



-APLUS Statement on FDA Policy Changes Related to Blood and Plasma Donation – April 2, 2020

Today, the FDA released several new guidance documents with permanent and temporary (during the COVID-19 emergency) changes to several policies related to blood and plasma donation. Our organizations represent end users of blood and blood products – patient populations that are both particularly vulnerable and reliant on these life saving and life extending blood and blood-derived therapies. We believe that complex blood safety policies such as those related to donor deferral should be based on science, and we support the adoption of revised eligibility criteria policies that can increase the potential pool of donors as long as the overall risk to end users is not increased.

We agree with the FDA that the policy changes announced today, including reducing the [deferral period for men who have had sex with other men](#) (MSM) to 3 months from last encounter, as well as the temporary change to allow source plasma collectors to [release plasma after 45 days in quarantine rather than 60](#), are changes that are consistent with the scientific evidence that will not elevate risk for end-users. The MSM policy change is also in line with policies present in other countries, from which data have informed the US policy change.

We also understand that crisis decision making is taking place that may have long term impact. There remain many unanswered scientific questions related to these issues, which is why our organizations have advocated for the establishment of the Transfusion-Transmissible Infections Monitoring System (TTIMS). Maintaining this national longitudinal and permanent hemovigilance system remains a very high priority for our organizations. Information from the TTIMS system will facilitate monitoring and safety surveillance of the changes announced today, as well as provide the ability to counter known and emerging infectious threats to the blood supply within overall blood collections or as a result of any other policy change.

Finally, the COVID-19 emergency has brought the need for adequate blood donations to the fore. We also reiterate the need for adequate plasma donations, to ensure that the life-saving therapies that many of our patients rely on can continue to be produced. In our current time of national emergency related to COVID-19, it has never been more clear that we need a national blood policy to promote donation and ensure safe, adequate and accessible blood, source plasma and blood products for all Americans.

To listen to the official announcement from the FDA on April 2, please dial 1-888-566-0618.

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