



State of California
Office of the Attorney General

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ATTORNEY GENERAL

April 22, 2020

Via Electronic Mail

The Honorable Admiral Brett Giroir, MD
Assistant Secretary for Health
U.S. Department of Health & Human Services
Mary E. Switzer Building
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Washington, DC 20024
Attn: ACBTSA-PAHPAIA Sec. 209
ACBTSA@hhs.gov

RE: “Solicitation for Public Comments on Section 209 of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act,” 85 Fed. Reg. 16,372 (March 23, 2020)

Dear Assistant Secretary Giroir:

The undersigned State Attorneys General from California, Colorado, Connecticut, Delaware, the District of Columbia, Hawaii, Illinois, Iowa, Maine, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, Oregon, Pennsylvania, Vermont, and Virginia submit this letter in response to the federal government’s “Solicitation for Public Comments on Section 209 of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act,” (85 Fed. Reg. 16,372). We support the Office of the Assistant Secretary for Health in the U.S. Department of Health and Human Services’ (HHS) efforts and work in maintaining an adequate national blood supply during the COVID-19 pandemic.

An adequate blood supply is critical to the 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 who have injuries caused by accidents or natural disasters.¹ Every day, the United States needs approximately 36,000 units of red blood cells, nearly 7,000

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



units of platelets, and 10,000 units of plasma.² As of April 9, 2020, the American Red Cross, which provides about 40 percent of our nation’s blood and blood components, had less than a five-day blood supply on hand.³

In the midst of the COVID-19 pandemic, blood drives and donations have dropped significantly. Kate Fry, of America’s Blood Centers, an organization that represents nearly 50 blood centers and collects close to 60 percent of the nation’s blood supply, confirmed that the country is facing a “national blood supply issue,” as “coronavirus fears intensify.”⁴ As of mid-March, over 4,000 blood drives have been canceled across the country due to coronavirus concerns and closures of schools and workplaces where these drives are usually held, resulting in over 100,000 fewer blood donations.⁵ In this “unprecedented situation,” the chief medical officer of biomedical services at the American Red Cross admits that they “are already actively triaging units, determining which hospitals can and can’t get blood.”⁶ The FDA Center for Biologics Evaluation and Research Director Peter Marks recently urged that the nation “need[s] people to start turning out in force to give blood.”⁷

Recently, the Food and Drug Administration (FDA) issued revised guidance for blood donation by men who have sex with men (MSM), changing the wait period to three months from

² American Red Cross, Blood Needs and Blood Supply, <https://www.redcrossblood.org/donate-blood/how-to-donate/how-blood-donations-help/blood-needs-blood-supply.html/> (last visited April 9, 2020).

³ American Red Cross, Critical Blood Shortage: Red Cross Urges Blood and Platelet Donors to Give Now, <https://www.redcrossblood.org/local-homepage/news/article/critical-blood-shortage-3A-red-cross-urges-blood-and-platelet-donors-to-give-now-1.html/> (last visited April 9, 2020).

⁴ America’s Blood Centers, Coronavirus Fears Put Nation’s Blood Supply at Risk (Mar. 10, 2020), <https://americasblood.org/press-release/coronavirus-fears-put-nations-blood-supply-at-risk/>.

⁵ American Red Cross, American Red Cross Faces a Severe Blood Shortage as Coronavirus Outbreak Threatens Availability of Nation’s Supply (Mar. 17, 2020), <https://www.redcrossblood.org/local-homepage/news/article/american-red-cross-faces-a-severe-blood-shortage-as-coronavirus-.html/>; *see also* Douglass Main, Blood and Organ Donations Shrink Amid Coronavirus Fears, National Geographic, (Mar. 20, 2020), <https://www.nationalgeographic.com/science/2020/03/blood-and-organ-donations-shrink-amid-coronavirus-fears/>.

⁶ Nancy Wartik, *How to Donate Blood as Coronavirus Threatens the U.S. Supply*, N.Y. Times (Mar. 19, 2020), <https://www.nytimes.com/2020/03/19/well/live/coronavirus-blood-donation.html/>.

⁷ America’s Blood Centers, “We Need People to Start Turning Out in Force to Give Blood” (Mar. 12, 2020), <https://americasblood.org/news/fda-urging-people-to-donate-blood/>.

twelve months before donating blood.⁸ The stated purpose of this and previous deferral policies is to prevent the spread of blood-borne infectious diseases such as the Human Immunodeficiency Virus (HIV). While this reform takes a step toward increasing blood donations made by healthy bisexual and gay men in a time when the nation's supply of blood and blood products is at risk of collapse due to the COVID-19 pandemic, it does not go far enough. The discriminatory restrictions against blood donations by healthy gay and bisexual Americans have persisted for far too long; the steps you have taken acknowledge current rules are informed more strongly by bias than science.

Ensuring that the blood supply is safe is an important goal and donor blood is extensively tested for infectious disease pathogens before a blood transfusion.⁹ Additional precautions regarding who can donate blood should be narrowly tailored to achieve safety goals while maximizing the blood supply. The revised guidance still precludes many LGBTQ Americans from fully contributing to the blood shortages while still requiring a waiting period for healthy individuals. Further, the FDA should immediately clarify that the new policies do not bar MSM from donating potentially lifesaving convalescent plasma to their loved ones.

Critically, data from a 2014 analysis by the University of California, Los Angeles School of Law Williams Institute indicate that lifting the blood donation ban for MSM completely, as compared to a twelve month "deferral period" from last MSM sexual contact, would produce over 2 million additional each eligible blood donors, including nearly 175,000 likely blood donors, and would produce nearly 300,000 pints of additional donated blood annually.¹⁰ Based on American Red Cross estimates that blood donation has the potential to be used in life-saving procedures on three individuals, the Williams Institute concludes that lifting the blood donation ban among MSM could be used to help save the lives of more than a million people.¹¹ The FDA's revised policy will help address the current shortage of blood and blood products during these unprecedented times. But transitioning to a risk-based model will further protect the blood supply and donor's dignity.

⁸ Peter Marks, Food and Drug Administration Coronavirus (COVID-19) Update: FDA Provides Updated Guidance to Address the Urgent Need for Blood During the Pandemic (Apr. 2, 2020), <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-updated-guidance-address-urgent-need-blood-during-pandemic/>.

⁹ Centers for Disease Control & Prevention, Blood Safety Basics, Screening Donated Blood, https://www.cdc.gov/bloodsafety/basics.html#anchor_1548881832/ (last updated Mar. 18, 2020).

¹⁰ See Ayako Miyashita & Gary Gates, Williams Institute, *Update: Effect of Lifting Blood Donation Bans on Men Who Have Sex With Men 2* (2014).

¹¹ *Id.*

I. A Revised, More Inclusive Policy Could Help Development of Convalescent Plasma Treatment for COVID-19

On March 24, 2020, the FDA approved convalescent plasma as an experimental treatment for COVID-19.¹² This treatment entails donation of anti-body rich plasma from someone who has recovered from COVID-19 to someone who is critically ill in the hopes that additional antibodies will suppress the virus and aid the recipient's recovery.¹³ Clinical trials to determine this treatment's effectiveness are underway.¹⁴

At this point in time, the FDA requires that convalescent plasma “must only be collected from recovered individuals if they are eligible to donate blood,” citing 21 C.F.R. § 630.10.¹⁵ The current policy, even as recently revised, appears to bar MSM from donating potentially life-saving convalescent plasma. Strict application of this policy could still bar a gay man who recovers from COVID-19 from donating convalescent plasma to his critically ill husband, even if they are both HIV-negative and even if their relationship is exclusively monogamous. “No union is more profound than marriage, for it embodies the highest ideals of love, fidelity, devotion, sacrifice, and family. In forming a marital union, two people become something greater than once they were.” *Obergefell v. Hodges*, 135 S.Ct. 2584, 2608 (2015). The survival of such a union—the survival of its members—should not depend on the manner in which they consummate their love. The FDA should immediately clarify that the new three month MSM deferral period announced does not bar MSM from donating convalescent plasma to their loved ones. This helps expand the pool of individuals eligible to donate convalescent plasma and potentially helps treat COVID-19.

II. International Experience Demonstrates a Risk-Based Approach is Feasible

International experience demonstrates that a shorter deferral period for MSM is warranted and that risk-based alternatives merit adoption. Mexico removed a permanent ban on MSM

¹² FDA, Investigational COVID-19 Convalescent Plasma - Emergency INDs (March 24, 2020), <https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/investigational-covid-19-convalescent-plasma-emergency-ind/>. Use of convalescent plasma has been studied in outbreaks of other respiratory infections, including the 2009-2010 H1N1 influenza virus pandemic, 2003 SARS-CoV-1 epidemic, and the 2012 MERS-CoV epidemic. *Id.*

¹³ *Id.*

¹⁴ *E.g.*, Denise Grady, Blood Plasma From Survivors Will Be Given to Coronavirus Patients, N.Y. Times (Mar. 26 2020), <https://www.nytimes.com/2020/03/26/health/plasma-coronavirus-treatment.html/>.

¹⁵ FDA, *supra* note 12.

blood donations in 2012 and replaced it with a screening tool for “risky sexual practices.”¹⁶ Spain, Italy, and Portugal use gender-neutral risk-based deferrals to determine who can donate blood.¹⁷ In Spain, donors are deferred for twelve months for engaging in sex with more than one concurrent partner and for engaging in sex with an occasional partner regardless of the donor’s sex or their partner’s sex.¹⁸ Italy eliminated its deferral period for MSM who donate blood in 2001 and replaced it with a gender-neutral risk-based process in which donors are deferred for four months from last sexual contact with a new sexual partner or for occasional sexual contact with a partner whose risk behavior is unknown.¹⁹ Donors are indefinitely deferred for usual or recurrent sex with more than one partner whose risk behavior is unknown and are indefinitely deferred for multiple new partners.²⁰

Even countries that have already significantly shortened the deferral period, like France and the United Kingdom, are considering gender-neutral risk-based models to increase blood donor selection while ensuring the safe supply of blood to patients.

III. A Sex-Based Deferral Policy is Problematic Under Equal Protection Principles Enshrined in the Constitution

A population-based policy singling out bisexual and gay men threatens constitutional Equal Protection principles under the Fourteenth Amendment and Fifth Amendment. The Fourteenth Amendment to the United States Constitution commands that “[n]o State shall ... deny to any person within its jurisdiction the equal protection of the laws.” U.S. Const. amend XIV § 1. The Fifth Amendment to the United States Constitution commands that “[n]o person shall ... be deprived of life, liberty, or property, without due process of law.” *Id.*, amend. V. In *Bolling v. Sharpe*, 347 U.S. 497, 499 (1954), the Supreme Court recognized that “discrimination” by the federal government “may be so unjustifiable as to be violative of due process.”

Governmental classifications based on “gender”²¹ require heightened scrutiny. *E.g.*, *United States v. Virginia*, 518 U.S. 515, 532–33 (1996). Specifically, the government must show

¹⁶ 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).

¹⁷ *Id.*

¹⁸ Mindy Goldman et al., *Donor Deferral Policies for Men Who Have Sex With Men: Past, Present and Future*, 113 *Vox Sanguinis* 95, 99 (2017), <https://onlinelibrary.wiley.com/doi/pdf/10.1111/vox.12623/>.

¹⁹ *Id.*, at p. 98.

²⁰ *Id.*

²¹ In *Virginia*, the Court appears to use the words “sex” and “gender” interchangeably. The modern view is generally that “gender” is a component of “sex” or the primary component of “sex.” *See, e.g.*, Cal. Civ. Code, § 51(e)(5) (defining “sex” to include “a person’s gender” and “gender” to mean “sex” and include a person’s gender identity and gender expression).

that the challenged classification serves important governmental objectives and that the discriminatory means employed are substantially related to the achievement of those objectives. *Id.*, at 533. The justification must be genuine, not hypothesized or invented post hoc in response to litigation, and it must not rely on overbroad generalizations about the different talents, capacities, or preferences of males and females. *Id.* Federal appellate courts have recognized that classifications based on sexual orientation are a form of sex discrimination. *E.g.*, *Altitude Express, Inc. v. Zarda*, 883 F.3d 100, 112 (2d Cir. 2018) (en banc) (Under Title VII of Civil Rights Act of 1964, sexual orientation discrimination is a subset sex discrimination), *cert. granted* 139 S.Ct. 1599 (2019). The Supreme Court has recognized that laws targeting gay and bisexual people are not rationally related to a legitimate government interest when they are motivated by “a bare ... desire to harm a politically unpopular group.” *Romer v. Evans*, 517 U.S. 620, 635 (1996) (quoting *Dept. of Agric. v. Moreno*, 413 U.S. 528, 534 (1973)).

Any sex-based deferral period targets MSM for a perceived and faulty belief that all MSM engaged in risky behavior that could put blood donations at risk. Internationally, other countries have moved away from this approach because it is not the least restrictive means to maintain a safe blood supply. Over the long term, the FDA should look at risk behavior and not sex for determining who should donate blood. Further, a revised policy should identify a date certain by which the FDA will replace a time-based deferral with a risk-based framework and identify any research or data needed to achieve this result. Risk-based assessments should apply regardless of sex. HHS’s report to Congress under the Pandemic and All-Hazards Preparedness and Advancing Innovation Act or PAHPAIA should include a plan and timetable to implement these sound, scientifically-based changes.

IV. Conclusion

The revised guidance is an important first step for protecting the nation’s blood supply, especially during these unprecedented times. However, for convalescent plasma donations, the FDA should make clear that this policy allows MSM and all COVID-19 survivors to donate convalescent plasma. Additionally, changes are needed in the coming years to make our HIV prevention policy fully consistent with science, public health, and equal protection by moving to a risk-based strategy.

Sincerely,



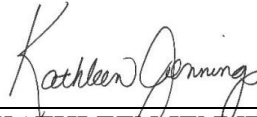
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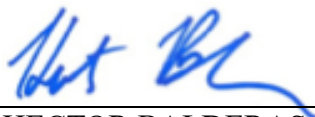
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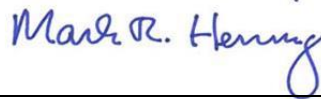
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