



# *Congress of the United States*

*House of Representatives*

*Washington, DC 20515*

April 30, 2020

Stephen Hahn  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Ave  
Silver Spring, MD 20993

Dear Commissioner Hahn:

We write to you today with concerns regarding the implementation process for the Food and Drug Administration's (FDA) revised policy regarding donations of blood by LGBTQ+ individuals. On April 2, the FDA released revised donor deferral guidelines intended to increase supply during the current coronavirus (COVID-19) pandemic. While this step was essential to increasing the current blood supply, and long overdue for the LGBTQ+ community, the implementation has been delayed because the FDA has failed to approve the AABB's (formerly American Association of Blood Banks) donor history questionnaire quickly. We ask that you expedite the process for approval of the questionnaire, saving lives and finally implementing this guidance.

On April 2, 2020, the FDA released three revised blood guidances that reflect the agency's current thinking on donor deferral recommendations for the risk of Human Immunodeficiency Virus, Malaria, and Creutzfeldt-Jacob transmission by blood transfusion.<sup>1</sup> Reduction of the deferral criteria for a man who has had sex with another man (MSM) from 12 months to 3 months is among the recommendations published.<sup>2</sup> These revised recommendations were released with the forethought that early implementation may help address potentially significant blood shortages as a result of the COVID-19 pandemic. I applaud your decision to take this step, following the science that has long shown that MSM blood donations are safe for our communities.

Implementation of this new guidance depends on revision to, and FDA approval, of the AABB's donor history questionnaire. Blood donor history questionnaires are designed to help blood donor clinics and other providers evaluate a prospective donor's history relative to current known blood safety risks and FDA guidance.<sup>3</sup> The Full-Length Donor History Questionnaire (DHQ) is designed to evaluate any donor in accordance with these criteria.<sup>4</sup> AABB's questionnaire is currently pending with the FDA.<sup>5</sup> After AABB's

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<sup>1</sup> FDA Provides Updated Guidance to Address Urgent Need of Blood During Pandemic, FDA, retrieved at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-updated-guidance-address-urgent-need-blood-during-pandemic>

<sup>2</sup> FDA, as cited.

<sup>3</sup> Blood Donor History Questionnaires, AABB, retrieved at: <http://www.aabb.org/tm/questionnaires/Pages/dhqaabb.aspx>

<sup>4</sup> AABB, as cited.

<sup>5</sup> AABB, as cited.

questionnaire is approved by the FDA, blood donor center procedures can be revised to ensure compliance and staff can be retrained as needed.

In recent reports, the FDA has opposed the necessity of this approval. An FDA spokesman told the Guardian that, “licensed blood facilities do not have to wait on any association’s revised donor questionnaire. They can instead come up with their own materials and implement the changes now.”<sup>6</sup> This is patently false. Licensed blood donation centers who choose to implement a new version of the DHQ materials other than those submitted by approval by AABB, that have not been officially recognized by the FDA must submit a formal request to the FDA for approval.<sup>7</sup> Regardless of whether or not a blood center uses the AABB DHQ or its own, the materials must be approved by the FDA.

If the FDA truly is committed to increasing the available blood supply to meet current need, the agency will stop scapegoating blood centers and instead, take the time needed to process the AABB DHQ materials, thereby putting the country’s blood centers in a position to execute the revised policy, ensuring more willing donors can donate their blood to save others.

We ask that you please reply to this letter no later than May 8, 2020. Thank you for your attention to this very important matter, and we look forward to hearing from you.

Very Truly Yours,

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Member of Congress

JERROLD NADLER  
Member of Congress

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<sup>6</sup> Gay men in US still unable to donate blood despite new coronavirus rules, *The Guardian*, retrieved at: <https://www.theguardian.com/us-news/2020/apr/18/us-blood-donation-gay-men-coronavirus>

<sup>7</sup> AABB, as cited.

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