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FDA Establishes Public Docket for Comment on Blood Donor Deferral Recommendations

by Winnie McCroy
EDGE Editor
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Elected officials, AIDS Service Organizations and other advocates are encouraged by The Food and Drug Administration's move to establish a **public docket** for comment on the Agency's blood donor deferral recommendations for reducing the risk of human immunodeficiency virus (HIV) transmission as described in the document entitled "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry" dated December 2015.

"I have long fought to end discriminatory blood donation policies and improve them, including for healthy gay and bisexual men," said U.S. Senator Tammy Baldwin. "It is

encouraging that the FDA is taking another step forward to develop better blood donor policies that are grounded in science, don't unfairly single out one group of individuals, and allow all healthy Americans to donate. I will continue to push for policies that secure our nation's blood supply in a scientifically sound manner based on individual risk."

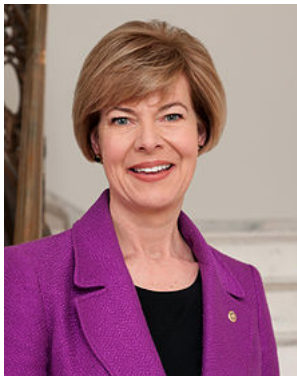
This announcement from the FDA comes following a **letter** Senator Baldwin led in June with 24 Senators calling on HHS Secretary Sylvia Burwell to end the outdated and discriminatory ban for men who have sex with men (MSM) and replace it by instituting a risk-based policy. Baldwin led a similar charge in 2014.

At the end of last year, the FDA released guidance that lifted the lifetime ban on blood donation and implemented a new policy requiring a year of abstinence prior to donating blood. While the Senators express support for this step forward, they maintain that a time-based deferral not based on individual risk remains discriminatory. In December 2014, over 75 members of Congress called on HHS Secretary Burwell to end the outdated and discriminatory ban, and replace it by instituting a risk-based policy.

In June, U.S. Representative Mike Quigley (IL-05), Vice-Chair of the Congressional LGBT Equality Caucus, led a letter with 115 House colleagues calling on the FDA to reexamine the time-based based donor deferral policy for gay and bisexual men. He was pleased to hear that the FDA had established a public docket to request comments on potential changes to the current blood donor deferral policy.

"I am encouraged by today's announcement that the FDA will look into policy solutions in order to move away from the discriminatory time-based deferrals and move closer to individual risk assessment as it relates to blood donor safety screenings," said Quigley. "The tragedy at Pulse nightclub in Orlando highlighted the discrimination gay and bisexual men face when attempting to donate blood to those in need. And while this potential policy change could have a positive impact on men who have sex with men (MSM) and other marginalized donors, it would also make our blood supply safer. Moving towards an individual risk assessment would provide for a fair, equitable, nondiscriminatory blood donation policy, one based in science that allows all healthy Americans to safely donate blood. I urge the FDA to move in this direction."

Interested persons are invited to submit comments, supported by scientific evidence such as data from research, regarding potential blood donor deferral policy options to reduce the risk of HIV transmission, including the feasibility of moving from the existing time-based deferrals related to risk behaviors to alternate deferral options, such as the use of individual risk assessments. Additionally, comments are invited



Tammy Baldwin (Source:en.wikipedia.org)

regarding the design of potential studies to evaluate the feasibility and effectiveness of such alternative deferral options.

FDA will take the comments received into account as it continues to reevaluate and update blood donor deferral policies as new scientific information becomes available.

AIDS Service Organizations were equally pleased, with New York City's Gay Men's Health Crisis (GMHC) CEO Kelsey Louie noting that they had been advocating for a change to the FDA's outdated blood donation policy for years, and were encouraged that they are extending a comment period on potential changes to a deferral policy that is based on stigma, not science.

"The policy in place prevents any man who has had sex with another man in the past year from giving blood, essentially serving as a de facto lifetime ban, and ignoring the modern science of HIV-testing," said Louie. GMHC is looking forward to submitting our comments on the importance of a fair, safe

policy for all. We are hopeful that the FDA will attend the medical advisory board panel we are hosting in September as part of our ongoing Blood Equality campaign, to bring together experts on HIV and blood safety and discuss a path forward from a discriminatory, one-year celibacy ban."

Blood Equality



Winnie McCroy is the Women on the EDGE Editor, HIV/Health Editor, and Assistant Entertainment Editor for EDGE Media Network, handling all women's news, HIV health stories and theater reviews throughout the U.S. She has contributed to other publications, including The Village Voice, Gay City News, Chelsea Now and The Advocate, and lives in Brooklyn, New York.

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AIDS | By EDGE | Jun 21

U.S. Rep. Mike Quigley led a bipartisan group of 113 House Members pushing the FDA to end their discriminatory ban on gay men donating blood.

LA Center Applauds Legislators For Blood Ban Letter

NATIONAL | By Winnie McCroy | Dec 23

On December 15, 80 members of the United States Senate and Congress sent a letter to the federal Department of Health and Human Services (DHHS), urging it to end the lifetime ban which prevents men who have sex with men from donating blood.

U.S. Rep Mike Quigley Discusses MSM Blood Ban with OutLaw

LOCAL | By Winnie McCroy | Apr 8

On March 31, U.S. Representative Mike Quigley (IL-05) spoke to OutLaw, an organization for LGBT students at the University of Chicago Law School, highlighting the need to reevaluate the FDA's blood donation criteria.

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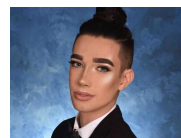
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