

**Congress of the United States**  
**Washington, DC 20515**

June 20, 2016

Commissioner Robert M. Califf, MD, MACC  
U.S. Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993-0002

Dear Mr. Commissioner:

In light of the tragic mass shooting at Pulse nightclub in Orlando, Florida, we write to highlight the urgent need to draw continued attention to the unsound FDA blood donation deferral policy for men who have sex with men (MSM).

While we were disappointed by the new policy, we appreciate your willingness to engage in discussions specific to the MSM deferral policy in the past, and acknowledge the step FDA took last December to change the guidance to industry from a lifetime ban to a 12-month deferral from last sexual contact with another man.

The atrocities in Orlando are now understood to be the largest mass shooting in U.S. history, where 49 victims were killed and another 53 were wounded, most of who were wounded critically. During times of tragedy, the American people are quick to demonstrate their resiliency and mobilize in solidarity with victims and affected communities. We are witness to that compassion as Floridians have quickly lined up to donate blood. Given the target, nature and timing of this particular attack, the LGBT community is especially eager to contribute to the response effort. Yet, due to the MSM deferral policy, many healthy gay and bisexual men are prohibited from donating desperately needed blood.

Additionally, we are concerned that the 12-month deferral policy, which suggests that the sexual relationships of MSM men and transgender women inherently pose a risk of HIV transmission, furthers a stigma that we have persistently fought to eliminate. The FDA questionnaire should reflect risk-based behaviors as opposed to sexual orientation.


It is our view that this tragedy, more than any other, shines a light on the need for a permanent reversal of this policy. The American Medical Association, the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA), the American Association of Blood Banks (AABB), the American Red Cross and America's Blood Centers have all routinely called for scientifically sound policies, applied consistently and fairly based on donor risk level. In practice, the current FDA deferral policy effectively leaves the majority of MSM ineligible to


donate blood, as the 12-month celibacy requirement is unrealistic for most healthy gay and bisexual men to meet.


In light of these tragic events, we respectfully request an update on the latest FDA actions specific to the MSM 12-month deferral policy and FDA engagement with local blood centers to ensure capacity building and readiness. We urge the FDA, under your direction, to move swiftly towards future changes in policy to promote a less discriminatory system based on risk of transfusion-transmissible infections, and not on sexual orientation.

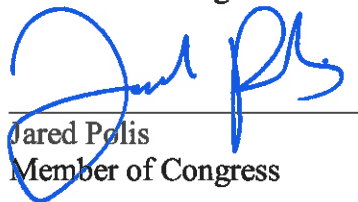
Your attention to this important issue is deeply appreciated. While we are aware that the task ahead is difficult, we know that the most difficult challenges are the ones worth solving. We await your response.

Sincerely,

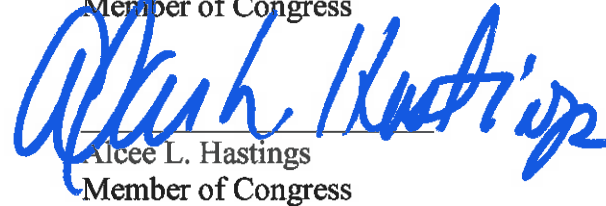
  
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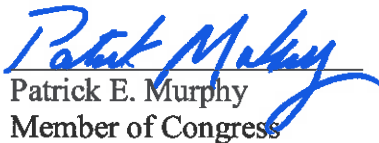
  
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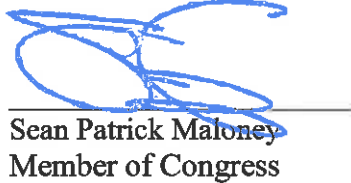
  
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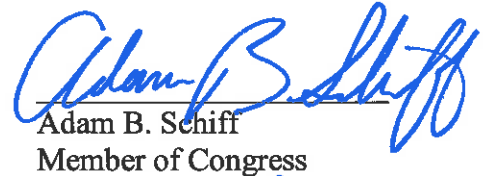
  
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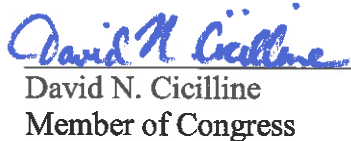
  
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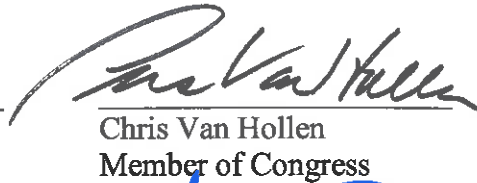
  
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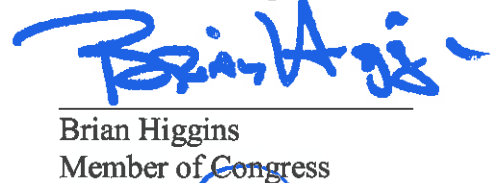
  
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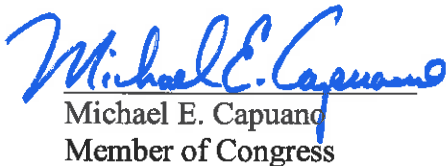
  
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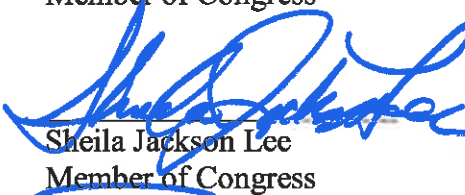
  
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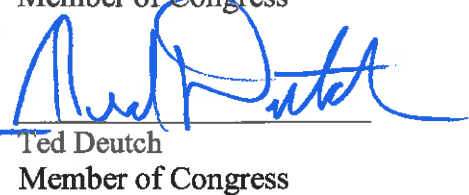
  
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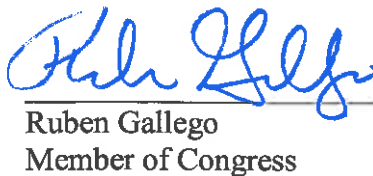
  
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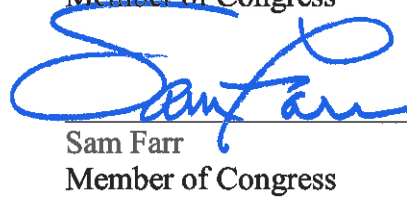
  
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