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February 19, 2020

The Honorable Dr. Stephen M. Hahn
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Hahn,

In December 2015, the Food and Drug Administration (FDA) 'loosened' the long-standing lifetime ban on blood donation by men who have sex with men (MSM). According to this new guidance, MSM are now eligible to give blood — provided they have abstained from sex for at least a year. While this may have been a small step in the right direction, it does not take into consideration the major improvements in the field of HIV testing and the latest scientific evidence on shorter deferral periods. We therefore write to urge the FDA to reassess their current blood donation restrictions on MSM.

As it stands, the current policy is discriminatory, outdated, and scientifically obsolete. Discriminatory because in practice, the new policy is a continuation of the lifetime ban: it excludes all sexually active gay or bisexual men, thus perpetuating the stereotype that all gay and bisexual men are inherently dangerous. Heterosexual men are given no such restrictions, even if their sexual behavior places them at high risk of HIV transmission (e.g. multiple partners within a short period of time).

The policy is outdated as in the last two years, Canada, France, England, Scotland, and Wales have reduced the donor deferral period for MSM from one year to three or four months. Most of these countries have also announced that this was only temporary as they plan on switching to a risk-based approach rather than a population-based approach when it comes to deferrals for blood donations.

Finally, it is scientifically obsolete because the one-year deferral period ignores the modern science of HIV-testing technology. HIV testing on blood donated in the U.S. is currently implemented in a variety of ways, including nucleic acid testing. Using this testing method the presence of the virus can be determined with high precision within 11-12 days after infection. Based on this, we do not believe that a one-year deferral period for MSM makes sense.

Furthermore, evidence from the British authorities published in September 2019 shows that the change from a one-year deferral period to a three-month one for MSM has "not resulted in an

increase in non-compliant donors or an increase in recently acquired infections due to a known deferrable risk factor.”¹

The FDA often asks the Blood Products Advisory Committee (BPAC) to review available scientific data on blood products issues and to vote on proposed policy changes. The last meeting of the BPAC on blood donation policies regarding MSM was held on March 21, 2019. The BPAC was notably asked to “comment on what has been learned from implementing other MSM policies Internationally.”² Unfortunately, at the time of this meeting, the data collected by the British authorities following their policy change had not yet been released and, as such, was not available to BPAC’s members for review. No vote on the issue was held at this meeting either.

We ask that you reconvene the BPAC so that its member can review the new data available and vote on reducing the current one-year deferral criteria for MSM. As we understand it, The American Red Cross also recently issued a statement requesting that you reexamine existing policy, noting a change in policy should be considered based on the most up-to-date data now available.³

We value patient safety as much as the FDA does and believe that anyone should be able to donate, provided their donation does not pose a risk to others. Thanks to the immense scientific improvements in the field of HIV detection in the past decades, and the recent evidence collected abroad, we believe that the one-year deferral period on blood donations by men who have sex with men cannot be rationalized anymore. We hope that the FDA will seek the expertise of the BPAC to reconsider the one-year deferral period.

Sincerely,



Chris Pappas
Member of Congress



Mike Quigley
Member of Congress



Barbara Lee
Member of Congress



Debbie Wasserman Schultz
Member of Congress


¹ <https://www.gov.uk/government/publications/safe-supplies-annual-review/safe-supplies-2018-monitor-inform-progress>

² <https://www.fda.gov/media/120953/download>

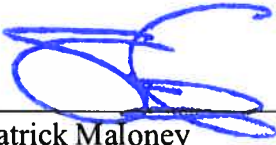
³ <https://www.redcross.org/about-us/news-and-events/press-release/american-red-cross-statement-on-fda-msm-deferral-policy.html>



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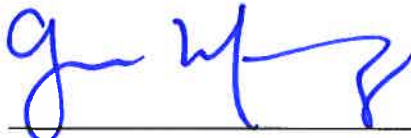
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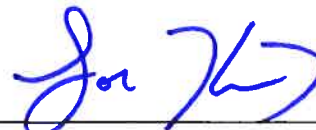
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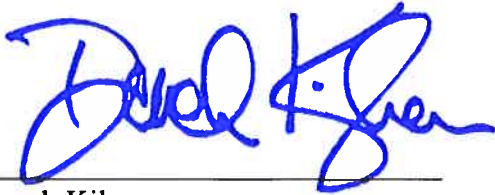
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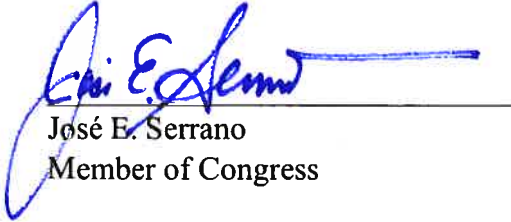
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