

# United States Senate

WASHINGTON, DC 20510

June 20, 2016

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

Dear Commissioner Califf,

We write to express our concerns with the Food and Drug Administration's (FDA) discriminatory blood donation policy for men who have sex with men (MSM), which has been highlighted by the tragic mass shooting at Pulse nightclub in Orlando, Florida. As you know from previous correspondence, we are steadfastly committed to ending the FDA's discriminatory policy that prohibits many healthy MSM from donating blood and moving to policies that secure our nation's blood supply in a scientifically sound manner based on individual risk.

We appreciate your willingness to engage in discussions on the MSM deferral policy in the past. We also acknowledge the important step that FDA took last December to institute a new one-year deferral policy for MSM after the last sexual contact, replacing the long-standing lifetime deferral. While we support this step forward, a time-based deferral that is not based on individual risk remains discriminatory.

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 them critically. During times of tragedy, the American people are quick to demonstrate their resiliency and mobilize in solidarity with victims and affected communities. We have witnessed that compassion as Floridians quickly lined up to donate blood for the wounded. Yet, some of those most touched by this tragedy—members of the LGBT community, who are especially eager to contribute to the response effort—are finding themselves turned away. Due to the FDA's current MSM deferral policy, many healthy gay and bisexual men remain prohibited from donating needed blood.

This tragedy shines an ever sharper spotlight on the need to move to a donor deferral policy based on individual risk factors. Based on advances in science and blood screening and safety technology, we expect that the new, one-year deferral policy is just the first step toward ending discrimination against MSM in our donor deferral policies. A one-year deferral continues to perpetuate inaccurate stereotypes about an entire group of individuals, and remains a de facto lifetime ban for many healthy gay and bisexual men.

In light of these tragic events, and given that it has been nearly 6 months since you announced the new one-year deferral policy, we respectfully request an update on your implementation efforts, including FDA's engagement with local blood centers to ensure capacity building and operationalization, engagement with the LGBT community, and work to support future changes to the donor deferral policy. We urge you to move swiftly to not only implement the new policy, but also to develop better blood donor deferral policies that are grounded in science, based on individual risk factors, don't unfairly single out one group of individuals, and allow all healthy Americans to donate.

Your attention to this important issue is deeply appreciated and we respectfully request a response by June 30, 2016.

Sincerely,

  
Tammy Baldwin  
United States Senator

  
Elizabeth Warren  
United States Senator

  
Patty Murray  
United States Senator

  
Mark Kirk  
United States Senator

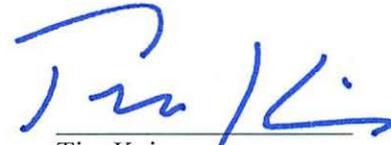
  
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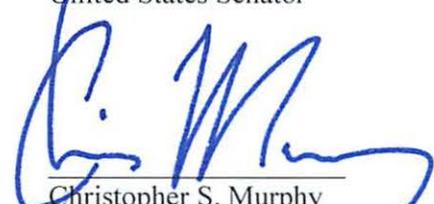
  
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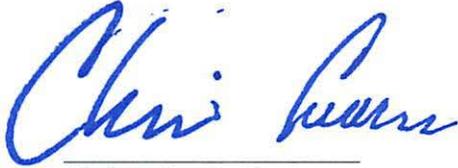
  
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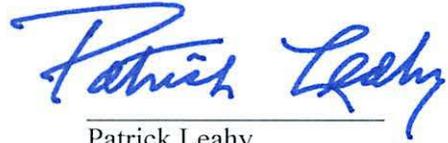
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United States Senator



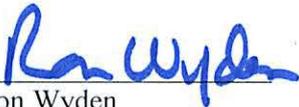
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