

HOUSE RESOLUTION NO.2003-4667, by Representative Schoesler

WHEREAS, Hundreds of thousands of people in the United States including the State of Washington depend on protein therapies derived from human plasma, known as plasma therapies, to treat serious and life-threatening diseases and conditions such as hemophilia, primary immune disorder, Alpha-1 Antitrypsin deficiency (Alpha-1), Rh Negative blood incompatibility, shock, and burns; and

WHEREAS, Assuring the continued quality and safety of plasma therapies is a top priority of patients, public health authorities, and the plasma collection and fractionation industry; and

WHEREAS, The plasma industry and its global trade association have developed the quality standards of excellence assurance and leadership and international quality plasma program standards that currently represent the highest reasonably attainable quality and safety standards for human source plasma used in the processing of plasma protein therapies; and

WHEREAS, These quality standards of excellence assurance and leadership standards include:

Strict criteria for the selection of qualified donors, including the requirements that the donor successfully pass a minimum of two separate health screenings and two separate validated laboratory tests before any donation can be used;

The use of a sixty-day inventory hold and the requirement that if new information is received indicating that a donor is no longer qualified, previous donations from that donor held in inventory are required to be destroyed;

The use of state-of-the-art Nucleic acid Amplification Technology (NAT) to detect any potential presence of human immunodeficiency virus (HIV), Hepatitis B virus (HBV), and Hepatitis C virus (HCV) and any potential presence at critical levels of parvovirus B19; and

The requirement that plasma used to produce plasma therapies be collected at centers that adhere to, and are judged by, specific strict viral marker standards; and

WHEREAS, These quality standards of excellence assurance and leadership and international quality plasma program standards provide an extra margin of safety beyond federal and state regulatory requirements for the collecting, processing, and testing of human plasma; and

WHEREAS, These quality standards of excellence assurance and leadership and international quality plasma program standards have helped drive the adoption of enhanced and consistent safety standards for plasma collection and processing; and

WHEREAS, It is important to further increase public awareness of the value of donating blood and plasma, as well as an appreciation of the safety of plasma therapies and the processes by which that safety is assured;

NOW, THEREFORE, BE IT RESOLVED, By the House of Representatives of the State of Washington, That the quality standards of excellence assurance and leadership and international quality plasma program certification programs are important ways to ensure that only the highest quality plasma is collected and used for processing of plasma-derived therapeutic proteins; and

BE IT FURTHER RESOLVED, That entities that collect plasma recovered from whole blood should implement a quality and safety standards certification program comparable to quality standards of excellence assurance and leadership and international quality plasma program; and

BE IT FURTHER RESOLVED, That health care professionals and health plans that purchase or provide plasma proteins for patient care should use therapeutics that employ rigorous quality systems, as exemplified by the quality standards of excellence assurance and leadership and international quality plasma program certification programs, which are aimed at assuring the highest quality and safety of plasma donations from which plasma therapies are derived; and

BE IT FURTHER RESOLVED, That all facilities that collect blood and plasma for fractionation into plasma therapeutic proteins that are certified under the international quality plasma

program, and processors that fractionate source plasma that are certified under the quality standards of excellence assurance and leadership program be commended for receiving such certification.