Plasma Protein Therapeutics Association

PPTA Statement on
Topic III. Blood Donation Policies Regarding Men Who Have Sex with Men (MSM)

120th Meeting of the Blood Products Advisory Committee
March 21, 2019

The Plasma Protein Therapeutics Association (PPTA) is pleased to provide comments to the Blood Products Advisory Committee (BPAC) on Topics III A and B related to MSM blood donation deferral policies.

PPTA is the international trade association and standards-setting organization for the world's major producers of plasma-derived and recombinant analog therapies. Our members provide 80 percent of the world's needs for Source Plasma and 60 percent for plasma protein therapies. These include clotting therapies for individuals with bleeding disorders, immunoglobulins to treat diseases in persons with immune deficiencies and certain acute and chronic neurological diseases, therapies for individuals who have alpha-1 anti-trypsin deficiency which typically manifests as adult onset emphysema and substantially limits life expectancy, albumin which is used in emergency room settings to treat individuals with shock, trauma, burns, and other conditions, and other plasma therapies for rare conditions. PPTA members are committed to assuring the safety and availability of these medically needed life-sustaining therapies.

PPTA agrees with FDA's stated overall concept of reviewing existing policies, monitoring the effect of policy changes, and evaluating future policy alternatives in all areas, including MSM donation policies. While PPTA agrees with FDA's overall concept, PPTA wishes to address several points in FDA's Issue Summary.

With respect to Topic III A, PPTA member companies operate nearly 750 US licensed plasma collection centers in the US. In 2018, these centers collected approximately 48 million donations of Source Plasma. As PPTA stated to the BPAC in 2014 at the time the committee considered the change in deferral policies from a life-time deferral to a 12-month deferral for MSM, Source Plasma is marketed globally. Our members must adhere to policies beyond the FDA's policies. While international thought is evolving, global changes have allowed only one-third of our members to adopt the 12-month deferral policy. Notwithstanding, changes in donor policies are generally applied broadly to both donors of blood and plasma. Without the plasma industry's participation in the design of the proposed FDA study incorporating an additional donor history questionnaire, the HIV High Risk Questionnaire (HRQ), it is unknown whether the results of such a study could be transferred to the source plasma collection community. Between the blood and plasma collection communities, there are several differences in methods of collection (fixed site v. mobile), degree of automation, and donor selection and monitoring that may affect operational applicability of the results of the study.

With respect to Topic III B, PPTA member companies are committed to providing safe and effective therapies. Patient populations who receive the therapies made from plasma have chronic and serious conditions. Donor selection is one of the several layers of safety in the manufacturing of plasma protein therapies and includes state of the art testing of individual plasma donations and manufacturing pools, followed by robust manufacturing processes with dedicated safety steps. Plasma protein therapies are a distinct class of therapeutic products which undergo complex purification processes with viral removal and inactivation capabilities offering significant

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virus safety margins. Companies have made substantial investments in all of these areas and in over two decades there have been no documented transmissions of HIV or hepatitis B or C. Almost all products employ two orthogonal methods for pathogen reduction. The log reductions obtained are generally higher than those achieved with the methods being used for pathogen reduction in transfusable products and address both enveloped and non-enveloped viruses.

Despite the remarkable safety record for final plasma protein therapies, PPTA member companies have retained donor selection and donation testing as key quality management tools within the construct of "layers of safety." FDA regulations [Title 21, Code of Federal Regulations, 630.10] include the assessment of behaviors associated with a relevant transfusion-transmitted infection and deferral of donors with behavioral risk factors. PPTA opposes an ad hoc variance approval that includes a specific set of risks in a specific indication (i.e., pathogen reduced apheresis platelets). PPTA and its members companies welcome a broader discussion of the value of behavioral risk assessments and other current requirements/recommendations in the face of robust pathogen reduction processes.