

Congress of the United States
Washington, DC 20510

August 1, 2013

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

Dear Secretary Sebelius:

We are writing to express concern with the progress of the Department of Health and Human Services (HHS) Advisory Committee on Blood & Tissue Safety & Availability (ACBTSA) evaluations of the current blood donation criteria for men who have sex with men (MSM). We applaud HHS and the ACBTSA for recognizing the need to alter the criteria and for launching research projects aimed at informing policy changes. However, we are deeply concerned about the timeline of such research. Accordingly, we seek more information about the activities conducted by HHS over the last year and those planned for the remainder of 2013, as well as how data from additional studies will inform policy-making decisions.

As you know, the American Medical Association (AMA) recently adopted a resolution opposing the Food and Drug Administration's (FDA) current lifetime ban on blood donations from MSM in favor of a policy based on individual risk-factors other than sexual orientation. We feel that AMA's recent vote in opposition to the current policy provides even greater impetus for HHS to move swiftly with its research and revision of the current ban.

Since the beginning of the HIV/AIDS epidemic more than 30 years ago, the scientific community's understanding of the virus has changed dramatically. We have seen vast advances in blood screening technology, blood donation policy changes in other countries allowing MSM to donate, and opposition from our nation's blood banks who have called the current ban "medically and scientifically unwarranted." Our current policies turn away healthy, willing donors, even when we face serious blood shortages. Further, the existing lifetime ban continues to perpetuate inaccurate stereotypes against gay and bisexual men, and fosters an atmosphere that promotes discrimination and discourages individuals from seeking HIV testing and treatment services.

In 2010, the Advisory Committee on Blood Safety and Availability, a non-partisan group of scientific experts convened by HHS, concluded that the current lifetime ban should be changed. The Committee found the ban to be "suboptimal" because it allows high-risk individuals to donate while prohibiting low-risk donors from giving blood. Since that time, several studies were initiated to assess the risks of MSM donation to assure that any changes in policy would not affect the safety of the blood supply.

According to Dr. James Berger's presentation at the June 2013 meeting of the ACBTSA, there are currently three ongoing studies and a task force that will help inform policy changes. The Quarantine Release Error Task Force is due to release a white paper in August 2013, and the REDS-II, and Donor History Questionnaire studies are both scheduled to report results in October 2013. The REDS-III study will be completed in 2014.

The most important study proposed in response to ACBTSA's recommendations was a pilot study to assess the feasibility and safety of new criteria for MSM blood donation, and to allow MSM donation on a small scale. In March 2012, HHS released an RFI on the design of the new pilot study and accepted comments through June 2012. Sixty-four Members of Congress wrote a letter stressing the importance of the pilot study and calling for a policy change. At the June 2013 ACBTSA meeting, Dr. Berger reported that HHS had received 11 responses to the March 2012 RFI, and that "a report to HHS senior leadership" was scheduled for "next month." According to the public record, ten responses were received from ten different organizations, totaling 75 pages, including supporting documents.

In light of the medical community's opposition to the current MSM ban, we request that HHS provide the following information to clarify what work has been done over the last year, and the agency's future plans with respect to reassessing blood donation criteria for MSM:

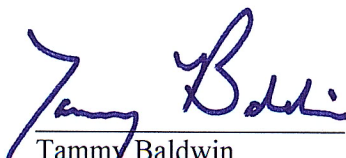
- (1) The criteria used to assess the 75 pages of comments and what assessment activities took place from June 2012 to July 2013;
- (2) A copy of the July 2013 report to leadership on the response to the RFI on pilot study design;
- (3) A detailed plan and a timeline for how results from the Quarantine Release Error Task Force, the Donor History Questionnaire study, the REDS-II and REDS-III studies will be used to inform changes to the blood donation criteria; and
- (4) Whether HHS plans to leverage data from other countries that currently allow MSM to donate to inform analysis of an alternative policy, and if not, why not.

We look forward to a timely response to our request. Further, we look forward to ending this outdated policy and moving forward with securing the nation's blood supply in a scientifically sound manner.

Sincerely,



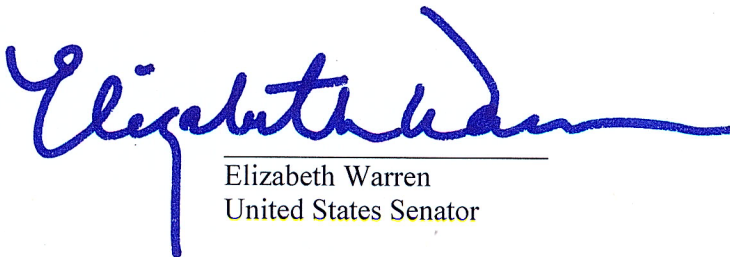
Mike Quigley
Member of Congress



Tammy Baldwin
United States Senator



Mike Enzi
United States Senator



Elizabeth Warren
United States Senator

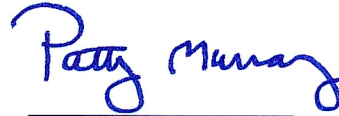


Barbara Lee
Member of Congress

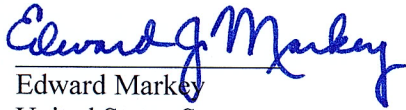
Cc: Dr. James Berger, Executive Secretary, Office of the Assistant Secretary for Health; Dr. Howard Koh, Assistant Secretary for Health, US Department of Health and Human Services.



Michael Bennet
United States Senator



Patty Murray
United States Senator



Edward Markey
United States Senator



Mark Begich
United States Senator



Jeanne Shaheen
United States Senator



Patrick Leahy
United States Senator



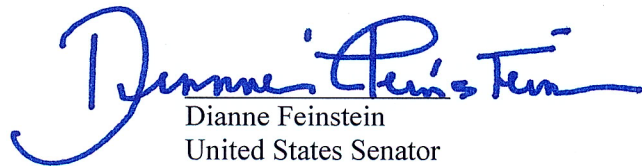
Mark Udall
United States Senator



Kirsten Gillibrand
United States Senator



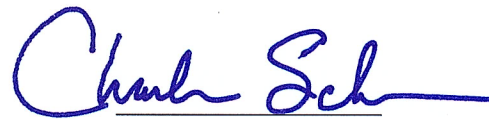
Sherrod Brown
United States Senator



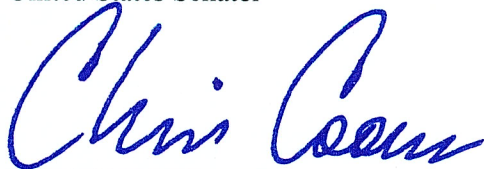
Dianne Feinstein
United States Senator



Martin Heinrich
United States Senator



Charles Schumer
United States Senator



Christopher Coons
United States Senator



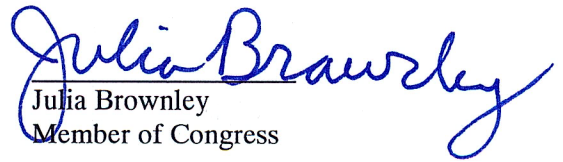
Bernard Sanders
United States Senator



Maria Cantwell
United States Senator



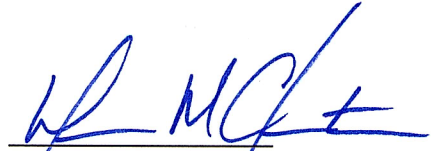
Xavier Becerra
Member of Congress



Julia Brownley
Member of Congress



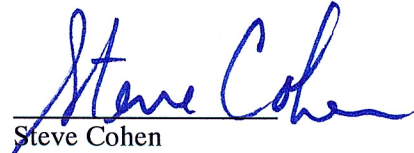
Matt Cartwright
Member of Congress



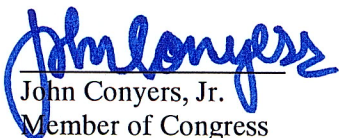
Donna Christensen
Member of Congress



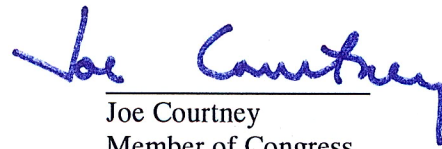
David Cicilline
Member of Congress



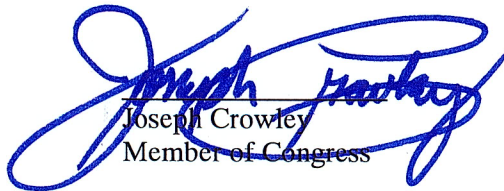
Steve Cohen
Member of Congress



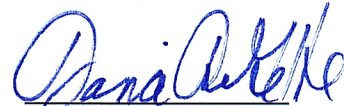
John Conyers, Jr.
Member of Congress



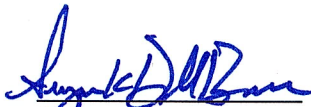
Joe Courtney
Member of Congress



Joseph Crowley
Member of Congress



Diana DeGette
Member of Congress



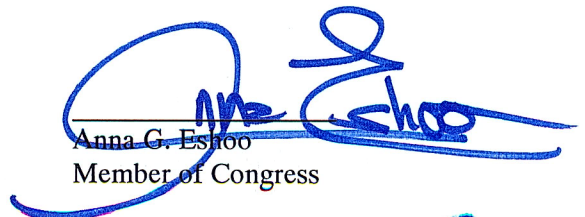
Suzan DelBene
Member of Congress



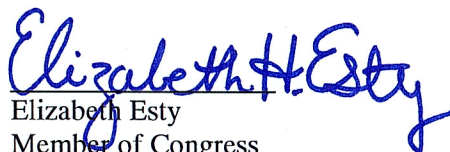
Ted Deutch
Member of Congress



Keith Ellison
Member of Congress



Anna C. Eshoo
Member of Congress



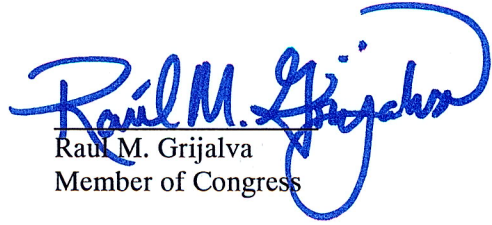
Elizabeth Esty
Member of Congress



Sam Farr
Member of Congress



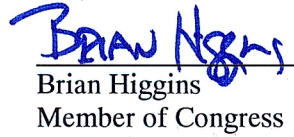
Bill Foster
Member of Congress



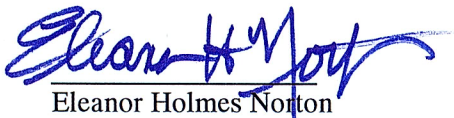
Raul M. Grijalva
Member of Congress



Alcee L. Hastings
Member of Congress



Brian Higgins
Member of Congress



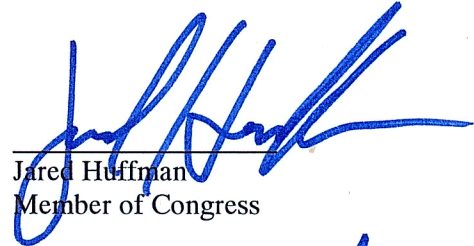
Eleanor Holmes Norton
Member of Congress



Rush Holt
Member of Congress




Mike Honda
Member of Congress



Jared Huffman
Member of Congress



Steve Israel
Member of Congress



Sheila Jackson Lee
Member of Congress



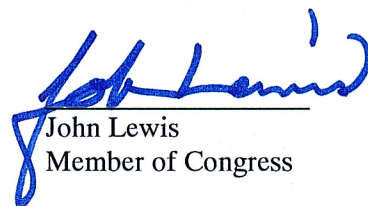
Eddie Bernice Johnson
Member of Congress



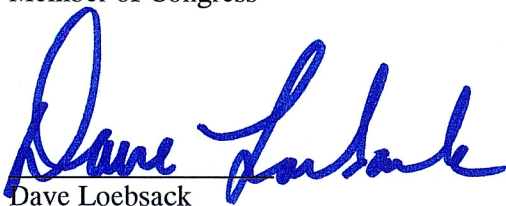
Dan Kildee
Member of Congress



Ann McLane Kuster
Member of Congress



John Lewis
Member of Congress



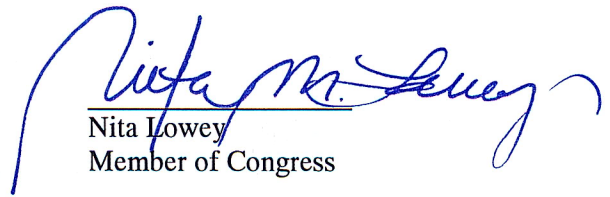
Dave Loebsack
Member of Congress



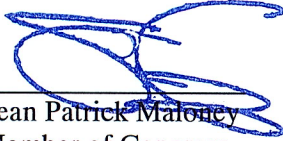
Zoe Lofgren
Member of Congress



Alan Lowenthal
Member of Congress



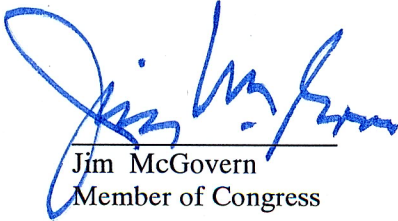
Nita Lowey
Member of Congress



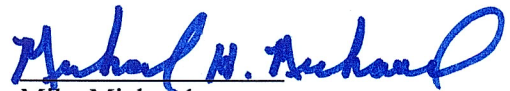
Sean Patrick Maloney
Member of Congress



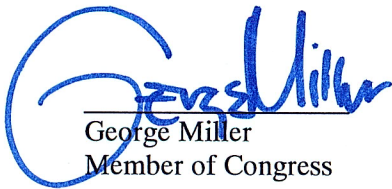
Betty McCollum
Member of Congress



Jim McGovern
Member of Congress



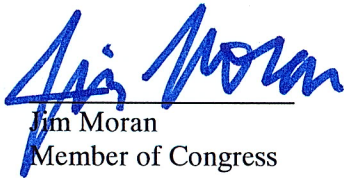
Mike Michaud
Member of Congress



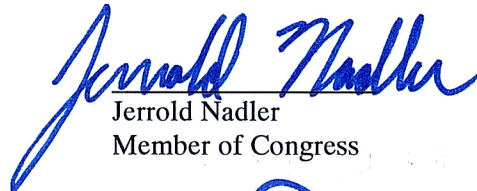
George Miller
Member of Congress



Gwen Moore
Member of Congress



Jim Moran
Member of Congress



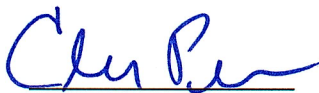
Jerrold Nadler
Member of Congress



Beto O'Rourke
Member of Congress



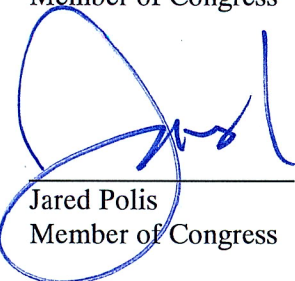
Scott Peters
Member of Congress



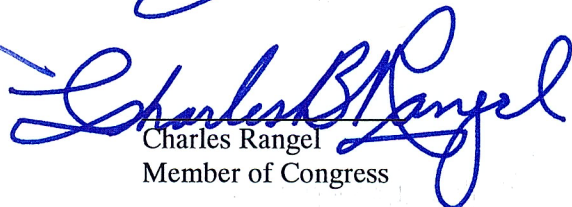
Chellie Pingree
Member of Congress




Mark Pocan
Member of Congress

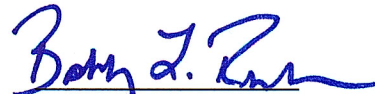


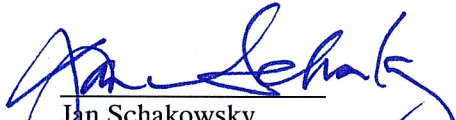
Jared Polis
Member of Congress



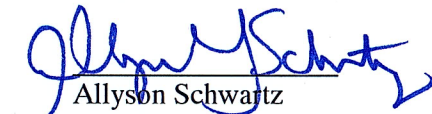
Charles Rangel
Member of Congress

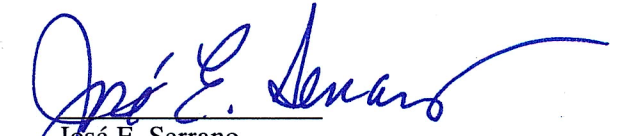

Lucille Roybal-Allard
Member of Congress



Bobby L. Rush
Member of Congress

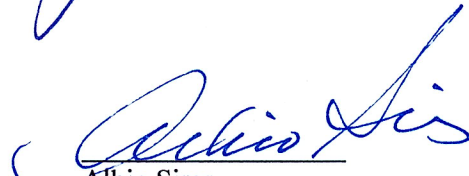

Jan Schakowsky
Member of Congress

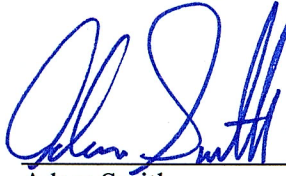

Adam Schiff
Member of Congress

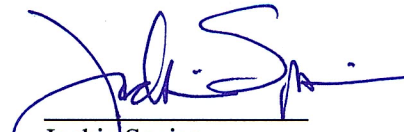

Allyson Schwartz
Member of Congress



José E. Serrano
Member of Congress



Brad Sherman
Member of Congress

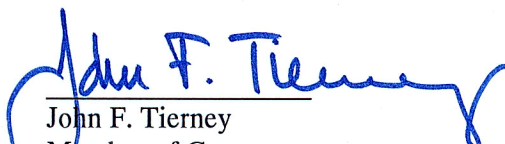

Albio Sires
Member of Congress

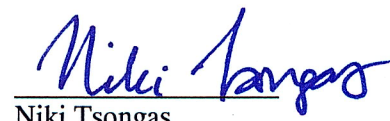

Adam Smith
Member of Congress



Jackie Speier
Member of Congress



Eric Swalwell
Member of Congress

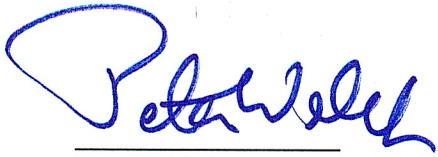

Mark Takano
Member of Congress


John F. Tierney
Member of Congress

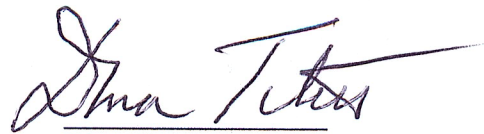

Niki Tsongas
Member of Congress


Chris Van Hollen
Member of Congress


Nydia M. Velázquez
Member of Congress



Peter Welch
Member of Congress



Dina Titus
Member of Congress