

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

Docket No. 97N-484S

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

I chose a friend to be my directed donor. We followed all the safeguards as defined in California law and went way beyond those safeguards. He 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 put at risk. This information was also documented in his medical chart. I realize that he could have lied to me and to our health practitioner, which would have put me at risk despite all of our efforts. But that was my choice to make. Given his potential liability if he had lied to us, I would guess that a much greater percentage of men in his situation are true to their word than most married men are to their marriage vows.

Freezing his sperm was not an option for us as his sperm cryosurvival was very poor. Additionally, I am aware that medical studies have shown that it is far easier to conceive using fresh sperm than frozen sperm. This was an important consideration as my own fertility was also a concern.

I applaud the FDA for trying to craft reasonable safeguards to protect the public. However, your present proposal imposes such severe restrictions that it would force many people to do 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 the recipient should be appropriately 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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5630 Fisher Lane, rm. 1061
Rockville, Md 20852*

