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 policymaking 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 ACB TSA’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 ACB TSA 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

Edward Markey  
United States Senator

Jeanne Shaheen  
United States Senator

Mark Udall  
United States Senator

Sherrod Brown  
United States Senator

Martin Heinrich  
United States Senator

Christopher Coons  
United States Senator

Maria Cantwell  
United States Senator

Patty Murray  
United States Senator

Mark Begich  
United States Senator

Patrick Leahy  
United States Senator

Kirsten Gillibrand  
United States Senator

Dianne Feinstein  
United States Senator

Charles Schumer  
United States Senator

Bernard Sanders  
United States Senator
Xavier Becerra  
Member of Congress

Matt Cartwright  
Member of Congress

David Cicilline  
Member of Congress

John Conyers, Jr.  
Member of Congress

Joseph Crowley  
Member of Congress

Suzan DelBene  
Member of Congress

Keith Ellison  
Member of Congress

Elizabeth H. Esty  
Member of Congress

Julia Brownley  
Member of Congress

Donna Christensen  
Member of Congress

Steve Cohen  
Member of Congress

Joe Courtney  
Member of Congress

Diana DeGette  
Member of Congress

Ted Deutch  
Member of Congress

Anna G. Eshoo  
Member of Congress

Sam Farr  
Member of Congress
Bill Foster  
Member of Congress

Alcee L. Hastings  
Member of Congress

Eleanor Holmes Norton  
Member of Congress

Mike Honda  
Member of Congress

Steve Israel  
Member of Congress

Eddie Bernice Johnson  
Member of Congress

Ann McLane Kuster  
Member of Congress

Dave Loebsack  
Member of Congress

Raul M. Grijalva  
Member of Congress

Brian Higgins  
Member of Congress

Rush Holt  
Member of Congress

Jared Huffman  
Member of Congress

Sheila Jackson Lee  
Member of Congress

Dan Kildee  
Member of Congress

John Lewis  
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