



# WHITMAN-WALKER HEALTH

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SUBMITTED ELECTRONICALLY

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

**Re: Draft Guidance for Industry on Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products (Docket No. FDA-2015-D-1211)**

Dear Sir or Madam:

Whitman-Walker Health (WWH) is pleased to submit these comments in response to the Food and Drug Administration's (FDA or Agency's) *Draft Guidance for Industry on Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products* (May 2015) (Draft Guidance).<sup>1</sup>

## I. Introduction and Summary

WWH is a Federally Qualified Health Center (FQHC) located in Washington, D.C. Our mission is to be the highest quality, culturally competent community health center serving greater Washington's diverse urban community, with a special focus on the lesbian, gay, bisexual, and transgender (LGBT) community; persons living with the Human Immunodeficiency Virus (HIV); and other individuals and families who face barriers to accessing care. For almost four decades, WWH has been a nationally-recognized leader in HIV treatment and prevention, and we have been committed to advancing LGBT health and wellness. We offer primary medical and specialty HIV and transgender care; dental care; mental health and addictions counseling and treatment; HIV education, prevention, and testing services; other community health services; legal services; and medical adherence care management. In calendar year 2014, we provided health services to more than 14,700 individuals.<sup>2</sup>

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<sup>1</sup> 80 Fed. Reg. 27973 (May 15, 2015); available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM446580.pdf>.

<sup>2</sup> Approximately one-half of those individuals identified as gay, lesbian, or bisexual, and approximately 13% of medical patients, and 6% of all persons receiving health services, identified as transgender. Our interest in recording and maintaining consistent and accurate data on patient sexual orientation and gender identity is grounded in our experience as direct health care providers and as an advocate for sound public health policies.

WWH applauds FDA's commitment to replace the outdated and discriminatory 1992 Agency memorandum, *Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products* (1992 Blood Memo), which among other things, recommended that blood establishments indefinitely defer male donors who have had sex with another male (MSM), even one time, since 1977.<sup>3</sup> As one of the first nonprofit health care providers in the U.S. to respond to the HIV epidemic, we are acutely aware of the importance of assuring the safety, purity, and potency of the country's blood supply. However, WWH would like to raise two fundamental concerns with the Agency's Draft Guidance, which when finalized, will supersede the 1992 Blood Memo:

- First, like the 1992 Blood Memo, the Draft Guidance's recommendations still prevent many low-risk individuals from donating blood. The arbitrary one-year deferral time period for MSM donors continues to stigmatize and stereotype these sexual minorities and conflicts with the National HIV/AIDS Strategy. Like an indefinite deferral, the one-year deferral for MSM donors remains a categorical exclusion simply based on the sex of an individual's sexual partner. Furthermore, the Draft Guidance continues to stigmatize and stereotype the transgender community by permitting medical directors of blood establishments to exercise "discretion" with regard to donor eligibility for individuals who assert a "change in gender identification."<sup>4</sup> In its Final Guidance, FDA should remove this reference to "discretion" and clarify that a transgender individual seeking to donate blood should be treated in a manner consistent with their gender identity: a transgender man should be treated the same as any other man, and a transgender woman should be treated the same as any other woman.
- Second, by relying on an arbitrary deferral time period, FDA fails to incorporate technological and scientific advances in HIV testing into the Draft Guidance's blood donation recommendations. Given the rapid progress of the highly-accurate fourth-generation antibody/antigen tests and the development of nucleic acid amplification tests (NATs), any deferral length for donors beyond the short "window period" of these tests is medically and scientifically unwarranted. In its Final Guidance, FDA should institute a policy of NAT testing all samples and recommend a "window period" deferral of 30 days for MSM donors, and for women who recently have had sex with an MSM.<sup>5</sup> If the Agency determines that NAT testing is not yet economically feasible for all

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<sup>3</sup> FDA, *Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products* at 3 (Apr. 23, 1992); available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/OtherRecommendationsforManufacturers/MemorandumtoBloodEstablishments/UCM062834.pdf>. FDA first recommended indefinite deferral for MSM donors in September 1985. See Draft Guidance at 2.

<sup>4</sup> Draft Guidance at 10.

<sup>5</sup> Although the ideal would be to impose this deferral period only on prospective donors who have recently engaged in sexual or other activity posing a significant risk of HIV transmission, we agree with the Agency that self-reporting of sexual activity has not been demonstrated to be sufficiently reliable. Therefore, pending further improvements in testing technology, the deferral period should be used for all MSM and for women who have sex with an MSM during that period.

establishments that test donated blood, then the Agency should clearly explain the basis for its conclusion in the Final Guidance and instead specify a deferral period of 45 days for MSM donors, consistent with the current window period for fourth-generation antibody/antigen tests.

In addition to issuing a non-discriminatory, technologically-based Final Guidance, FDA should actively review its blood donation recommendations every five years to ensure that such recommendations reflect the current scientific and technological landscape. FDA should be a leader--not a follower--in the international community with regard to blood donation, and this requires consistent, proactive review of Agency recommendations.

Finally, FDA should encourage improvements in testing technology to reduce the window period and enable the deferral period to be further shortened and ultimately eliminated. The Agency should also issue Request for Applications (RFAs) to enlist the academic and biotechnology communities in assisting in this endeavor.

## **II. FDA's Draft Guidance Still Prevents Certain Low-Risk Individuals From Donating Blood, Continues to Stigmatize and Stereotype Sexual and Gender Minorities, and Conflicts with the National HIV/AIDS Strategy.**

WWH appreciates FDA's commitment to replace the outdated and discriminatory 1992 Blood Memo, which includes a recommendation of indefinite deferral for MSM donors. FDA's decision to finally revise the memorandum comes after nearly two decades of robust advocacy grounded in the latest advances in science, medicine, and technology. For example, as early as 1997, AABB (formerly American Association of Blood Banks) testified before FDA's Blood Products Advisory Committee (BPAC) and urged FDA to revise its indefinite deferral recommendation for MSM donors.<sup>6</sup> At a 2006 BPAC meeting, the American Red Cross (ARC) and America's Blood Centers (ABC) joined AABB and stated that the MSM indefinite deferral recommendation was "medically and scientifically unwarranted" and "unfair and discriminatory."<sup>7</sup> Over two years ago, the American Medical Association (AMA) adopted a policy that the lifetime ban for MSM donors was "discriminatory and not based on sound science."<sup>8</sup>

Based on this long history of advocacy, we applaud FDA for finally agreeing to revise the 1992 Blood Memo. However, the Draft Guidance still prevents certain low-risk populations from

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<sup>6</sup> At the time of its testimony, AABB was "responsible for virtually all the blood collected and more than 80 percent of the blood transfused in this country." See AABB Testimony, FDA Blood Products Advisory Committee Transcript at 247-50 (Sept. 18, 1997); available at <http://www.fda.gov/ohrms/dockets/ac/00/transcripts/3649t1c.pdf>.

<sup>7</sup> See America's Blood Centers, "Statement: Behavior-Based Blood Donor Deferrals in the Era of Nucleic Acid Testing (NAT)" (Mar. 9, 2006); available at [http://www.americasblood.org/media/27919/stmnt\\_060309\\_deferrals-msm.pdf](http://www.americasblood.org/media/27919/stmnt_060309_deferrals-msm.pdf).

<sup>8</sup> See AMA, "AMA Adopts New Policies on Second Day of Voting at Annual Meeting" (Jun. 18, 2013); available at <http://www.ama-assn.org/ama/pub/news/news/2013/2013-06-18-new-ama-policies-annual-meeting.page>.

donating blood, with the one-year deferral period excluding an estimated two million eligible donors and approximately 300,000 pints of blood annually.<sup>9</sup>

Furthermore, the Draft Guidance continues to stigmatize and stereotype sexual and gender minorities. For example, it is well documented that “HIV risk is not uniform among MSM.”<sup>10</sup> A one-year deferral for all MSM donors ignores this fact -- treating a married, monogamous gay man in the same manner as a single man who has unprotected sex with multiple male partners. The Draft Guidance’s MSM donor recommendation is a categorical exclusion simply based on the sex of an individual’s sexual partner. This is no different than the deferral recommendation in the 1992 Blood Memo, and as a result, for most gay and bisexual men, a one-year deferral is a “de facto lifetime ban.”<sup>11</sup>

The Draft Guidance’s “de facto lifetime ban”-- applicable to even the most low-risk MSM donors -- perpetuates the myth that gay and bisexual men are all disease carriers and that all sex between men is inherently risky. Such a deferral for MSM donors directly contradicts the National HIV/AIDS Strategy’s goal of combatting stigma and misinformation associated with HIV/AIDS transmission.<sup>12</sup> Such stigma and misinformation will negatively affect gay and bisexual individuals.<sup>13</sup>

The Draft Guidance also continues to stigmatize and stereotype the transgender community. For example, the Draft Guidance provides that in instances where a donor has “asserted a change in gender identification, medical directors may exercise discretion with regard to donor eligibility.”<sup>14</sup> WWH believes this is a highly unsatisfactory approach to the problem. Endorsing the exercise of “discretion” by blood establishments is likely to result in continued irrational discrimination against the transgender community. Gender identity is not the same as sexual orientation.<sup>15</sup> Under FDA’s Final Guidance, medical directors should not be afforded

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<sup>9</sup> See Cohen and Adashi, “New Blood-Donor Policy, Same Gay Stigma,” *The New York Times* (May 21, 2015).

<sup>10</sup> See Harvey Alter (Chief, Clinical Studies; Associate Director of Research; Department of Transfusion Medicine, NIH), *HHS Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) Presentation of MSM Blood Policy Deferral Options* (Nov. 13, 2014).

<sup>11</sup> See Cohen and Adashi, *supra* n.9 (“To ask, for example, a married, monogamous gay man who has been tested and shown to be HIV-negative to remain celibate for a year to be eligible to donate blood to his own children is an unrealistic burden we would never impose on heterosexual individuals.”).

<sup>12</sup> See generally Office of National AIDS Policy (White House), *National HIV/AIDS Strategy for the United States* (July 2010) (“The United States will become a place where new HIV infections are rare and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity or socio-economic circumstance, will have unfettered access to high quality, life-extending care, free from stigma and discrimination”); available at <https://www.whitehouse.gov/sites/default/files/uploads/NHAS.pdf>.

<sup>13</sup> For example, given the prevalence of blood donation drives at schools, places of employment, and other central community meeting points, the one-year deferral for MSM donors will continue to create unease and discomfort for such individuals who may not wish to disclose their sexual orientation or gender identity to their peers or community.

<sup>14</sup> Draft Guidance at 10.

<sup>15</sup> See Dawn Ennis, “To The FDA, Everyone Transgender is a Gay Man,” *The Advocate* (Feb. 2, 2015) (“A trans woman, for example, may have sex with cisgender men, cisgender women, transgender men, or other transgender

“discretion” in cases where a donor has “asserted a change in gender identification.” For purposes of accepting or rejecting a blood donation, a transgender man should be treated the same as any other man; a transgender woman should be treated the same as any other woman.

### **III. FDA’s Final Guidance Should Adopt a Technologically-Based “Window Period” Deferral Method Utilizing Highly-Accurate HIV Testing.**

The majority of gay and bisexual men are HIV-negative, and many, if not most, do not engage in sexual behavior that subjects them to a significant risk of HIV infection: they avoid unprotected anal intercourse; are in monogamous relationships with other HIV-negative persons; are otherwise at extremely low-risk because their sexual partners are HIV-positive but on medication that has rendered their viral loads undetectable; or they are on a Pre-Exposure Prophylaxis (PrEP) regimen that substantially reduces their risk of contracting HIV.<sup>16</sup> Ideally, rather than stigmatizing every MSM donor as potentially high-risk regardless of his actual behavior, any deferral period should apply only to individuals whose recent behavior actually puts them at *significant* risk.

However, WWH agrees with FDA that sufficient data, including statistics concerning the reliability of self-reporting, are not currently available to assess the effectiveness of selecting MSM donors with low HIV risk.<sup>17</sup> Until such sufficient data is available, FDA should balance the stigma associated with FDA’s Draft Guidance recommendations with the current state of testing technology. The Draft Guidance’s one-year deferral period for MSM donors (and women who have sex with MSM) should be replaced in the Final Guidance with a “window period” deferral method based on highly-accurate HIV testing. Blood collection establishments and advocacy groups have long urged FDA to adopt this method.<sup>18</sup>

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women. A significant number don’t have sex at all. Treating all these groups the same is too simplistic and will prevent some very low risk persons from donating” (quoting Rebecca Allison, board member of the Gay and Lesbian Medical Association)). WWH Legal Services collects statistics on the sexual orientation of all of our legal clients. Of our transgender clients who provide their sexual orientation, approximately one-half identify as heterosexual, approximately one-third identify as homosexual, and the remainder identify as bisexual.

<sup>16</sup> On the probability of HIV transmission associated with different sexual acts with someone who is HIV-infected, see Centers for Disease Control and Prevention (CDC), *HIV Transmission Risk*; available at <http://www.cdc.gov/hiv/policies/law/risk.html>; on the effectiveness of condoms in reducing the risk of HIV transmission through anal or vaginal intercourse, see CDC, *Condom Effectiveness: Fact Sheet for Public Health Personnel*; available at <http://www.cdc.gov/condomeffectiveness/latex.html>; on the effectiveness of antiretroviral therapy in dramatically reducing the likelihood that someone with HIV can transmit the virus even through unprotected intercourse, see CDC, *Prevention Benefits of HIV Treatment*; available at <http://www.cdc.gov/hiv/prevention/research/tap>; on the effectiveness of PrEP in reducing the possibility of HIV transmission, see CDC, *Pre-Exposure Prophylaxis (PrEP)*; available at <http://www.cdc.gov/hiv/prevention/research/prep>.

<sup>17</sup> See Draft Guidance at 7. In WWH’s experience, self-reports of sexual activity by patients and individuals presenting for HIV testing often are unreliable, for a number of reasons.

<sup>18</sup> See America’s Blood Centers, *supra* note 7 (“Current duplicate testing using NAT and serologic methods allow detection of HIV- infected donors between 10 and 21 days after exposure. Beyond this window period, there is no valid scientific reason to differentiate between individuals infected a few months or many years previously.”).

- A. *In its Final Guidance, FDA should institute a policy of NAT testing all samples and recommend a “window period” deferral of 30 days for MSM donors (and women who have sex with MSM).*

Over the past fifteen years, blood establishments have effectively implemented three types of donor screening tests--antibody tests,<sup>19</sup> antigen tests,<sup>20</sup> and NATs<sup>21</sup>--to screen HIV-infected donations out of the donor pool.<sup>22</sup> Currently, FDA considers antibody testing for both HIV-1 and HIV-2 antibodies as “necessary,”<sup>23</sup> and provides supplementary guidance on NAT testing for HIV-1 following a non-reactive antibody test.<sup>24</sup> Following implementation of NAT testing, the residual risk of HIV-1 in screened blood donations is estimated to be approximately 1 in 2,135,000 donations.<sup>25</sup>

The Final Guidance should institute a policy of NAT testing with a “window period” deferral. NATs have the shortest window period compared to antibody and antigen tests, and therefore require the shortest deferral. Whereas antibody tests have an average window period of 25 days,<sup>26</sup> and antigen tests have an average window period of 19 days,<sup>27</sup> NATs have an average window period of only nine to 14 days.<sup>28</sup> This means that NATs will detect the presence of HIV

<sup>19</sup> Antibody tests screen for human-made antibodies produced as the body fights the HIV infection.

<sup>20</sup> Antigen tests screen for the presence of p24 antigens that trigger the immune response.

<sup>21</sup> NATs screen for the presence of viral nucleic acids.

<sup>22</sup> See FDA, *Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry* (2010 Guidance) at 3; available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM210270.pdf>.

<sup>23</sup> See Draft Guidance at 17. *But see* FDA, *Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components (Including Source Plasma and Source Leukocytes) to Adequately and Appropriately Reduce Risk of Transmission of HIV-1 and HCV* (2004 Guidance) at 4; available at

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm074934.htm> (“To meet the requirement [under 21 C.F.R. § 610.40(b)] to . . . reduce the risk of [HIV] transmission . . . , we recommend that you . . . test for the detection of antibodies to *HIV-1*. . . .”) (emphasis added).

<sup>24</sup> See 2004 Guidance at 4.

<sup>25</sup> See 2010 Guidance at 3.

<sup>26</sup> See Ling AE *et al.*: Failure of routine HIV-1 tests in a case involving transmission with preseroconversion blood components during the infectious window period. *J. Am. Med. Ass’n* 2000: 284: 210-214. The immune system usually takes three to eight weeks to make antibodies against HIV, and ninety-seven percent of people will develop antibodies in the first three months after they are infected. See CDC, *HIV/AIDS, Testing*; available at <http://www.cdc.gov/hiv/basics/testing.html>.

<sup>27</sup> See Ling, *supra* note 26 (explaining that p24 antigens “on average, can be detected about 6 days before antibody tests become positive”). See also CDC, *HIV/AIDS, Testing*, *supra* note 26 (suggesting antigen tests can find HIV “as soon as 3 weeks after exposure to the virus”).

<sup>28</sup> See Ling, *supra* note 26 (explaining that NATs can detect HIV RNA “5 to 10 days prior to p24 antigen detection”); see also 2010 Guidance at 3 (explaining that pooled sample NAT reduces the window period by an average of “11 to 15 days relative to antibody testing and 5 to 9 days relative to HIV-1 p24 antigen testing”); See also CDC, *HIV/AIDS, Testing*, *supra* note 26 (suggesting NATs can detect HIV about 10 days after infection).

in the blood, on average, within two weeks of infection. Future tests may be able to further shorten the window period.

If NATs are used, the window period deferral could be relatively short. Even a conservative NAT-based deferral should be no longer than four weeks. If an antigen or antibody test is used, the deferral might be a little longer, perhaps up to six weeks. Because donor screening tests are effective and NATs have the shortest window period, FDA should institute a policy of NAT testing all samples and recommend a window-period deferral for a period of 30 days.

If FDA concludes the increased cost of NAT testing is a significant obstacle for implementation of this policy, the Agency should clearly articulate its reasoning for coming to this conclusion in the Final Guidance. FDA should then adopt antibody/antigen testing, with a “window period” deferral length of 45 days.<sup>29</sup>

- B. *FDA should reconsider the indefinite deferral of persons who have ever exchanged sex for money or drugs or who have ever engaged in non-prescription injection drug use.*

While the principal focus of our comments pertain to MSM and transgender donors, WWH sees no scientific basis for FDA to continue its longstanding “lifetime ban” on blood donations by individuals who have ever exchanged sex for money or drugs and individuals who have ever engaged in non-prescription drug use.<sup>30</sup> Since all donated blood would be subjected to HIV testing under our proposal, the same 30- to 45-day deferral period applicable to MSM (and to women who have had sex with MSM) should apply to these subgroups as well. We see no basis to stigmatize individuals as “high-risk” who may have engaged in prostitution, or used non-prescription injection drugs, in the very distant past.

- C. *Another approach: requiring MSM donors (and others subject to the Draft Guidance deferral period) to take HIV tests at the time of donation and at the end of the window period.*

An alternate possibility is to permit *all* individuals to donate blood but require donors subject to deferral in the Draft Guidance to take an HIV test at the time of donation, and then to return to the blood establishment after the window period (30 days if NAT testing, and 45 days if fourth-generation antibody/antigen testing) to take a second HIV test. If both HIV tests are

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<sup>29</sup> Likewise, if FDA concludes the cost of antibody/antigen testing is a significant obstacle, the Agency should clearly articulate its reasoning for coming to this conclusion in the Final Guidance. Even if FDA does not adopt a deferral period based on NAT testing or fourth-generation antibody/antigen testing in the Final Guidance, the Agency should actively consider such testing in future policymaking decisions and should adopt a deferral period for MSM that is no longer than the window period for the HIV testing technology that the Agency would recommend.

<sup>29</sup> See Draft Guidance at 3

negative, the previous donation could obviously then be utilized. This approach would have the advantage of individualized treatment of donors in “higher-risk” populations rather than treating such individuals in a generalized manner that may not acknowledge actual behavior. This approach may not be feasible at smaller blood donation centers or in large blood drives at, e.g., schools or workplaces. Moreover, such a protocol would require safeguards to protect the confidentiality of donors undergoing HIV testing, while ensuring that donors are promptly informed of any positive test and provided with necessary referrals for follow-up testing, counseling, and treatment.

#### **IV. Over the Next Five Years, FDA Should Actively Re-Examine Blood Donation Recommendations and Focus on Technological and Scientific Solutions to Eventually Eliminate Any Deferral Period.**

While WWH appreciates FDA’s commitment to revise the 1992 Blood Memo, the Agency should not deliberate as long in addressing potential revisions to the Final Guidance. FDA should be an international leader in terms of blood donation recommendations. The Draft Guidance is actually reactive to decades of scientific and medical advocacy and to policies implemented in peer countries.<sup>31</sup> For example, the Draft Guidance cites the experiences in countries that have changed their policies to a one-year MSM deferral (Argentina, Australia, Brazil, Hungary, Japan, Sweden, and the United Kingdom) as support for change.<sup>32</sup> But, the Draft Guidance fails to address the experiences in countries that have no MSM deferral policy, or have policies of less than one year (for example, Chile, Italy, Mexico, Poland, Spain, and South Africa).<sup>33</sup> FDA should actively re-examine the Final Guidance’s blood donation recommendations over the next five years and then every five years thereafter.<sup>34</sup> This review of Agency recommendations should include a survey of various countries and their blood donation policies. Particular focus should be paid to studies that examine the safety of the blood supply in countries without a one-year MSM deferral.

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<sup>31</sup> For example, Australia phased in a one-year deferral for MSM donors starting in 1996, almost two decades ago. See Cohen and Adashi, *supra* note 9. Recently, an independent review commissioned by the Australia Red Cross Blood Service recommended shortening this period. See “Review of Australian Blood Donor Deferrals Relating to Sexual Activity” (May 2012); available at [http://www.bloodrulesreview.com.au/files/upload/blood\\_review\\_report\\_may\\_2012\\_electronic\\_version.pdf](http://www.bloodrulesreview.com.au/files/upload/blood_review_report_may_2012_electronic_version.pdf).

<sup>32</sup> See Draft Guidance at 7.

<sup>33</sup> “Italy has adopted an ‘assess and test’ approach in which all prospective blood donors--regardless of sexual orientation--undergo extensive physical and psychological testing and get an individualized risk assessment. The existing evidence shows no sign that Italy has seen an increase in infected blood in its supply.” See Cohen and Adashi, *supra* note 9.

<sup>34</sup> Indeed, the Blood Donation Rules Opinion Study (BloodDROPS), cited in the Draft Guidance, specifically posed questions about deferral period lengths based on the possibility that “shorter periods might be considered after confirming the safety of the new policy.” See Draft Guidance at 6.

Furthermore, FDA should focus on technological and scientific solutions to eventually eliminating *any* deferral period. For example, in December 2014, FDA approved the use of a new pathogen inactivation system to reduce the risk of transfusion transmissible infections in platelets and plasma.<sup>35</sup> The Intercept Blood System is highly effective in inactivating bacteria and viruses, such as HIV, in platelet and plasma blood components used for transfusions.<sup>36</sup> WWH encourages FDA to consider such technology and the technological advances in the near future to shorten, and to eventually eliminate, any deferral period. The Agency should also issue Request for Applications (RFAs) to enlist the academic and biotechnology communities in assisting in this endeavor.

## V. Conclusion

Whitman-Walker Health appreciates FDA's commitment to revising the outdated and discriminatory 1992 Blood Memo; however, as outlined above, further revisions should be incorporated into the Final Guidance. WWH is acutely aware of the importance of assuring the safety, purity, and potency of the country's blood supply. Given its unique 40-year history as a community health center and as one of the first nonprofit health care providers in the U.S. to respond to the HIV epidemic, WWH wishes to continue to serve as a constructive partner on these issues and would be happy to meet with the Agency to discuss the Final Guidance's blood donation recommendations. Please do not hesitate to contact us if you have any questions about our comments.

Sincerely,



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<sup>35</sup> FDA, *FDA Approves Pathogen Reduction System to Treat Platelets* (2014); available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm427500.htm>.

<sup>36</sup> Irsch J and Lin L: Pathogen inactivation of platelet and plasma blood components for transfusion using the INTERCEPT blood system. *Transfusion Medicine and Hemotherapy* 2011; 38: 19-31; *published online at* <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3132977/>.

<sup>37</sup> These comments were prepared with the assistance of Christopher Hanson, Esq., of Covington & Burling LLP.