

1 HOUSE RESOLUTION

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

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

13 WHEREAS, The plasma industry and its global trade
14 association have developed the QSEAL (Quality Standards of
15 Excellence Assurance and Leadership) and IQPP (International
16 Quality Plasma Program) standards that currently represent
17 the highest reasonably attainable quality and safety
18 standards for human source plasma used in processing of
19 plasma protein therapies; and

20 WHEREAS, These QSEAL standards include: strict criteria
21 for the selection of qualified donors, including the
22 requirements that the donor successfully pass a minimum of
23 two separate health screenings and two separate validated
24 laboratory tests before any donation can be used; the use of
25 a 60-day inventory hold and the requirement that if new
26 information is received indicating that donor is no longer
27 qualified, previous donations from that donor held in
28 inventory are required to be destroyed; the use of
29 state-of-the-art Nucleic acid Amplification Technology (NAT)
30 to detect any potential presence of human immunodeficiency
31 virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C virus
32 (HCV) and any potential presence at critical levels of

1 parvovirus B 19; and the requirement that plasma used to
2 produce plasma therapies be collected at centers that adhere
3 to, and are judged by, specific strict viral market
4 standards; and

5 WHEREAS, These QSEAL and IQPP standards provide an extra
6 margin of safety beyond federal and State regulatory
7 requirements for the collecting, processing, and testing of
8 human plasma; and

9 WHEREAS, These QSEAL and IQPP standards have helped drive
10 the adoption of enhanced and consistent safety standards for
11 plasma collection and processing; and

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

16 RESOLVED, BY THE HOUSE OF REPRESENTATIVES OF THE
17 NINETY-THIRD GENERAL ASSEMBLY OF THE STATE OF ILLINOIS, that
18 the IQPP and QSEAL certification programs are important ways
19 to ensure that only the highest quality plasma is collected
20 and used for processing of plasma-derived therapeutic
21 proteins; and be it further

22 RESOLVED, That all facilities which collect blood and
23 plasma for fractionation into plasma therapeutic proteins are
24 strongly encouraged to become certified under the IQPP
25 program, and processors which fractionate source plasma are
26 strongly encouraged to become certified under the QSEAL
27 program; and be it further

28 RESOLVED, That entities which collect plasma recovered
29 from whole blood are encouraged to implement a quality and
30 safety standards certification program comparable to QSEAL
31 and IQPP; and be it further

1 RESOLVED, That health care professionals and health plans
2 that purchase and/or provide plasma proteins for patient care
3 are encouraged to utilize therapeutics that employ rigorous
4 quality systems, as exemplified by the IQPP and QSEAL
5 certification programs, which are aimed at assuring the
6 highest quality and safety of plasma donations from which
7 plasma therapies are derived.