Congress of the United States

Washington, DC 20510

July 14, 2015

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

Re:FDA-2015-D-1211-0001

The below members of Congress submit these comments in response to the FDA's "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products: Draft Guidance for Industry" ("the Draft"). This guidance, if finalized, would change the blood donation policy for men who have sex with men (MSM) from a lifetime deferral to a one-year deferral from last sexual contact with another man. We are steadfastly committed to ending the outdated lifetime ban on MSM blood donation and moving to a policy that secures the nation's blood supply in non-discriminatory, scientifically sound manner.

The Draft signals a positive step in a long overdue change to a policy that the blood bank community,[1] the American Medical Association,[2] and the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA)[3] have all recognized as medically and scientifically unwarranted. While we appreciate the FDA's willingness to address this issue and release draft guidance to alter the current policy, we continue to have deep concerns about many of the conclusions and statements made in the Draft, and about the lack of plan to move towards a fully risk-based system.

Neither our current blood donation policy, nor the proposed one year deferral for MSM, allows the many healthy gay and bisexual men across America to donate blood. The Draft's proposed policy change would, in practice, leave the lifetime ban in place for the vast majority of MSM, even those who are healthy. This serves to perpetuate the stereotype that all MSM pose a risk to the health of others. Both deferral policies are discriminatory and not based on science, and both approaches are unacceptable. Low-risk MSM who wish to donate blood and help save lives should not be exclusively and categorically excluded because of outdated stereotypes.

We ask that as you implement the one year deferral policy, you do so in a way that ensures that this is only a first step toward implementing a risk-based blood donation policy for MSM. We also request that you consider the following points:

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[1] AABB (formerly the American Association of Blood Banks), the Red Cross, and America's Blood Centers, "Joint Statement before the Advisory Committee on Blood Safety and Availability," 6/11/2012 available at http://www.redcross.org/news/article/HHS-Advisory-Committee-on-Blood-Safety-and-Availability-Meets

[2] American Medical Association, "AMA Adopts New Policies on Second Day of Voting at Annual Meeting," 6/18/2013 available at http://www.ama-assn.org/ama/pub/news/news/2013/2013-06-18-new-ama-policies-annual-meeting.page

[3] ACBTSA recommendation, December 2010

A time-based deferral applied to all men who have had sex with a man, regardless of individual risk, is discriminatory.

A one-year deferral policy, like a lifetime ban, is a categorical exclusion based solely on the sex of an individual donor's sexual partner – not on the individual donor's actual risk of carrying a transfusion-transmittable infection.

The Draft states "the prevalence of HIV infection is significantly higher in MSM with multiple male partners compared with individuals who have only multiple opposite sex partners." While this statement is accurate, it is not the pertinent scientific question. The pertinent scientific question is *not* whether a cross-section of the population is more likely than another to transmit an infection, but rather whether screening of all donors for specific behaviors that put them at higher risk for an infection will reduce the likelihood of all infectious contaminations.

FDA's own data in the Draft demonstrates that taking broad population cross-sections do not accurately account for risk. The BloodDROPS survey cited in the Draft found that "the prevalence of HIV infection in male blood donors who reported that they were MSM was determined to be 0.25%." The guidance makes clear that the prevalence in this group is much lower than the prevalence in the overall MSM population; however, the draft guidance fails to note that the overall prevalence of HIV in the total US population is 0.384%.[4] This glaring omission fails to acknowledge or appreciate that not all groups of MSM have a higher prevalence of HIV than the general population, and that this subset of MSM has a *lower* prevalence of HIV than the general population. This illustrates that the only way to capture low risk populations is to institute risk-based screening, not place arbitrary deferrals on some cross-sections of the population.

MSM are the only cross-section of the population who have a higher prevalence of an infection *and* are categorically banned from donating blood, regardless of an individual donor's risk. No other group of people is subject to such blatant discrimination. For instance, *all* residents of Washington DC are not deferred from donating blood simply because the prevalence rate of HIV in the District exceeds the World Health Organization's definition of a "severe epidemic,"[5] and is higher than the general population. However, *all* MSM are excluded from donating blood because HIV is more prevalent in the MSM population than in the general population. Instituting a deferral period for all MSM is no less discriminatory than banning donations from individuals based simply on where they live.

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[4] Centers for Disease Control and Prevention, "HIV/AIDS Basic Statistics" available at http://www.cdc.gov/hiv/statistics/basics.html ("About 1.2 million people in the United States were living with HIV at the end of 2011").
United States Census Bureau. "Vintage 2011: National Tables" available at http://www.census.gov/popest/data/historical/2010s/vintage_2011 (312,602,730 million U.S. residents in December 2011)

[5] Washington Post, "City officials: Fewer new HIV cases in D.C. in 2012, but infection rate still 'epidemic'," 7/2/14 available at http://www.washingtonpost.com/local/dc-politics/city-officials-fewer-new-hiv-cases-in-dc-in-2012-but-infection-rate-still-epidemic/2014/07/02/cbce2be4-01f0-11e4-b8ff-89afd3fad6bd_story.html

Despite acknowledgement at the November 2014 ACBTSA meeting and in the Draft guidance that HIV risk is not uniform among MSM, the FDA has still not made public any plans to move toward a policy based on individual donors' risk. We ask that the agency acknowledge that the one-year deferral is not based in science and provide a timeline detailing the agency's plans to move toward a fully science- and risk-based policy in conjunction with the finalization of this guidance.

The FDA should consider a fully science-based deferral policy.

Current blood screening techniques are effective at detecting a newly infected individual with Hepatitis C in approximately one week, a newly infected individual with Hepatitis B after 3 to 4 weeks, or a newly infected individual with HIV after 7-10 days.[6] Individuals who become infected with these transfusion transmissible infections and donate before the infections can be detected (the 'latency period') pose a risk to the blood supply.

A fully science-based policy would defer all individuals who engage in a behavior that puts an individual at risk for these infections from donating blood for a window of time that places them outside of the latency period. Behaviors that put an individual at highest risk for acquiring a transfusion transmissible infection include needle sharing, needle sticks, and receptive anal sex. Men and women who engage in vaginal sex, penetrative anal sex, or oral sex are at much lower risk of infection. It should be the higher-risk behaviors that serve as the basis for donation deferral, regardless if a male donor has had sex with a man. In addition, since the longest latency period is 3-4 weeks for Hepatitis B infection, a time-based deferral after a risky behavior would need to be in line with the latency period.

A fully science-based policy would be based on an individual donor's risk behaviors, not the behaviors of their sexual partners, as there is no way for a donor to guarantee the accuracy or completeness of information about the behaviors of a their sexual partners.

The proposed one-year deferral period for any man who has sex with another man does not consider an individual donor's risk, nor is it in line with the latency periods noted above. FDA has not put forward any data that supports a scientific rationale for this draft policy.

The FDA should amend the recommendations in the Draft with regard to donations from transgender individuals.

We appreciate that the FDA included clarification that in regards to the blood donor referral criteria, "male or female gender if taken to be self-identified and self-reported." However, we are deeply concerned that the FDA is leaving decisions about donor eligibility of individuals who have "asserted a change in gender identification" up to medical directors of blood donation centers.

Transgender individuals often face discrimination, unfair stigma, and misunderstanding, including by some medical professionals. By leaving the decision about whether a

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[6] Red Cross, "Blood Testing," retrieved 7/6/15 available at http://www.redcrossblood.org/learn-about-blood/what-happens-donated-blood/blood-testing

transgender individual can donate blood to the individual blood center, FDA increases the chances that a transgender individual will be unfairly turned away, and sets the stage for discrimination. The FDA needs to make clear that the self-reported male or female gender is the gender that will be used to assess whether the individual meets the donation criteria. We also note that a risk-based deferral system based on behaviors would eliminate any and all confusion about who is eligible to donate, regardless of gender identify.

The FDA should clearly delink the establishment of the Transfusion Transmissible Infections Monitoring System (TTIMS) from the change in the MSM blood donation policy.

The TTIMS is a critical and well overdue step to better ensure the safety of blood for all recipients. While we are pleased that FDA is moving forward with the TTIMS, we are still troubled that this system is being linked to a change in the blood donation policy for MSM. This system has never before been deemed necessary to allow any other group of individuals to donate – including those that carry a much higher-risk of transmitting an infection via transfusion and are currently subject to a one-year deferral policy.

The TTIMS is a long overdue system that should have been implemented years ago to enhance and protect our blood supply. In an increasingly global society, it will allow us to more quickly identify emerging infections and better assess the effectiveness of screening policies. However, linking the implementation of this system to changes in the blood donation policy for MSM, and linking it to concerns about HIV specifically, undercut the real scientific value of the system and continue to perpetuate outdated stereotypes and stigma. The FDA needs to make clear the rationale and benefits of the TTIMS are, and should remain, independent from the change in the MSM blood donation policy.

The FDA should take action to reform and improve the Uniform Donor History Questionnaire.

According to the draft guidance:

> "[I]ndividuals responded to the questions posed by the questionnaire as if they were answering the more general and subjective question in the self-assessed context of 'is my blood safe' rather than providing an answer to the literal questions asked. In addition, the study found that potential donors might have benefitted from shorter donor education materials and the ability to answer 'I don't know' to questions that currently only accept 'yes' or 'no.'"

Yet the FDA does not provide any recommendations to address the deficiencies of the questionnaire.

Several reasons given by the ACBTSA to justify why the agency is not moving to a fully risk-based deferral framework involve the administrative barriers in the donor screening process, such as "administering rigorous questions on sexual practice will be difficult in the blood donor setting," and "screening questions to select low risk MSM as donors are unvalidated."[7] Comments in the Draft also refer to administrative barriers, including "pretesting would be logistically challenging, and would likely also be viewed as discriminatory by some individuals, and individual risk assessment by trained medical

[7] ACBTSA Presentation of *MSM Blood Policy Deferral Options* by Harvey Alter, November 13, 2014

professionals would be very difficult to validate and implement in our current blood donor system due to resource constraints."

It is disconcerting that – after spending years conducting a study on the questionnaire that revealed gross inadequacies, and laying out administrative questions to be addressed in order to move to risk based screening – the FDA would not take *any* action to improve the screening process, or at a minimum, delineate plans to do so in the future.

FDA should clearly delineate the agency's plan to move to a fully risk-based deferral system when finalizing the Draft.

We ask that you stay committed to issuing a policy recommendation to implement a fully risk-based policy for all donors. When the Draft is finalized, we ask that you include benchmarks and a timeline (including rationales for both) that the agency plans to meet in order to move our blood donor deferral system to one that is based on risk, and not sexual orientation.

While the move to a one-year deferral policy is a step forward, this policy is still not based on an individual donor's risk of carrying a transfusion transmissible infection, still prevents many low-risk individuals from donating blood, and continues to let higher risk individuals donate. With the shared goal of protecting and enhancing our nation's blood supply, we must continue to embrace science, and also reject outdated stereotypes and methods that are not based in science.

Science has shown us that neither the current policy nor the policy put forward by the Draft is justified. There is a better path – a path that will make for a safer and more robust blood supply for everyone, while also respecting the life-saving contributions of all Americans. It is up to the FDA to lead the world and make meaningful changes to address the inadequacies and discrimination in the current system.

Sincerely,

Elizabeth Warren
United States Senator

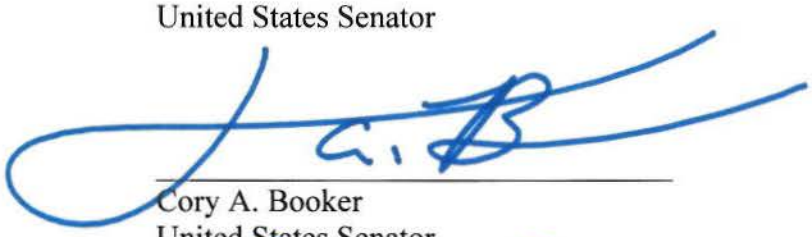
Mike Quigley
Member of Congress

Tammy Baldwin
United States Senator

Barbara Lee
Member of Congress

Michael F. Bennet
United States Senator

Richard Blumenthal
United States Senator



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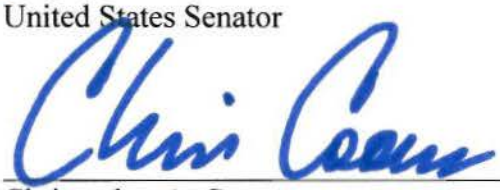

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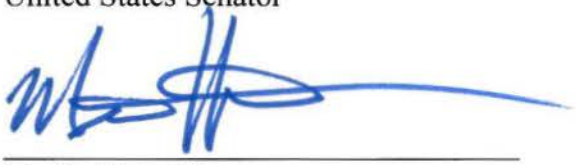

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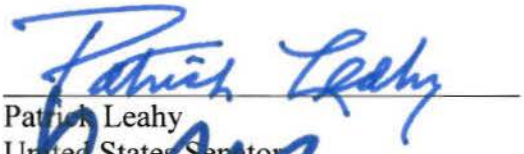

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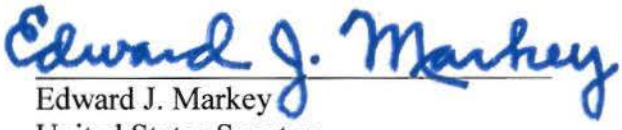

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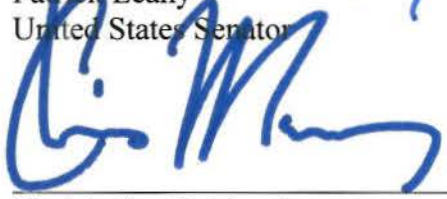

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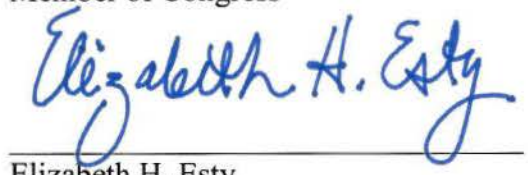

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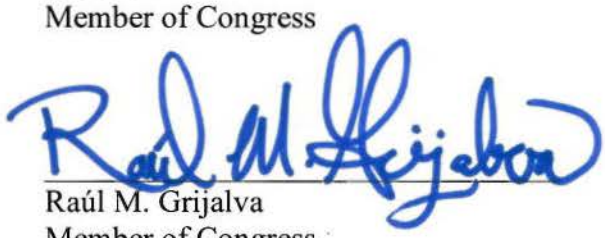

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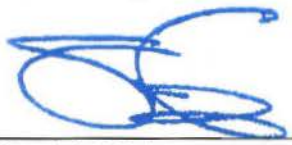

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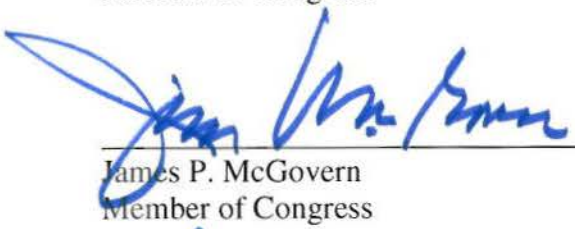

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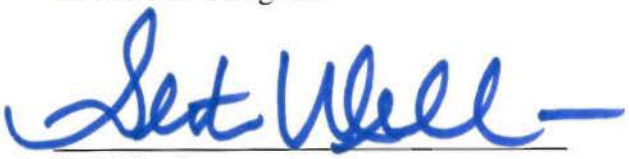

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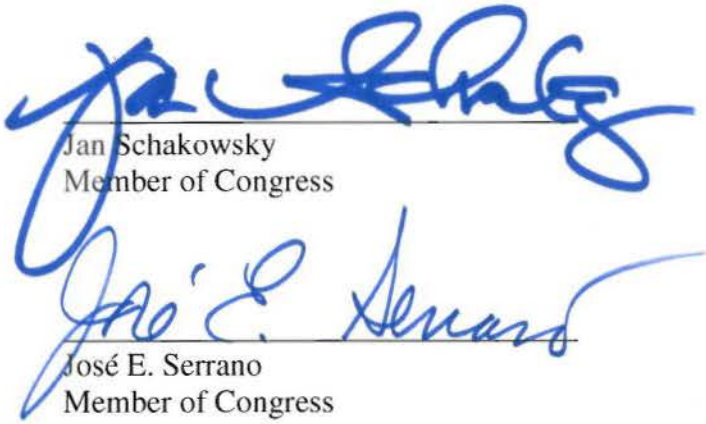

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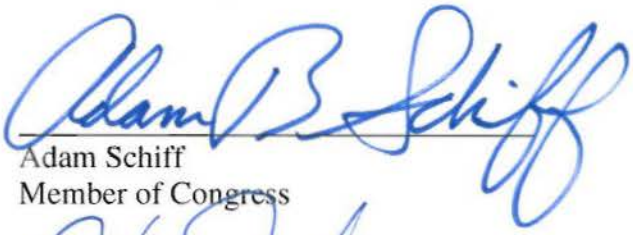

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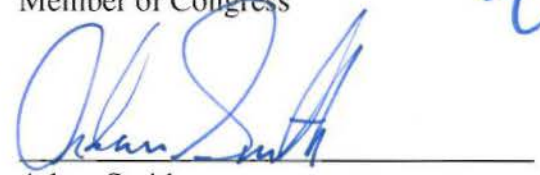

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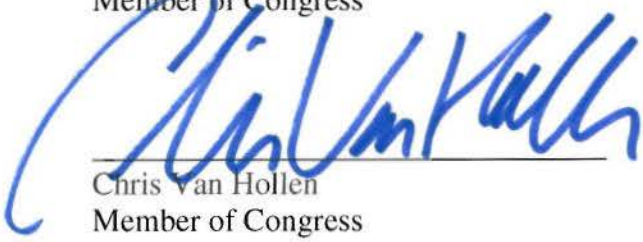

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