

Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

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Docket No. 97N-484S

I am writing to voice my objection to the proposed FDA regulations. Had they been in place at the time that I conceived my child, these regulations would have prevented me from choosing the type of semen donor I wanted. In fact, these regulations might have stopped me from conceiving my son at all.

My son is four and half months old now. He has blonde hair and blue eyes and a sunny smile. He is in the ninety-seventh percentile for height and he already has his first tooth! I am lucky to have a whole year off of work and am ecstatic to spend all my time, day and night, with him. He is beyond a doubt the best thing that has ever happened to me. He is happy, healthy, and well-loved by both me and his donor father.

I chose a friend to be my directed donor. Using a donor I knew was always my first choice. It was important to me that my child know and have regular contact with his biological father. However, for a long time, I could not find such a person. I spent over a year trying to get pregnant using frozen sperm. Month after month, I failed to conceive. I was about to use invasive, expensive fertility drugs, when a friend decided he was interested in being the donor. I was ecstatic!

We followed all the safeguards as defined in California law and went way beyond those safeguards. He (and I) had thorough medical testing to insure safety. I also discussed with him, in detail, his sexual practices so that I felt that neither my child nor I would be at risk. This information was also documented in his medical chart. I realize he could have lied to me and to our health practitioner, which would have put me at risk despite all our efforts, but that was my choice to make. I chose to trust.

Once our waiting period had elapsed and we began to do inseminations, I conceived easily and quickly using the fresh sperm and intrauterine inseminations. And now we are proud and happy parents!

I applaud the FDA for trying to craft safeguards to protect the public. However, your present proposal imposes such severe restrictions that many people would end up doing inseminations without the assistance of the medical establishment and, therefore, without thorough safety screening. Your present proposal will accomplish exactly the opposite of its stated purpose. Directed sperm donors should be appropriately screened and the donor and recipient should be counseled as to their risks. However, fresh insemination should remain legal and accessible to insure that it remains as safe as humanly possible. California's Health and Safety Code 1644.5 does exactly that and is a good model for the FDA to follow. Please do not restrict our rights or our choices.

Sincerely,

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