

February 2, 2022

Janet Woodcock, MD Acting Commissioner Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Dear Acting Commissioner Woodcock,

On behalf of the American College of Physicians (ACP), I am writing to urge the Food and Drug Administration (FDA) to expedite its study of the donation of blood by sexually active gay and bisexual men, and immediately make appropriate updates to existing blood donation policy as supported by the best available data and information. Given the negative shocks on the supply of blood associated with the recent Omicron wave and uptick in COVID-19 cases, action is urgently needed to address a national blood shortage which threatens countless lives during one of the deadliest public health crises in our nation's history.

The American College of Physicians is the largest medical specialty organization and the second-largest physician membership society in the United States. ACP members include 161,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness. Internal medicine specialists treat many of the patients at greatest risk from COVID-19, including the elderly and patients with pre-existing conditions like diabetes, heart disease and asthma.

On January 11, 2022, the American Red Cross announced a nationwide shortage of blood and platelets, calling it "the worst blood shortage in over a decade." Since the start of the COVID-19 pandemic in March 2020, Red Cross blood donations have declined by roughly 10 percent, including a 34% decrease in new donors in 2021 alone. This decrease in blood supply has arisen from an unfortunate combination of factors, including virtual classes for high school and college students, resulting in a 62 percent decrease in campus blood drives; blood drive cancellations due to recent bouts of extreme winter weather; staffing limitations; and recent surges in COVID-19 and influenza cases. As a result, there has been less than a one-day supply of critical blood types at times in recent weeks, limiting the distribution of blood products to hospitals and causing some trauma centers to temporarily close.

Despite a shortage of blood that could potentially risk countless lives, the FDA maintains a discriminatory blood donation policy that prevents millions of individuals from donating blood. Historically, FDA policy imposed a lifetime ban on the donation of blood by men who have sex with men out of fears of higher risk of HIV and hepatitis transmission by such individuals through donated blood. In December 2015, the FDA amended its lifetime ban to restrict the donation of blood by men who have had sex with men within the past 12 months; this restriction was further lowered to 3 months in 2020. The FDA's current approach requires gay and bisexual men to abstain from sex with other men for three months prior in order to be permitted to donate blood. Such an approach treats at-risk populations uniformly and categorically rather than targeting or screening for specific at-risk activities. While protecting the integrity of the U.S. blood supply is paramount, the FDA should expedite the study and implementation of alternative policies that would safely increase the blood donor pool in a manner that does not discriminate against donors on the basis of sexual orientation and gender identity. Other countries, such as the United Kingdom and France, among others, do not impose a deferral period for men who have sex with men and rather screen for high-risk activities at the individual level as part of the donation process.

ACP's policy on LGBTQ+ health has long supported the continued review of blood donation deferral policies for men who have sex with men and the establishment of evidence-based deferral policies that take into account a comprehensive assessment of the risk level of all individuals seeking to donate. While we commend the FDA for decreasing the deferral period to three months in recent years, further action is needed. The College calls for the expedited monitoring and study of existing deferral policies and for the agency to make further strides toward policies that assess donor eligibility on the basis of scientific data and individual risk factors, such as the length of time since a high-risk behavior has occurred, type of sex that occurred, number of partners during a period of time, or a combination of factors.

As the U.S. grapples with a dire blood shortage, ACP urges the FDA to take immediate action to reassess its current blood donation policies to allow for the safe donation of blood by all of those who wish to do so. ACP welcomes your agency's leadership on this issue and looks forward to working with you, the rest of the medical community, and other policy stakeholders on this issue. Please contact Josh Serchen, Associate, Health Policy at <a href="mailto:issue.">issue.Please contact Josh Serchen</a>, Associate, Health Policy at <a href="mailto:issue.">issue.Please contact Josh Serchen</a>, Associate, Health Policy at <a href="mailto:issue.">issue.Please contact Josh Serchen</a>, Associate, Health Policy at <a href="mailto:issue.">issue.Please contact Josh Serchen</a>, Associate, Health Policy at <a href="mailto:issue.">issue.Please contact Josh Serchen</a>, Associate, Health Policy at <a href="mailto:issue.">issue.Please contact Josh Serchen</a>, Associate, Health Policy at <a href="mailto:issue.">issue.Please contact Josh Serchen</a>, Associate, Health Policy at <a href="mailto:issue.">issue.Please contact Josh Serchen</a>, Associate, Health Policy at <a href="mailto:issue.">issue.Please contact Josh Serchen</a>, Associate, Health Policy at <a href="mailto:issue.">issue.Please contact Josh Serchen</a>, Associate, Health Policy at <a href="mailto:issue.">issue.Please contact Josh Serchen</a>, Associate, Health Policy at <a href="mailto:issue.">issue.Please contact Josh Serchen</a>, Associate, Health Policy at <a href="mailto:issue.">issue.Please contact Josh Serchen</a>, Associate, Health Policy at <a href="mailto:issue.">issue.Please contact Josh Serchen</a>, Associate, Health Policy at <a href="mailto:issue.">issue.Please contact Josh Serchen</a>, Associate, Health Policy at <a href="mailto:issue.">issue.Please contact Josh Serchen</a>, Associate, Health Policy at <a href="mailto:issue.">issue.Please contact Josh Serchen</a>, Associate, Health Policy at <a href="mailto:issue.">issue.Please contact Josh Serche

Sincerely,

George M. Abraham, MD, MPH, MACP, FIDSA

President