; however, the reality is that truly sufficient information and maintaining donor anonymity are mutually exclusive.
The practices of the fertility industry have been constructed over decades to accommodate the preferences of industry professionals, of the donors, and of the recipient parents. The best interests and medical needs of the people undeniably most affected by those practices the people they produce have been systematically ignored. Please do not allow this injustice and willful medical negligence to continue.

49. There absolutely has to be regulations on this. We recently found out that there's a possibility of 120 siblings for my child. Not only is this extremely shocking to us but I can't imagine what it will be like for the ID release donor. You have to put yourself in my shoes. How do you explain to your child but there is a possibility of 120 siblings? What if my beautiful daughter has a desire to meet him but she is the 120th in line? I can only imagine how quickly any communication would be dropped after the 120th call. It's unreal, it's a tsunami of emotions that I'm not prepared for. It is crucial that the number of donations be regulated to stop this from happening again. These children and donors have real feelings, they are real people. Regulation has to be enforced. Until children can give their consent to being raised without a connection to their biological father or mother, this practice should stop. The children, ultimately, are the ones who can be most negatively effective and their health and well being, needs and best interest ought to be driving any oversight on third party conception.

50. I donated sperm at the Fairfax Genetics and IVF Institute in Fairfax, Virginia, appx. 30 years ago. Over the years, I have repeatedly communicated with the Institute in efforts to obtain my own donor number - which would facilitate my connecting ONLY with any offspring who were interested and actively attempting to find me. The Institute continues its refusal to provide any information to me, including but not limited to, my own donor number, to what other clinics they sold my sperm, what offspring of mine have reached out to them in efforts to contact me, etc. Through the Donor Sibling Registry, I have met and built amazing relationships with two offspring (and their families) who had been searching for me. Yesterday, I met (on the phone) a third daughter!

51. Regulation of this industry is LONG overdue to bring about not-so-common-sense reforms protecting the humanity and consenting relationship of donors, donor offspring, donor siblings, the parents of donor offspring, and countless other modern family members.

52. Until children can give their consent to being raised without a connection to their biological father or mother, this practice should stop. The children, ultimately, are the ones who can be most negatively effective and their health and well being, needs and best interest ought to be driving any oversight on third party conception.

53. Animal breeding is far better regulated than the human sperm and egg donor industry. We currently have inconsistent genetic testing for disease, with documented cases of families receiving donor gametes that contain known genetic issues. We have inconsistent tracking and

no limits on the number of children created, resulting in hundreds of children from a single donor. We have no consideration for the feelings and needs of the human beings created through this process, who generally believe they (like other humans) have a right to know who their parents are and a right to be told the truth. None of these needs are supported or even considered under current regulations. This means that our current regulations are not in the best interest of the child or the family. The current situation is one of the fox watching the hen house, where the same industry that profits from infertility is allowed to regulate itself however it likes. This has resulted in a situation that does not serve the participants (donors), the consumers (infertile couples) and the children who should be at the center of everything we do. Instead of looking to horse breeding or blood donation, we should look to the regulation of adoption, since that is the only other process in modern society by which the genetic children of one person are raised by a different person. Donor conceived adults are not blood cells and we are not a new breed of animal. We are human beings and citizens with the same rights and emotional needs as all other human beings. Anyone who doesn't want to deal with the messy feelings of human beings should not be in the business of creating them.

I was conceived in 1967 with an anonymous donor and am now almost 50 years old. I will probably never know my genetic father but I would like to reform the system so that future generations are born into better circumstances.

54. Sperm/Egg donation banks and fertility clinics should be held to federal regulation and transparency for the sake of the offspring conceived through donations for medical and moral reasons...Transparency and TRUTH!

55. I donated semen for more than a decade in the 1980s and have numerous unknown, anonymous offspring. Beginning around the year 2005, I began to appreciate the unprofessional and exploitive terms under which my own donations were solicited, and by which they were provided to women who could not possible have provided informed consent. I have believed ever since that the lack of proper regulation of gamete acquisition and donation is a public health risk as well as an inappropriate and unnecessary abrogation of the human rights of the donor conceived children thus created. I support the Donor Sibling Registry petition.

56. This is long overdue!

57. To whom it may concern,

I am a donor conceived person with an anonymous donor. This means I will never know the person responsible for half of my genetic being. In fact, all I have is a single sheet of paper with basic facts: his hair, eye, and skin color. You know how many brown hair, blue eyed, white guys there are in the world? A lot. And I have to live my entire life wondering which of them I share 50% of my DNA with. While it hasn't ruined my life, I don't want others to know this heartache and mystery. I demand that you please take action-look at current regulations (or lack thereof) and regulate this industry so that children and adults don't have to wonder who they come from.

58. As the FDA currently mandates minimal medical testing (communicable disease, eg, STD's) of sperm and egg donors (no other regulation exists), I strongly recommend 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.
We know that couples do not only travel to other countries to undergo infertility treatment with donor sperm and egg, but that many sperm bank also send cryopreserved sperm abroad. So this is not only an issue of national, but of international concern.

59. I'm writing to show my support in the efforts to put regulation behind sperm donor facilities. It's important to the parents and future children that use these cryobanks to know that the donor they have chosen to create a human is truly represented in the paperwork surrounding the purchase of sperm for fertilization.

There are promises made by these cryobanks that say they can contact the donor during his lifetime to pass medical information along or for the child to contact once they reach adulthood. Families are trusting that cryobanks will do this. A promise is good but regulations would require this to happen.

60. I am a parent of a donor conceived child, and I support this petition whole-heartedly. I wish these regulations had been in place when I conceived. I particularly worry that our donor could change his mind at any point and decide that he doesn't want contact with offspring. From the very beginning that has felt like a gamble I'm making, and it's made me very uncomfortable. If you read anything at all about donor conception, you know that the opportunity for even a brief contact to have basic questions answered and look into the face of the person responsible for half of your genetic material is a question of well-being for these children.

We take an AWFUL LOT on faith in these donor profiles and on the part of the cryobanks. And it's too important not to have more assurances when assurances are actually possible. The only road block seems to be cost, and that is a criminal reason to leave the situation as is.

61. I am the parent of a donor conceived child through a California clinic. I deliberately chose open / willing to be known donors. However, our experience so far has raised considerable alarm.

Our egg donor is willing to be known and the egg donor agency facilitated a meeting prior to donation but it was supervised and we were not permitted to exchange identifying information or contact details. This is despite two consenting adults desiring and willing to be known to each other. The agency then refused to pass on any information to the donor, not even a thank you card notifying the birth of the child which did not contain any identifying information. They also refused to request some medical information requested by my child's pediatrician, despite the donor agreement stating that such information was to be sought. I have since found out that the egg donor agency does not have any process for connecting the donor conceived people to their donors, even after they reach 18 years old. The agency stopped responding to my emails, calls or letters within the first year after the donation. They still offer willing to be known donors and indicate that it is advantageous to the children to know their heritage.

The sperm bank offered open donors. There were supposed to be medical updates every year for 6 years. I asked each year but there was nothing. There is supposed to be a process when my child turns 18 where she can be put in contact with her sperm donor. The paperwork said that an open donor committed to at least one contact. However, I have since learned that people's experience of trying to make contact is a lengthy, frustrating process for many. Some do make contact, for others the bank says it is impossible. I have had to adjust my child's expectations on future contact which is hugely disappointing for her.

My donor conceived child would like to know all of her biological relatives, donors, extended families and half-brothers and sisters all of her life. We do know some half-brothers and half-sisters through the Donor Sibling Registry.

I would like there to be mandatory reporting of the identifying information for all donors and the resulting donor conceived people. This information should be held in a central, secure database and made available to biologically related parties on request. All eggs, sperm and embryos should also be tracked to their final destination.

Furthermore, all doctors, clinics, agencies recruiting egg or sperm donors or surrogates should do their due diligence as to the identity, qualifications, medical status, criminal record and employment history of these donors. These people are essentially being employed. Their employers should conduct reference checks such as any other employer would conduct to verify claims.

Donor conceived family groups tend to be significantly larger than average. It is very important that any reported health issues which may have a genetic contribution, whether or not proven to have been passed on by the donor, should be recorded and disseminated to the other donor conceived individuals and their families to enable preventive or diagnostic health checks to be conducted.

62. Please help provide more oversight for the sperm donation industry. They need more regulation and they need to be held more accountable! They can say and do almost anything they want, and there is quite a lot of secrecy. Men should not be allowed to father 30, 50, 100 or more children...especially if they can pass on inheritable disorders.

Thank you.

63. Dear FDA official:

As the Director of the Psychological Services program at the Duke University Fertility Center, I support increased oversight of egg and sperm donation and the cryobanks that make these important fertility services possible. In my work as a PhD Clinical Psychologist providing patient care to donors, recipients, and donor-conceived children, I regularly see the ways in which having more extensive, verified, and updated information on donors is vital. Other key issues that would be addressed with increased oversight/regulation include communicating critical donor medical information to donor-conceived offspring, enforcing limits on donors to prevent large numbers of children being born from one person, and decreasing risks of consanguinity when donor-conceived offspring inadvertently meet.

This type of record-keeping and communication of medically-relevant (sometimes medically-critical) information is done in other types of donation (i.e., organ) and in other sectors (e.g., agriculture; livestock breeding). The lack of record-keeping, vetting, and communication in gamete donation reflects an earlier era where the problem of infertility was simplistically framed as needing a "work around" with viable gametes and makes little sense in the modern era. We know better and now need to do better to protect the health and welfare of donor-conceived offspring.

Sincerely,

Julia T. Woodward, Ph.D.
Director, Psychological Services Program
Duke Fertility Center
Department of Psychiatry & Behavioral Sciences
Department of Obstetrics & Gynecology
Duke University Health System
919.572.8853

64. Please hold the (sperm donor) industry accountable. We should have the right to know where we came from and about our medical history. There are so many us that could be siblings, and we have no way of knowing, other then through DNA testing, as we try to find out families.

Thank You,
Donor Offspring 1953

65. I am a Canadian parent of a donor conceived child for whom the sperm came from a US sperm bank. I have many concerns for my son's future mental health and for the sperm donor industry as a whole. While I am thankful to have had this avenue to pursue becoming a biological parent, and I think there is a very important role for this industry to play in our society worldwide, there must be better regulation and oversight surrounding the sperm donation industry and a shift in thinking about the donor offspring who came into being due to this industry and the concept of anonymous donation.

I utilized the services of a sperm bank which provided the option for Open Identity Donors. Prior to becoming pregnant, asked questions about how such contact would be facilitated, to what lengths the bank would go to facilitate it, and on what terms, but I was met with very non-specific responses. Having no other options, I moved forward. However I fear that if such contact becomes important to my son once he reaches 18, the bank is not under any obligation to assist or in the meantime to maintain current records on the donor. Will we know if the donor develops any health concerns? Will we know of any donor siblings who develop any health concerns that could be hereditary and shared among offspring? Can we rely on the banks to facilitate the promised contact when my son turns 18? I expect the answer to all of these would be "no".

I also belief that anonymous donation should not be an option for donors. In fact, despite what the clinics may be telling their donors, due to the availability of DNA testing and the prevalence and ease of locating individuals through internet and social media research, anonymous donation is already a thing of the past. Donors and their families are able to be found with ease in many situations and donors should not be given a false sense of anonymity when it does not exist. Additionally, donors and their offspring should have the option and the right to contact at any age, provided both parties are amenable.

I have concerns over the number of donor offspring from each specific donor. I know that there is loose language from sperm donor clinics and fertility clinics about caps on the number of donor families permissible in a particular geographic region, but these numbers seem to fluctuate and also change from clinic to clinic and country to country with no concensus. And with no mandatory reporting from birth parents, and in fact no mandatory maximum number of offspring for clinics from government, how am I to believe that any numbers being kept or communicated from the clinics are accurate or even honest accounts. I already know that information about the numbers and locations of donor siblings which has been provided to me by the sperm bank are inaccurate due to communications I have had with other parents I met through the Donor Sibling Registry (DSR). There is no oversight of this aspect of the sperm donor industry and no compliance to the industry's own stated standards on record keeping and on self imposed caps on the number of families permissible from a donor in a specific region.

I would like to see more physical and mental health evaluation of donors. While the report received from the donor clinic for our donor is lengthy, there is no guarantee of its accuracy. My son has developed multiple non-life threatening health issues. Have some of these originated with the donor? Are there more health issues that I should be aware of and looking out for? There is no way of knowing as his health records are not verified by the clinic in any way. And do any of his other offspring have these same issues? I'll never know as there is no mandatory reporting or record keeping of such issues.

There needs to be more oversight, regulation, and policing of the sperm donor industry from government. The current self regulation is not enough and not enforceable. Families need to know that they are choosing donors whose profiles and whose mental and physical health histories are accurate and have been confirmed. They need to know that if contact with a donor is important to them, that the process will be reliably facilitated by the clinic or a third party. Donor conceived children need to have the ability to know where they come from and in fact, have the option to have contact with their sperm or egg donor much earlier than 18 years if both parties are amenable to such a relationship. And donors need to understand that their anonymity is no longer reality. I understand that some donor conceived children may not choose to pursue contact with their donors however they should have the option to have access to information from BOTH sides of their biological background. I hope the FDA will seriously consider establishing proper oversight and enforcement for this industry to the benefit of the donors, the offspring, and their families.

66. I am a single mother by choice via willing-to-be-known sperm donation. While I have had a largely positive experience with Pacific Reproductive Services (California), there is one thing that bothers me. I do not feel that they have been completely honest with customers about the number of reported offspring from their donors. In the beginning of my journey to motherhood, I asked a customer service representative, "How many children has this donor produced?" I was told that information could not be given out, but she could tell me that use of his sperm had indeed resulted in pregnancy. Well, a couple of years ago I was contacted through the Donor Sibling Registry by a woman who was interested in using the same donor I had used. I was told by this woman that PRS told her he had SIXTEEN known offspring. I would like to see policies put in place that mandate the banks tell customers how many offspring have resulted from a donor. Additionally, I would I would like to see a cap put on the number of children that a donor can produce. I believe most banks do have this policy in place. I don't, however, feel that all banks enforce that policy.

Another important issue that needs to be addressed throughout the cryobank industry is thorough pre-conception medical genetic testing for diseases. While my child has thus far not been the victim of any medical ailment, disease or disorder that was not expected, I am aware that many parents have been caught unaware when their children have been diagnosed with a disease that the donor passed on, something that could've have been tested for but was not and therefore was not in the donor's medical history.
To go along with this, it is also imperative that donors be required to contact their banks if any medical problems should arise.

Lastly, I would like to see the option to be an anonymous sperm donor taken off the table completely. When I made the decision to become a single mom by choice, I never had any other plan than to use a willing-to-be-know donor. This was solely for my child's benefit. We have a lot of information about his donor through the full profile and a short video interview produced by PRS, but I know that as he grows he will have so many questions that the video and profile can't answer. In his video, my son's donor states that he is more than willing to meet with his offpsring when they are 18 and that he's excited at the prospect. He states that by choosing to be a WTBK donor, it "puts the ball in their court" about when or if they should meet.

67. Dear Sir or Madam,

I am a donor conceived person. Unlike most people, I have no idea who my biological father is or who his parents, brothers, sisters, or cousins are. This is due to the industry under which I was brought into this world. The fertility is left in charge of monitoring itself, not regulating the amount of offspring created by one donor (sometimes into the hundreds), not checking the donor's credentials, allowing donors to be anonymous so that people will be born into this world with no information about who their parent is. Donors' health information isn't even checked so that multiple births affected with serious genetic disorder or disease can easily occur. The industry operates largely in secret, pretending to run the checks and balances but they do not. Worse yet is that no government official or department is there to intervene and stop this from happening. This is an outrage. As a donor-conceived person I ask you to please help ensure that this corrupt process and industry is regulated an that all donor conceived people are treated with dignity. Thank you.

68. Currently there are few or no regulations in the donor conception industry governing genetic and medical testing and the follow up of health issues. As a parent of a donor conceived teen, I believe there is a need for comprehensive medical testing and updating and sharing medical information at the very least. Our donor sibling group is very large (36+ known offspring) and we share medical information among ourselves but I would like to receive a medical update on our donor.

I also believe that it is in all parties best interest to eliminate anonymity. Donor conceived people have the right to know who contributed half their DNA. In this age of easy DNA testing there is no true anonymity anyway. Each child's level of interest in knowing more about their donor is different, but I believe that more transparency only benefits all parties.

69. As the parent of donor conceived children who are healthy, even for the mainstream parents--it wasn't until DNA testing revealed my two boys' high risk for prostate cancer in the future. What health disasters could be prevented if only there was a uniform standard in data, and not only that, a requirement for physicians and pediatricians to actually ASK on their forms if a child is donor conceived? Donor sperm and eggs should be screen as well as any other donated organ (and its actual result is creating a new human who has medical information rights.)

Having brought this petition before the FDA behooves it to take action and demand that sperm and egg banks stop their reckless and inconsistent behavior under the guise of revenue generation, and be responsible to the children born of donor material (after all, they are real people.)

70. As a parent of donor conceived children I went into this process not fully aware of all of the risks I was taking in creating life in this way. I expected that my government was exercising some level of regulation to ensure the ethical and safe creation of offspring. There is more regulation and oversight for our the conception of our full breed Siamese cat than my human sons. We need immediate regulation on this billion dollar industry.

71. I believe that donor sperm banks should be banned. Just because men can donate sperm for profit does not mean that they should do so. There are plenty of children who need to be adopted by loving parents.

72. I write in support of the petition of the Donor Sibling Registry to provide regulation and a minimum standard of practice in the assisted fertility industry. My interest in the subject comes about as a result of my experience as a sperm donor.

As a prospective donor I was asked to fill out a detailed questionnaire about personal medical history and family health history. Though I answered the questions honestly, I did note that there was no attempt to verify the information provided. For example, I reported that I had a graduate degree but I was not asked to provide a transcript or any other documentation in support of that claim. My report that my father had diabetes elicited follow-up questions as to whether it was type I or type II and the age at which he contracted the disease. These were all appropriate questions. But my report of the problem was volunteered. An individual who was strongly motivated to be a donor – you do get paid after all – could simply omit questionable health history without fear of detection.

As a young donor I had a clear health history. Some years later I submitted a sample to one of the now popular DNA genetic testing sites. The results of that test informed me that I am a carrier of a problematic syndrome. I do not know if this would presently exclude me from being a donor, but it would certainly merit testing a recipient to see if she was also a carrier. Contributions of this faulty gene from both parents would result in a serious complication for the child. If a genetic testing service can discover this problem for the cost of $99, should it not be a part of every donor screening?

My own experience provides an additional example of the advisability for regulation as it pertains to the need to limit the number of offspring per donor. Prior to my marriage and the birth of my child, I had zero history of mental illness in my large extended family. My wife also had no history of mental health problems in her family. Notwithstanding this background, our child has a serious mental illness. With this result, I have learned that I am six times as likely to produce a child with this malady as the average person. I dearly hope that none of my donor offspring share this life altering impairment. In fact, the odds in each individual case are good that they do not. But, if I had been one of these donors who was permitted to have 100 or even 200 children (these examples do exist), it is likely that there would be multiple individuals out there with this debilitating illness.

As the industry currently operates, answers that donors give to quite relevant questions are entirely on the honor system. Even if they are being completely honest, they may be unaware of genetic faults that can be passed on. Given these facts, what sense does it make to allow an individual donor to have dozens upon dozens of children.

Sperm banks do have a problem in finding suitable donors. Freezing and thawing sperm is not a natural process. It is expensive to find the relatively rare male whose sperm can be subjected to this process and still be there in sufficient quantities to fund the multiple vials that sperm banks wish to harvest from each sample. When they find that guy, especially if he has in demand characteristics, it makes perfect financial sense to continue to collect his sperm indefinitely. But think of the multiple ruined lives that can result if an inadequately screened donor has a tribe of children.

We regulate the production and distribution of bull semen. Maybe some care should be taken in the case of human semen.

73 As a donor conceived child who was unaware of this fact until recently, I am hopeful that there will be government insight and regulation of this industry. Through DNA testing I learned that I was conceived through the use of a sperm donor. Although this occurred many years ago (in the early 1970s) I was able to find the doctor who performed my mother's insemination. He is highly regarded in the industry and professed that he scrutinized the potential donors as much as possible during that time frame. I was assured that he worked in partnership with medical students and interns at NYU, and that he only recruited men under the age of thirty to be donors (who had to provide a detailed medical history). In addition, he explained that once conception occurred five times from an individual donor, they would no longer be used. The relief I experienced after speaking with the doctor was short lived due to further DNA testing where I matched a half sibling (also donor conceived) and the close relatives of my actual donor. Through communication with his family, I've learned that my donor was not in medical school at any point in time and that he was thirty-five when he donated his sperm for my conception. In addition, my donor has suffered from life-long health problems, which led to him living with a colonoscopy bag that replaced part of his intestines. My half sibling (who is also conceived through my donor) has lived with chronic pain and intestinal issues for many years- which seems to connect to the health issues of my donor. Aside from the psychological issues sperm and egg donation create, the potential health issues of tens of thousands of American citizens should be a priority for the government to begin an overhaul of this unethical industry. I hope that reading about the personal experiences of the donor conceived will exact a change in sperm banks.

74. As a parent of a donor conceived child I feel more regulation of this industry is necessary. My daughter, now 7, has over 69 half siblings. The family limits at our sperm bank keep going up and they now allow 60 family units instead of the 40 we agreed to. We had absolutely no recourse when they changed this policy. There's nothing from stopping them from going even higher. Other countries have limits set by law on the number of children that can be conceived with one donor. It makes sense to do so.

75. From a donor perspective, I would also like to mention that very little research is done with regards to the effects on donors after they donate, i.e certain cancers and fertility problems. I have donated and now suffer with PCOS and fertility problems which I was not warned about when applying to donate and I was in perfect health prior to donating.

76. This is important and necessary for the health both mental and physical of our future children and world. This has to be implemented; it is the right thing to do.

77. I am definitely in favor of all of this. As a donor many years ago the hospital contacted me to say that a family was trying to contact me. The hospital refused to give them my details or me their details. How inhumane is that?

78. With the ever increasing use of donor IVF. It is important to the physically and emotional health of our species that there is genetic testing & limits placed on the number of genetic offspring a donor may have. It is also unethical to remove rights from the lives created from the shared genetic material. I have also had personal experience where despite contracts being signed that clinic did not convey information shared by myself or the families to me. I was fortunate enough to have contact with 2 families from the start & to cross paths with an additional family who had wished contact from the start. But there are still 3 families I donated to that I sadly may never know. And I have no way of knowing if any of them adopted out embryos to any additional families. Many aspects of the current lack of regulation are extremely disheartening.

79. I am a donor-conceived adult in support of better oversight of the sperm/egg donation industries. I know from experience that the impact on people's lives is too great to leave it up to the "Wild West" to regulate itself. We don't even know how many children are conceived each year with donor sperm and eggs--that research should be the bare minimum--and putting into place mechanisms where families can be alerted if there is a health concern is another important task.

80. My daughter was conceived using a donor egg. It is extremely important that clear regulations be developed for testing of both sperm and egg donors rather than leaving it to individual companies. Parents need to be reassured that there are no genetic issues or the possibility of sexually transmitted infections. In addition, there should be a clear method for donors to submit significant changes in their health history that might affect an offspring so that this information can be passed on. Thank you.

81. This industry should be more regulated and controlled. Donors should be able to be contacted by offspring. No financial responsibility is to be held against the donor! DO IT! Get this done!

82. The market for human gametes, both eggs and sperm, should be monitored, and regulated. Full disclosure of information is critical to the successful operation of a market like this one.

83. Like many others, I discovered in my mid-30s that I was donor conceived. A 23andme test uncovered the fact that my dad couldn't have possibly been my biological father. It was revealed to me that my parents' fertility doctor told them never to tell me about my real origins courtesy of a sperm donors I wasn't even aware that I had Ashkenazi Jewish ancestry. All throughout my life, Jewish people have asked me if I had Jewish roots, but I always said no because I didn't even know this crucial part of my own heritage. I feel saddened by the fact that I may never get the chance to meet my immediate biological family members, and it feels as if there is a huge part of my life that is missing. I don't agree with the ethics of manufacturing children who will never have the opportunity to meet their bio relatives.

However, I have to count myself as extremely lucky after hearing the stories of other donor-conceived children and their parents. I am so blessed and fortunate that I do not have a hereditary disease, I don't have hundreds of siblings, and I have been welcomed by my biological cousins. This industry DESPERATELY needs oversight, and people have the right to know and understand their genetic backgrounds. At the very least, there needs to be a halt to anonymous 'donations', and donors must be screened for all of the diseases they could pass on to children. As the industry grows even more, the need for such oversight is only going to increase in the coming years. So many of the problems that it creates are preventable, so for the love of God, let's prevent them.

84. I am a university instructor whose area of specialization is human genetics, and I was also an overly utilized sperm donor at several fertility practices in Berkeley,CA while I was a doctoral student in the 1970's.

I was requested to be the donor for 169 inseminations, and given my stated "success" rate provided by the principle Ob-Gyn who organized donors, I convievably have between 56-80 genetic offspring. This is simply unethical, and it shouldn't have taken my realization that this was too many and thereby choose to stop donating; the onus should have been on the medical professionals who were the one's truly profiting by this practice.

I was not motivated by the $20-$25 I received per donation; I became a donor when I learned that none of the existing donors were willing to allow lesbian couples to use their donation.

I have been a member of Donor Sibling Registry for years, as I completely support the rights of all humans to have access to their genetic history. I further support this petition to regulate a clearly profit-driven industry and to open up access to medical, genetic, and educational backgrounds for all donor offspring and their social parents. Without such legislation, I will continue to be ignored when I approach two of the fertility practices that utilized my semen for artificial inseminations and ask that my contact information be made available to all of their ex-patients who received my donations as well as the orogeny that resulted. This, to me, is simply unconscionable.

85. I am a female and have twice donated ovum in San Francisco, both times in the mid-1990s. Beyond any personal physical issues I may have incurred as a result of my participation, latent personal genetic/medical knowledge has come my way since birthing my own two children, both of whom inherited this genetic disorder where all of us have a genetic counselor and issues which must be addressed medically and on a conscious, daily level. The depth of research my family has undertaken to learn about our issues is something that should be [allowed to be] shared with genetic direct descendants.

Please take to heart all of the research submitted by Wendy Kramer and Donor Sibling Registry. In my opinion, these are human rights issues.

86. I request that the FDA look into the state of affairs surrounding the sperm donation industry and, then, develop the appropriate and much needed regulation/oversight.

87. From a donor perspective, I would also like to mention that very little research is done with regards to the effects on donors after they donate, i.e certain cancers and fertility problems. I have donated and now suffer with PCOS and fertility problems which I was not warned about when applying to donate and I was in perfect health prior to donating.

88. 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 (and egg) donation industry, and then develop the appropriate and much needed regulation/oversight.

89. As a sperm donor offspring, I think it is extremely important that further regulations be made on sperm donation. More tests should be run and more background checks should be run in order to test donors to assure that the people that are donating are actually who they say they are. Too much of the system relies on the honor code. I have heard too many horror stories from other donor conceived children and parents that have used donors that they found out devastating information about the egg or sperm they used post conception - information that could have been known much earlier in the process if sperm banks vetted the donors more carefully.

Banks should also be required to follow up with conceived children and their parents to track any genetic information that may be of importance to other families considering using the donor's sperm in the future.

90. As a donor-conceived person, I firmly stand behind Donor Sibling Registry's attempts to convince the FDA to look into sperm, egg, and other donation centers and the affairs surrounding their regulation. The man whose donated sperm I was conceived with expressed his wishes to the bank to never be contacted, so his identity is completely hidden to me. I do not have any historical or current medical information about him or his family. I am lucky to not have encountered any serious medical issues, but hearing so many stories from other donor conceived people scares me for the simple reason that I have ZERO information and I should have it all. I (and my parents, no doubt) will be very very upset if I develop a serious medical condition and later find out that it was hereditarily tied to my father's family. I have had a sense of emptiness and incompleteness in my heart and soul since I came to the realization that I would likely never know my father. I think that if a person is taking such a step to create lives and build families, the least they could do is be held accountable for what they are doing. Thank you for your time and consideration of this petition. Please think of how many lives you would change. Thank you.

91. Dear FDA,

We request that the FDA look into the state of affairs surrounding the sperm (and egg) donation industry and, then, develop the appropriate and much needed regulation/oversight.

As a former sperm donor, and now the proud father of 3 beautiful children as a result of my donating. It is appalling to me that virtually no federal regulations/oversight exists to manage it appropriately.

I hope you will at least open an inquiry into this issue.

Thanks
Tim

92. I am neither a sperm donor nor recipient. I learned about this through my job as a journalist and wanted to comment, not as a professional, but as a person.
There's no doubt, these businesses fill a need. But it seems the industry is short sighted, filling only an immediate void that can be monetized. Whether or not regulations reduce the number of donors seems trivial to everyone except the sperm bank industry. Recipients want donors that are interested in background checks, genetic information and transparency. Even the companies that seem to offer these services as a way to distinguish themselves from other providers appear to have gaps or weaknesses in their system. Since there are no requirements, there is no recourse. So they can promise something without even the intention of delivering on it.
I understand in this political climate, regulation isn't a popular word. But we're talking about the creation of human life. The issues being discussed could impact the cost of health care (known defects/illnesses that are not caught and shared with multiple kids), birth defects if unknown related children procreate, and lead to unnecessary emotional instability (recipients learning their donors lied about health history or are no longer willing to share medical information).
Why should families have to fight costly battles in court? How hard is it to track actual births? To cap the number of children that can be born from the donations of one person? Or to keep, maintain and share the information from an ACTIVE database of health information regarding donors?
I asked several sperm banks and even the lobbying group that represents them these questions. I never received a response from any of them. I don't know what changes should be enacted, but I know the era of secrecy and silence needs to end and this issue should be openly debated and discussed.

93. I think it is extremely important for regulation and oversight into the Fertility Centers. Donor children and the parents need full access to the genetic backgrounds of the donor for medical and ethical purposes. There really is no such thing as anonymous donors in this day and age with DNA testing and most likely the donor children will be searching for their biological parents for a variety of reasons. The FDA may be wanting to protect the ASMR industry just as the government turned a blind eye the tobacco industry but in the end the lawsuits that began to trickle in against corporate giants such as Philip Morris ended that. Predictably in the near future, there will be lawsuits against Fertility centers that witheld vital information on their donors or neglected to test them for genetic medical abnormalities may find that the centers that do these types of oversight protection for their clients will do marketably better and have less backlash than those that don't.
Anne N. (Rockland County, NY)

94. As a donor-conceived person with no access to half of my medical history, I fully support this petition. All donor-conceived children deserve the right to know what medical issues they may have to deal with or possibly prevent in the future. Families looking to conceive via sperm donation should have access to the donor's medical history. Anonymity should be illegal on this basis alone. This industry must be regulated to ensure the validity of donor information and make cryobanks accountable for providing families with incorrect information that could potentially affect their future children.
In addition, cryobanks should require that a limit be imposed on the amount of offspring a donor can have. It is unethical and immoral to have one donor with an unlimited amount of offspring, who at any point in their lives, can meet and fall in love, resulting in dangerous outcomes for THEIR future offspring through no fault of their own. It is mindboggling that no one in this country has yet to consider this unscrupulous. It's time something gets done to put an end to this industry full of greedy and corrupt individuals that profit from it.

95. I am a "donor baby", and when I was 7 years old I was diagnosed with tourrette syndrome. This is something that is completely genetic, and there is no trace of it on my birth mother's side of the family. If this was more regulated, then my donor would not have been able to donate.

Although I am grateful for his contribution because I would not be here today without it, I would have a lot of less struggles in my everyday life if this process was regulated and my moms had chosen a different donor.

96. Children and adults born as a result of gamete donation should have equal rights to those of all children (including adopted children) of tracing their genetic roots and ancestry.

Information regarding the donor prevents potential medical complications & accidental incest AND provides a basis on which to continue building one's identity. In contrast, a paucity of information often leaves a sense of something crucial that is lacking, and with it, a sense of not fully belonging to one's family and community, and at times, perhaps, even of profound alienation.

Information about the donor (his/her donor code, medical information, why he/she donated, what he/she looks like, does for a living, has studied, likes etc) is the bare minimum the child should have access to. A letter from the donor, perhaps accompanied by a picture of him/her (e.g., at a younger age), even if anonymous, would go a long way, and could be given to the mother and also kept by the clinic for the child, or even better, filed in a national registry or the DSR. Ideally, there should be the possibility of mutually agreed-upon contact of some sort, at least when turning 18.

Many countries, including the US, can definitely learn from countries such as the UK and Victoria, Australia, where the best interests of the child are paramount.

Ruth Shidlo, PhD

97. From my research about genetics testing for cryobanks across the country, it seems that the choice to test sperm or egg donors is at the discretion of the cryobank instead of following any regulation or standard way of testing the specimens. This concerns me because I am a gay man and my only options for having children are adoption and surrogacy. And without a willing donor of my own, I will have no choice but to turn to a cryobank for an egg donor to supply one-half of the necessary parts needed for reproduction. I think there should be standards for these centers to follow. I don't want to have to worry that after I receive an egg and have a child that they could develop a genetic disorder that could have been prevented had the donor been tested ahead of time. No one wishing to have a child should have to worry about preventable diseases.
If these tests were regulated by the FDA, then no potential parent would have to worry about whether their child is at risk for contracting a genetic disease. And while many genetic diseases are treatable with modern medicine, it is much easier and cost effective to avoid them altogether. Many people turn to egg and sperm donors because they don't have a choice, whether because they are LGBTQ or because they cannot conceive on their own. These families already cannot have a child on their own, so they should at least be able to have one without any potential harms to their health.

98. My Fairfax ID donor committed suicide in 2013. I learned of his death one week after the birth of my second child in 2016. That means I posthumously conceived one or both of my children with a Fairfax Cryobank donor. I did not consent to this, and I do not know if the donor would have consented to this.

When we were making the critical decision on who would be biological father of our children, we specifically required two things: 1) the donor had to be an "ID option" donor so that our children would have the access to learn as much, or as little, about their biological father as they desire; and 2) the donor have no history of mental illness.

In the two sentence informal letter I received in 2016, Fairfax advised me that the donor committed suicide in 2013. Fairfax said they last got a medical update on the donor in 2013 and no mental illness was reported or "noted by any staff member". As a result of Fairfax's lack of action, my children have not only lost their right to seek out their donor at age 18, but they also may or may not have inherited a predisposition to suicide. Fairfax still has this donor listed on their website as "inactive" - with no indication whatsoever that he is dead.

This is unconscionable. The FDA needs to step in and regulate this industry on a federal level.

99. I am a donor offspring (1953). My bio father turned out to be my mother's very own physician. She was assured that it would be a resident from the hospital, but he confessed to her later, when she asked him about the color of my eyes. They looked like his. He died at the age of 41, very young. I was told about him when I was in my early teens, and she gave me a copy of his obituary and a photograph.
My son was 16 when he ended his life. I have battled depression for years. I decided to research my paternal side and was shocked by my findings. Both of my paternal grandparents died in a psychiatric hospital in Iowa. I sent for copies of the medical records and found that my grandfather suffered with psychosis and my grandmother lived out her life in a catatonic state. My bio father had a son, who ended his life by an overdose, when he was in his early 30's. My bio father had one brother and three of his children ended their lives. One drove her car over a cliff and the other two overdosed on prescription medication. I found a history of depression, schizophrenia and bipolar disorder in the family. I went back further in the family tree, and there I found self inflicted gunshot wounds, overdoses, and one even took poison.
My paternal grandfather was really unbalanced. He was a bigamist and married to four different women (no divorce) that he simply walked away from. He walked away from his first two children as well. That is not normal.
I have many serious health problems as a result of that donor. Unfortunately, so do my children, and now my Four year old grandson is showing signs of a disorder.

100. I was conceived by an anonymous sperm donation in 1989. My mother and I have zero documentation - only a receipt of payment. A few years ago I joined a DNA website and found a half-brother who lives very close-by and I wonder how many other half-siblings I may have or if I have accidentally dated any of them. The lack of information about my possible relatives and my genetic background continues to haunt me and it has caused several adverse psychological symptoms: anxiety, depression, substance abuse, destructive relationships, etc. The lack of oversight/regulation in this industry dealing with PEOPLE'S LIVES is not just PATHETIC - it's DANGEROUS and I know I'm not alone in this opinion.

101 I am a donor-conceived person born to a Single-Mother-by-Choice through artificial insemination. I have no donor ID number, no contact with any half-siblings or any of my donor's family. Although I am completely ok with this and have had no issues not knowing my biological father or his family, there is one issue I have with the practice of anonymity in assisted reproduction. I happen to be active duty U.S. Navy and am currently in a high risk assignment as a primary phase flight instructor in the U.S. Navy. It is current practice in the Navy, along with the other branches of the military, to have what are known as CACOs (casualty assistance call officer). These individuals have the thankless job of showing up to parents houses and informing them that their son or daughter has either died (KIA, killed in action) or is now a POW or MIA (missing in action). I've done my research and as the law stands in accordance with the UCMJ (Uniform Code of Military Justice) along with the specific instruction regarding CACOs, there will be no attempt to inform my biological father if I to be killed while in military service. Identifying information regarding my biological father is not on any of my paperwork and is not legally what is described as my "primary or secondary next of kin". I feel this needs to be changed. I feel that if I were a sperm donor, I would like to know if my biological offspring was killed serving their country. I feel I would deserve to know if they died in the line of duty as a police officer, firefighter, or federal agent. I also feel that as a donor-conceived person, I deserve to know if my biological father is killed in action serving his country, or dies in the line of duty. And as a donor-conceived person, God forbid I am killed in service to my country, I hope that my surviving family and friends

make every effort to track down my biological father and inform him that his biological offspring has died in service to his country. With the current system in place, with the current culture that supports anonymity, and the contracts that are signed to protect anonymity for donors, that is not possible. By outlawing anonymity, it can be possible. Fair winds and following seas to this petition.

102. Full disclosure is coming to rear its ugly head.. we need our system to Protect those who don't have a voice, our children, its unfair to them that we should have secrets.. how do we resolve this inequity. We make anonymous no longer an option. Figure out a way to at a minimum let the offspring know of siblings. Require any pregnancy as result be recorded at the state level. Requires the donor id and bank be listed on all birth certificate, make it a federal law. This will deter those who want to keep everything a secret and thus potential problems Down the road. Then it would be at the discretion of the offspring to register or not on sites like dsr or dna.

103. I am a lawyer who has, unfortunately, had to represent too many couples who had a child born with donor sperm that was not tested for common genetic diseases, even though the cryobanks represented that such genetic testing was performed. I strongly support FDA regulations regarding the genetic testing of donor sperm, not just infectious disease testing.

104 I have a son conceived with donor sperm who has ADHD and a behavior disorder which has yet to be identified. ADHD does not run in my family and although I can't say for certain it "came from" his donor father, I am suspect. More testing needs to be done and more information needs to be gained/given from/to donor and recipient. I chose an identity release donor based on being an adopted child myself. It was mentally, the only way I could do this. If I discover later that this donor did not truly choose to be a release donor...I will go ballistic!! Cryobanks need to be looked at and be held to higher standards. Not just for those who use them, but especially for those who are created by them!!! Having read many other comments here it's almost as if they are right out of a sci fi movie! These are peoples lives!!!

105. I strongly support regulation of the cryobank industry, especially limits on the number of births conceived with the sperm from any given donor.

106. I am definitely in favor of all of this. As a donor many years ago the hospital contacted me to say that a family was trying to contact me. The hospital refused to give them my details or me their details. How inhumane is that?

107. As the parent of donor conceived children who are healthy, even for the mainstream parents--it wasn't until DNA testing revealed my two boys' high risk for prostate cancer in the future. What health disasters could be prevented if only there was a uniform standard in data, and not only that, a requirement for physicians and pediatricians to actually ASK on their forms if a child is donor conceived? Donor sperm and eggs should be screen as well as any other donated organ (and its actual result is creating a new human who has medical information rights.)

Having brought this petition before the FDA behooves it to take action and demand that sperm and egg banks stop their reckless and inconsistent behavior under the guise of revenue generation, and be responsible to the children born of donor material (after all, they are real people.)

108. My fertility clinic, OHSU Andrology in Portland, Oregon promised my donor that he would have two layers of anonymity. For example, they promised that they would provide him with confidentiality where they would never disclose or use his name with the recipients or offspring. In addition, the fertility clinic explained that they would not only used his specimen, but, another anonymous sperm donor's specimen (as a mixture) for their artificial reproductive technologies

when inseminating their female patients. This was inaccurate information, as I was able to receive some paperwork from my fertility clinic, inadvertently, when speaking with their LCSW in 2001. She provided me with paperwork that provided me with my donor's identification number and there was only one sperm donor's identification number - not two. Thus, the clinic provided their donors with inaccurate information.

From a sociological perspective, the clinic is negligent. They recommended for their infertile couples to keep the origins of their child's conception a secret, denying their children of their medical and biological roots. The clinic presents an altruistic image of donating to help an infertile couple, however, the clinic and most sperm donors see their donations as simply donating blood. If the clinic was truly altruistic donor offspring would have full medical and cultural histories available. My clinic did not have a donor profile for me. Their reasoning: Charting was "spotty" in the late 70s to early 80s. However, if a donor would like to come forward and provide his offspring with genetic information then he is allowed access. Donor offspring are not accounted for in the equation. The donors and the clinics receive ample compensation, while the recipients receive their goal of a pregnancy and the offspring are a byproduct who are treated as commodity.

My clinic promised their patients that they would find donors who matched the social father, in attempts to conceal the reality of their child's identity. The aforementioned was not the reality of their protocol. I have learned that when a patient is ovulating, they call their donors to see who is available to provide a fresh specimen. Apparently whomever is available is the donor who is selected for that particular recipient.

They provided their patients with self-serving information, where they explained that the sperm donors were donating to help infertile couples. There is a reason why they do not discuss their donors' pay scale and their donors' desire for anonymity. The image of the fertility clinic is a big deal because it is crucial that society accepts their role in playing God. It makes sense why religion plays into family dynamics and how they are created because religion is the only element that considers the donor offspring (partial makeup of society). When you send people into the world, who are hurt then you are going to experience a broken society and the fertility clinics are at the hands of it.

In my opinion, the whole industry needs an overhaul and there needs to be a bridge built between science and psychology. All in all, fertility clinics have egos and a bank roll and their ethics need to be overseen to manage the broken societies they have created. Studies show that open donor programs and honesty regarding a child's conception are paramount and aspects that need to be regulated.

109. My daughter suffers from bipolar disorder which is highly genetic. Through the donor sibling website we made contact with the donor only to discover that he also suffers from bipolar disorder and was hospitalized psychiatrically when he was an adolescent. Participants in talk shows and reality T.V. shows are interviewed by a mental health clinician prior to their appearance on these shows. Certainly a mental health evaluation should be given to a man prior to his donating his sperm twice a week for two years. One of his other offspring completed suicide at the age of 18. Another was in residential treatment as a adolescent and then was in jail due to his being bipolar. Unfathomable suffering is the result of this lack of oversight of these agencies and their gross negligence.

110. I am a donor-conceived person (born 1968). I agree with all parts of the DSR's citizen petition and I urge the FDA to consider it carefully. Most other Western countries have ended donor anonymity and instituted far better regulation and tracking. I believe it is in the best interests to all parties (donors, families, children) to do the same.

Unlike manufacturing a new drug or medical device, the product that the infertility industry produces are human beings. Human beings, unlike cells, tumors, or organs have emotional, psychological and spiritual needs. They also have rights. Despite the fact that no law in the United States recognizes our right to know our genetic parents, most donor-conceived people feel strongly that this right does belong to them. We are human and we have the same needs as any other person.

The infertility industry knows exactly how much biological connections matter. If no one cared about their genetic relatives -- if every family was simply mix-and-match -- their industry would not exist. Infertility treatment exists because biology matters to people. Doctors and researchers make their living in this area because biology matters to people. Parents seek treatment because biology matters to them. Otherwise, they would adopt rather than pursue donor conception.

How much sense does it make to tell the resulting child that biology should not matter to him or her? Our parents paid thousands of dollars and endured painful treatments, all so that at least one parent could have a biological connection to us. After that, we are told that biology is not important and to pretend that we are not missing half of our genetic story.

The number of children born from any donor should be limited for both biological and emotional reasons. No human being wants 200 half-siblings. No human being wants to feel like a mass-produced product. Genetic problems should not be given a chance to reproduce themselves to this degree. There is also a serious chance of unintentional incest. The limits set by the industry rest on the presumption that people mate randomly. Nothing could be further from the truth. Parents with Ph.D's seek out donors with high education. Christian parents seek donors who share their faith. African American parents seek African American donors. When you look at the people who are actually using donors and their social networks, the chance of incest is much higher than the "standards" suggest. Both parents and donor children want real limits on the number of children born from any single donor.

Please look at the best practices suggested by the DSR seriously and start down the path of regulating this industry. The market cannot guide itself in this area, where human beings and human reproduction is involved. We need to set clear guidelines that cover both health and safety and emotional / psychological issues.

In previous generations, children were often taken from their birth families and given out for adoption under questionable circumstances. Some children were not told they were adopted until late in life, resulting in lifelong trauma and alienation from their adoptive family. To repeat these mistakes and re-inflict this trauma on donor families is a serious mistake. Please take action so that we can learn from the past and move forward towards a better future.

110. Regarding donor-sibling registry's petition:

I am a past donor (1992-4 in New Jersey) and therefore believe I have particular standing to comment on this matter.

Common sense should apply here, as well as rigorous and meaningful privacy protections including anonymity for those who desire them.

That said, a slew of unethical transactions logically must have occurred in past due to the lack of oversight. I for example was asked to lie on my profile by my firm to maximize sale-ability. My clinic also have refused and even suggested I'm bizarre, for saying that I am open to hearing from or even meeting any successful children, if they want that. Children and parents not having the option to know one another may promote or increase unhappiness in the world. Because this desire may change over time, more options - including not ever knowing, or not disclosing until death - will most often lead to better outcomes for all parties according to their wishes. Therefore I feel strongly that the option to be contacted must be put in place, with a default notification upon death.

Thank you for the opportunity to comment.

EFK

111. I am the 'product' of an anonymous sperm donor. I am 27 now, but I have gone through (and am still going through) a lot in terms of coming to terms with my identity (and its missing pieces). Knowing that other countries have outlawed anonymous donation makes me feel like the only reason it is allowed in the U.S. is to bolster the profits of the industry, which is morally wrong, because the 'products' it creates are human beings. I will never know my father, see a picture of him, or be made aware of medical issues he may have passed to me. I am completely in the dark about my own origins, and in a time when people can pay to know about their ancestry, it is so backwards that a for-profit entity was allowed to take that knowledge from me. No one deserves to live a life where one of their parents was taken away from them on purpose, but that is what happened to me.

U.S. adoption rules state that all actions from parents and agencies must be in the best interest of the child, but when it comes to tissue donation, there is no such rule. Instead, because money is exchanged and contracts signed, we have NO rights, even as adults, and our best interests are not even considered (parents aren't even required to undergo counseling or home visits to ensure that they are equipped to handle a child). There is no question the policies around anonymous donation need to be evaluated and changed. They are not right. Period. Please do something about this. I will never know my father or half of my family, please do something to make sure this does not keep happening to other innocent people.

112. Dear FDA,

I have a son though anonymous donor sperm. While he has no health issues that I know of, I think regulation of the industry is long overdue. I have to take on faith that the information provided on his profile is accurate. When it comes to someone's life (the children of these sperm donors), there should be more than just trust in the accuracy of the information provided. At the very least, genetics tests for diseases and criminal background checks should be required.

Thank you for addressing this matter.

Sincerely,

Diane Nielsen

113. I conceived a son thanks to a sperm donor. He is healthy now, but he does have some deafness on the left, which I was told is congenital. We would both like to know more about the donor's ongoing health, especially as he ages. We would also just like to send a Christmas card or whatever, and not be totally locked out. It seems kind of inhumane to be so totally separate. We're not looking for ongoing emotional or financial support, just basic humanity.

114. Civil rights of individuals should come before profits, period. My son is donor-conceived and we've been as honest as possible with him from the start. He deserves to know about half of his biological history, like adopted individuals.

115. As someone that has used donor sperm to create a family, I have witnessed first hand, a need for government regulations! It imperative that mistakes not be made when they can lead to devastating consequences. No one should have to "find out" that their donor conceived children are half-siblings after thinking otherwise. Having the incorrect specimen can lead to potential

health problems or conditions and can cause many issues for those involved. This is unacceptable and can cause countless issues for everyone involved! Please put strict regulations in place for those of us who have used cryobanks and the children who have been conceived using donor sperm. Mistakes cannot be made when dealing with the basic human right to know who we are and where we came from.

116. I just today found out that my two sons, ages 12 and 14, were not conceived by the donor that I requested through the cryobank. I have been in touch with their "half siblings" parents for over 10 years now, only to find out TODAY that they are not related. If it were not for DNA testing, I would never have found out. We need regulations on these cryobanks so that these types of issues do not happen to anyone else. The donor that I chose was a decision that I made very carefully. I based it not just on physical features, but on personality traits, education, and most importantly, medical history. So, now instead of having a donor with what I thought was a good medical history, I have subjected my two kids to something that has never fun in my family...Alzheimers, and Brain Cancer! This is unacceptable! We must have regulation so that this does not happen to anyone else.

117. My older son is donor conceived (sperm). The cryo bank (CCA) did discover that the donor seemed to have a genetic disorder (he reported it to them). This was after my son was born. CCA did not attempt to contact me to tell me. I only found out when I called them to see if I might be able to contact my donor. Otherwise I would never have known. I also contacted CCA when my son became psychotic at age 14; they did not contact his half-sister and let her mom know. We connected with the half-sister through Donor Sibling Registry (and the donor himself) when my son and his sister were 21. These cryobanks can do anything they want without consequence. They need over sight. Thank you.

118 My name is Dr. Laura McMillian, and I'm a 37-year old sperm donor conceived person. I was shocked to find out about my conception 3 years ago, initially through a 23andme genetic test which revealed that I'm not related to my dad, and the rest I figured out through deductive reasoning. My parents did not and were not going to tell me, as was commonly advised in that time period, and many social and psychological problems have resulted (explained further below).

Another fact revealed by the 23andme test is that I'm a carrier of cystic fibrosis, and my mother is not. That means my donor was a carrier of cystic fibrosis and had passed the gene on to me. Had my mother also been one, there would have been a 25% chance for me to have contracted the disease. (And, had I not gotten tested, my future children would have the same chances, since my spouse is also a carrier. My parents certainly didn't know I was a carrier.) It's dangerous for donors not have have adequate testing for genetic disorders and diseases and unfair to the resultant offspring who suffer as a result of such oversights.

Regarding the psychological side of things: I've always felt different somehow and had identity problems until very recently, which negatively impacted my self-confidence and ability to succeed in life. Even though I wasn't aware of my conception, the toxic secret affected me adversely. Although I've excelled academically, becoming successful in a career has been a significant challenge in part because I haven't felt strongly enough about what I have to offer the world based on who I am as a person.Only now - in my mid-thirties and having learned the truth about my mystery traits - am I overcoming these problems. And I had a significant conflict with my dad over my recent discovery of the truth and my search for the identity of my donor, almost leading to him disowning me at a time when I was extremely dependent and vulnerable (both financially and emotionally). Anonymous gamete donation in general is psychologically harmful to many donor conceived people, as I've personally experienced. i call for comprehensive genetic and disease screening of donors and the banning of anonymous donations so that all donations are necessarily open (identities known to the parents and child and medical histories shared). Several other countries have already passed laws against anonymous donation for ethical reasons, and it's time for the United States to follow suit.

119. I don't believe that I can say anything here that hasn't already been said before, but I feel that, as yet another donor-conceived offspring (born 1993) who has been burned and lied to by the industry, that I should add my voice to this call for regulation and oversight. It is maddening that I, like so many others, have been denied knowledge of half of my genetic heritage, including medically-relevant updates and all information regarding potential family members. It is especially painful knowing that my parents were told I would be granted more information when I turned 18, but that the bank that provided my specimen has since "lost" (or destroyed, or misplaced, depending on what time of the day they are called) the files that were supposed to become mine. The deception and callousness should not be allowed to continue, and with advances in DNA testing and the availability of information on the internet, changes that have already come about will only continue. Thus, it is imperative that there be some form of oversight or regulation into this industry. Real, human lives, like mine and so many others, are being created by these technologies, and our rights should be considered and protected.

120. I am writing in response to your letter datedJune 26, 2017 addressed to Wendy Kramer regarding petition FDA-2017-P-0052.

The type of regulation we are requesting is not complicated.We are not asking that the government limit the reproductive rights of the people. We are asking that the sperm industry comply with minimum requirements. At this moment a fabric mesh used for hernia surgeries and the fabrication of pills is much more regulated than sperm used to produce an unlimited number of individuals (i.e., 200 children from the same donor). If this continues without regulation the government will have in its hands a population of genetic disorders of epidemic proportions. I ask that you please, consider this an FDA priority and investigate with more urgency than a Tylenol recall or an error on an IFU which nobody reads.

My name is Lynnette Rios. I am the mother of twin boys born in 2009with the use of a sperm donor. I have a PhD in Biomedical Engineering and completed a postdoctoral program from one of the National Laboratories, I have worked in projects with the DOD, DOE, NIH and as an engineer in private medical devices and pharmaceutical industries, so I know what I am talking about.

Since my boys were 3 years old I have been contacting California Cryobank (CCB) hoping to get more detailed and updated health history from our sperm donor, since the health history provided by CCB shows zero family health concerns for this donor. My boys were speech delayed and in trying to find the cause and before moving forward with an uncertain diagnosis we visited multiple specialists (speech pathologists, hearing specialists, allergy doctors, genetic doctors, etc) all of whom asked about my boys' health history and I had to answer that I do not know half of their genes. CCB's genetic specialist originally stated they would contact the donor for an update. I stayed in touch every few days, then every few weeks and eventually every fewmonths to ask if they had reached him, but always received a negative answer. I have to explain that I paid extra money for an Open Donor, one which would be open to contact when my children reach 18 years of age. If CCB cannot reach this donor 3 years after I initially used him, what are my hopes of them being able to reach him when my kids turn 18?
(I have come to understand that 18 is a relative number that has more to do with the sperm industry being able to discard medical documents soon after, rather than an age at which donor kids are capable of understanding their origins.

In 2015 one of my boys was diagnosed with cancer (T-cell Lymphoma/Leukemia) a rare disorder with possible genetic pre-disposition, a week after celebrating his 6th birthday. I once again reached out to CCB in tears asking them to please contact the donor or allow us to contact him. They said they will ask him for an update during his next scheduled appointment or when my boy turned 18.

My boy's biopsy was abruptly halted when the anesthesiologist realized she didn't know what type of anesthesia to use for my boy's surgery. The tumor in his chest was so large and heavy over his lungs that if she put him under general anesthesia the results would be "catastrophic" (to use her words). Since at age 3 a genetic specialist had diagnosed my boy with a metabolic disorder, she could not use lipid-based anesthesia. I remember a group of about 7 doctors arguing next to my boy's bed about how to proceed (while CCB wanted to wait until the donor's next scheduled appointment). Finally they put my boy under hallucinogens, which means he was conscious during his surgery, and then gave him meds to forget.

Fast forwardto 2017.My boy has been in chemotherapies for almost 2.5 years.CCB has no updates on our donor and no scheduled visits. Luckily I am in contact with a dozen families who used the same donor (about 25 children)and I informed them of my boy's diagnosis because CCB has not contacted any one of them to provide this health update. Recently a representative denied there was a health update of cancer, even though I have written prove that I provided evidence of my son's diagnosis.

Anonymity is not an option we choose.It is imposed on donors and families to hide information such as health history. How could you possibly suggest the FDA has more important priorities?!

Obtaining health information, genetic information and genetic origins is a Human Right. Most people have come to accept that adoptees have a right to obtain their records and to know their origins. It has taken them decades of hard fight to get to this point. We are not willing to wait that long. There is no reason to. The evidence of why regulation is needed is clear. Perform an inspection of the documents from these sperm companies (or the lack of documents) to have more evidence for the need for regulation.
http://www.9news.com/news/local/investigations/mother-worries-about-sperm-donors-medical-history/406656420

121. I fully support “The Citizen Petition” created by Wendy Kramer and would like to share my concerns.

The horror stories told, untold and yet to be uncovered are the proofs that the FDA’s regulations, non-binding recommendations and gamete bank inspection protocols were clearly not conceived of with health and well-being of donor-conceived people and gamete recipients in mind. Sadly, as a result of the conception of such inadequate and inappropriate regulations, the FDA has played a large part in the birth of a deeply flawed global donor gamete industry that has encouraged morally bankrupt individuals to make a lucrative living off the vulnerability and desperation of parents-to-be while exercising blatant disregard for the donor-conceived humans being created.

The above harsh and unanticipated reality is the ill-fated certainty when regulations governing the creation of humans are disconcertingly similar blood donation regulations; the pressing health concern is “relevant communicable disease agents and diseases”. Additionally, the vernacular used throughout the FDA documentation threatens the health and safety of donor-conceived people and gamete recipients as it provides a foundation of inappropriate/misleading/deceiving language to be used by the gamete banks as they lure desperate parents-to-be.

I came to realize the unimagined truths of this industry first hand in June of 2014 when the identity of my son’s donor accidently became known. Note that there are at least 26 other families that used the same donor accounting for 36+ children collectively. Sperm banks don’t actively track births, so there is no way of knowing exactly how many children were created.

With the donor's name known, internet searches were conducted which resulted in the discovery of unfathomable verifiable truths about my son's donor who was vetted, processed and promoted by the FDA approved sperm bank. What was discovered is **a convicted felon with multiple inheritable debilitating mental health issues who lied about his education successfully donated sperm for 14+ years at the hands of a sperm bank's so called arduous, intensive and rigorous, testing and screening procedures dictated by the FDA's regulations.**

To determine how this could be possible, I spent the past three years performing my own investigation of FDA approved Canadian compliant US sperm banks and the regulations governing their operations. What I can say for certain is **given the current state of affairs within the sperm banking industry, it is strictly a matter of luck if a sperm donor is an upstanding and healthy individual, not a matter of testing, screening or regulating. Nothing the sperm banks do after the donor passes through their doors guarantees anything beyond a semen sample that is likely viable and possibly free of some "relevant communicable disease agents and diseases"**

My story puts a spotlight on all the issues that arise when regulations and non-binding recommendations governing the donor gamete industry are predominately focused on testing for "relevant communicable disease agents and diseases" alone. FDA personnel are invited explore a small sampling of the 100s of articles worldwide regarding my story:

1. Investigative pieces by Rebecca Lindstrom for NBC's 11 Alive out of Atlanta, GA:
Sperm buyers beware: Man with checkered past fathered 36+ kids
http://www.11alive.com/news/investigations/buyer-beware/newsinvestigationsbuyer-bewaresperm-buyers-beware-man-with-checkered-past-fathers-36-kids/395317352;
Sperm for sale: fighting for change:
http://www.11alive.com/news/local/sperm-for-sale-fighting-for-change-1/395429427

2. Investigative pieces by Theresa Boyle of the Toronto Star out of Toronto, ON. Please note that these pieces were written after 10 months of investigation:
https://www.thestar.com/life/health_wellness/2016/04/09/he-was-the-perfect-sperm-donor-then-26-families-found-out-he-wasnt.html

https://www.thestar.com/life/health_wellness/2016/04/13/three-ontario-families-sue-sperm-bank-and-canadian-distributor.html

https://www.thestar.com/life/health_wellness/2016/04/19/sperm-bank-encouraged-donor-to-lie-about-iq-lawsuit-alleges.html

https://www.thestar.com/news/canada/2016/08/30/sperm-donor-admits-he-falsified-information-say-georgia-police.html

3. Radio interviews conducted by CBC radio for a program called "As It Happens":
Me: http://www.cbc.ca/radio/asithappens/as-it-happens-tuesday-edition-1.3532219/sperm-donor-9623-seemed-perfect-it-was-a-complete-lie-1.3532222

Nancy Hersh: http://www.cbc.ca/radio/asithappens/as-it-happens-tuesday-edition-1.3741615/donor-embroiled-in-canadian-lawsuit-confesses-he-lied-to-sperm-bank-1.3741618

As alluded to earlier, the FDA approved sperm banks carefully craft their wording to speak to the yearning of desperate parents-to-be. Said wording is adopted from the documentation the FDA publishes regarding the regulations governing sperm bank operations. Terms like "medical records" and "relevant medical records" have no place being used on any FDA documentation as there is nothing medical about a sperm donor self-reporting his medical history. Nothing the donors report is verified by any FDA approved sperm banks meaning donor eligibility hinges on the honour system and unfortunately, humans lie.

People would be shocked to learn that the "physical examination" performed on donor's every 6 months to a year (depends on the bank), may not include taking the donor's height, weight, blood pressure, pulse, or age – those five BASICS when compared with one another and tracked over time can actually tell quite a telling story about many factors of a donor's health. In theory, a 5'8", 200lb donor with blue eyes can sign up as a 5'11" 170lbs donor with hazel eyes. His weight over the time of his donations could have dramatic fluctuations due to a variety of factors such as mental illness, illicit drug use or prescription antipsychotics, cancer meds imprisonments, etc. and all of which will go unnoticed or ignored.

In order to ensure donor-conceived people are not being handed a disturbing and debilitating genetic heritage, the following must be used in determining donor suitability/eligibility:

> ***1. Medical records must be used in the determination of gamete donor eligibility/suitability.*** The term "medical records" is to be defined as that collection of health information collected and stored by the donor's family physician who is not employed by a gamete bank.
>
> ***2. Educational/professional claims must be properly verified during the application process and whenever the donor makes a claim of advanced education, certification acquisition or enrolment changes.***
>
> ***3. Gamete banks must do annual criminal background checks on donors and this is to be binding.*** No one wants to procreate with someone who has been jailed.
>
> ***4.*** **Gamete banks must perform regular unannounced drug testing of their donor for illicit drug use, antipsychotic meds, and cancer meds.** Note that our US, FDA approved donor was on various antipsychotics and illicit drugs at various times throughout his 14+ years donation career.
>
> ***5. Gamete banks must be inspected/audited at least once annually by the inspectorate. This inspection/audit must occur without notice.***

Thank you for taking note of these recommendations. I do have many more recommendations to share and welcome the opportunity to share them throughout the updating process. You can reach me through Wendy Kramer.

Sincerely,

Angie Collins
Ontario, Canada

122. In 2015 I randomly took a DNA test and submitted it to Ancestry.com. The events that followed forced my mother to admit her secret, that my father was not my biological father. She and my father had not told one single other person in 42 years. She was devastated. In 1973 the doctors at John's Hopkins told them not tell anyone. Had I not taken that DNA test, I would still be in the dark. I have no idea how many siblings I might have.

My DNA test led my half-sister to find me. She had waited for 20 years to connect with someone. Knowing my history and being able to interact with her has greatly enriched my life.

123. I am a PhD scientist who was conceived using an anonymous donor in 1988. As I have gotten older and more educated in the scientific field, I am shocked at how abysmal the regulation for sperm donation is in this country. We rigorously test new drugs and devices over and over again before giving approval, and yet we allow totally unregulated (and barely screened) genetic information to be supplanted into women and to create entirely new lives. It truly is astounding how little genetic and background screening goes into the process, especially in 2017, nearly 30 years after the human genome has been sequenced.

At the very least, the industry *must* begin basic genetic testing prior to approval for sperm or egg donation. Additionally, there must exist a mechanism by which donors can report later acquisition of diseases to be distributed anonymously and securely to children conceived from donors. To do anything less is extremely irresponsible, careless and even harmful to the children conceived in this way.

124. As a nurse practitoner in OB/GYN I have had many patients who have used donor egg and donor sperm to build their families. The fact that there is not full disclosure about the donor has caused many patients undue stress and concern not only about the donor's genetic testing and whether or not it is complete, but also whether there may be a need to contact the donor in the future regarding a child's genetic illness, and not being able to. I completely support mandated complete genetic testing, and the end to donor anonymity.

125. I spent a great deal of time and effort researching and choosing a sperm bank when I decided to use donor gamer to create my child. Most important to me was that my daughter be able to meet her donor one day. I paid a high premium to ensure that happen. My daughter is now 11. Since her birth I have read story after story about willing to be known donors changing their minds and not fulfilling their commitment. This loop hole has left countless children devastated. If you have children of your own, you know that when your child suffers, you suffer. We are always only as happy as our unhappiest child. Something is very wrong here. I do not understand how people like Sherron Mills (former owner of Pacific Reproductive Services in San Franscico) are permitted to advertise donors as willing to be known, charge the parents a high premium and then nonchalantly say, sorry, they changed their mind. My daughter is 11. She is counting the days until she can meet her donor. I'm holding my breath. Please listen to the voices of the donor conceived-they have a right to know where they come from. Please regulate the sperm industry. This billion dollar industry is supported by real people- parents who suffered from infertility and the desire to have children and children who were born into a contract they never had the option of signing. Please hear our cries.

126. I did not find out that I was donor conceived until I was 22. Since then I have found 1 sibling through donor sibling registry and 2 siblings via DNA. We were able to find our donor father as well, and we also match several of his cousins through DNA. It would be so easy for those who are related to him to figure out that he has other children when really they should just be told. There is no reason to keep these secrets any longer.

127. I support this request, because oversight of the sperm donation industry is badly need.
Please act on this.
Thank you,
David Seaborg

128. I am in favor of this. Please pass.

129. I am a sixty-four years old donor conceived woman and one of eighteen, so far, confirmed through 23 &Me DNA testing,
paternal half siblings. I also have one maternal half sibling. There is no comprehensive medical and genetic testing conducted by US sperm banks. In the US the FDA only mandates for STD testing and for a few other diseases. Testing for STD's does nothing to prevent transmission of genetic illness.
There is little to no regulation or oversight of the US sperm banks that ship sperm to over 50 countries around the world (this is a global issue). This industry is not required to maintain or update records regarding genetic disease transmitted to donor offspring. 84% of surveyed sperm donors and 97% of surveyed egg donors were never contacted for medical updates.
No accurate record keeping exists about how many offspring are conceived for any one donor. There are many large cohorts of half-siblings, some now as large as 200.
Sincerely,
Diane Andersen

130. As a donor conceived person with children of my own I can't understand why there is no universal register for donors. I have no recourse to genetic relatives or paternal medical records for myself or my children. The clinic where I was conceived no longer exists and records have vanished. It is criminal that there's not more oversight into this unregulated industry.

131. As a sperm donor baby (1996), I respect my donor's choice of anonymity. I understand that he has a family of his own and may not want his offspring to disrupt the life he has built for himself. I, though, would like to know about my half-siblings -- or at least have the option to find out who they are or even just know how many I have.

132. I write in strong support of regulating donor conception, and in particular to end the practice of anonymous donation. I do so for the following reasons:

1. Most donors and recipients are not properly educated or counseled beforehand about the needs of the children they are about to create. This includes the innate desire of donor offspring to know about their first-degree genetic relatives.

2. There is no comprehensive medical and genetic testing conducted by US sperm banks. In the US the FDA only mandates for STD testing and for a few other diseases. Testing for STD's does nothing to prevent transmission of genetic illness.

3. There is little to no regulation or oversight of the US sperm banks that ship sperm to over 50 countries around the world (this is a global issue). This industry is not required to maintain or update records regarding genetic disease transmitted to donor offspring. 84% of surveyed sperm donors and 97% of surveyed egg donors were never contacted for medical updates.

4. No accurate record keeping exists about how many offspring are conceived for any one donor. There are many large cohorts of half-siblings, some now as large as 200.

5. 75% of surveyed donor offspring advise that prospective parents do not use "anonymous" donors. Many countries have banned anonymous donation after asking, "what is in the best interests of the child to be born?" "Anonymity" is never the answer.

6. Many donor offspring long to connect with their half siblings and their donors long before they are 18.

7. DNA: Donors Not Anonymous. Anonymity shouldn't be promised to any donor or to any prospective parent. Donor offspring have been locating their biological parents via DNA testing (along with Google and social media) since 2005.

8. Because of this end to guaranteed anonymity, non-disclosure is no longer an option. Many people who swabbed their cheeks to learn more about their ancestry and family tree have been shocked to find out that they are not genetically related to one of their parents, because their parents used a donor, and kept it a secret.

9. Telling is just the beginning. Parents need to know that their child may view this invisible one half of their DNA to be a very important part of their identity and they may feel urgency about connecting with their previously unknown genetic relatives.

10. The choices that parents make early on about creating a family with a donor will affect the donor-conceived child for many decades to come.

133. This endeavor has to include donor conceived people as drivers, currently it does not. The FDA must take note of the lack of this and specifically give collaborative status to panel of donor conceived adults who will likely discuss issues from Nicholas Isel's similar petition. It would be a shame for the FDA to get this wrong and have to revisit it later.

134. This isn't a trivial matter-what we're discussing is the creation of life. Please look into your hearts and consider what it must be like to have your own creation story be so muddled by politics and third-party agendas, then maybe you can see why this is issue is so sacred and deserves your full attention.

135. Please don't forget about the children that are brought into the world with no choice or voice. I'm happy I'm alive and wish I would have had much more support offered instead of searching for and creating it myself.

136. I was a sperm donor back in the 1970's and I signed up as an anonymous donor. I knew that I must have a number of donor children, but thought that I would never get to know any of them. Thanks to DNA testing, I have recently found that I have a number of children. It is the most special thing in my life and I would like to respond to the issues listed.
1. I received no counseling at all. As an "anonymous donor, I thought that it was the only way it could be done.
2. As far as I can remember there were no tests required when I signed up and I never got any feedback about children born from my donations or if there were any problems with my offspring.
3. I don't believe that sperm was shipped in the 1970's.
4. I have no idea how many biological children were the result of my donations. I assumed if there were too many, they would ask me to stop. So far I know of seven biological children.
5. Some of my donor children had been hoping to find me for years. At least one of my offspring did not know until he/she received the results of an ancestry test. I do not believe that donors should be anonymous.

6. At least two of my donors wanted to know about me before they were 18.
7. Anonymity should not be an option. With all that we know about heritability of disease alone, it should be outlawed.
8. At least one of my offspring experience this exact shocking occurrence.
9. It has been very special to me as a donor to now have amazing relationships with several of my adult donor offspring.
10. Obviously true on so many different levels.

137. As a donor conceived person, I'm begging potential parents not to use unknown donors. Not knowing half of my ancestry or medical history is anguish.

138. As a donor conceived person born in the late 1970s, the circumstances of my birth were kept secret from me (and everyone else) until I was in my mid-20s. I was fortunate enough to be told the truth by my mother rather than finding out by accident like so many others. This information, obviously, shocked me and threw my whole sense of identity into question. The man I thought was my father for 26 years no longer had any connection to me. My siblings, whom I cherish deeply, became half-siblings. The ancestral heritage I'd grown up being proud of...half was now a lie. What makes up the other half of me? Where do I get my crazy, wild, thick hair from? No one in my mother's family has it. Where does my nearsightedness come from? My mother is farsighted. When I fill out heath history forms at a doctor's office, half of that information is left blank. What should be there? Are there genetic diseases I should be aware of? Should I be having annual exams done to check for early onset of some disorder or disease? Is there some preventative measure I should be taking now to prevent or delay some health issue hidden in that unknown half of my dna? What possible mental health issues will my family and I have to deal with? How many possible half-siblings do I have? How do I know that a young man my daughter dates in the future isn't actually her cousin? There are too many unanswered questions, too many what ifs. The fertility industry needs regulation and oversight, and donor anonymity needs to end NOW.

139. I am a "donor"-conceived person born in 1970, before the days of sperm banks, when the "donor" was hand-picked by the doctor and my mother was ill-advised never to tell. My mother was married to my Dad, so I had no reason to believe he wasn't my father until the truth came out one day via a "long lost" relative when I was 33. I was shocked and devastated. I felt as though someone had reached in and ripped out half of my soul. Half of who I always thought I was turned out to be a complete lie. Family is very important to me, and I want to know my biological relatives. But mostly, I want to meet the man I look like, who gave me my brown eyes, my olive complexion, my height, and so many aspects of my personality that definitely didn't come from my mother's side, such as my love of science, my adventurous spirit, my love of nature.

Those dark days of secrecy (what you don't know won't hurt you) were proven wrong by the adoption community, giving adoptees the right to know their biological parents. For the DC, it's no different; we were just adopted before birth. Yet our rights haven't been recognized yet. I have the same desire to know my genetic heritage, to know who I look like, to know my medical history. If medical history didn't matter, it wouldn't be the first thing you're asked in any medical office, yet I don't have the answers I need.

At 47, I'm now at risk of developing medical problems I could have had a heads up to look for and possibly prevent if I'd only known I had a history of them. I know time is running out to find my biological father, but I have so many questions that I will not stop looking for answers. My quest would be made easier if the laws on the books were revised to recognize my rights to my own heritage. I have met the doctor who "helped" my mother conceive, but he has denied everything, citing concern for his client's privacy. How can some guy's privacy for ejaculating into a cup 48 years ago trump my right to my own identity??!! This flies in the face of the notion to "first do no harm". There has indeed been harm done, and it's time to make things right for all donor-conceived people like myself.

Please revise the regulations to allow those conceived to know who their biological parents are, including retroactively for all of us born in previous decades, to limit the number of offspring from any one donor, to follow up with donors on medical updates, to adequately screen potential donors, to conduct medical and genetic testing, and ban anonymity once and for all.

140. It has been incredibly difficult to find the sperm donor my parents used, which is incredibly important to me because I don't know half of my genetic history or if I have other siblings or not. My brother (who was conceived from the same donor) and I have tried in vain to find him but it's been next to impossible since we were born before the anonymity laws changed.

141. I was born 19 years ago thanks to OHSU fertility clinic. As a a donor baby I have always had curiousities regarding my direct genetic lineage and was told from a young age I would be able to find out more information when I turned 18. When I turned 18 I was fortunate enough to find my donor had provided follow up information and a packet for me to recieve once I turned 18. Unfortunately the same is not true for other kids.
It has been such an incredible experience to meet my donor father who I now have a great relationship with. I also lucky enough to have connected with my half sibling thanks to donor sibling registry.
I hope all donor offspring have the opportunities I have had to meet and connect with their genetic relatives. The legal system surrounding sperm donation is flawed and many will never be lucky enough to gain the knowledge and connection I have been blessed with.
I hope the FDA can regulate this system and help those willing to connect find each other.

142. I can totally see all the points of this petition. As a donor offspring, there is this longing to know about the other half about what make yo, you. About what gave you the blue eyes no one else has in your family. Or the fair pale skin, so different from your Hispanic mom. Or the annoying heart condition.

143. I have a thyroid disorder and my girls have peanut allergies. I would like for my recipients to be aware before its too late. I often wonder if the recipients live in the same area as us. My child may be interested in dating someone who is actually their half sibling. I know it's too late now, but I yearn for the offspring as if they were given up for adoption. There should be a way to know about each other but with a nondisclosure agreement.

144. I am not only a donor but an adult who, resulting from an extramarital affair, was never told about his biological father until later in life. And they werent going to tell me, either; I found out after my biological father died through a supernatural experience. I am 61 & if I've learned any one thing in my life it is that EVERY HUMAN BEING HAS THE CIVIL RIGHT TO KNOW WHO HIS/HER BIOLOGICAL PARENTS ARE. Knowledge is POWER & FREEDOM to chose & make intelligent & informed decisions is as fundamental & basic a human right as we can possibly ever ask for. FAILURE to communicate this potentially vital information to one's child is in my experience a form of EMOTIONAL & PSYCHOLOGICAL - potentially even PHYSICAL ABUSE.

ANYTHING less than full disclosure is a violation of the child's basic human rights, sense of wholeness & dignity.

145. To: FDA
July 3, 2017

I am writing to you as the parent of a donor conceived child, to urge you to put forward legislation that adequately protects donor conceived people.[1] I have met many families affected by donor conception, both through our own half sibling group, and through a support group I had attended when my child was small. At the end of this letter is a point form (not exhaustive) list of some aspects of legislated change that is desperately needed, and that you are urged to enact in the strongest possible way, as soon as is possible.

I have been open with my child about the child's origins from an early age. My child has asked about the donor from a very young age. This did not come from any prompting by anyone else. Among the questions were: what is his name? Where does he live? Does he like pizza? Does he like children? What does he look like? When can I talk to him? I can now see that there is a deep and intrinsic human need that all people have to know where they come from. To be able to look in the mirror and know the parts that went into making up that face. To know that our biological parents know and care for us, and that we know them and know our family history.

One of the most heartbreaking questions came at age 4, when my child, to whom I would often say "you're so wonderful", asked:

> "If I'm so wonderful, why doesn't he want to know me?"

I became pregnant while single. I, like many other single women and homosexuals who turn to this avenue, had absolutely no fertility problems. I had been advised that it was highly unlikely that I would be able to adopt a child, since I was single and birth parents overwhelmingly choose two parent families.

Families who have a child through a donor, unlike those who adopt, are not required to undergo any assessment that ensures that they are fit to be parents. Such a requirement should be incorporated into legislation.

I chose a sperm bank that offered "open identity" so that my child, upon reaching the age of 18 would be able to obtain information identifying the donor. The ability for my child to some day find out the donor's identity was critical for me in the choice of a bank, and in a donor, and was by far the most important consideration to me, far moreso than any other characteristic. I am discovering (well after the fact) that the "open identity" donor practices of the sperm banks is not at all what I had understood it to be. <u>**After**</u> I became pregnant, the sperm bank asked me to sign a waiver stating that neither my child or I would hold them responsible for failure to provide contact information for our donor. This was in direct conflict with the open identity donor that had been selected!

Our donor did not disclose any significant medical concerns, but was asked by the sperm bank only about a narrow range of very specific direct family members. Further, I understand that there are few if any consequences to either the donor or the sperm bank for providing inaccurate or

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[1] I have used the word "donor" , but am compelled to point out that I do not like to use the word "donor." I prefer to use "third party" for "donor" and "third party assisted reproduction" for "donor conception". As stated by Barry Stevens (film maker and donor conceived person), "A donor is obviously somebody who donates, and the meaning carries a clear distinction from somebody who sells. I know that in the UK, payment is no longer made, and have heard this is also the case in Canada. And indeed, in the 40s and 50s, the early donors were not paid and so back then the term was accurate as well. But in the years since then, and in countries all over the world (most dramatically in the USA) donating a gamete as gift is not the norm. An egg provider in the US can be paid upwards of $10,000. And yet they use the word 'donor' universally. As far I can tell reproductive medicine is the only area where the word's meaning is routinely changed to mean 'seller,' and it is done to sugarcoat and obscure the fact that the practice involves a commercial trade in gametes and embryos. Since the practice that made us **has long been riddled with deception**, I would be sorry to see us continue this particular falsehood…" [emphasis added] – available at: http://www.americanadoptioncongress.org/assisted_stevens_article.php

misleading information. With about 30,000 genes now identified as carrying higher risk of certain diseases such as breast and colon cancer, family genetics is increasingly recognized as key to diagnosis and disease prevention. Information supplied by donors and sperm banks ought to be clearly legally binding, and with significant liability attached for inaccurate, incomplete or misleading information.

It is curious that telecommunications and utilities are regulated because they usually are a monopoly or oligopoly, and as a public policy matter we do not want to allow them unlimited opportunities to abuse their monopoly position, to the disadvantage of consumers. But we do not yet prevent sharp practices by monopoly/oligopoly fertility clinics, who serve a significantly more vulnerable clientele, and who deliberately create people whose deepest needs and interests have not at all been adequately considered, let alone respected and served.

My experiences led me to research how the field of (so-called) "reproductive medicine" works, and what protections exist for the children created by these efforts.

As I delved deeper, I was horrified to discover that there is in fact little or no meaningful legislative protection for children whose origins began with donor conception through an American donor. These children, who will grow into adults and likely have families of their own, may want or need information about their genetic origins, both for purposes of identity formation and in order to have medical information about his/her donor and his extended family. The contrast in the legislative protection available to children who are adopted as compared to those who are donor conceived is shocking and surprising. Whereas donor conceived people are possibly denied (through the absence of the state to legislate this area) a legal right to know their genetic origins, legislation of most jurisdictions acknowledges the right of adoptees to know their genetic origins. How can this discrepancy honestly be morally justified, I wonder, as a parent? Of course, it can't. Why on earth is the state allowing people to being deliberately created, while at the same time (through failure to act) forever denying them half of the information they need in order to form their identity, and to make informed, pro-active choices to protect their own health and that of their children and further descendants?

The situation is in stark contrast with legislation in a growing number of jurisdictions. Jurisdictions which have banned donor anonymity include the Netherlands, Germany, the United Kingdom, Sweden, Norway, Switzerland, Austria, New Zealand, and the Australian states of Victoria and Western Australia,[2] to name only a few.

One academic has observed:

> When decisions have required striking a balance between the interests of birth parents and donors on the one hand, and the interests of donor offspring on the other, the presumption appears to have been in favour of the former. But **because of the vulnerable nature of children … it would, in fact, be proper to give primary weight to the interests and rights of donor offspring when setting laws and policies in assisted reproduction**.
>
> … donor offspring have no control over the secrecy about either the mode of their conception or the identity of their gamete donor(s). They are, in effect, at the mercy of their birth parents, their gamete donors and the ARD system when it comes to knowing about their genetic heritage. **Given donor offspring's reliance on others for knowledge of the existence and identity of their donors, it seems appropriate to consider donor offspring's interest in accessing this information as being of particular importance when formulating laws on this topic**.
>
> … The problem with secrecy in ARD is that donor offspring are never given the chance to assess for themselves the importance of knowing people with whom they share a genetic, as distinct from a familial, association. The decision as to the importance of this information is made for donor offspring by their birth parents and by **a system that facilitates, or even imposes, secrecy**.

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[2] E.Blyth, "Donor anonymity and secrecy versus openness concerning the genetic origins of the offspring: international perspectives" (2006), Jewish Medical Ethics, 2006, V, 2, 4-13. (ISSN 0793 2952), available at: http://www.medethics.org.il/articles/JME/JMEM10/JMEM.10.1.asp

> …**The interests of donor offspring require that neither their donors, nor anyone else, hold the power of veto over complete and full information about their genetic ancestry**.[3] [footnotes omitted] [emphasis added]

Conduct of Sperm Banks and Fertility Clinics – Experiences Encountered

Sperm banks are generally profit based corporations, which operate in an environment of little or no regulation.

Playing Hardball with Waivers or Release Forms- Attempts to Remove All Rights From Families & Limit Recourse for Families

Some parents, including myself, have been presented by the sperm bank with oppressive and strongly one-sided forms to sign, which protects *only* the rights of the sperm bank and to an extent also the donor, and purports to remove rights from the donor conceived child and his/her family. It was a shocking document to read! Any attempt to negotiate a more reasonable agreement with a sperm bank is likely to be futile. I know this because I tried, only to be told (by a senior executive of the sperm bank) that they do not personalize their forms, and that I must sign their form or none at all. If I signed none at all, then the sperm bank would take the position that we have no ability to obtain identifying information regarding the donor. If I signed their form, then it would purportedly remove all of our rights of recourse if the sperm bank later chose not to honor the open identity aspects. I had already paid a higher price for an open identity donor.

In many other areas where consumers are deemed worthy of protection, such forms would be declared illegal, and these vulnerable consumers would be given minimum protections as a matter of statute, and attempts to contract out of those minimum protections would be declared void. I urge you to ensure that your legislation provides adequate protections to both prospective parents and to donor conceived people.

Many parents are completely unaware of the magnitude of the rights they are asked to waive by signing such forms. They sign them under duress, and (correctly) believing there is no true ability to do otherwise, and at a very vulnerable time in their lives, because they are told that they must sign them in order to obtain any identifying information about the donor. Yet, in signing the form, they waive all rights to exactly that!

Please do all that you can to ensure that your legislation affords adequate levels of protection to donor conceived people and their families.

Failures to Limit the Number of Siblings

There is no requirement to report a birth of a donor conceived child in North America, and I believe that many families do not report the births. I have met many other families, through a support group I had attended, and not one had reported their child's birth. Nor is there any requirement on a sperm bank or fertility clinic to even to tell a parent to do so. I was not told or even encouraged to do so. I reported the birth of my child only after reading on a yahoo message board that it was a good idea to do so.

It is almost impossible to know how many half siblings exists, let alone the location of their birth or where the families are living. This is most unfortunate, and is not consistent with the best interests of the people created. Misinformation seems to be the rule, and not the exception.

The sperm bank I used stated at the time that it retires a donor after 35 families have been created (and that following retirement, any remaining inventory can be sold until 40 families have been created). There is no requirement that a sperm bank retire a donor at all, or at any particular time. I know someone who used the same sperm bank as I did, and who was told (at about the time of her child's birth) that 23 babies had already been born from their donor. She was advised a few months later that even though the donor had already been retired, at least 40 more (and possibly as many as 100 or more) vials were released. Despite its statement that the sperm bank retires a donor after 35 families, the sperm bank advised her within 2 years of her child's birth that the number of children born from their donor that had been reported exceeded 70. Yes, seventy, and that is just what is *reported*. The sperm bank refused to disclose any of this information to her prior to her choice of a donor, and prior to the birth of the child.

I understand that one deposit at a sperm bank can be broken down into as many as eight to 20 or more vials.[4] I also understand that many banks require donors to donate at regular intervals (no

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[3] J. Johnston, *infra*.

less than monthly, preferably more often) for at least 2 years. I know of a family who used our sperm bank and who was able to obtain details on the frequency with which their donor provided samples. This donor had provided more samples than this, but let's assume he provided one sample per month between January 2005 and November 2007, meaning he would have provided 35 samples. If we further assume that each sample was broken down into 14 vials, this means that 490 vials would have been created from this donor alone. If we assume that 75% of those vials resulted in a treatment (ie, 367 vials used), and further assume a 40% live birth rate, then a child conceived from such a donor quite likely has in excess of 100 (and close to 150) siblings. Two samples per month during that period could have resulted in over 700 vials, and over 200 (close to 300) siblings. Imagine the emotional toll on the families involved, including the donor himself, but especially the people created. Higher than that, are completely possible.

All of this from a sperm bank which states that a donor would be retired after 35 families.

I can only conclude that the so-called self-imposed/voluntary limitations on the number of children that the sperm banks say they have are in fact *not followed*, in any way, shape or form. Strict legislation requiring limits is necessary.

Even though the sperm bank has received at least 70 reports of births from one of the donors described above, and there are surely more half-siblings than that, less than 20 children from that donor have presently been registered on the Donor Sibling Registry (DSR).[5] As wonderful as the DSR is, it is not an adequate substitute for a requirement to report births of donor conceived children, and for all such births to be contained in a government registry. A governmental registry is desperately needed (as opposed to a privately sponsored one (which would give rise to the risk that the sponsor of the registry may go out of business).

I have reason to believe that there are several families in our own jurisdiction with children who are half siblings to my child, and who are close in age to my child. To date, none have registered on the DSR, and there is presently no formal way of us knowing who they are, even though the sperm banks and clinics have that information.

I urge you to put into force a mandatory requirement that all parents who have had a child through donor conception report the birth as one resulting from their donor. This could be done for example through the vehicle of birth certificates.[6] These births must be contained in a government registry that can be accessed by donor conceived families at any time.

When families are unaware of who the other half siblings are, or where they are located, this of course increases the risk of consanguinity to unacceptable levels and **poses a health risk to**

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[4] "Confessions of a Sperm Donor: Hundreds of Kids: Films 'The Switch' and 'The Kids Are Alright' Paint Pretty Picture of an Ugly Fertility Industry", ABC News, Apr 19, 2010, available at: http://abcnews.go.com/Health/sperm-donors-admit-fathering-hundreds-children-call-regulation/story?id=11431918 . This article includes the comments of former sperm donors, including one who has likely fathered over 400 children, as follows: "Maxey is also critical of the "commercialism," of sperm banks that make greater profits by dividing up a single ejaculate. 'Make sperm distribution a mandatory non-profit activity, matching the status of all other traffic in living human tissue,' said Maxey. 'Disclose to all women all that is actually known about their prospective donor, and maintain a strict registry so that the knowledge base will be substantial. Make the information supplied by donors to banks legally binding, and obtained under oath. Make donor records indistinguishable from other medical records, but require them to be maintained a very long time. I suggest 100 years would be a good start. Make them discoverable and subject to HIPPA.' " In ABC News, Real-Life, "Sperm-Donor Siblings Find Each Other: After Years of Searching, Ryan Kramer Finds Sperm-Donor Father, Six Half-Siblings", by Kelly Hagan, July 27, 2010, available at: http://abcnews.go.com/GMA/Parenting/sperm-donor-siblings-find/story?id=11258047 , a donor is referred to who learned through the Donor Sibling Registry that he had more than 125 children, 70 of them under the age of 7.

[5] http://www.donorsiblingregistry.com/

[6] For an excellent discussion of this as a method of tracking the number of donor conceived people being born, and a workable model that promotes disclosure without compromising privacy, see "The Role of Birth Certificates in Relation to Access to Biographical and Genetic History in Donor Conception", E. Blyth, L. Frith, C. Jones, J. Speirs, *International Journal of Children's Rights,* 17 (2008) 1-27, available at: http://eprints.hud.ac.uk/5744/

many thousands and possibly millions of people. In today's world, it can not be assumed that a child will be born, grow up, and live their entire lives in one location.

It is of great concern to me that my child could meet and become romantically involved with a half sibling but not know it. The numbers of siblings that sperm banks and fertility clinics are creating, together with the absence of any requirement to report births into a government registry, and coupled with donor anonymity, is a deeply troublesome combination. Not only is the risk of certain diseases higher among siblings, but any marriage in this situation would be illegal and invalid. These possibilities lead to further heartache for all involved: the child, the child's potential romantic interest, and both of the families involved. And, for what? Why?

Prior to selecting a donor, some sperm banks (such as the one I used) disclose only whether "a successful pregnancy" had been achieved with that donor (a yes/no proposition). They will not provide any information on the number of children born or reported to have been born to any particular donor. Legislation must require births of donor conceived children to be tracked (such as through requirements to register a child as donor conceived when the birth certificate is registered). Legislation must also require fertility clinics and sperm banks to disclose to their clients the number of children born, before a final selection of a donor is made.

There must be limits on the numbers of children created from a particular donor, and strict and severe penalties for sperm banks who fail to comply with those limits.[7] We are starting to hear far too many stories in the media, and personal testimonials of families whose children have hundreds of siblings. This must be ended, promptly and fully. The higher the number of children that a donor has, the greater the likelihood that the donor will ever meet all of the children, let alone let each child get to know him/her or have a relationship with them, but it also increases the risk of consanguinity to unacceptable levels. A donor conceived person must be able to go to a government registry to determine who their half siblings are…. Many parents still do not share with their donor conceived children the fact that they were donor conceived (thereby leading the child to believe in a false genetic heritage).

Lack of Meaningful Counseling for all involved, prior to conception

Donors must be counseled, so that they realize that their children will likely want to contact them some day, and not only meet them, but get to know them, and to have a relationship with them. They must be counseled that their spouse, the children they raise, and their extended family will also be affected by the existence of half siblings. They must realize that the people created have the same innate and deep need that we all do (but which many of us take for granted) to know where they came from. They must realize that they have permanent ethical responsibilities towards, and biological ties with, the people that they have helped to create.

Geographic restrictions on Gamete Transfers

One practice that the industry uses is to have a 'blackout' area geographically around the area in which the donor lives. Samples are sent to prospective parents only outside of this blackout zone. This creation of distance specifically discourages relationships among the donor and his children, as a relationship is obviously harder to establish if there are thousands of miles in between. In fact, my child has siblings (through the donor) all over the world. This is the opposite of the way it should be…. Samples should be restricted to an area that IS close to where the donor resides. In order to facilitate relationships between the donor and people he assists in creating, legislation ought to prohibit gametes from being transferred a certain distance away from the donor's location of residence. For example, if a donor is resident in a particular city, his sperm should be prohibited from being shipped outside the donor's jurisdiction/ state and also be prohibited from being shipped outside a certain radius of that city (eg. 50 miles), and transfers outside that area be prohibited. In our case, we live thousands of miles away from where our donor resides (and in another country), thereby reducing the chance that my child will ever get to know or have a

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[7] Countries which limit the number of children that can be conceived from a particular donor include: Austria (limit of 10 children), Belgium (limit of 10 children), France (limit of 5 children), Germany (limit of 10 children), Netherlands (limit of 25 children), Singapore (limit of 3 children), Sweden (limit of 6 children), United Kingdom (limit of 10 families): cited in Health Canada, Canadian Fertility and Andrology Society, 54th Annual Meeting, Work Book, "Assisted Human Reproduction Implementation Office Policy Development Directorate Strategic Policy Branch Health Canada, November 26, 2008", page 4 of 9, in turn citing "Sawyer and McDonald (2008)."

relationship with the donor. This should also be an issue that families are counselled about, prior to attempting conception.

Failure to Allow Donors Personally Known to the Prospective Parents (Known Donors)

At least some fertility clinics (such as the one I used) seem to take the position that they will not perform assisted reproduction using a donor that is personally known to the prospective parent (but with whom the prospective parent is not in a relationship). That is the response I received from the clinic in my jurisdiction when I approached them about a friend who had offered to be a known donor. This donor lived close to us, and would have been willing to have a relationship with my child, not to mention we would have had ready access to health and other information about him.

I would strongly urge that you enact legislation that requires a fertility clinic to:

- use samples from a known donor, if requested by the prospective parent,
- advise prospective parents that this is an option, and
- not discourage them (through statements they make or policies they administer) from using a known donor.

Use of a known donor is obviously more likely to be consistent with the best interests of the child. Since the identity of the donor is known, the child will be able to at least refer to a name when referring to the biological parent, which allows there to be a humanization (rather than dehumanization) for the child of his/ her genetic ancestry. A known donor also allows the prospective parent to know more about the donor than would be the case about an anonymous donor, and thereby be in a better position to answer the child's questions about the donor. Also, since the donor is known to the parent, it is far less likely that any particular known donor will have had other (and especially staggering numbers of other) children, thereby greatly increasing the likelihood that the donor and the person conceived could realistically have a relationship some day if they so chose. Finally, since the identity of the donor is known, it is obviously easier for the child (person conceived) to locate the donor in the future if the desire or need to do so was present.

<u>Require Release of ALL Donor Identities</u>

It is my hope that the FDA will decide to clearly prohibit donor anonymity for future births as well as for those who have been born in the past, during a time when the law had not kept pace with reproductive initiatives.

I understand that for the most part, adoptees in North America were given the right to know the identities of their biological parents decades ago, and that the adoption laws were made retrospective out of respect for the needs of adopted persons to know their identities. That these rights have not to date been available to donor conceived people (which some have referred to as half-adopted) is shocking.[8]

Donor conceived people are now becoming adults, and in the age of the internet, are able to discuss their pain and common experiences with each other. They agree in overwhelming numbers that anonymity must be ended, and should never have been a practice sanctioned or allowed (including through inaction) by any government.

Failing to abolish anonymity retrospectively would result in two classes of people, and the perpetuation of injustices to those who have already been born, and who (like those about to be born) were not consulted on the manner of their conception. To refuse them similar rights will perpetuate and continue the mistakes of the past, and relegate them to second class citizens. It is also likely to result in time consuming and expensive litigation, in which the government is unlikely to be successful. Once it is acknowledged that donor anonymity is inhumane to the people created and is against public policy, there is simply no justification for maintaining or allowing it to continue for any segment of the population.

Legislation ought to require that all donor conceived people and their families be given immediate access to all information held by physicians, sperm banks, fertility clinics, regulators and others

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[8] Many have commented on the unjustified discrepancy between the present lack of legal rights for donor conceived people as compared to adopted people. A recent example is "Telling is more important than ever: rights and donor conception", L. Frith, *BioNews*, Issue 542 (25 January 2010), available at: http://www.bionews.org.uk/page_53094.asp .

relating to the donor (including his/her full identity, and complete information on the donor's medical history and that of his/her family), and sufficient information regarding half-siblings (for example, dates of birth, place of birth, and gender), including half siblings being raised by the donor. All those within the system (whether fertility clinics, sperm banks, medical personnel and others) who have such records in their possession or control must be required to provide them immediately upon request to the donor conceived person and to his/her parents, guardians and representatives, without exception. Destruction of records must be prohibited. Very serious consequences (fines far in excess of the cost of doing business, and jail time) must be attached to any destruction of such records.

Information Be Made Available To All Donor Conceived People, at an Early Age

Information about donors must be made available (a) immediately (at an early age), (b) continuously (if any change in the information, or additional or supplemental information is received), and (c) to all donor conceived people and their families, regardless of when they were born. Withholding this critical information until the child becomes 18 years of age means that donor conceived children will not be privy to this information during the time that they need it most…. their formative years. Withholding this information for any period of time results in the state sanctioning the infliction of unnecessary psychological pain on a child, and during a time when the child desperately needs to be able to freely discover his/her identity, and form a stable identity. Does a difficult time forming one's' identity increase the risk that a child could turn to drugs, alcohol, eating disorders or other methods of attempted outlets for the pain that they feel? Why would we want to wait to find out? We are talking about children, here, and decisions that are made about their lives without their consent, and before they are even created. Requiring such a long period of time to elapse increases the likelihood that records will go missing, businesses will close down, buildings will burn down or otherwise be destroyed, and of people moving, dying or otherwise going missing. Requiring donor conceived people and their families to wait until an **arbitrary age** to access this information can only serve to continue to protect the interests of others (such as medical professionals, sperm banks and donors) over the people they have deliberately created. There is absolutely no reasonable justification for a requirement to become 18 before accessing records.

Information must also be made available retrospectively, to all donor conceived people. Once it is acknowledged (as it surely must be) preserving donor anonymity hurts the person created, and was an erroneous, misguided and incorrect approach toward donor conception, then it follows that these wrongs need to be corrected, for all (and not just some) donor conceived people. When we look back on things that were allowed to happen in the past, and realize that we were wrong, we ought to right our wrongs, not just in the future, but also in the past. When slavery was abolished, it was abolished not just for those about to become slaves, but also for those who had already become slaves. Donor anonymity must be promptly and fully abolished, and the interests of donor conceived people acknowledged — regardless of the date on any particular person may have been born. The pain caused by lack of information must not be permitted to remain, for anyone.

Prohibit Waivers and Releases

As part of the requirement to make donor information available, it will also become necessary to prohibit attempts (by fertility clinics, sperm banks and others) to request that prospective parents or donor conceived people waive any of their rights (to identifying information, health information or otherwise). It is urged that legislation contain a provision that declares as invalid all documents purporting to waive these rights. In other words, 'contracting out' of those rights (and the corresponding obligations placed on fertility clinics, sperm banks, physicians and others) must be strictly prohibited.

Reductions in Number of Donors? So What? Legislative Focus on the People Conceived is Needed

Some have argued that bans on donor anonymity would result in a reduction in the number of donors available. The number of donors is a very complex issue, and that these claims have not necessarily been realized in countries where anonymity has been removed (such as in the UK). Regardless, ultimately, as a parent, I can't help but see these arguments as **irrelevant** diversions. Surely we want to do what is RIGHT for the children created through donor conception, do we not? Human lives, innocent and vulnerable children, are being created— and these human beings have rights. Donor conception is not about making widgets in a factory (where supply, demand or cost may be the primary factors). Surely legislation must be based on principles which acknowledge and protect the rights of the children created, and let the chips fall wherever they will on donor numbers. Each party has his or her own interests and vulnerabilities. The people created, though, are the most vulnerable of all, and were not given the opportunity to consent to the arrangements that will profoundly shape their developing identities, and which will follow them for their entire lives, and those of their children.[9] No other party is affected by these choices for a greater period of time than the people created. Their interests must therefore always be given the greatest weight in any legislation and whenever any reproductive choices are made. They are the vulnerable ones, and they ought to be the focus of legislative protections.

One in-depth study examined the experiences and issues of young adults conceived through sperm donation. [10] The study examined a sample of 485 adults between the ages 18 and 45, drawn from over one million households. The authors report that "on average, young adults conceived through sperm donation are hurting more, are more confused and feel more isolated from their families" than those who were either adopted or raised by their biological parents. This is not surprising. The study recommends (among other things) ending anonymous sperm donation, increasing the screening process for donor conception to the level of adoption, and limiting the number of children that can be born from a single donor.

Legislation *must* fully and clearly be based on the all-important principle that the needs of the people created through assisted reproduction must, without question, and *without exception,* be protected as the *absolute first priority*. Any interests that conflict or could potentially conflict with the interests of the people created *must not at any time be allowed to encroach* on the protections afforded to the people being created. Decisions made about the donor, and the donor conceived person's ability to access information about the donor, will have permanent effect on the life of the person created, and on the lives of those who love that person. The people created are vulnerable children, many of whom who will have difficulty forming a solid identity without receiving identifying information about their donor at an early age. For the person created, the issues arise due to decisions made prior to their conception. We must immediately stop forcing them to pay the price for unethical decisions made by others.

A Final Word on Prohibitions

It is urged that any activities prohibited by the legislation be backed up with severe fines in the event of a breach – fines that exceed the 'cost of doing business', as well as jail time. Fines of at least $1 million per day while in breach plus possible jail time for directors, officers and employees who were aware of the breach (or were willfully blind to it) would be appropriate.

* * *

Thank you for the opportunity to make this submission. I look forward to seeing positive changes soon to the legislation governing donor conception in and originating from the United States.

146. I have been extremely fortunate that my donor has been willing to have contact, and I cannot imagine the hurt and emotional turmoil it would cause a child to never be able to have the answers he/she deserves about a biological parent.

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[9] Many academics have made this point.

[10] Marquardt, E., Glenn, N., and Clark, C. (2010). *My Daddy's name is Donor*. New York: The Institute for American Values. Retrieved July 5, 2010 from http://www.familyscholars.org/assets/Donor_FINAL.pdf pp. 5., referenced in "How do donor conceived children fare and feel?: A new report examines the outcomes", Charles Andreasen, Researcher, Institute of Marriage and Family Canada, eReview, vol.10, no 13, July 14, 2010, available at http://www.imfcanada.org/article_files/e-Review_July_14_10.pdf . Studies of donor conceived people invariably demonstrate what they and their families already know: withholding information from donor conceived children with the intent of protecting the donors and clinics has inadvertently harmed the child.

147. We believe that every child has a right to know who the donor was.

148. I donated 11 eggs in August of 2003 here in Colorado. It was an anonymous procedure and I know nothing about the outcome. I'm hoping that one day I will become aware of how many babies were born as a result of my donation. I would love to answer any questions that the recipients may have regarding health issues.

149. Recipients are trying to contact me as the hospital informed me BUT despite agreeing to contact the hospital won't allow it to happen! Not even to show me the postcard and other documents that were addressed to me!

150. As a donor who has waived anonymity and made contact with one of my biological offspring, I am acutely aware of the importance of connection along the line of heredity. This is not a trivial thing.

151. My parents never told me I was a donor child, it was only after I confronted them with the mysterious genetic differences that they coughed up the information that led me on a ten year quest. As a donor child, one of the true blessings in my life was finding my Biological father. It took me over 10 years and countless hours tracking down genetic possibilities, taking DNA tests and endless cold calls to distant relatives before I was able to identify the correct genetic branch of my family lineage through a long monotonous process of elimination. It wasn't until I found my Biological Father, and my half brother, half sister, and countless nephews and cousins, that I finally felt that my life was complete.
I can't quite explain why it is so important to know or meet your biological parents, but I can say (at least in my case) that it is a great feeling.

152. As a donor conceived individual, I find it extremely difficult to accept the lack of regulation surrounding this industry. I often feel like there is no thought given to the children created in this way. We deserve to know our true heritage and any possible hereditary conditions that we may be effected by.
Sperm banks need to thoroughly educate any donors about what exactly they are doing, including the fact that anonymity is nearly impossible nowadays. Donors need to expect their offspring to make contact in the future, asking for health information, or even just wanting to know who they share half of their genes with.
Sperm banks should also be required to keep up to date and accurate records on the number of children conceived by each donor. Many children long to know their half-siblings, including myself. As far as I know, I have at least one older half sibling, but due the lack of record keeping by the sperm bank, I could have several more. I was raised an only child and long to make a connection with my half siblings.
Personally, being donor conceived has taken a huge toll on my mental health, as I often find it emotionally exhausting knowing that half of me is just one big question mark and that it is near impossible to fill this void due to the lack of regulation. I know that this will have a lifelong effect on me, so please, consider this important petition very carefully as it will change the lives of the donor conceived community.

153. Please regulate this industry.

154. As a former sperm donor, I fully support this proposal. I find the lack of regulation of US gamete donation very disturbing.

It's 20 years since the Brittany Johnson case. CCB ignored serious warning signs on a profile, rewrote that page of the profile (which said "at risk for kidney disease"), and tried to argue that physician-patient privilege prevented them from providing any information about the donor.

http://caselaw.lp.findlaw.com/data2/californiastatecases/b137002.doc
http://caselaw.findlaw.com/data2/californiastatecases/B155896.PDF
<< Specifically, on the original page nine, Donor No. 276's affirmative answers to the questions concerning the presence of kidney disease in his mother and his aunt/uncle were circled, a question mark was written next to each "X", and the notation "at risk for kidney disease" was written directly above the "X" denoting his mother's kidney disease. The document contained three different colors of ink. On October 2, 2001, after a number of requests to Cryobank's counsel, petitioners were provided with a color-copy of the original Donor Profile. The color-copy of page nine revealed that the donor's responses were written in blue ink, the question marks next to the donor's Xs for his family's kidney disease were written in black ink, the notation "at risk for kidney disease" was written in black ink, and the circles around the Xs were written in red ink. >>

There have been many similar cases since, and yet the FDA continues to focus solely on preventing STI transmission to recipients, rather than the genetic health of donors and of donor-conceived people, or even whether recipients are getting gametes from the donor that they actually chose. The mere fact that California Cryobank are still in business despite their quite appalling behaviour suggests to me that there is something very wrong with the way that sperm banks are run in the US.

The ending of donor anonymity is also long overdue. The donor-conceived, rather than the parents, clinics, or donors, are the people most directly affected by donor conception, and they are the ones who have to live with the consequences the longest. Why should anyone's desire to have a child override a donor-conceived person's desire to know the identity of their genetic parent? Other countries that have ended donor anonymity include the UK, Ireland, Germany, the Netherlands, Sweden, Norway, Iceland, Finland, Switzerland, Austria, Australia, and New Zealand.

It's over 12 years since the UK ended donor anonymity, and according to HFEA figures, the numbers of UK sperm donors went *up* eight years in a row after that btw, thus reversing a three year decline. The 631 donors in 2012 was the highest figure since they started keeping records, and well over double the figure in 2004 (239) just before anonymity ended.

155. I'm in favor of this petition.

156. This needs to be regulated so much better. My mum was inseminated in 1991 and both the institute that inseminated her and the sperm bank claim to have to record of the procedure. It has also come to light that they didn't use the "chosen" sperm - they used sperm with similar characteristic on hair and eye colour. The clinics promised anonymity to my donor, but with DNA testing it was relatively easy to track down my close paternal relatives, even from distant cousin

matches. The rest of the world is moving away from anonymous donations, and are even retrospectively releasing identifying information to DC adults (look at Victoria, Australia), America needs to put the children first and move in the same direction.

157. I would love to connect with my biological children. I donated eggs anonymously 6 times to 7 different women. I don't know how to even begin to find them... or make myself available for them to find me. I wish there was a registry where we could attempt to connect. I have a daughter. She is 9. I would like her to know her half siblings one day.

158. We deserve the right to know our biological families.

159. As the parent of a donor conceived child, I am extremely concerned about the lack of oversight of the sperm donation industry and the industry's current ability to make random changes to policy and practice that affect my daughters life.

160. I am a 27 year old female, and the result of my parents using a sperm donor to conceive myself and my younger sister. In my later adulthood, I am concerned about what genetic predispositions I might have for illness and disease - and I have no way of knowing what my risks are for congenital issues, cancer, etc. as this information is not accessible to me. Not being able to have knowledge of my own medical-genetic related potential problems is scary, and I should have the right to prepare for what may come my way. This isn't information I could, or even would use to contact my donor, but rather having the power of information and knowing what to look out for health wise, which I feel is a right that I currently don't have. Can you imagine not having 50% of your medical history? I have no idea what I might have in store for myself later in life, which can be quite daunting. Consider allowing us donor children to at least have access to that information, and keep the information updated as to the later living history of said donors.

161. I am a donor from 1979-1980. My records were not kept updated and despite attempts to contact the bank I worked with they fail to even acknowledge that I was a donor, much less offer to keep my "open door" request for potential offspring to contact me available.

The system needs oversight. Although my case probably will not have any bearing on potential contact with my own offspring I would hope this changes for future generations.

162. I am the mother of two donor children. One does not care and the other would like to know more about the donor. I agree with all points listed.

163. I support this petition.

164. I am writing in support of this petition to regulate gamete donation. Before I started dating my boyfriend, I did not possess the understanding of what it was like to have been conceived through

anonymous gamete donation. The question of who he is and where he came from has been torturing my friend for years since his parents told him that his father was not his bio-father. He has spent years of his life trying to understand himself and trying to find his bio-father and half-sisters. His relationship with his parents is uneasy as he feels betrayed yet loving to them. His conception has directly disrupted his life and the life of those who love him as he will never regain some of his most prosperous years. I wish that he could find his bio-father and half-sisters to begin the healing process so that life can get back to what some people may consider "normal". Please stop anonymous gamete donation so that future generations do not have to suffer as he does.

165. To Whom It May Concern:

I am 37 years old and 2 years ago I received an online DNA test as a holiday present. The heritage analysis of the test came back with strange results. After months of badgering my parents about my results they finally admitted that I am the product of artificial insemination by donor sperm, my dad is not my biological father. Initially when I found out the truth I felt vindicated, vindicated because I had always questioned my place in my family. Dozens of times in my life I asked my parents if I was adopted, begged them to tell me what was going on, and the reality laid out before me was that it was all in my head. Had I not been given that holiday present my parents never intended to tell me the truth.

It is important to understand that my experience is not uncommon. Simply put, donor anonymity is dead. It is also important to understand that the emotional pain felt from years of lies is immensely deep and the wound easily opens- actually I'm not convinced it has the ability to fully heal. Since finding out about my truth I've spent large sums of money as well as countless hours searching for the truth about my past. I must admit, I remain confused as towards why the truth about my life is allowed to be withheld by corporations capitalizing on a system that is affirmatively injuring individuals like me. I understand the desire to help (and capitalize on) infertile couples/individuals; however, to provide such assistance to these would be parents while callously ignoring the known detrimental ramifications to the child produced by these procedures is unconscionable and it has gone on for too long.

All of the above (and much more) has been troubling to me; however, to be blunt, what I have been most disheartened by is the utter and complete lack of oversight in this industry. I am a medical device engineer as well as an attorney. I've worked on products that were put into the market only after FDA scrutiny. A scrutiny I, and many others, deeply respect. That being said, in the present situation it appears FDA oversight is nonexistent, which is particularly worrisome given that this matter falls squarely under your jurisdiction. These companies have had ample time to address the problems they manifest. The reality is they have not taken, nor will they take, any such action; rather they exude a clear lack of compassion for us, the final product, as we don't really factor into their business model. And that is why we need you, the FDA, the governing body over the health and human services of the United States, to intervene. The health of people like me, other donor conceived children, is being affirmatively injured.

I implore you, please intervene and help us and future donor conceived children by regulating this industry.

Thank you,

David

166. Sperm donors should go through the same rigorous testing as egg donors to ensure genetic illness is not passed along to the offspring, or to at least make them aware of any potential medical issues

167. I believe that the requests within this petition are vital to the health, welfare and safety of the generations that will be born using these methods.

168. As a donor-conceived person, I support this petition.

Although cryobanks and fertility clinics ("gamete brokers") profit from the absence of regulation at the expense of the physical and psychological well-being of donor-conceived people ("DCP"), it is difficult for DCP to publicize their concerns. Many DCP fear that broadcasting their criticisms will distress the parents who raised them or cause their donor to refuse contact. Donor-conceived children of LGBTQ parents or single mothers worry that their criticisms of the industry will be seen as a lack of support for their parent's identity or feminist values. For DCP who are themselves queer and/or single females, speaking out carries the risk of ostracization by peers. Donor-conceived children of heterosexual parents must grapple with the fact that publicizing their criticisms will entail revealing private information about their parent's fertility and/or gender identity.

It is difficult for parent recipients of donor gametes to protest bad acting by cryobanks and fertility clinics for different reasons, including that parents depend on banks and clinics for access to updates to their child's medical history, donor information, and/or gametes from the same donor to conceive future siblings for their existing children.

Meanwhile, gamete brokers have no incentive to educate donors or parents about the practical and psychological consequences of donor conception for DCP. They have no incentive to investigate DCPs' perspectives, create accountable policies to promote DCPs' best interests, or to work with their competitors to standardize tracking donors and medical information. In fact, the only force with real influence over how cryobanks and fertility clinics broker gametes is the market.

The US government should not allow the brokering of gametes to be ruled by what is most profitable to vendors.

Being donor-conceived is intimately tied to an individual's identity, medical history, familial bonding, cultural and ethnic heritage, and bodily integrity. Donor-conceived people should have the first and strongest voice on how donor conception is regulated. But currently, there is not even legislation to track how many DCP exist in the USA.

In 2016, Mother Jones reported on a bill requiring agencies to ask questions about sexual orientation and gender identity in demographic surveys. Rep. Grijalva stated, "To go uncounted is to be unseen in the eyes of policymakers, which is why we must develop a credible and confidential understanding of these vulnerable populations we currently know too little about." In an article by Time, Rep. Becerra said, "If you're not on paper, you're invisible when it comes to the federal government." DCP need regulation so we can be counted and have our opinions considered.

In closing, I ask the individuals reviewing this comment to take a moment to imagine four things that I have experienced as a donor-conceived person:

First, I would like you to imagine looking in a mirror and not knowing where your face comes from--not because you were adopted due to your biological parents being unprepared to raise a child, but rather because a company sold half of the genetic material that created you, and that company has decided that your knowing the identity of your biological parent could jeopardize their bottom line.

Second, I would like you to imagine having health concerns that go undiagnosed for years due to gaps in your medical history--not because that history is unavailable, but because a company has decided that giving you your medical history could jeopardize their bottom line.

Third, I would like you to imagine that every time you pass someone on the street who shares your features, you wonder if that person is your sibling, and every day you carry the knowledge that you will never know all of your siblings, or even how many exist--not because it would be impossible for that information to be recorded and shared, but rather because a company has decided that knowing how many siblings you have could jeopardize their bottom line.

Finally, I would like you to imagine that, as a donor-conceived person, you have more profound knowledge of what it feels like to be donor-conceived than any non-donor-conceived doctor or cryobank employee could ever have--but no one from the American Society of Reproductive Medicine, the American Medical Association, the cryobanks, or the fertility clinics has ever asked you for your opinion on how donor conception ought to be conducted. Not because they couldn't, but rather because all of the people who benefited financially from the sale of your genetic material realize that if they had to take your opinion into account, your opinion would jeopardize their bottom line.

It is time for the USA to follow the examples of Canada, the UK, Germany, Austria, Switzerland, Sweden, Norway, the Netherlands, Australia, and New Zealand by passing laws to regulate donor conception. Thank you.

169. I am a donor-conceived person who only discovered this massive fact about my identity this year, at the age of 54, and purely by accident, as a result of DNA testing. It is a staggering thing to make this discovery in midlife, both psychologically, spiritually, and medically. To think that I have been giving misinformation to physicians for my entire life, and also misinformation about my son's family history for his entire life (he is now 18) is hard to comprehend. The culture of secrecy and anonymity that existed in the early 1960's when I was conceived could make a certain amount of sense, given the context of the times. But the thought that secrecy and anonymity continues to this day, and that there exists a stunning lack of regulation in an industry -- and make no mistake, it is an industry -- that does nothing less than create human life, is beyond comprehension. This must be stopped. There is more regulation when it comes to purchasing a purebred dog (my Labradoodle is asleep at my feet as I write this) than there is in creating human beings.

170. I’m 34 years old, and still trying to put together my life history.
I want to be able to tell me 2 boys more about where their family came from, not just a one sided story.

171. I am commenting in support of FDA regulation of sperm donation. Most donors and recipients are not properly educated or counseled beforehand about the needs of the children they are about to create. This includes the innate desire of donor offspring to know about their first-degree genetic relatives. Moreover, there is no comprehensive medical and genetic testing conducted by US sperm banks. In the US the FDA only mandates for STD testing and for a few other diseases. Testing for STDs does nothing to prevent transmission of genetic illness.

Regulation and transparency are imperative for the emotional wellbeing and physical health of donor-conceived people.