WHITMAN-WALKER HEALTH

Mailing Address:
Elizabeth Taylor Medical Center
1701 14th St., NW
Washington, DC 20009

March 28, 2017

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

Re: Docket No. FDA-2017-N-0001; Blood Products Advisory Committee; Notice of Meeting

To the Blood Products Advisory Committee:

Whitman-Walker Health (WWH) provides these comments to the Blood Products Advisory Committee (BPAC) in preparation for the April 4-5 public advisory committee meeting. *See* FDA, Notice of Meeting of Blood Products Advisory Committee, 82 Fed. Reg. 12229 (Mar. 1, 2017). 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.

Agenda items for the upcoming BPAC public advisory committee meeting include "an update presentation on a summary of responses to Docket FDA–2016–N–1502: Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products." *Id*.

On November 23, 2016, WWH submitted the attached comments to Docket FDA–2016–N–1502. As articulated in our comments, WWH supports FDA's decision to move toward the use of individual risk assessments for blood donation deferrals. The current one-year deferral policy for the MSM population: (1) prevents certain low-risk populations from donating blood; (2) continues to stigmatize and stereotype sexual and gender minorities; and (3) conflicts with the national HIV/AIDS strategy. Specifically, in our comments:

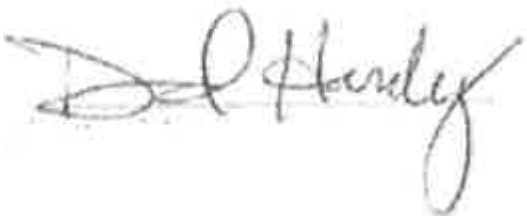
- We provide a study design to assess the efficacy of an individual risk deferral policy. This study would test the validity of certain screening questions and their effectiveness in identifying individuals at higher risk of transmission during the window period for HIV.

- We urge that, while the proposed study is being conducted, FDA should reduce the deferral period from one year to one month for MSM. A one-month deferral is scientifically based on the window period for HIV when using nucleic acid testing (NAT), and therefore would be sufficient for maintaining the safety and purity of the blood supply without

unnecessarily restricting the donor pool. In the alternative, if FDA chooses to be very conservative, it could temporarily implement a two-month deferral based on its donor reentry policy for seronegative individuals with a reactive NAT.

WWH appreciates the opportunity to provide these comments, and we look forward to speaking before BPAC. If you have any questions, please contact me at the phone number or e-mail address included below.

Sincerely,



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ATTACHMENT

WHITMAN-WALKER HEALTH

Mailing Address:
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November 23, 2016

SUBMITTED ELECTRONICALLY

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

Re: Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products (Docket No. FDA-2016-N-1502)

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) public notice, *Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products* (July 2016) ("Request for Comments").[1]

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 2015, we provided health services to more than 15,300 individuals.[2]

[1] 81 Fed. Reg. 49673 (July 28, 2016).

[2] Approximately one-half of those individuals identified as gay, lesbian, or bisexual, and approximately 14% of medical patients, and 7% 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 "continuing to reevaluate and update blood donor deferral policies as new scientific information becomes available."[3] This commitment is especially meaningful in light of the Agency's decades-long deliberation leading up to the most recent deferral policy revision. In 1992, FDA recommended a lifetime deferral of blood donation by any man who had had sex with another man (MSM), even one time, since 1977.[4] In 2015, after two decades of robust public advocacy,[5] the Agency revised the MSM donor policy to a one-year deferral.[6] FDA demonstrates its current commitment to reviewing its policies based on available science by issuing its Request for Comments concerning the use of individual risk assessments eight months following the implementation of the one-year MSM deferral recommendation.

WWH supports FDA's decision to move toward the use of individual risk assessments. The current one-year deferral policy: (1) prevents certain low-risk populations from donating blood; (2) continues to stigmatize and stereotype sexual and gender minorities; and (3) conflicts with the national HIV/AIDS strategy.[7] WWH, therefore, proposes the following in response to FDA's Request for Comments:

- *First*, WWH provides a study design to assess the efficacy of an individual risk deferral policy. This study will test the validity of certain screening questions and their effectiveness in identifying individuals at higher risk of transmission during the window period for HIV. Following a description of the study design, WWH responds specifically to the six questions FDA poses in its Request for Comments.
- *Second*, while the proposed study is being conducted, FDA should reduce the deferral period from one year to one month for MSM. A one-month deferral is scientifically based on the window period for HIV when using nucleic acid testing (NAT), and therefore would be sufficient for maintaining the safety and purity of the blood supply without unnecessarily restricting the donor pool. In the alternative, if FDA chooses to be very conservative, it could temporarily implement a two-month deferral based on its donor reentry policy for seronegative individuals with a reactive NAT.

Finally, FDA should be a leader—not a follower—in the international community with regard to blood donation. This requires consistent, proactive review of Agency recommendations. We conclude by summarizing recent progress made by other countries to

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[3] 81 Fed. Reg. at 49674.

[4] FDA, "FDA Memorandum to All Registered Blood Establishments: Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products" (Apr. 23, 1992) ("1992 Blood Memo").

[5] For a discussion of this history, *see* Whitman-Walker Health, "Comments 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)" (July 14, 2015) at 3 ("WWH July 2015 Comments").

[6] *See* FDA, "Guidance for Industry: Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products" (Dec. 2015) ("2015 Final Guidance").

[7] *See* WWH July 2015 Comments at 3–5.

revise their blood donation policies and by urging FDA to continue actively reviewing its blood donation policies as new scientific evidence becomes available.

II. Study Design to Test the Validity of Screening Questions and Their Effectiveness in Identifying Individuals at Higher Risk of Infection During the Screening Period.

WWH proposes a study to evaluate the feasibility and effectiveness of an individual risk deferral policy. This study design is directly responsive to the sixth question that FDA proposes in its Request for Comments. WWH responds to FDA's other five questions implicitly within the study design, and then expressly in the subsection immediately following the study design.

A. Study Design.

The basic concept of WWH's study design is to test the validity of screening questions and their effectiveness in identifying individuals at higher risk of transmitting HIV during the screening period based on certain high-risk behaviors.[8] The study would proceed in four steps:

- *Step One*: Accept blood samples from individuals who are 17 years of age and older, have answered questions about specific risk activities during the screening period, and have otherwise met the eligibility health criteria to donate.
- *Step Two*: Test the donated blood samples for HIV.
- *Step Three*: Re-test the participant for HIV one month after the initial sample donation.
- *Step Four*: Conduct an electronic survey of every such participant who tested negative at sample donation and who returned following the one-month quarantine, asking different follow-up questions depending on whether the second test was negative or positive.

Step 1 will involve asking specific, intimate questions to assess each participant's individual risk. Because it will be critical that participants understand the screening questions and provide accurate answers, WWH suggests that the risk-related screening questions be preceded by language such as the following:

> *Why the intimate questions?*
>
> Through the following questions, we want to know your risk level for Human Immunodeficiency Virus (HIV) based on specific activities **within the last one (1) month**. Even though all blood donations are screened for this virus, there is a period of time at the beginning of infection during which a test may not detect the presence of the virus, despite the high performance of the tests used. Thus, the virus may be present in the donor's blood, and the infection may be

[8] WWH's study design is based on the study currently being conducted in France to assess the compliance of blood donors to selection criteria. *See* Santé publique France, "Étude: Compliance des Donneurs de Sang aux Critères de Sélection" (Working Document, May 31, 2016), http://ffdsb.monsite-orange.fr/DSB_Infos/DSB75/Protocole_Compliance_20062016.pdf.

transmitted to a patient by transfusion. Accurately communicating risks is critical to safeguarding the blood supply from various infections.

For the study, WWH proposes the following specific screening questions, which will need to be validated:

1. With how many people were you sexually active within the last one month? (*If zero, skip questions 2 and 3.*)

2. In the last one month, with how many people have you engaged in penetrative anal sex? (*If zero, skip the rest of question 2 and question 3.*)

   A. In the last one month, when you engaged in penetrative anal sex, did you engage passively ("bottom"), actively ("top"), or both?

   B. In the last one month, when you engaged in penetrative anal sex, did you and your sexual partner(s) use a condom every time, whether or not you or your sexual partner(s) were using Pre-exposure Prophylaxis (PrEP) and/or were on continuous Antiretroviral Therapy (ART)?

3. In the last one month, were you sexually active with any person who is HIV positive? (*Answer "Yes," "No," or "I don't know."*)

Based on an analysis of participants' answers to the above questions (Step 1), the correlating sample blood donation test results (Step 2), and re-testing of the participants after one month (Step 3), the study should determine whether and how the blood supply might be affected by:

- Deferring only MSM who reported that they were sexually active and did not have penetrative anal sex in the last one month.
- Deferring only MSM who reported that they had penetrative anal sex in the last one month.
- Deferring only MSM who reported that they had penetrative anal sex where a condom was not used in the last one month.
- Deferring only MSM who reported that they had penetrative anal sex in the last one month with more than one person with or without a condom.
- Deferring only MSM who reported that they had penetrative anal sex with or without a condom in the last one month with at least one person who they were not certain was HIV-negative.

Analysis of the answers to the follow-up survey for returning participants (Step 4) will provide further data to help FDA evaluate the effectiveness of the initial screening questionnaire.

WWH proposes conducting the study under similar circumstances as the federally-funded research outlined in the manuscript, Risk Factors for Retrovirus and Hepatitis Virus Infections in

Accepted Blood Donors ("REDS -II Study").[9] This would include similar study funding, powering, recruiting, and population parameters. FDA cites to the REDS-II Study in its recent public notice, Donor Risk Assessment Questionnaire for the Food and Drug Administration/National Heart, Lung, and Blood Institute-Sponsored Transfusion-Transmissible Infections Monitoring System—Risk Factor Elicitation.[10] WWH is submitting comments concerning the notice (Attachment 1).

WWH also proposes that participating study sites should primarily be blood donation centers that have a community partner that can help recruit eligible individuals. Involvement of community partners will ensure sufficient participation of persons who might not otherwise enroll. WWH recommends that this study be initiated and completed in a timely fashion through federal and/or private funding, including a National Institutes of Health (NIH) grant.

B. Answers to FDA's Specific Questions.

In this section, WWH provides answers to the six questions that FDA posed in its Request for Comments.

1. What questions would most effectively identify individuals at risk of transmitting HIV through blood donation?

As discussed in the study design above, the questions that would most effectively identify individuals at risk of transmitting HIV are those that identify all donors who have engaged in high-risk behaviors within the screening period. Potential high-risk behaviors are:

- Penetrative anal sex:
  - During the screening period,
  - With any person whose HIV status is not known to be negative, **and/or**
  - Without a condom.

In the study above, WWH suggests using specific questions to identify participants who have engaged in potentially high-risk behaviors during the screening period. The study will help identify which of these behaviors are high-risk for blood donation purposes. WWH emphasizes that any such screening questions should be validated using standard scientific techniques.

2. Are there specific questions that could be asked that might best capture the recent risk of a donor acquiring HIV infection, such as within the 2 to 4 weeks immediately preceding blood donation?

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[9] Custer, B., *et al.*, Risk Factors for Retrovirus and Hepatitis Virus Infections in Accepted Blood Donors. *Transfusion*. May 2015; 55(5): 1098-1107.

[10] FDA, "Agency Information Collection Activities; Proposed Collection; Comment Request; Donor Risk Assessment Questionnaire for the Food and Drug Administration/National Heart, Lung, and Blood Institute-Sponsored Transfusion-Transmissible Infections Monitoring System—Risk Factor Elicitation," 81 Fed. Reg. 67358, 67359 (Sept. 30, 2016).

See answer to Question 1.

3. How specific can the questions be regarding sexual practices while remaining understandable and acceptable to all blood donors? For example, could questions about specific sexual behaviors be asked if they helped to identify which donors should be at least temporarily deferred because of risk factors? To the extent the questions are explicit about sexual practices, how willing will donors be to answer such questions accurately?

In general, WWH believes that very specific questions are likely to elicit more accurate answers than questions using general or vague language that can be misunderstood or misinterpreted.[11] Additionally, WWH believes that screening questions should be administered electronically, without a blood donation center staff person present, to the extent feasible. This is likely to encourage accurate completion of the questionnaire.[12] Potential donors should be assured, orally and in writing, that their answers will remain confidential.

4. Under what circumstances would a short deferral period for high risk behavior be appropriate? For each short deferral period identified, please specify the duration of the deferral and provide the scientific rationale.

WWH framed its questions around a one-month screening/deferral period based on the window period for HIV using NAT (approximately nine days).[13] Given the accuracy of tests currently being used at blood banks, a screening period of one month is conservative enough to safeguard the blood supply from infected donations. This is discussed in more detail in Section III below.

5. What changes might be necessary within blood collection establishments to assure that accurate, individual HIV risk assessments are performed?

First, electronic administration of donor questionnaires is likely to encourage accurate completion of the questionnaire.[14]

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[11] *See* William Foddy, CONSTRUCTING QUESTIONS FOR INTERVIEWS AND QUESTIONNAIRES: THEORY AND PRACTICE IN SOCIAL RESEARCH 42 (1993) ("When more than one plausible interpretation exists, the respondent needs to consider the various possibilities and often must think up and answer an *internal* questionnaire to help decide which interpretation to accept.") (internal citation omitted) (emphasis in original).

[12] Estes, LJ., *et al.*, Perceptions of Audio Computer-Assisted Self-Interviewing (ACASI) among Women in an HIV-Positive Prevention Program. *PLoS ONE*. 2010; 5(2): e9149 ("Research indicates that some methods of data collection may increase disclosure and minimize socially desirable responses. One such method, [ACASI] is a tool used in data collection to collect sensitive data about health and risk behaviors.").

[13] *See* 2015 Final Guidance at 9.

[14] Estes *et al*. 2010.

Second, giving respondents the option to answer each question with "I don't know" is likely to discourage guessing.[15] This assures accurate responses to the questionnaire. Recording "I don't know" responses will provide information regarding donors' ability to recall activities during the screening period. This may in turn inform how questions are phrased or how the screening period is presented (one month versus four weeks versus 30 days). This method is consistent with other countries' blood donor questionnaires. For example, France's blood donor questionnaire includes an "I don't know" option.[16] Canada's plasma donor questionnaire includes space for respondents to comment after every question.[17]

6. How best to design a potential study to evaluate the feasibility and effectiveness of alternative deferral options such as individual risk assessment?

See Section II.A.

III. In the Interim, FDA Should Shorten the Deferral Period to One Month for MSM.

While the Agency evaluates the feasibility and effectiveness of alternative deferral options such as individual risk deferral, FDA should implement a shorter deferral period of one month for MSM. This deferral period is based on the nine-day window period for HIV using a nucleic acid test (NAT).

A. Because the Window-Period for NAT is Only Nine Days, the Deferral Period Should Be Reduced to No More Than One Month.

First, WWH recommends reducing the HIV deferral period to no more than one month for MSM. This is based on the HIV window period using NAT. The window period is the period when the donor is infected with a virus, but neither the virus nor antibodies to the virus are detectable by current tests.[18] The risk of accepting a blood donation from a donor with HIV is highest during the window period for that virus, since even testing the particular donation may

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[15] *See* Foddy at 8 ("Respondents frequently answer questions that appear to be marginally relevant to them or about which they have thought little. It has been found, for instance that up to 25% of respondents will check substantive options when a 'Don't know' is not offered but check a 'Don't know' option when it is offered.") (internal citation omitted).

[16] *See* Établissement Français du Sang, "Document de Préparation à l'Entretien Préalable au Don de Sang" (May 2016), https://www.google.fr/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&cad=rja&uact=8&ved=0ahUKEwiPsu6nnprQAhVm_4MKHdIKDbYQFgguMAE&url=https%3A%2F%2Fdondesang.efs.sante.fr%2Fsites%2Fdefault%2Ffiles%2FDST%2FdocumentPredon.pdf&usg=AFQjCNH-EE6wF-ZRb46DMzoKFLVZ2zrwCg&bvm=bv.138169073,d.eWE (last visited November 22, 2016).

[17] *See* Canadian Plasma Resources, "Questionnaire to Determine Suitability of the Donor," http://giveplasma.ca/wp-content/uploads/Questionnaire.pdf (last visited Nov. 15, 2016).

[18] *See* FDA, "Guidance for Industry: 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" (May 2010) at 3 ("2010 Guidance").

not detect presence of the virus.[19] Any deferral period, therefore, should be at least as long as the window period for HIV.

As WWH discussed in its July 2015 comments, blood establishments have effectively implemented three types of donor screening tests—antibody tests, antigen tests, and nucleic acid tests (NATs)—to screen HIV-infected donations out of the donor pool.[20] FDA considers HIV antibody testing to be "necessary," and recommends NAT testing following any non-reactive antibody test.[21] FDA likely recommends this order of testing because antibody tests are less expensive, but they are also associated with a longer window period.[22] A NAT, which has a shorter window period, is more likely to screen out donors who were infected more recently. [23]

According to FDA, "[t]he window period when recent HIV infection might be missed using [NAT performed on pools of 6 to 16 donor samples] is approximately 9 days."[24] Further, the donor screening tests applied to all blood donations are highly accurate after the window period. This makes the risk of an infected donation being included in the blood supply exceptionally low. Following implementation of NAT for pooled blood samples, the residual risk of HIV-1 in screened blood donations is estimated to be approximately 1 in 2,135,000 donations.[25] Therefore, a deferral period of one month—more than three times the window period—is sufficient to safeguard the blood supply.

B. Alternatively, the Deferral Should Be No More Than Two Months Based On FDA's Established Policy For Reentry of HIV Seronegative Donors With a Reactive HIV-1 NAT.

If FDA chooses to be very conservative, it could temporarily rely on a two-month deferral, consistent with FDA's recommendation for reentry of seronegative donors who had a previous reactive HIV-1 NAT.[26] In its 2010 Guidance, the Agency supported reentry of donors into the donor pool if they had a non-reactive HIV antibody test and a non-reactive HIV NAT

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[19] *See id*. at 5 ("According to a recent report, donations during the window period constitute most of the risk of HIV-1 and HCV transmission.").

[20] *See* 2015 Final Guidance at 2; *see also* WWH July 2015 Comments at 6.

[21] *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 the Risk of Transmission of HIV-1 and HCV" (October 2004) at 4 ("2004 Guidance").

[22] *See* Centers for Disease Control and Prevention, "HIV Basics: Testing: How Soon After An Exposure to HIV Can An HIV Test Detect If I Am Infected?," http://www.cdc.gov/hiv/basics/testing.html (last visited Nov. 15, 2016).

[23] *See* 2015 Final Guidance at 9 ("The window period when recent HIV infection might be missed using [NAT] is approximately 9 days.").

[24] *Id. See also* Kucirka LM., *et al.,* Risk of Window Period HIV Infection in High Infectious Risk Donors: Systematic Review and Meta-Analysis. *Am J Transplant*. 2011; 11:1176-1187.

[25] *See* 2010 Guidance at 3.

[26] *Id*. at 8.

after an eight-week waiting period.[27] If non-reactive tests after an eight-week waiting period are sufficient to confirm that a previously deferred donor is not infected with HIV, then non-reactive tests after an eight-week/two-month deferral period should likewise be sufficient to confirm that an MSM donor is not infected with HIV.

IV. FDA Should Lead the International Community With Regard to Blood Donation.

It is important that FDA remain committed "to continuing to reevaluate and update blood donor deferral policies as new scientific information becomes available."[28] FDA should be a leader—not a follower—in the international community with regard to blood donation. This requires consistent, proactive review of Agency recommendations.

Other countries have continued making progress in revising their blood donation deferral policies. As WWH discussed in its December 2015 supplemental comments, Argentina officially abandoned its one-year MSM deferral in favor of a more scientifically-based policy of deferring individuals who participate in high-risk sexual activities.[29] France has initiated a study to determine whether MSM actually present an additional risk when individual risk factors are assessed.[30] Since WWH submitted the supplemental comments, there have been additional developments by other countries to revise their blood donation policies. For example, the United Kingdom and Australia have both announced that they are reconsidering their one-year deferrals.[31]

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[27] *Id.*

[28] 81 Fed. Reg. at 49674.

[29] *See* Whitman-Walker Health, "Comments 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)" (Dec. 11, 2015) at 2.

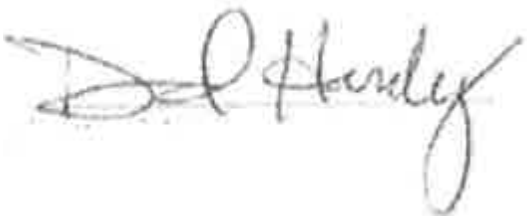
[30] *Id. See also* Santé publique France, "Étude: Compliance des Donneurs de Sang aux Critères de Sélection."

[31] *See* Nick Duffy, "MPs Launch Inquiry Into Gay Blood Ban," www.PinkNews.co.uk (Oct. 19, 2016), http://www.pinknews.co.uk/2016/10/19/mps-launch-inquiry-into-gay-blood-ban/; Staff reports, "Australia to Reconsider Gay Blood Ban," www.WashingtonBlade.com (Oct. 14, 2016), http://www.washingtonblade.com/2016/10/14/australia-reconsider-gay-blood-ban/.

V. Conclusion.

Whitman-Walker Health appreciates FDA's commitment to continuing to reevaluate and update its blood donor deferral policies. 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 its blood donation recommendations. Please do not hesitate to contact us if you have any questions about our comments.

Sincerely,



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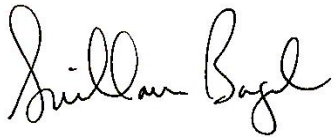

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[32] These comments were prepared with the assistance of Christopher Hanson, Esq. and Amy Leiser (Law Clerk), of Covington & Burling LLP.

ATTACHMENT 1

WHITMAN-WALKER HEALTH

Mailing Address:
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November 23, 2016

SUBMITTED ELECTRONICALLY

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

Re: Donor Risk Assessment Questionnaire for the Food and Drug Administration/National Heart, Lung, and Blood Institute-Sponsored Transfusion-Transmissible Infections Monitoring System—Risk Factor Elicitation (Docket No. FDA-2016-N-2836)

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) public notice, *Donor Risk Assessment Questionnaire for the Food and Drug Administration/National Heart, Lung, and Blood Institute-Sponsored Transfusion-Transmissible Infections Monitoring System—Risk Factor Elicitation* (September 2016) (Proposed Collection).[1]

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 2015, we provided health services to more than 15,300 individuals.[2]

[1] 81 Fed. Reg. 67358 (Sept. 30, 2016).

[2] Approximately one-half of those individuals identified as gay, lesbian, or bisexual, and approximately 14% of medical patients, and 7% 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 adopt data-driven policies and supports the Agency's Proposed Collection that will inform future blood donor deferral recommendations.[3] Revising current blood donor deferral policies is important, because the existing one-year deferral for men who have sex with men (MSM): (1) is not grounded in science; (2) prevents certain low-risk populations from donating blood; (3) continues to stigmatize and stereotype sexual and gender minorities; and (4) conflicts with the national HIV/AIDS strategy.[4]

WWH anticipates the Proposed Collection will assist the Agency in implementing a blood donor deferral policy that replaces the existing time-based deferrals related to risk behaviors with alternative deferral options, such as the use of individual risk assessments. Further, in response to FDA's request for comments on the public notice, "Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products," WWH proposes a study design to assess the feasibility of adopting a deferral policy based on individual risk (Attachment 1).[5] The study involves testing the validity of certain screening questions and their effectiveness in identifying individuals at higher risk of transmission during the window period for HIV. While FDA collects information and conducts further research, WWH also proposes reducing the one-year MSM deferral period to one month based on the nine-day window period for HIV using nucleic acid testing (NAT).

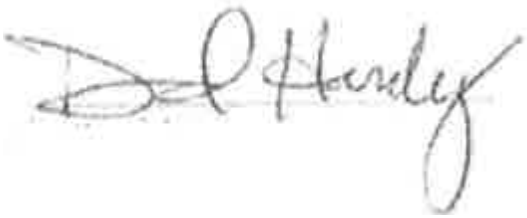
[3] 81 Fed. Reg. at 67360; *see also* FDA, "Request for Comments on Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products," 81 Fed. Reg. 49673, 49674 (July 28, 2016) (". . . FDA [is] committed to continuing to reevaluate and update blood donor deferral policies as new scientific information becomes available.").

[4] *See* Whitman-Walker Health, Comments on "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)" (July 14, 2015) at 3–5.

[5] 81 Fed. Reg. at 49674.

Whitman-Walker Health appreciates FDA's commitment to continuing to reevaluate and update its blood donor deferral policies and recognizes the importance of this Proposed Collection in implementing the use of individual risk assessments. 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 its blood donation recommendations. Please do not hesitate to contact us if you have any questions about our comments.

Sincerely,



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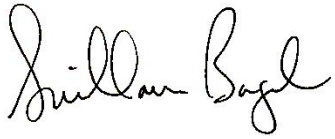

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