



WHITMAN-WALKER HEALTH

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December 11, 2015

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

SUBMITTED ELECTRONICALLY
AND BY MAIL

Re: Draft Guidance for Industry on Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products (Docket No.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 Health¹ (WWH) is pleased to submit these supplemental comments in response to the Food and Drug Administration's (FDA or Agency's) *Draft Guidance for Industry on Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products* (Draft Guidance).² WWH electronically submitted comments on July 14, 2015.³ These supplemental comments address newly issued blood donation policies in other countries concerning male donors who have had sex with another male (MSMs).

In our July 14 comments, WWH urged the FDA to be an international leader in terms of blood donation recommendations. The Draft Guidance recognizes decades of scientific literature, medical advocacy, and policies implemented in peer countries.⁴ Further, FDA cites countries

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 2014, we provided health services to more than 14,700 individuals.

² 80 Fed. Reg. 27973 (May 15, 2015); *see also* <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM446580.pdf>.

³ *See* <http://www.regulations.gov/#!documentDetail;D=FDA-2015-D-1211-0076> (Comment Tracking Number 1jz-8jz6-j518).

⁴ For example, Australia phased in a one-year deferral for MSM donors starting in 1996, almost two decades ago. *See* Cohen and Adashi, "New Blood-Donor Policy, Same Gay Stigma," *The New York Times* (May 21, 2015). 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.

that have changed their blood donation policies to a one-year MSM deferral as support for a one-year deferral in the United States. This list includes Argentina.

After the filing of our comments, Argentina officially abandoned its one-year MSM deferral in favor of a less discriminatory and more scientifically-based blood donation policy. In September 2015, Argentina's Ministry of Health passed Resolutions 1507, 1508, and 1509.¹ Under these Resolutions, the Ministry requests that individuals who participate in "high risk sexual activities"² do not donate blood. These activities do not focus on a particular sexual orientation or sexual identity. The Ministry will continue its policy of testing blood donations. Minister of Health Daniel Gollan states the Resolutions will prevent any discrimination on the basis of sexual orientation and "will make blood even safer than it was before."³

In addition, France announced on November 4, 2015, that it is also revising its MSM blood donation policy. Previously, France prohibited MSMs from donating blood. The new French policy is divided into two steps: the first, to be implemented in spring 2016, ends the ban on MSM donors.⁴ Men who, within the preceding four months, have either not been sexually active with another man or have had only one partner may donate plasma through the creation of a secure industry quarantine. The second step of the policy begins a year later, after authorities have had the chance to study the effects of the quarantine. If the study demonstrates that there is no increased health risk, the rules for MSM donors will be brought in line with heterosexual donors.

FDA should consider 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). Furthermore, FDA should consider the recent approaches of Argentina and France.

As expressed in our prior comments, by relying on an arbitrary one-year deferral time period, FDA fails to incorporate technological and scientific advances in HIV testing into the Draft Guidance's blood donation recommendations. Other countries have adopted approaches

¹ Resolution No. 1507, Sept. 14, 2015, 33.217, B.O., 48 (Arg.); Resolution No. 1508, Sept. 14, 2015, 33.217, B.O., 49 (Arg.); Resolution No. 1509, Sept. 14, 2015, 33.217, B.O., 49 (Arg.).

² Such "high risk sexual activities" include: 1) sexual relations (oral, vaginal, or anal) without using protection and without knowing whether the person has any sexually transmitted infections; 2) sexual relations while being under the influence of alcohol or drugs and without knowing whether the person has any sexually transmitted infections; 3) protected sexual relations with a person who has HIV, Hepatitis, or HTLV I-II; 4) protected sexual relations with a person in a dialysis treatment or frequent blood transfusions; 5) sexual relations with persons who frequently change sexual partners; 6) protected sexual relations with two or more people at the same time and without knowing if either of the persons has a sexually transmitted infection; and 7) protected sexual relations in places with high risk of HIV.

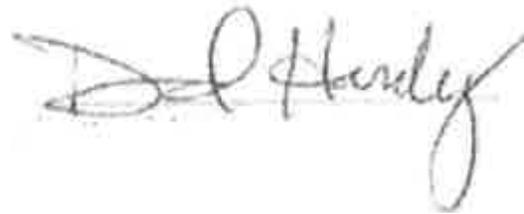
³ Ministry of Health, *Gollan: A partir de ahora en Argentina la sangre va a ser más segura de lo que ya era* (Sept. 16, 2015); available at <http://www.msal.gob.ar/prensa/index.php/noticias/noticias-de-la-semana/2848-gollan-a-partir-de-ahora-en-argentina-la-sangre-va-a-ser-mas-segura-de-lo-que-ya-era>.

⁴ Ministry of Social Affairs, Health, and Women's Rights, *Marisol Touraine Ends Ban on Gay Men Donating Blood* (Nov. 4, 2015); available at http://www.social-sante.gouv.fr/IMG/pdf/04_11_15_-_CP_-_Don_du_Sang_HSH_-_VF.pdf.

reflecting these advances. 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. FDA should institute in the Final Guidance 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.

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 United States 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.⁵

Sincerely,

A handwritten signature in cursive script that reads "W. David Hardy".

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⁵ These comments were prepared with the assistance of Christopher Hanson, Esq., of Covington & Burling LLP.