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ABC Statement on the FDA's Blood Donor Deferral Policy for Men Who Have Sex with Other Men (MSM) & the ADVANCE Study

(April 4, 2022)

As the U.S. Food and Drug Administration's (FDA) landmark Assessing Donor Variability and New Concepts in Eligibility (ADVANCE) study passes 50 percent of planned enrollment, America's Blood Centers (ABC) today reiterated its call for a safe and available blood supply that treats all potential donors with fairness, equality, and respect.

ABC supported the FDA change in 2020 that reduced the donor deferral period from 12 to three months for men who have sex with other men (MSM). Important work is now occurring to collect the needed scientific evidence to further evaluate the current policy. ABC strongly supports this effort as a pathway to the establishment of donor-screening based on individual risk behaviors, not sexual or gender identity. The use of rational, science-based deferral periods must be applied fairly and consistently among blood donors.

The ADVANCE study is a pilot study funded by the FDA that focuses on the blood donor deferral policy for men who have sex with other men (MSM). Three blood collection organizations, including ABC-member's OneBlood and Vitalant, are currently collaborating with LGBTQ community centers and organizations in eight locations to enroll participants. The study seeks to determine if different eligibility criteria can be used at blood centers nationwide that focuses on each donor's individual risk behavior rather than their sexual orientation.

The FDA initially instituted a lifetime deferral on blood donations for MSM in 1983 to reduce the chance of HIV in the blood supply at a time when testing was limited or non-existent. In 2015, the FDA revised this policy and moved to a 12-month deferral in response to comprehensive testing and data demonstrating safety in shortened deferral. This policy was revised again in 2020 to the current 3-month deferral during the COVID-19 public health emergency.

Gay and bisexual men are being enrolled in the ADVANCE study to collect data on the performance in assessing risk of new questions that may be added to the donor history questionnaire in the future. The results, which are expected in late 2022, will be submitted to the FDA for review and the agency will then decide the next steps in this process, including how the data will be released to the public.