

Emily T. Prince, Esq.

Lorrie H. McNeill
Director
Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Building 71 Room 4120
Silver Spring, MD 20993-0002

Transmitted via e-mail

Re: Decision of Blood Products Advisory Committee Regarding “MSM” Ban

Dear Ms. McNeill,

I was disappointed to hear of the recent decision by the FDA’s Blood Products Advisory Committee to remain silent on the question of whether to eliminate the ban on blood donation from “men who have sex with other men at any time since 1977,” sometimes referred to as the “MSM” ban. However, when I contacted your office for more information I was horrified to hear confirmed that the FDA, to this very day, considers sex assignment at birth both immutable and internet, such that transgender women and other individuals assigned male at birth are perpetually considered “men” for the purposes of the ban.

This fact underscores the arbitrary and capricious nature of the “MSM” ban. Rather than looking at actual risk factors, the FDA has concluded that if a person born with (probably) a penis and assigned male at birth, the fact of that person’s sexual interaction with another person born with (probably) a penis and assigned male at birth renders both individuals categorically tainted and ineligible to donate blood. The set of people affected by the “MSM” ban includes the following pairs:

- * a cisgender heterosexual man who has a sexual relationship with a transgender heterosexual woman;
- * a transgender homosexual woman who has a sexual relationship with another transgender homosexual woman;
- * a transgender bisexual woman who has a sexual relationship with a genderqueer person assigned male at birth; and
- * a genderqueer person assigned male at birth who has a sexual relationship with a cisgender bisexual man.

This policy creates significant harm to transgender people and people with non-binary gender identities, for instance by reifying the false belief that transgender women are “actually men.” This incorrect understanding of what it means to be transgender underlies so much discrimination against transgender people. In a

month where the Department of Labor has finally begun the hard work of eliminating discrimination on the basis of sexual orientation and gender identity among Federal contractors, the FDA's Blood Products Advisory Committee's decision is particularly frustrating.

When the full reach of the "MSM" ban is stated, the purported basis for the ban falls away. The policy can include cisgender men of any sexual orientation, transgender women of any sexual orientation, and anyone with a non-binary gender identity who was assigned male at birth who has sexual relationships with anyone else assigned male at birth. Yet the FDA, in defiance of its own acknowledged interpretations, continues to refer to it as a ban on donations by "men who have sex with men" and defends it against salient attacks by the American Red Cross, the American Association of Blood Banks, America's Blood Centers, the American Medical Association, and patient groups such as the National Hemophilia Foundation. In response to the sound science presented by these organizations, the FDA responds with flawed statistics about "men who have sex with men" without even acknowledging the full set of people impacted by the ban.

Were the FDA to attempt to defend its actual policy, rather than the straw-man it has created, it would be forced to admit that sex assignment at birth does not meaningfully impact the risk of contracting HIV, and that there are too many confounding variables in the total population affected to justify categorically prohibiting all donations from that population for life.

I look forward to hearing from your office regarding how the FDA will improve its rules regarding blood donations in the future to eliminate this arbitrary and capricious ban.

Sincerely,

A handwritten signature in black ink, appearing to read "E. Prince". The signature is fluid and cursive, with a long horizontal flourish at the end.

Emily T. Prince, Esq.

cc:

Jocelyn Samuels, Director, Office of Civil Rights, U.S. Department of Health and Human Services