



Institute for
Policy Integrity

NEW YORK UNIVERSITY SCHOOL OF LAW

June 19, 2020

VIA ELECTRONIC SUBMISSION

Department of Health and Human Services

Attn: Office of Infectious Disease and HIV/AIDS Policy

Re: Request for Information—Pandemic and All-Hazards Preparedness and
Advancing Innovation Act Section 209, 85 Fed. Reg. 16,372 (Mar. 23, 2020)

The Institute for Policy Integrity at New York University School of Law¹ respectfully submits the following comments to the Office of Infectious Disease and HIV/AIDS Policy (“OIDP”) at the Department of Health and Human Services (“HHS”) in response to a request for information relevant to Section 209 of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019.² Policy Integrity is a non-partisan think tank dedicated to improving the quality of government decisionmaking through advocacy and scholarship in the fields of administrative law, economics, and public policy.

In connection with a forthcoming report to Congress, HHS solicits public input on “challenges associated with the continuous recruitment of blood donors,” strategies for “ensuring the adequacy of the blood supply in case of public health emergencies,” and “implementation of new . . . procedures to improve the safety and reliability of the blood supply.”³ On these topics, our observations and recommendations are as follows:

- Eliminating the current deferral policy for men who have sex with men (“MSM”) could significantly increase the nation’s blood supply.
- The deferral policy for MSM is not necessary to mitigate the risk of HIV transmission through blood products.
- Any increase in HIV transmission risk associated with eliminating the deferral policy is likely outweighed by the benefits of eliminating the policy, including a reduced risk of HIV transmission from heterosexual donors, reduced risk of blood shortages, and decreased stigmatization of gay and bisexual men.

Accordingly, HHS’s report to Congress should support elimination of the deferral policy.

¹ This document does not purport to present New York University School of Law’s views, if any.

² 85 Fed. Reg. 16,372 (Mar. 23, 2020).

³ *Id.*

I. Eliminating the deferral policy for MSM could significantly increase the nation's blood supply

The COVID-19 pandemic has depleted the nation's blood supply, resulting in 130,000 fewer donations and over 4,000 canceled blood drives as of March 16, with current losses likely exceeding those figures.⁴ The New York Blood Center alone, which serves the regions most affected by the pandemic, lost 25,000 potential donations and continues to experience blood shortages.⁵

In response to these nationwide shortages, the Food and Drug Administration ("FDA") released updated guidance on blood donation.⁶ Whereas prior agency guidance had recommended deferring donations from MSM for a period of 12 months from the donor's last sexual contact, the updated guidance shortens this deferral period to 3 months.⁷ This change will likely increase the donor pool, but the U.S. could further increase donations and mitigate the risk of future shortages by eliminating the deferral policy in favor of individual risk assessment, whereby all donors would be evaluated based on a set of identified behavioral risk factors, such as number of recent sexual partners, condom use, and drug use.⁸

A 2014 report from the Williams Institute at UCLA School of Law estimated that, relative to a 12-month deferral, completely eliminating the MSM deferral period would render 2 million additional men eligible to donate and increase donations by almost 300,000 pints per year.⁹

⁴ Letter from Debra BenAvram, Chief Exec. Officer, AABB, to Stephen M. Hahn, Comm'r, Food & Drug Admin. (Mar. 20, 2020), <http://www.aabb.org/advocacy/correspondence/Documents/Joint-Letter-to-FDA-on-Blood-Supply-Chain.pdf> ("COVID-19 is quickly evolving and has the potential to result in even more blood drive and individual donor appointment cancellations, fewer healthy donors available to sustain the blood supply and potential absenteeism among blood centers' staff, which may limit the ability to draw and process blood.").

⁵ *New York Blood Center Issues Urgent Call for Healthy Donors as Blood Supply Drops to Dangerously Low Levels*, N.Y. BLOOD CTR. (May 12, 2020), <https://nybloodcenter.org/news/articles/new-york-blood-center-issues-urgent-call-healthy-donors-blood-supply-drops-dangerously-low-levels/>.

⁶ U.S. DEP'T OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMIN., CTR. FOR BIOLOGICS EVALUATION AND RESEARCH, FDA DOCKET NO. FDA-2015-D-1211, REVISED RECOMMENDATIONS FOR REDUCING THE RISK OF HUMAN IMMUNODEFICIENCY VIRUS TRANSMISSION BY BLOOD AND BLOOD PRODUCTS: GUIDANCE FOR INDUSTRY (2020) [hereinafter GUIDANCE].

⁷ *Id.*

⁸ BROAD INSTITUTE, BLOOD DONOR DEFERRAL POLICY FOR REDUCING THE RISK OF HUMAN IMMUNODEFICIENCY VIRUS TRANSMISSION BY BLOOD AND BLOOD PRODUCTS: APPENDICES (2016), https://www.broadinstitute.org/files/sections/community/public/Broad_Institute_Appendices_Docket_No_FDA-2016-N-1502.pdf ("[D]eferral of all sexually-active MSM excludes many potential donors who are at low risk and who can likely be identified by appropriate criteria This suggests both the safety of the blood supply and the fairness of blood donation policy would benefit from an individualized risk assessment.").

⁹ AYAKO MIYASHITA & GARY J. GATES, WILLIAMS INSTITUTE, UCLA SCH. OF LAW, UPDATE: EFFECTS OF LIFTING BLOOD DONATION BANS ON MEN WHO HAVE SEX WITH MEN 1–2 tbl.2 (2014) (comparing number of eligible donors and estimated donation volume under 5-year deferral, 12-month deferral, and no deferral); Walter Liszewski et al., *The Beliefs and Willingness of Men who Have Sex with Men to Comply with a One-Year Blood Donation Deferral Policy: A Cross-Sectional Study*, 57 TRANSFUSION

While the gains from eliminating the current, 3-month deferral will presumably be smaller, it undoubtedly remains the case that many potential MSM donors are unnecessarily excluded by the deferral policy, because it bars donations from low-risk, sexually active men who are in monogamous relationships, taking pre-exposure prophylaxis, or using condoms.¹⁰ In fact, the deferral policy is simultaneously over- and under-inclusive; even as gay and bisexual men in monogamous relationships are excluded, heterosexual men and women who have multiple sexual partners face no deferral period,¹¹ despite the fact that heterosexual individuals accounted for 24% of the country's new HIV diagnoses in 2018.¹²

The benefits of eliminating the deferral period may even extend past the ordinary need for blood. Shifting to an individual risk assessment would also increase the availability of convalescent plasma, which has been used as an experimental treatment for COVID-19.¹³

By standardizing blood-donation requirements across sexual orientations, the U.S. can increase donor eligibility while eliminating the arbitrary and discriminatory exclusion of low-risk MSM. Given that only 2% of the American population donates blood each year,¹⁴ this increase would help guarantee an adequate blood supply, both in times of crisis and under normal circumstances.

II. The deferral policy for MSM is not necessary to mitigate the risk of HIV transmission through blood products

In its 2015 guidance, FDA recognized the possibility of replacing the 12-month deferral period with an individual risk assessment, but the agency ultimately decided that “the available information was not sufficiently compelling to adopt the approach.”¹⁵ In support of this decision, the agency cited concerns of partner infidelity, condom failure, and the increased risk of HIV transmission for MSM.¹⁶ In its updated 2020 guidance, FDA asserted that it “remains committed to further investigating individual risk assessment as an alternative to time-based deferrals,” but the agency again declined to seriously consider an individual risk assessment despite mounting evidence supporting the efficacy of the approach.¹⁷

2234, 2235–2236 (2017), <https://onlinelibrary.wiley.com/doi/epdf/10.1111/trf.14217> (finding that 90% of self-identified MSM are interested in donating blood, but only 9% meet a 12-month deferral criteria).

¹⁰ See Chana A. Sacks et al., *Rethinking the Ban—The U.S. Blood Supply and Men who Have Sex with Men*, NEW ENG. J. OF MED., Nov. 16, 2016, <https://www.nejm.org/doi/full/10.1056/NEJMms1613425>; *Open Letter to FDA from Medical Professionals*, GLAAD, <https://www.glaad.org/blog/open-letter-fda-medical-professionals> (last visited June 15, 2020).

¹¹ Sacks, *supra* note 10. *But see* GUIDANCE, *supra* note 6, at 9 (recommending that women who have sex with MSM be deferred from donating blood for 3 months from the most recent sexual contact).

¹² *HIV in the United States: At a Glance*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/hiv/statistics/overview/ataglance.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fhiv%2Fstatistics%2Fbasics%2Ffataglance.html (last visited June 12, 2020).

¹³ *Open Letter to FDA from Medical Professionals*, *supra* note 10.

¹⁴ *Facts About Blood Donations*, CEDARS SINAI, <https://www.cedars-sinai.org/programs/blood-donor-services/about-donation.html> (last visited June 15, 2020).

¹⁵ GUIDANCE, *supra* note 6, at 5.

¹⁶ *Id.*

¹⁷ *Id.* See also BROAD INSTITUTE, *supra* note 8, at 6–7 (offering evidence from other countries that have adopted an individual risk assessment without significant impact on blood supply safety).

Data from other countries suggests that individual risk assessment policies prevent HIV transmission as effectively as deferral policies for MSM.¹⁸ For example, Italy has experienced no significant change in the incidence of HIV infection in donations received from MSM since implementing its individual risk assessment in 2001.¹⁹ Similarly, Spain has not documented any HIV transmission from blood donation since it adopted an individual risk assessment in 2005.²⁰ Other countries have followed suit: Argentina, Chile, Mexico, and South Africa have all eliminated their deferral policies for MSM in recent years.²¹ Last month, Brazil's Supreme Court ruled that the country's 12-month deferral period for MSM was unconstitutional.²²

This international shift from deferral to individual risk assessment reflects the reduced risk of transmission that has resulted from improvements in HIV testing capabilities.²³ Indeed, current RNA tests reliably detect HIV within 10 days of infection—a significant improvement from the 3-month detection window characteristic of older technologies.²⁴ With all blood donations screened using this modern testing method, the risk of HIV transmission through blood products is extremely low; testing improvements have decreased the risk of HIV transmission through blood donation to 1 in 1.5 million.²⁵ This risk is significantly lower than the risk of transmitting other viruses through blood donation; there is a 1 in 1.1 million chance that a donation recipient will become infected with hepatitis C and a 1 in 282,000 chance of hepatitis B infection.²⁶ Accordingly, other countries have reasonably concluded that deferral policies are no longer necessary to mitigate the risk of HIV transmission through blood products.

¹⁸ BROAD INSTITUTE, *supra* note 8, at 6–7.

¹⁹ See Christopher McAdam & Logan Parker, *An Antiquated Perspective: Lifetime Ban for MSM Blood Donations No Longer Global Norm*, 16 DEPAUL J. OF HEALTH CARE L. 21, 40–41 (2015) (finding that an increase in HIV-positive blood donations in Italy was driven primarily by high-risk heterosexual donors); Barbara Suligoi et al., *Changing Blood Donor Screening Criteria from Permanent Deferral for Men who Have Sex with Men to Individual Sexual Risk Assessment: No Evidence of a Significant Impact on the Human Immunodeficiency Virus Epidemic in Italy*, BLOOD TRANSFUSION 441, 441–447 (2013) (finding no significant increase in HIV-positive blood donations from MSM following Italy's adoption of an individual risk assessment).

²⁰ See BROAD INSTITUTE, *supra* note 8, at 6.

²¹ Matthew L. Morrison, *Bad Blood: An Examination of the Constitutional Deficiencies of the FDA's "Gay Blood Ban"*, 99 MINN. L. REV. 2363, 2398; Alexandra Sifferlin, *Argentina Lifts Ban on Gay Men Giving Blood*, TIME (Sept. 17, 2015), <https://time.com/4038742/argentina-gay-blood-donation/>; BROAD INSTITUTE, *supra* note 8, at 6.

²² Rachel Savage & Elsa Ohlen, *What Are the Blood Donation Rules Globally for Gay and Bisexual Men?*, REUTERS (May 11, 2020, 1:26 PM), <https://www.reuters.com/article/us-global-lgbt-health-factbox-trfn/what-are-the-blood-donation-rules-globally-for-gay-and-bisexual-men-idUSKBN22N2GS>.

²³ See McAdam & Parker, *supra* note 19, at 30–31 (noting the changing global policy on blood donation in contrast to the deferral policy of the U.S.).

²⁴ R.T. Winston Berkman & Li Zhou, *Ban the Ban: A Scientific and Cultural Analysis of the FDA's Ban on Blood Donations from Men who Have Sex with Men*, COLUM. MED. REV. (May 25, 2015), <https://academiccommons.columbia.edu/doi/10.7916/D8T72GQV>.

²⁵ Sacks, *supra* note 10.

²⁶ *Id.*

III. Any HIV transmission risk associated with eliminating the deferral policy for MSM is likely outweighed by the benefits of eliminating the policy

Evidence from other countries overwhelmingly supports the safety of blood donation without a blanket deferral for MSM.²⁷ However, even if shifting to an individual risk assessment were to marginally increase the risk of HIV transmission from MSM-donated blood, it would also eliminate other, potentially larger health risks associated with maintaining the deferral policy, as well as the stigmatizing effect of the deferral policy for gay and bisexual men. In other words, the benefits of an individual risk assessment relative to the status quo likely outweigh any associated costs.

A. Shifting from a blanket deferral to individual risk assessment could reduce the risk of HIV transmission from heterosexual donors

As discussed in section I, the deferral policy not only excludes donations from some low-risk MSM but also allows donations from some high-risk heterosexual donors. An individual risk assessment, by contrast, would assess known risk factors—such as number of recent sexual partners, condom use, and drug use—for donors of all sexual orientations.²⁸ Accordingly, replacing categorical deferrals for MSM with individual risk assessments for all potential donors could reduce the risk of HIV infection in donations from heterosexual donors.

B. Shifting from a blanket deferral to individual risk assessment would reduce the risk of blood shortages

As also discussed in section I, a deferral period of any length reduces the overall blood supply by excluding eligible donors based solely on their sexual orientation. This reduction will likely contribute to blood shortages both during public health emergencies—such as the current pandemic, which is expected to persist for up to two more years²⁹—and during periods of relative normalcy. For example, in the summer of 2014, the American Red Cross received 80,000 fewer donations than expected, resulting in “an urgent need for blood and platelets.”³⁰ Eliminating the deferral period would thus generate benefits in the form of an avoided risk of shortage-related health consequences.³¹

²⁷ See BROAD INSTITUTE, *supra* note 8, at 6–7.

²⁸ *Id.* at 10 (identifying behaviors associated with a reduced risk of HIV infection).

²⁹ Kristine A. Moore et al., *COVID-19: The CIDRAP Viewpoint*, UNIVERSITY OF MINNESOTA CENTER FOR INFECTIOUS DISEASE RESEARCH AND POLICY (Apr. 30, 2020), https://www.cidrap.umn.edu/sites/default/files/public/downloads/cidrap-covid19-viewpoint-part1_0.pdf.

See also Letter from Debra BenAvram, *supra* note 4.

³⁰ Berkman & Zhou, *supra* note 24.

³¹ See Victoria Bekiempis, *‘This Could Kill Our Patients’: US Faces Blood Shortage as Donation Sites Shutter*, GUARDIAN (Mar. 21, 2020) (explaining that blood shortages “impact patients who need surgery, victims of car accidents and other emergencies, or patients fighting cancer” and can result in death), <https://www.theguardian.com/us-news/2020/mar/21/us-blood-donations-shortage-coronavirus>.

C. Shifting from a blanket deferral to individual risk assessment would be less stigmatizing of gay and bisexual men

In addition to an increased risk of blood shortages, the current deferral policy carries the less tangible cost of stigmatization. The U.S. first banned blood donations from gay men in the 1980s, when the discovery of HIV and AIDS spurred widespread uncertainty and fear across the country.³² At that time, scientists lacked sufficient knowledge about the virus to adequately test and screen donors.³³ Accordingly, FDA established regulations preventing certain groups of high-risk individuals from donating blood.³⁴ However, despite scientific advances, testing improvements, and nationwide blood shortages, the antiquated ban on MSM persists.³⁵

The persistence of the deferral policy arbitrarily prevents gay and bisexual men from donating blood, regardless of their behavioral risk factors for HIV infection. By prioritizing stereotypes over scientific evidence, the policy impugns the dignity of MSM.³⁶ Though difficult to quantify, this stigmatization is a real social cost that should be taken into account when weighing the advantages and disadvantages of shifting to an individual risk assessment.³⁷

Conclusion

The FDA deferral policy for MSM relies on outdated science regarding HIV transmission risk from blood products and stigmatizes gay and bisexual men. Most importantly for purposes of HHS's forthcoming report to Congress, the deferral policy increases the likelihood of blood shortages. Accordingly, HHS's report should recommend elimination of the policy.

Respectfully,

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³² See McAdam & Parker, *supra* note 19, at 22–24 (“With much of the nation still gripped in fear and ignorance, coupled with lack of scientific knowledge about HIV/AIDS, the government thought it imperative and necessary to take action and place appropriate procedures to control the spread of HIV/AIDS and keep the nation’s blood supply safe.”).

³³ *Id.* at 27–29.

³⁴ *Id.*

³⁵ *Id.* at 25.

³⁶ *Id.* at 29–30.

³⁷ See Exec. Order 13,563 § 1(c), 76 Fed. Reg. 3821 (Jan. 21, 2011) (urging agencies to “consider (and discuss qualitatively) values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts”).