



STATE OF CALIFORNIA
OFFICE OF THE ATTORNEY GENERAL
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July 11, 2016

Robert M. Califf, MD
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993

Dear Dr. Califf,

I urge you to reconsider the Food and Drug Administration's (FDA) donor deferral guidance for preventing the transmission of HIV through blood products. Specifically, FDA should abandon the discriminatory recommendation that blood establishments defer blood donations from men who have had sex with a man (MSM) even one time within twelve months of an attempt to donate blood. Understanding FDA's responsibility for maintaining the safety of the nation's blood supply and your steadfast commitment to implementing data-driven policies, I call on you to consider less categorical risk-based donation policies that will ensure blood safety through non-discriminatory, scientifically-sound methods.

Throughout my career in public service, I have been a proud ally in the LGBTQ community's struggle for full equality. As a partner in efforts to bring down California's Proposition 8 and ban "gay panic" defenses in violent crime cases, I have seen that some of the greatest obstacles LGBTQ people face are rooted in government-sponsored stereotyping, stigmatization, and discrimination. Despite recent progress, our government still fails to respect the full dignity of our LGBTQ family, friends, and neighbors. America has come a long way from the time when AIDS was considered a "gay disease" and President Reagan refused to act in the face of thousands of deaths, but this legacy of intolerance still taints our public policies.

Many laws and regulations remain based on outdated conceptions of gender identity and sexual orientation. As we work to achieve the Constitution's promise of equal protection of the laws, it is our duty to amend or repeal policies that keep us anchored to a shameful past. To those who suffer under lingering injustices and indignities, it is no answer to say: "Be patient and wait." And with regards to the FDA's MSM deferral guidance, the time for patience is over.

At the time it was finalized on December 23, 2015, FDA's "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products: Guidance for Industry" represented a positive step and updated FDA's outdated lifetime ban on MSM blood donations. I appreciate FDA's willingness to address this issue, and I commend you for leading the effort to fully update recommendations that had been in place since 1992.

But the revised recommendations did not go far enough. This became clear after the mass shooting at the Pulse gay nightclub in Orlando, Florida on June 12, 2016. When close friends and loving companions of the victims answered urgent calls for blood donations in the wake of the deadliest mass shooting in U.S. history, many were turned away in order to comply with the FDA's deferral guidance. As a public official, I find this deeply disturbing. When gay and bisexual men come forward to help save lives, they should be welcomed as equal members of the community, not turned away because of who they love. Yet that is precisely what FDA's guidance recommends to blood establishments. When science-backed alternative policies exist, such discriminatory guidance is suboptimal and offensive.

Importantly, the categorical exclusion of men across the United States based solely on the sex of their sexual partner is an unnecessary limit on the pool of eligible blood donors. When FDA reduced the MSM deferral period from a lifetime to twelve months in 2015, it cited the suboptimal deferral rate as a reason for issuing new guidance. But because the guidance remains functionally equivalent to a lifetime ban for the vast majority of gay and bisexual men, the FDA's purported update failed to maximize the eligible donor pool. Maintaining this policy based on regressive societal assumptions only frustrates efforts to overcome the nation's routine blood shortages.

The adoption of deferral guidelines that consider an individual donor's actual risk of carrying HIV, rather than base deferral decisions on the sex of a donor's sexual partner, would help write a new chapter in our nation's civil rights history. One lesson of the mass shooting in Orlando should be that the implicit messages our leaders communicate about the LGBTQ community have real impacts. When our actions subtly validate ignorance and intolerance, we contribute to a culture that too often excuses violence against LGBTQ people and allows LGBTQ youth to be mistreated and abandoned. And presently, the deferral's categorical exclusion of sexually-active gay and bisexual blood donors perpetuates incorrect, harmful stereotypes about homosexuality and suggests that MSM are an inherent health risk to other people. By conflating male-to-male sexual contact with risky sexual behavior and HIV, FDA's guidance reflects and entrenches the United States government's unsophisticated understanding of HIV epidemiology during the early days of the AIDS epidemic. A policy of discrimination in blood donation that was adopted out of desperation in a time before highly sensitive and specific blood testing cannot be allowed to remain simply due to bureaucratic inertia.

Notably, MSM are the only major subset of the population subject to such blatant discrimination in blood donations. While various other groups, such as Washington, DC residents, have an HIV prevalence rate that is significantly higher than the general population,

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they are not subject to a categorical deferral period. While FDA may find such an arbitrary deferral policy to be easier to administer than individualized risk assessments and testing, such reasoning can no more support sexuality-based discrimination in the blood safety context than racial demographic data could justify racial-profiling policies in the public safety context.

The FDA has stated that its MSM deferral recommendations are warranted because HIV infection is significantly higher in MSM than among individuals who only have sexual partners of the opposite sex. Accordingly, FDA believes that further reduction of the MSM deferral would not reliably “maintain or enhance” the safety of the blood supply. In reaching this conclusion, FDA asks the wrong question. Rather than base its decision on whether a new deferral policy could have any possible negative impacts on the near zero risk of HIV transmission through a blood infusion (currently about 1 in 1.47 million), FDA should ask: If there were no MSM deferral policies currently in effect, would available scientific data support the imposition of a discriminatory policy with significant dignitary and social harms? In light of the American Medical Association’s recognition that MSM deferrals are medically and scientifically unnecessary, the FDA’s acknowledgement that the deferral policy for MSM had become less effective over time, and the existence of accurate and reliable testing methods, I believe such an imposition would be indefensible.

FDA’s current deferral policy succumbs to a false choice between blood safety and inclusion. Rather than stigmatize an entire group of people and defend a patently discriminatory policy, FDA should lead on this issue and adopt inclusive science-based recommendations supported by the medical and blood establishment community. Revising the MSM deferral guidance to base deferrals on a science-backed assessment of risk factors, not stereotypes about sexual orientation, would vindicate the dignity and life-saving potential of all citizens, including gay and bisexual Americans. I urge the FDA to follow this better path.

Sincerely,



KAMALA D. HARRIS
California Attorney General