



NEW YORK CITY DEPARTMENT OF  
HEALTH AND MENTAL HYGIENE  
Mary T. Bassett, MD, MPH  
Commissioner

November 23, 2016

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

RE: "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products" (Docket No. FDA-2016-N-1502)

To Whom It May Concern:

The New York City Department of Health and Mental Hygiene (DOHMH) appreciates the opportunity to comment on the Food and Drug Administration (FDA)'s blood donor deferral policy as set forth in "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products," published in December 2014. DOHMH calls on the FDA to eliminate its current policy prohibiting men who have had sex with men in the last 12 months from donating blood, and to replace it with an evidence-based, three-step screening process that does not exclude potential donors on the basis of sexual orientation or gender of their sexual partners.

DOHMH is the largest public health department in the United States, with more than 6,000 employees serving 8.4 million New Yorkers from a diverse array of ethnic, cultural, and economic backgrounds. DOHMH coordinates the city's response to the HIV/AIDS epidemic, including prevention, care and treatment, and surveillance efforts, and addresses the health and health care needs of an estimated 756,000 LGBTQ-identified residents through services and programming related to sexual and reproductive health, mental and behavioral health, and capacity-building for LGBTQ-focused community-based organizations. As a public health department at the epicenter of the domestic HIV epidemic, we are uniquely qualified to weigh in on the FDA's blood donation deferral policy for men who have sex with men (MSM).

The FDA has a responsibility to establish blood donation policies grounded in scientific evidence regarding the risk of transmission of HIV and other blood-borne pathogens, in order to maintain the safety of the blood supply. The FDA's current recommendation that blood donation centers defer potential donors who are men who have had sex with another man during the past year – even once – does not comport with current evidence. The policy unnecessarily stigmatizes all sexually active gay and bisexual men as vectors of HIV transmission, suggesting that all sex between men is high-risk regardless of frequency, number of partners, and proven

protective measures, including condoms and HIV prophylaxis such as PrEP and PEP.<sup>1</sup>

DOHMH strongly recommends that the FDA lift its time-based deferral policy for potential donors who are MSM, and replace it with a screening process for all potential donors to include a behavioral risk screen, followed by point-of-care rapid testing for donors who report sexual risk-taking behavior. These steps would supplement the FDA's current recommendation to perform nucleic acid based testing of donated blood for HIV and other pathogens. DOHMH's recommended three-step screening process, based on our extensive clinical expertise and community engagement, is as follows:

**STEP #1:** The blood donation center should conduct a behavioral risk screen for every potential donor, regardless of assigned sex at birth, gender identity, presumed or actual sexual orientation, and sexual history. This screen should ask potential donors about behaviors during the past six months, including:

- HIV testing and status → Potential donors who report having tested positive for HIV should be excluded from donation;
- Syringe use → Potential donors who report having used a syringe not prescribed by a physician should be excluded from donation; and
- Sexual risk-taking behavior → Potential donors, regardless of presumed or actual sexual orientation, who report having had condomless sex, regardless of sexual partners' assigned sex at birth or current gender identity, should proceed to step 2.

**STEP #2:** Potential donors who report having had condomless sex during the past six months should be offered on-site HIV testing, pursuant to the laws of the jurisdiction in which the blood donation center is located. For this step, centers should use sensitive point-of-care rapid diagnostic tests which enable detection of HIV early in the course of infection, such as fourth generation or higher sensitivity antibody tests. A deferral period based on the testing technology, on the order of week, may further supplement this strategy to address the window period of the selected HIV testing algorithm. Test results should direct potential donors as follows:

- Negative → Potential donors who test negative for HIV should proceed to donation;
- Positive → Potential donors who test positive for HIV should receive post-counseling services as required by local law and be referred to care and treatment services. They should be excluded from donation; and
- Invalid → Potential donors with invalid test results should be tested again using a second device. If the second device produces a similar result, potential donors should be excluded from donation and referred to an alternative site for further testing.

**STEP #3:** Perform nucleic acid based testing of donated blood for pathogens, including HIV, pursuant to current protocol.

Not only does this three-step screening process utilize the most advanced HIV testing technology currently available, but it relies on an evidence-based assessment of an individual donor's epidemiological risk of acquisition of HIV. The Centers for Disease Control and Prevention (CDC) estimates that more than 1.2 million persons in the United States are living with HIV, and one in eight of them remain undiagnosed.<sup>2</sup> A 2015 CDC analysis of national data that found that an estimated 1,232,000 adults – including 624,000 heterosexually active

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<sup>1</sup> Virginia A. Fonner et al., *Effectiveness and Safety of Oral HIV Preexposure Prophylaxis for All Populations*, 30 AIDS 1973-1983 (2016); CENTERS FOR DISEASE CONTROL & PREVENTION, *PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2014: A CLINICAL PRACTICE GUIDELINE* (2014). CENTERS FOR DISEASE CONTROL & PREVENTION, *UPDATED GUIDELINES FOR ANTIRETROVIRAL POSTEXPOSURE PROPHYLAXIS AFTER SEXUAL, INFECTION DRUG USE, OR OTHER NONOCCUPATIONAL EXPOSURE TO HIV – UNITED STATES, 2016* (2016).

<sup>2</sup> CENTERS FOR DISEASE CONTROL & PREVENTION, *HIV IN THE UNITED STATES: AT A GLANCE* (JUN. 2016).

adults – are at substantial risk for HIV acquisition consistent with PrEP indications set forth by the CDC.<sup>3</sup> Offering HIV testing to potential donors at high risk for sexually acquired HIV infection and linking those who test positive to care are critical public health interventions for populations that may not otherwise access traditional health care systems. Our recommended three-step screening process is an opportunity to increase testing rates and link more people to care while further improving the safety of the blood supply using science rather than sexual minority stigma-based exclusions. Replacing the FDA’s time-based deferral policy for MSM with a more epidemiologically sound screening process will maintain the safety of the blood supply, eliminate the stigma and discrimination currently imposed against many potential donors, and increase testing rates among potential donors at high risk for HIV. The new screening process will allow thousands, if not hundreds of thousands, of altruistic gay and bisexual men to once again give the life-saving gift of blood.

Thank you for the opportunity to weigh in on this important matter.

Sincerely,



Mary T. Bassett, MD, MPH  
Commissioner  
New York City Department of Health and Mental Hygiene



Carmelyn P. Malalis, JD  
Chair and Commissioner  
New York City Commission on Human Rights



Lisette Camilo, JD  
Commissioner  
New York City Department of Citywide Administrative Services

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<sup>3</sup> Dawn K. Smith et al., *Vital Signs: Estimated Percentages and Numbers of Adults with Indications for Preexposure Prophylaxis to Prevent HIV Acquisition – United States, 2015*, 64 (46) MORBIDITY & MORTALITY WKLY. 1291-1295 (2015). (“An estimated 24.7% of MSM (492,000 [95% confidence interval {CI} = 212,000–772,000]) without HIV infection aged 18–59 years who reported sex with a man in the past year have indications for PrEP . . . . An estimated 18.5% of persons aged ≥18 years who inject drugs (115,000 [CI = 45,000–185,000]) have indications for PrEP. An estimated 0.4% of heterosexually active adults aged 18–59 years (624,000 [CI = 404,000–846,000]) have indications for PrEP. Among these heterosexually active adults, 157,000 (CI = 62,000–252,000) are men, and 468,000 (CI = 274,000–662,000) are women. Overall, an estimated 1,232,000 adults (CI = 661,000–1,803,000) have substantial risk for HIV acquisition, for whom PrEP and other effective prevention methods are indicated.”)