

**Congress of the United States**  
Washington, DC 20510

December 15, 2014

The Honorable Sylvia Burwell  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Burwell:

We are writing in response to your November 25<sup>th</sup> letter to some members of Congress, and to express our deep concerns regarding the changes recommended by the HHS Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) to the blood donation policy for men who have sex with men (MSM). As you know from our previous correspondence, we are steadfastly committed to ending the outdated MSM blood donation policy and moving forward with securing the nation's blood supply in a scientifically sound manner. On November 13<sup>th</sup>, the ACBTSA recommended changing the current lifetime MSM deferral policy to a new policy of a one-year deferral period after a sexual encounter. Additionally, this change in policy is conditioned on the implementation of a blood safety surveillance system.

The recommendation to move to a one-year deferral policy is a step forward relative to current policies; however, such a policy still prevents many low-risk individuals from donating blood. If we are serious about protecting and enhancing our nation's blood supply, we must embrace science and reject outdated stereotypes. As such, we urge you to implement a risk-based blood donation policy for MSM, rather than simply another arbitrary time-based deferral.

The blood bank community,<sup>1</sup> the American Medical Association,<sup>2</sup> and the ACBTSA<sup>3</sup> have all recognized that the current lifetime deferral from blood donation for MSM is unwarranted. In addition, in a concurrent resolution passed unanimously on January 29, 2014 designating that month as "National Blood Donor Month," the Senate noted that "it is vital that the blood donation policies, including donor deferral policies, in the United States keep pace with medical science."

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<sup>1</sup> AABB (formerly the American Association of Blood Banks), the Red Cross, and America's Blood Centers presented their position that "the current lifetime deferral for men who have had sex with other men is medically and scientifically unwarranted" to the FDA Blood Products Advisory Committee in 2006.

<sup>2</sup> American Medical Association, June, 2013, "The lifetime ban on blood donation for men who have sex with men is discriminatory and not based on sound science."

<sup>3</sup> ACBSA recommendation, December 2010

While we appreciate the ACBTSA's willingness to address this issue, we are deeply troubled by their conclusions and final recommendations. Despite clear statements at the ACBTSA meeting that "HIV risk is not uniform among MSM,"<sup>4</sup> the committee nonetheless rejected a policy based on actual individual risk. A one-year deferral policy, like a lifetime ban, is a categorical exclusion based solely on the sex of an individual's sexual partner – not his actual risk of carrying a transfusion-transmissible infection. Furthermore, while we agree with both the ACBTSA and the FDA Blood Products Advisory Committee (BPAC) that a national blood safety surveillance system is a critical and overdue step to better ensure the safety of blood for all recipients, we are troubled that such a system has suddenly become a prerequisite to change the blood donation policy for MSM. This system has never before been deemed necessary to allow any other group of individuals to donate – including those that carry a much higher-risk of transmitting an infection via transfusion and are currently subject to a one-year deferral policy.

Furthermore, we are concerned that the one-year policy endorsed by ACBTSA does not rationally follow the Committee's own purported justifications. One justification provided by ACBTSA, for example, states that "the prevalence of HIV markers is remarkably higher in MSM with multiple partners than in heterosexuals with multiple partners."<sup>5</sup> While this statement is accurate, it is not the pertinent scientific question. The pertinent scientific question is not whether a cross-section of the population is more likely than another to transmit an infection, but rather whether across-the-board, risk-based screening will reduce the likelihood of all infectious contaminations. Additional justifications demonstrate similar flaws. For example, the suggestion that "administering rigorous questions on sexual practice will be difficult in the blood donor setting,"<sup>6</sup> and the claim that "screening questions to select low risk MSM as donors are unvalidated"<sup>7</sup> are not science-based reasons why risk-based screening is ineffective, but rather are simply administrative challenges that could be straightforwardly addressed under a risk-based system. Perhaps most tellingly, despite the extensive research that has already been conducted on this topic, the committee concluded that "further studies would be needed to determine the practicability and safety of [a risk-based deferral] option" – yet provided no information as to what scientific questions remain to be answered, or why the extensive existing analyses are insufficient to answer them.

Similarly, the ACBTSA's recommendation to hinge *any* change in the MSM blood donation policy to the establishment of a blood safety surveillance system is an arbitrary condition that will inevitably result in further unnecessary delays. To be clear, a comprehensive surveillance system for our blood supply is a critically important initiative to protect the blood supply from Hepatitis, HIV, and emerging diseases, and is long overdue. The ACBTSA previously recommended such a system in 2006. Years of HHS inaction on this issue is problematic, but so is the fact that ACBTSA has now suddenly chosen to make such a system a precondition of revising the donation policies specific to MSM. One-year deferral policies have been implemented for many groups in the past – including women who have had sex with a MSM, individuals who have engaged in sexual activity with someone of the opposite sex who has HIV, people who have had sex with a commercial sex worker, and people who have had sex with or

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<sup>4,5,6,7</sup> ACBTSA Presentation of *MSM Blood Policy Deferral Options* by Harvey Alter, November 13, 2014

lived with someone with Hepatitis A or B – and were never conditioned on the implementation of a surveillance system. We urge you to consider the important work of implementing an infection monitoring system separately from the MSM deferral policy and, in both cases, make your decisions based on the scientific data that are relevant to each issue.

The ACBTSA recommendation does not give the agency permission to abdicate its work toward a true, risk-based policy. In order to better understand how HHS plans to address this issue going forward, we request answers to the following questions:

- (1) Will you commit to replacing the current lifetime deferral policy by the end of 2014?
- (2) Will you pursue the “further studies needed to determine the practicability and safety of risk-based screening” referenced by the ACBTSA, and if so, when will they begin, and what is the projected timeline for completion?
- (3) What was learned from the four studies launched in 2010 that can be used to inform the practicability and safety of risk-based screening, and what limitations in these studies prevented HHS from making a determination at this point?
- (4) Do you plan to pursue recipient surveillance policies suggested by the FDA BPAC?
- (5) Please provide an explanation for why a blood safety surveillance system was not established after each instance (2006, 2009, 2010, and 2013) when such a system was considered by HHS and/or recommended by the ACBTSA.
- (6) Australia, Japan, Argentina, Brazil, Hungary, the United Kingdom, Italy, Spain, South Africa, and Mexico all have either one-year or risk-based deferral policies for MSM. How many of these countries have blood safety surveillance systems in place?
- (7) If you were to accept the ACBTSA’s eight-year old recommendation to establish a surveillance system -
  - a. Which of the government agencies and private entities involved (FDA, CDC, NIH, blood banks) will ultimately be responsible for the implementation and maintenance of such a system?
  - b. Who will be responsible for inter-agency coordination?
  - c. What is the start-up and yearly cost associated with such a system?
  - d. We understand that some funds are being committed by the FDA and the National Heart, Lung, and Blood Institute to launch a system. How much money is being committed, are the funds guaranteed over the next 10 years, and do you need additional Congressional action to secure funds for this long term project?
  - e. What is the timeline for implementation, including a projected launch date?
  - f. Will any change in the lifetime deferral policy for MSM be delayed until the system launch date?

We appreciate your response to our questions by December 22, 2014. We also ask that you stay committed to issuing a policy recommendation for how to implement a risk-based policy for all donors, and a donation policy change for MSM by the end of 2014, a timeline also promised by former Secretary Sebelius.<sup>8</sup> Any additional delays in publicly addressing how HHS plans to change the deferral policy for MSM and implement a surveillance system are unacceptable.

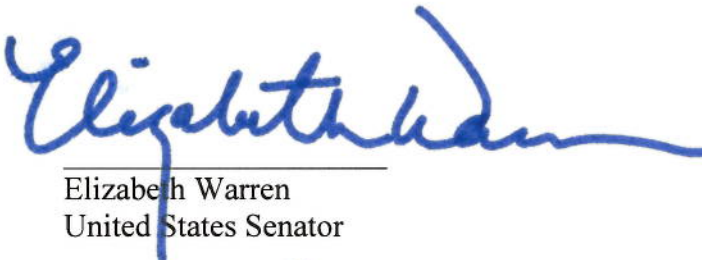
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<sup>8</sup> Letter to 86 members of Congress from Secretary Sebelius, September 18, 2013.

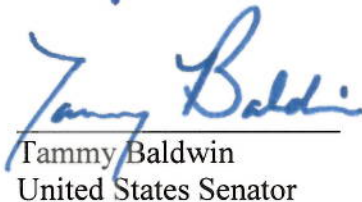
Our current blood donation policy prevents many healthy gay and bisexual men from donating blood for their entire lives. The ACBTSA's proposed policy change would, in practice, leave that lifetime ban in place for the vast majority of MSM, even those who are healthy and low-risk. Both policies are discriminatory, and both approaches are unacceptable. Low-risk individuals who wish to donate blood and help to save lives should not be categorically excluded because of outdated stereotypes.

Science has shown us that our current policy is not justified. So we know there is a better path – a path that will make for a safer and more robust blood supply for everyone, while also respecting the contributions of all Americans. It is up to us to take it.

Sincerely,

  
Elizabeth Warren  
United States Senator

  
Mike Quigley  
Member of Congress

  
Tammy Baldwin  
United States Senator

  
Barbara Lee  
Member of Congress

  
Tom Harkin  
United States Senator

CC:

Douglas M. Brooks, MSW, Director, Office of National AIDS Policy

Margaret Hamburg, M.D., Commissioner, FDA

Jay Epstein, MD, Director, FDA Office of Blood Research and Review

Ronald Valdiserri, M.D., M.P.H., Deputy Assistant Secretary for Health, Infectious Diseases;  
Director, HHS Office of HIV/AIDS and Infectious Disease Policy

James Berger, M.S., M.T. (A.S.C.P.), S.B.B., Senior Advisor Director for Blood and Tissue  
Policy, HHS Office of HIV/AIDS Infectious Disease Policy

Jay Menitove, M.D., Chair, HHS ACBTSA

Matthew Heinz, M.D., Director of Provider & LGBT Outreach, HHS Office of  
Intergovernmental and External Affairs





Sherrod Brown  
United States Senator



Michael F. Bennet  
United States Senator



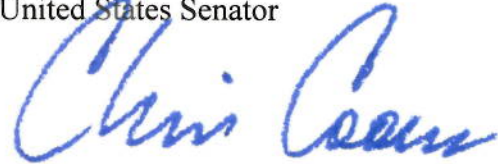
Richard Blumenthal  
United States Senator



Maria Cantwell  
United States Senator



Benjamin L. Cardin  
United States Senator



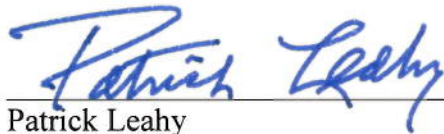
Christopher A. Coons  
United States Senator



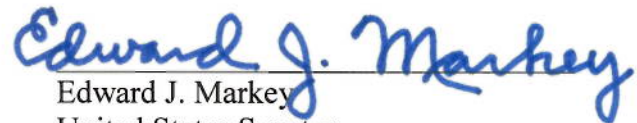
Kirsten Gillibrand  
United States Senator



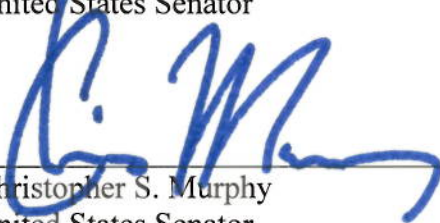
Al Franken  
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Patrick Leahy  
United States Senator



Edward J. Markey  
United States Senator



Christopher S. Murphy  
United States Senator



Bernard Sanders  
United States Senator



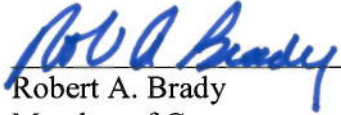
Charles E. Schumer  
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Earl Blumenauer  
Member of Congress



Suzanne Bonamici  
Member of Congress



Robert A. Brady  
Member of Congress



Julia Brownley  
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Michael E. Capuano  
Member of Congress



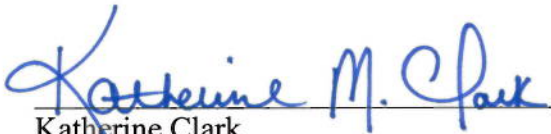
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Katherine Clark  
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Yvette Clarke  
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Steve Cohen  
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Joe Crowley  
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Danny K. Davis  
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Susan A. Davis  
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Suzan DelBene  
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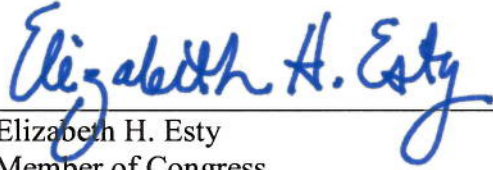
Ted Deutch  
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Mike Doyle  
Member of Congress



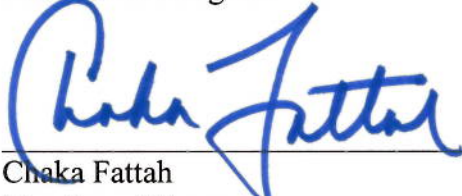
Keith Ellison  
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Elizabeth H. Esty  
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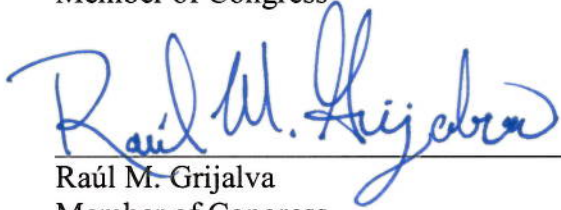
Sam Farr  
Member of Congress



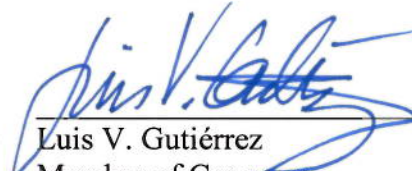
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Michael Honda  
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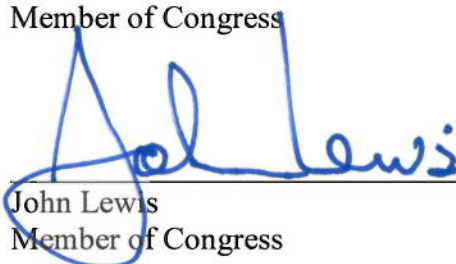
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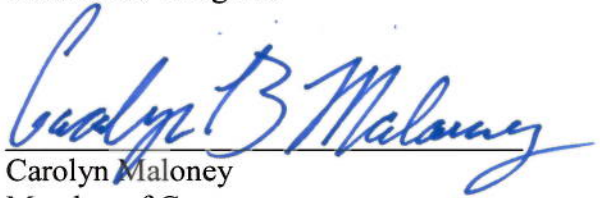
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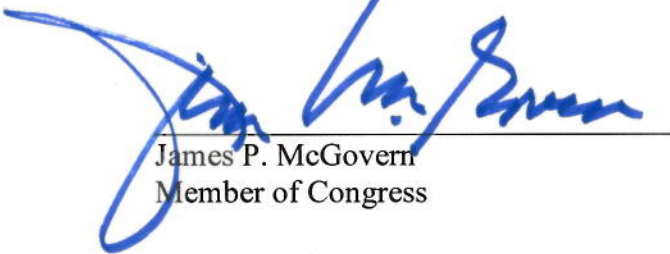
Carolyn Maloney  
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Sean Patrick Maloney  
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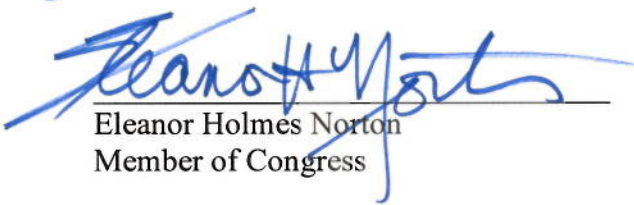
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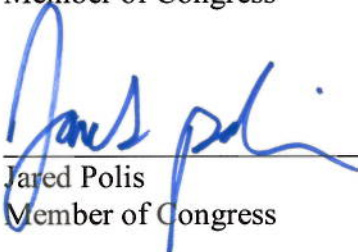
Scott Peters  
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Chellie Pingree  
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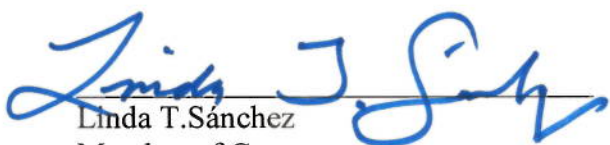
Mark Pocan  
Member of Congress



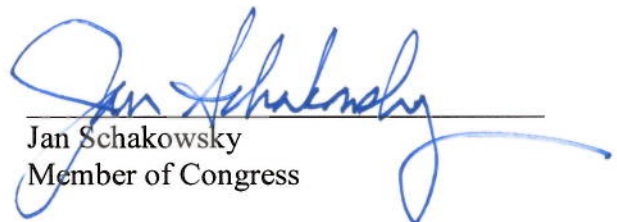
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Jose E. Serrano  
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Kyrsten Sinema  
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Albio Sires  
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Adam Smith  
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Jackie Speier  
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Eric Swalwell  
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Mark Takano  
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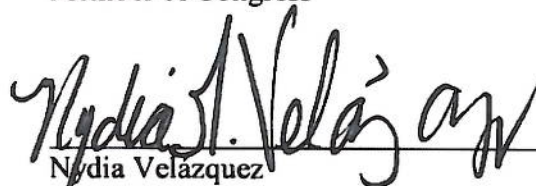
Dina Titus  
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Paul Tonko  
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John Yarmuth  
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Nydia Velázquez  
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Peter Welch  
Member of Congress



Niki Tsongas  
Member of Congress