

Congress of the United States
Washington, DC 20515

December 18, 2020

The Honorable Stephen Hahn
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Hahn,

We write to you today regarding our strong concerns with the U.S. Food and Drug Administration's (FDA) guidelines for the donation of plasma that continue to discriminate against men who have sex with men (MSM). The ongoing – and worsening – COVID-19 pandemic has put severe stress on the nation's supply of plasma, and it is imperative that FDA's donor guidelines move away from reliance on harmful stereotypes to allow all healthy adults who wish to donate to do so.

As you know, FDA's guidelines on the donations of blood and blood products, including plasma, have imposed restrictions on MSM donors for the past 35 years and have outlived any usefulness they may once have had. Originally instituted in 1985 in response to an initial wave of the AIDS epidemic in order to reduce the transmission of HIV via donated blood and blood products, the donation ban has already been modified based upon scientific advancements. First, when the agency revised its guidelines to allow MSM to donate beginning 12 months after their last same-sex sexual contact and the most recent guidance from FDA, first issued in April and updated in August of this year, revising these guidelines from a 12-month deferral to a 3-month deferral.¹

While these changes are undoubtedly important steps forward, and we appreciate the agency's initiative in shortening the deferral policy in recognition of the blood and plasma shortages caused by the COVID-19 pandemic, they do not go far enough. We urge the agency to move towards adopting donation guidelines that consider individual risk rather than paint an entire demographic with such a broad – and harmful – brush. The current policy continues to perpetuate stigma around MSM and HIV/AIDS and deters many healthy gay and bisexual men from donating. Advances in the understanding of HIV transmission as well as in the screening and testing of donated blood and blood products over the past three decades are surely sufficient to keep the supply safe for use without requiring discrimination against MSM donors.

In the case of donated plasma, the need for donors is particularly acute during this pandemic. Plasma is a critical tool used to treat trauma and burn victims, and is the only effective treatment for many individuals with hemophilia and other clotting factor deficiencies. Plasma donation has decreased significantly and both patients and hospitals across the country are now worried about

¹ <https://www.fda.gov/media/92490/download>

their ability to access the amount of plasma they need.² Makers of plasma treatments are also concerned about sourcing enough donated plasma to meet demand and are already anticipating a drop in the amount of product they will be able to produce.³ It can take up to 1,200 plasma donations to treat one patient with hemophilia each year, and refining plasma into an infusion therapy can take up to a year from the time of donation.⁴ This means that a severe decrease in plasma donations as a result of COVID-19 may continue to negatively impact the supply chain for some time even after the pandemic ends, further imperiling the health and safety of patients who rely on plasma-based treatments to survive.

Outdated and arbitrary guidelines that discriminate against MSM attempting to donate plasma unnecessarily constrains its supply during a time when it is more important than ever to increase the donor pool. Plasma donation is an act of generosity that helps save lives, and FDA's policies should be informed by the best science available to ensure that the maximum number of people who can donate safely can do so. We therefore urge you to revise the agency's guidelines on plasma donation and remove the blanket deferral policy for MSM.

Thank you for your attention to this critical public health issue.

Sincerely,



Brian Higgins
Member of Congress



Judy Chu
Member of Congress



José E. Serrano
Member of Congress

² <https://www.thedenverchannel.com/news/national/looming-plasma-shortage-has-some-worried-about-treatment>

³ <https://www.bizjournals.com/triangle/news/2020/10/19/slowdown-in-plasma-shortage-has-drugmakers-worried.html>

⁴ <https://www.pptaglobal.org/plasma>