

Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852
email: FDADOCKETS@oc.fda.gov

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Docket No. 97N-484S

I am writing to voice my objection to the proposed FDA regulations. I was a directed sperm donor for a friend. My sperm had poor cryosurvival and our funds were limited, so the only option we had was to use fresh insemination. I would not been a sperm donor if I thought that I would have put my friend or our child at risk. Consistent with California law, I was thoroughly screened to insure safety. And we discussed , in detail, my sexual practices so that I felt that neither my friend nor the child would be put at risk. This was documented in my medical chart. I also knew if I was not completely honest about my practices and I infected my friend or the child that I could have been financial liable for my dishonesty. Not to mention the terrible guilt of having hurt my friend and the child.

I applaud the FDA for trying to craft reasonable safeguards to protect the public. However, if the FDA's proposed regulations would have been in effect when we tried to conceive they would have had the effect of preventing me from having a child with my friend. Yes, we could have done home insemination without the assistance and screening of the medical establishment. But isn't that exactly the opposite of what your present proposal is trying to accomplish? Directed sperm donors should be appropriately screened and the donor and the recipient should be appropriately counseled as to their risks. Informed consents should be signed by both parties. Fresh insemination should be allowed to continue to insure that it remains safe. To do that, safeguards must be reasonable and allow us to use the medical establishment to safely bring children into our families. California Health and Safety Code 1644.5 does all of that. Please do not compromise our safety by restricting our rights or our choices. Please follow the model of California Health and Safety Code 1644.5 which insures both our reproductive rights and our safety.

Sincerely,

Seth Rockman

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