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Attachment





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Attachment



## Comment

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 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 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 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 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 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.

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.

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.

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. I have spoken out about reforms necessary for the fertility industry in this TEDx San Francisco talk [https://www.ted.com/talks/ashley\\_burns\\_i\\_was\\_17-700](https://www.ted.com/talks/ashley_burns_i_was_17-700). Also, I am grateful to have the

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 ~~information that could potentially affect their future children.~~ In addition, ~~cryobanks should be~~ ~~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~~

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.

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, and the ability to understand their own health status. Donor-conceived people should~~

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. << 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"

As a nurse practitioner 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

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

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 offsprings. 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

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

As a sperm donor baby (1996), I respect my donor's choice of anonymity. I understand that he has a family of

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

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

As the mother of a 19 year old conceived with a known-identity donor, I disagree with the over-reaching, over-regulating mandates requested in this petition. I agree all donors should be tested for sexually transmitted diseases; as blood donors and organ/tissue donors are. I agree a donor should be limited in number of offspring, such as 10 or 20 families (not including siblings raised in same family) to reduce the chance of accidental reproduction between half siblings later in life. But, as a former attorney for governmental agencies and current public health nurse, I am deeply concerned that these proposed restrictions will not only drive up the cost (and many consumers of fertility svcs. don't have health insurance coverage for fertility, must pay out of pocket) but also restrict the number of willing donors. A limited donor pool then may lead to higher risk of accidental half-sibling mating later in life; as well as a lack of diversity among available donors. Indeed, it smacks of eugenics. Many conditions that concern prospective parents, such as bi-polar disorder, major depression, schizophrenia, autism and ADHD, do not have a known specific gene that can be tested for, so testing is no guarantee. Not all donors know their family health histories well: mental illness may not have been discussed in the donor's family; or have been undiagnosed/misdiagnosed (ie autism diagnostic criteria has changed greatly); the donor may have been adopted, or simply not well connected to one parent. Requiring complete genome testing and genetic testing for any possible disease is costly and ineffective. Do non-donor parents do this before they conceive a child together? Rarely- and usually only if one parent is known to have a recessive gene and wants to ensure the other does not. In fact, according to the 2013 Shriver report & a 2011 study noted in the 2016 Guttmacher Institute; nearly 50% of US pregnancies

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

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 Attached is a report on the review into the South Australia legislation that was tabled in parliament today. If this gets through, South Australia will become the second place in the world to grant retrospective access to identifying information via legislation for donor conceived people. Additional countries where donor anonymity has already been banned: Austria, Finland, Germany, The Netherlands, New South Wales, New Zealand, Norway, Sweden, Switzerland, UK, Victoria and Western Australia.

Attached is also a new paper published in the Journal of Law and Medicine on the effect of removing donor anonymity on sperm donor numbers in Australia: "Does the removal of anonymity reduce the number of sperm donors in Australia?" The media and other industry "experts" frequently report that ending donor anonymity will automatically result in a drop in donor numbers. Quite to the contrary, there has been a 10 fold increase in the number of sperm donors AFTER removal of anonymity in the state of NSW, Australia. (The numbers of UK donors have also gone up since the ending of anonymity in 2005.) From one of the authors: 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. Better regulations just make sense

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

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 the contributed half of their DNA. In this 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, 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 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 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. General health information isn't even checked so that multiple births affected with serious genetic 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 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 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 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 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 services is not thorough, donations are not

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 I am a "donor baby", and when I was 7 years old I was diagnosed with tourette 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 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 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

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 believe 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. 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 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 change for 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 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 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

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

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

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

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

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

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

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

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

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 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

I am a university instructor whose area of specialization is human genetics, and I was also an overutilized 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 conceivably 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 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 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 I am in favor of this. Please pass.

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 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 weren't 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 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 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 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.

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 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

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 their own genetic information, it is a tragedy that I am in the dark about my own.

I am writing in response to your letter dated June 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 2009 with 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 told us that we would never know. 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 I believe that donor sperm banks should be banned. Just because men can donate sperm for profit does not mean that the requests within this petition are vital to the health, welfare and safety of the generations to come. I 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+ children. I can hardly believe this is not being done already! I think it is imperative to have oversight of donors initially. I can totally see all the points of this petition. As a donor offspring, there is this longing to know about the donor 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 since 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 him. I donated 11 eggs in August of 2003 here in Colorado. It was an anonymous procedure and I know nothing about the donor. 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 I donated sperm at the Fairfax Genetics and IVF Institute in Fairfax, Virginia, approx. 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. 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

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 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 I have been extremely fortunate that my donor has been willing to have contact, and I cannot imagine the I notified the sperm 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 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 I request that the FDA look into the state of affairs surrounding the sperm donation industry and, then, I spent a great deal of time and effort researching and choosing a sperm bank when I decided to use donor sperm 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 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 I strongly support regulation of the cryobank industry, especially limits on the number of births conceived I support this petition.

I support this petition.

I support this request, because oversight of the sperm donation industry is badly need. Please act on this. 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 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 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

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.

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 my donor. 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

I was born 19 years ago thanks to OHSU fertility clinic. As a donor baby I have always had curiosities 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 receive once I turned 18. Unfortunately the same is not true for 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 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

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 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 genetic testing to discover the donor's identity. 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 I work with infertile individuals and couples who desperately seek regulation of the sperm bank industry. 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 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.

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's testing? I'm 34 years old, and still trying to put together my life history. I want to be able to tell my 2 boys more about their father. I'm in favor of this petition.

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 many stories of donors who have been discovered to be carriers of genetic diseases. In 1987 they opposed my marriage based on my fiction novel political writing. A Western Asian descendant of the Eiges and Varsbergs from Eastern Europe, a lineage on my mother's side almost all killed in genocide during WW II, when my marriage was stressed one way to ease the emotional pressure was to make sure to genetically reproduce. Later testing showed that what we already knew was confirmed but also that the total percent ethnically Jewish was only about 4 percent in the identifiable statistics. Of course, when you are also talking about traits that are one in a million in 1974, then some of these statistics probably will change with update of data as time goes on in the genetic research. In any case, political organizations seeking to implement their genetic theory on reproduction are moral hazard. Genetic diversity is important to species.

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 their 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. 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 another. In the end we are the voices for our children. For me providing both my children who were conceived using a sperm donor. 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 don't know his name. It's imperative to provide oversight and protections for a donor as well as protections for the recipient. Thank you for your support. 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 donor so 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 part of me that is missing.

MEDICAL ISSUES: A few articles highlighting medical issues in donor families: (Many more articles about medical issues in donor families, testimonials, and a list of all reported medical and genetic issues can be found here: <https://www.donorsiblingregistry.com/library/medical-issues>)

Attachment #1: 2/12: Human Reproduction: California Cryobank Donor With NF1. Gonosomal mosaicism for an NF1 deletion in a sperm donor: evidence of the need for coordinated, long-term communication of health information among relevant parties.

Attachment #2: 5/12: The New York Times: In Sperm Banks, a Matrix of Untested Genetic Disease  
The case of a child with cystic fibrosis, which was genetically linked to the donor used to conceive him, highlights the need for more regulation of the sperm bank industry, specifically around the genetic testing of sperm by cryobanks. In this case, the sperm had been purchased from New England Cryogenic Center (NECC) who had purchased it from a bank that is no longer in business, and was at least 20 years old.

Attachment #3: 2/12: CBS: Parents Sue Cryogenic Center Over Child's Cystic Fibrosis  
This CBS report of the lawsuit brought against New England Cryogenic Center exposes that the sperm bank has faced very little oversight in its 30-year history. It also points out that New York will not allow sale of NECC's sperm donated at and purchased from another defunct cryobank. It is reported that NECC initiated internal regulations surrounding that restriction, but did not remove that donor from their catalog.

Attachment #4: 4/08: O Magazine: The Children of Donor X

Oprah's magazine follows the stories of several families who used the same anonymous sperm donor from California Cryobank. All of them are navigating medical issues that they attribute to genetic defects from the sperm donor.

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

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,

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 sentences informal letter received in 2016, Fairfax advised me that the donor committed suicide. 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 use 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



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

See attached file(s)

Sperm donors should go through the same rigorous testing as egg donors to ensure genetic illness is not Sperm/Egg donation banks and fertility clinics should be held to federal regulation and transparency for the 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 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 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 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.

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 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.

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 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. 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!

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 This is important and necessary for the health both mental and physical of our future children and world. This This is long overdue!

This isn't a trivial matter-what we're discussing is the creation of life. Please look into your hearts and 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 anonvmitv to mv donor. but with DNA testing it was relatively easy to track down mv close

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.

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, 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 affected and We believe that every child has a right to know who the donor was.

We deserve the right to know our biological families.

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 psychologist said 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 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 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 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

To: FDA

3-Jul-17

[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.](#)

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 One of the most heartbreaking questions came at age 4, when my child, to whom I would often say "you're  
"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, Families who have a child through a donor, unlike those who adopt, are not required to undergo any 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 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 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 My experiences led me to research how the field of (so-called) “reproductive medicine” works, and what 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 [The situation is in stark contrast with legislation in a growing number of jurisdictions. Jurisdictions which](#)

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 ... 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 ... 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 [...The interests of donor offspring require that neither their donors, nor anyone else, hold the power](#)

#### 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 *Playing Hardball with Waivers or Release Forms- Attempts to Remove All Rights From Families & Limit* 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 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 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 Please do all that you can to ensure that your legislation affords adequate levels of protection to donor *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 It is almost impossible to know how many half siblings exists, let alone the location of their birth or where the 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 [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 \(no less than monthly, preferably more often\) 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](#) 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 [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](#) I have reason to believe that there are several families in our own jurisdiction with children who are half [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](#)

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 many thousands and** 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 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

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  
*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  
*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 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  
*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 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

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  
Require Release of ALL Donor Identities

It is my hope that the FDA will decide to clearly prohibit donor anonymity for future births as well as for those 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 Donor conceived people are now becoming adults, and in the age of the internet, are able to discuss their 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 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 relating to the donor (including his/her full identity, and complete information on the donor's medical history and that of his/her  
*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, 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  
*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  
*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, 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

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.

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

\* \* \*

Thank you for the opportunity to make this submission. I look forward to seeing positive changes soon to the

[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

[2] F. Blivth "Donor anonymity and secrecy versus openness concerning the genetic origins of the offspring" international [3] [J. Johnston, infra.](#)

[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

[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 [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](#)

[8] Many have commented on the unjustified discrepancy between the present lack of legal rights for donor conceived [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](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

I fully support "The Citizen Petition" created by Wendy Kramer and would like to share

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

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

I came to realize the unimagined truths of this industry first hand in June of 2014 when the identity of my son's donor accidentally became known. Note that there are at least

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

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**

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

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->

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

[https://www.thestar.com/life/health\\_wellness/2016/04/09/he-was-the-perfect-sperm-donor-then-26-](https://www.thestar.com/life/health_wellness/2016/04/09/he-was-the-perfect-sperm-donor-then-26-)

[https://www.thestar.com/life/health\\_wellness/2016/04/13/three-ontario-families-sue-](https://www.thestar.com/life/health_wellness/2016/04/13/three-ontario-families-sue-)

[https://www.thestar.com/life/health\\_wellness/2016/04/19/sperm-bank-encouraged-](https://www.thestar.com/life/health_wellness/2016/04/19/sperm-bank-encouraged-)

<https://www.thestar.com/news/canada/2016/08/30/sperm-donor-admits-he-falsified->

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->

Nancy Hersh: <http://www.cbc.ca/radio/asithappens/as-it-happens-tuesday-edition->

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

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

In order to ensure donor-conceived people are not being handed a disturbing and

- 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
- 2. Educational/professional claims must be properly verified during the application**
- 3. Gamete banks must do annual criminal background checks on donors and this is**
- 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
- 5. Gamete banks must be inspected/audited at least once annually by the**

Thank you for taking note of these recommendations. I do have many more

Sincerely,

Angie Collins  
Ontario, Canada

[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 fundamentally different from other HCT/PS in that they are not being used to treat a

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 Hypertrophic obstructive cardiomyopathy (HOCM) is one of the most common autosomal dominant diseases

with an estimated prevalence of 1 in 500.<sup>[1]</sup> 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 Additional genetic diseases transmitted to children from donor sperm, most likely unknowingly, include

[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](#)

The true scope of these problems is impossible to know. Because of the following circumstances, we suspect

· [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](#)  
· [Frozen human sperm has been used up to 40 years after collection.\[x\]](#)  
· [Shockingly large numbers of offspring may result from a single prolific donor. One donor has been](#)  
< There is no standardized identification system for each donor, therefore one man can donate at multiple  
< Families are not required to register live births with the sperm bank. All other registries, such as the  
[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](#)

[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](#)

The FDA must act to protect children created through the use of donor eggs and sperm. A vital first step would

Respectfully,

Victoria Powell, MD  
Baltimore, MD  
vpowell6@jhmi.edu

[i] Tissue and Tissue Products. <http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm>. accessed

[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\*](#)

[iv] Boxer, L.A., et al. [Strong evidence for autosomal dominant inheritance of severe congenital neutropenia](#)

[v] Wirojanan J., et al. [A girl with fragile X premutation from sperm donation. \*Am J Med Genet Part A\* \(2008\),](#)

[vi] Heisel, W. [Code Unknown: Trvina to connect with sperm donor throuah online communitv.](#) Center for Health

[vii] [Sperm donor with aenetic illness speaks out.](#) Copenhagen Post. <http://cohpost.dk/news/national/sperm-donor-with->

[viii] Hauser, C. [Sperm donor's profile hid mental illness and crime. lawsuits sav.](#) New York Times.

[ix] U.S. Congress. Office of Technologv Assessment. [Artificial Insemination: Practice in the United States: Summarv of a](#)

[x] Human Fertilisation and Embrvologv Authoritv. [Freezing and storina sperm.](#) <http://www.hfea.gov.uk/74.html>.

[xi] Mroz, J. [One sperm donor. 150 offsprina.](#) New York Times. <https://nvti.ms/1Axi4VZ>. accessed Januarv 15. 2017.

[xii] Human Fertilisation and Embrvologv Authoritv. [HFEA aarees new policies about familv donation and the number of](#)  
[xiii] [Ethics Committee of the American Society for Reproductive Medicine. Interests, obligations, and rights in gamete donation: a committee opinion,](#)

**DC      Parent      Donor      Practitioner Not specified/ Oth Wendy**

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