

August 2, 2016

Dr. Robert M. Califf, M.D., MACC, Commissioner of the U.S. F.D.A.;
Dr. Peter Marks, M.D., Ph.D, Director of Center for Biologics Evaluation and Research, U.S. F.D.A.;
Dr. Owen Davis, M.D. President of American Society for Reproductive Medicine.

Dear Drs. Califf, Midthun, and Davis:

As medical professionals, public health advocates and clinical researchers, we collectively are writing to urge the U.S. Food and Drug Administration (FDA) as well as the American Society for Reproductive Medicine (ASRM) to update the sperm donation guidelines for men who have sex with men. We applaud the FDA's December 2015 stated affirmation to make progress in blood donation deferral standards for gay men, however sperm donation was not, and should be, updated to reflect current screening technologies. FDA policy, reaffirmed by ASRM's 2015 Committee opinion on gestational surrogacy exclude sperm donation from "men who have had sex with another man...." and those with "evidence of anal intercourse."

The FDA first formalized tissue donation policies restricting men who have sex with men in 1983. Since then, substantial advances in HIV screening technology have dramatically improved the accuracy of screening and narrowed the diagnostic window to 2-3 weeks following HIV acquisition. RNA or combined p24 antigen/antibody, along with sperm quarantine, followed by repeat HIV testing 3 weeks later, eliminates the possibility of a false negative result during the window period. With current standard HIV screening practices, using sexual practices or preferences as a screen for sperm donation is scientifically unsound, unnecessary and discriminatory.

There is no evidence-based screening methods to accurately identify "evidence of anal intercourse," as is described by both organizations. Moreover, there is no evidence supporting self-reported sexual behavior as more accurate than widely available HIV screening tests.

With the available highly sensitive, objective laboratory screening tests for HIV, excluding sperm donation on the basis of demographics, self-reported sexual history, or non-validated physical examination, represents an outdated approach resulting in discriminatory practices ([Obstetrics and Gynecology, June 2016](#)). A policy update on sperm donation is urgently needed to assure men who have sex with men, for whom assisted reproductive technology may be their only means of genetic reproduction, have equal reproductive rights supported by science not fear.

Sincerely,

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