



State of California  
Office of the Attorney General

**ROB BONTA**  
ATTORNEY GENERAL

March 31, 2023

**Via Regulations.gov**

The Honorable Robert Califf  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

RE: Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products, 88 Fed. Reg. 5894 (Jan. 30, 2023)

Dear Commissioner Califf:

The undersigned State Attorneys General from California, Arizona, Connecticut, Delaware, the District of Columbia, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, and Wisconsin submit this letter in support of the Food and Drug Administration's (FDA) "Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products" (88 Fed. Reg. 5894) ("the recommendation" or "proposed guidance"). The recommendation would remove the blanket three-month deferral period for men who have sex with men (MSM). Instead, all donors will be screened and deferred based on risk factors for Human Immunodeficiency Virus (HIV) infection regardless of gender or sexual orientation.

We applaud the FDA's decision to replace its outdated gender- and sexuality-based screening with a risk-based framework. This approach will increase the available blood supply, addressing crucial shortage issues. It also discards the discriminatory aspects of the prior framework, while following sound science to ensure the protection of the blood supply. We urge the FDA to adopt the proposed guidance.

## I. Adopting the Recommendation Will Increase the Blood Supply While Protecting Its Safety

An adequate blood supply is critical to our nation's healthcare. Blood transfusions and blood products are needed for major surgeries, to treat diseases such as sickle cell anemia and some cancers, and to treat victims injured by accidents, violence, or natural disasters. The blood supply is vulnerable to disruption and shortages, as demonstrated by the COVID-19 pandemic.<sup>1</sup> The American Red Cross, which provides about 40 percent of our nation's blood and blood components, experienced a ten percent decline in the number of people donating blood since the beginning of the pandemic.<sup>2</sup> The organization had to limit blood distributions to hospitals in January 2022 and made emergency calls for blood donation.<sup>3</sup>

Since the beginning of the HIV epidemic in the 1980s, the FDA has recommended blanket bans, or "deferrals" for gay or bisexual men.<sup>4</sup> Over time, the FDA has revised these deferrals, culminating with the 2020 guidance, which established a three-month donation deferral period.<sup>5</sup> These shortened deferral periods still barred blood donation by MSM without evaluating specific risk factors. The longstanding effect of this policy has been to prevent non-celibate gay and bisexual men from giving blood.

As many States pointed out in 2020, enforcing the MSM deferral period simultaneously excludes low-risk donors while allowing other donors with comparable risk profiles to donate blood without comparable scrutiny.<sup>6</sup> We know now that specific sexual behaviors, not gender or sexual orientation, present the greatest risk for HIV infection.<sup>7</sup> Enforcing an MSM deferral period in spite of these disparities has contributed to sustained criticism of the FDA.<sup>8</sup>

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<sup>1</sup> E.g., Anna Nagurney, *How Coronavirus is Upsetting the Blood Supply Chain*, Live Science (Mar. 13, 2020), <https://www.livescience.com/coronavirus-blood-supply-chain.html>.

<sup>2</sup> American Red Cross, *Red Cross Declares First-ever Blood Crisis amid Omicron Surge* (Jan. 11, 2022), <https://www.redcross.org/about-us/news-and-events/press-release/2022/blood-donors-needed-now-as-omicron-intensifies.html#:~:text=The%20American%20Red%20Cross%20is,concerning%20risk%20to%20patient%20care.>

<sup>3</sup> *Id.*

<sup>4</sup> U.S. Food & Drug Admin., FDA-215-D-1211, Draft Guidance for Industry: Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products 3 (January 2023).

<sup>5</sup> *Id.* at 3-4.

<sup>6</sup> Multistate Attorneys General Comment Letter (April 22, 2020), <https://www.oag.ca.gov/system/files/attachments/press-docs/Blood%20Donation%20RFI%20Response%2004-22-2020%20FINAL.pdf>.

<sup>7</sup> See, e.g., Pragna Patel et al., *Estimating per-act HIV Transmission Risk: a Systematic Review*, 28 AIDS 1509 (2014); C.E. Copen et al., *Sexual Behavior, Sexual Attraction, and Sexual Orientation Among Adults Aged 18–44 in the United States: Data From the 2011–2013 National Survey of Family Growth*, 88 Nat'l Health Stat. Reps. 1, 7 (2016).

<sup>8</sup> See, e.g., Camila Domonoske, *Blood Banks See Massive Response After Orlando Attack*, NPR: The Two Way (June 12, 2016), <https://www.npr.org/sections/thetwo-way/2016/06/12/481795633/blood-banks-see-massive-response-after-orlando-attack> ("[A]s some people noted with frustration and anger,

Modern HIV testing techniques enhance the safety of donated blood. Donor blood is tested extensively for infectious disease pathogens before a blood transfusion.<sup>9</sup> In the past three decades, no HIV transmissions through U.S.-licensed plasma-derived products have been documented.<sup>10</sup> Modern HIV tests can detect the virus well within a three-month period following initial infection.<sup>11</sup> Indeed, the most sensitive tests can detect HIV within 10 days of infection.<sup>12</sup> The risk of HIV transmission through blood products is now 1 in 1.5 million, significantly less than risks of other transfusion-related complications.<sup>13</sup> These safeguards will continue to be available under the proposed guidance.

Thus, the FDA's proposed guidance would protect the blood supply while addressing shortage concerns. Indeed, a 2014 analysis by the Williams Institute indicates that lifting the blood donation ban for MSM completely (as compared to a twelve-month deferral period) would produce over 2 million additional eligible blood donors, and would produce nearly 300,000 pints of additional donated blood annually.<sup>14</sup> As the American Red Cross estimates that a single blood donation has the potential to be used in life-saving procedures for three individuals, lifting the blood donation ban could help save the lives of more than a million people.<sup>15</sup>

## II. International Experience Demonstrates the Feasibility of a Risk-Based Approach

The proposed guidance will be well in line with international guidelines. Many countries have successfully eliminated gender- and sexuality-based restrictions on blood donation without incident. Italy eliminated its deferral period for MSM who donate blood in 2001 and replaced it with a gender-neutral risk-based process.<sup>16</sup> Mexico removed a permanent ban on MSM blood donations in 2012 and replaced it with a screening tool for "risky sexual practices."<sup>17</sup> Spain and Portugal used gender-neutral risk-based deferrals to determine who can donate blood well before

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FDA restrictions currently bar sexually active gay and bisexual men from donating blood, leaving many members of the LGBT community unable to contribute" after a mass casualty attack targeting the LGBT community.).

<sup>9</sup> *Blood Safety Basics*, Centers for Disease Control & Prevention, (last reviewed Aug. 30, 2022), [https://www.cdc.gov/bloodsafety/basics.html#anchor\\_1548881832](https://www.cdc.gov/bloodsafety/basics.html#anchor_1548881832).

<sup>10</sup> Robert Klamroth et al., *Pathogen Inactivation and Removal Methods for Plasma-Derived Clotting Factor Concentrates*, 54 *Transfusion* 1406 (2014).

<sup>11</sup> FDA-215-D-1211, *supra* n.4 at 4.

<sup>12</sup> Christopher Park, et al., *Blood Donation and COVID-19: Reconsidering the 3-Month Deferral Policy for Gay, Bisexual, Transgender, and Other Men Who Have Sex With Men*, 111 *American Journal of Public Health* 247, 248 (2021).

<sup>13</sup> *Id.*

<sup>14</sup> See Ayako Miyashita & Gary Gates, *Update: Effect of Lifting Blood Donation Bans on Men Who Have Sex with Men 2* (2014), Williams Inst., UCLA/SL.

<sup>15</sup> *Id.*

<sup>16</sup> Mindy Goldman et al., *Donor Deferral Policies for Men Who Have Sex With Men: Past, Present and Future*, 113 *Vox Sanguinis* 95, 98 (2018).

<sup>17</sup> Christopher McAdam & Logan Parker, *An Antiquated Perspective: Lifetime Ban for MSM Blood Donations No Longer Global Norm*, 16 *DePaul J. Health Care L.* 21, 44 (2014).

2020.<sup>18</sup> The United Kingdom implemented a risk-based approach in 2021,<sup>19</sup> while Canada did so in 2022.<sup>20</sup>

Further, international research confirms that these countries' experiences are directly relevant to policymaking in the United States. Studies from countries with similar HIV epidemiology to the United States, such as Canada, predict no change in HIV infection risk after eliminating deferral periods for MSM.<sup>21</sup> A 2022 Canadian study predicted that removing a three-month deferral period for MSM would not result in statistically significant changes to HIV infection risk.<sup>22</sup> There is every reason to expect a similar result in the United States under FDA's proposed guidance.

### **III. Gender- or Sexuality-Based Deferral Policies Undermine Equal Protection, Perpetuating Bias**

As Attorneys General, we strive to ensure the protection of our state residents. A gender- or sexuality-based policy singling out bisexual and gay men implicates constitutional Equal Protection principles of the Fifth and Fourteenth Amendments. Further, governmental classifications based on gender are disfavored and require heightened scrutiny. *United States v. Virginia*, 518 U.S. 515, 532–33 (1996). Classifications based on sexual orientation and gender identity are a form of sex discrimination because “it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual based on sex.” *Bostock v. Clayton County*, 140 S. Ct. 1731, 1741 (2020).

The current 2020 policy implicates these equal protection principles and increases the stigma often associated with homosexuality. For example, a gay man in a monogamous relationship with another man would face a three-month deferral regardless of whether he engages in any risky behavior. In contrast, a blood donation from a heterosexual woman who does engage in the same risk factors would not receive the same screening. Indeed, application of the 2020 guidelines would bar a gay man from donating blood to his critically ill husband, even if they are both HIV-negative and even if their relationship is exclusively monogamous. The FDA's proposed guidance will correct this incongruity.

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<sup>18</sup> *Id.*

<sup>19</sup> Nat. Health Serv., *U.K. to Change Eligibility to Give Blood on World Blood Donor Day With Launch of New Donor Safety Assessment* (May 11, 2021), <https://www.nhsbt.nhs.uk/news/uk-to-change-eligibility-to-give-blood-on-world-blood-donor-day-with-launch-of-new-donor-safety-assessment>.

<sup>20</sup> Can. Blood Serv., *Canadian Blood Services to Remove Eligibility Criteria Specific to Men Who Have Sex With Men* (Apr. 28, 2022), <https://www.blood.ca/en/about-us/media/newsroom/canadian-blood-services-remove-eligibility-criteria-specific-men-who-have>.

<sup>21</sup> FDA-215-D-1211, *supra* n.4 at 4.

<sup>22</sup> Niamh Caffrey et al., *Removing the Men Who Have Sex with Men Blood Donation Deferral: Informing Risk Models Using Canadian Public Health Surveillance Data*, 29 *Transfusion Clinique et Biologique* 198 (2022).

**IV. Conclusion**

Discriminatory restrictions against blood donation by healthy gay and bisexual Americans have persisted for far too long. The proposed guidance vindicates science and civil rights by reversing these outdated and discriminatory restrictions. Sound science, international experience, blood supply needs, and important civil rights principals all support this change. We urge the FDA to adopt the proposed guidance.

Sincerely,



ROB BONTA  
California Attorney General



KRISTIN K. MAYES  
Arizona Attorney General



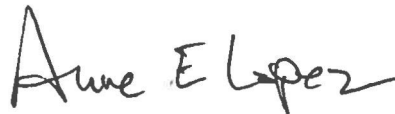
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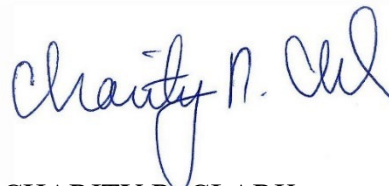
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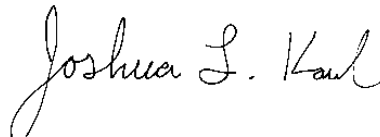


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BOB FERGUSON  
Washington Attorney General

A handwritten signature in blue ink that reads "Joshua L. Kaul". The signature is cursive and elegant, with a large initial "J" and a long horizontal stroke.

JOSHUA L. KAUL  
Wisconsin Attorney General