

PPTA Statement on Review of Donor Blood Pressure Requirements

FDA Blood Products Advisory Committee

July 22, 2004

The Plasma Protein Therapeutics Association (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 60 percent of the world's needs for Source Plasma and protein therapies. These include clotting therapies, immunoglobulins, therapies for alpha-1 anti-trypsin deficiency, and albumin.

PPTA welcomes the efforts made by the Food and Drug Administration (FDA) in reviewing the requirements governing blood pressure testing. PPTA firmly believes that donor screening and testing procedures required by regulation without a scientific basis hold little value in protection of both the donor's health and the public health. We agree with the American Association of Blood Banks' (AABB) statement that a requirement for lower limits for blood pressure does not add value.

A strategic goal for the global plasma industry and PPTA is harmonization of regulatory requirements. PPTA encourages the FDA to study current European requirements regarding blood pressure and make efforts in the direction of harmonization. As noted in both the FDA background document and AABB statement, current European requirements do not call for lower blood pressure limits, and a U.S. requirement to do so would be discordant with European requirements.

Similarly, PPTA would encourage FDA to review all regulatory requirements that are not scientifically based and do not add appreciably to donor or public health. While PPTA supports requirements that can add measurable improvements to donor health and final product safety, outdated or valueless requirements add burdens without benefit.

PPTA supports the FDA's review of requirements that have become obsolete, and we encourage the FDA to continue to examine regulations and guidance criteria that limit efficiency and do not generate enhanced safety.