

By: Carona

S.R. No. 893

R E S O L U T I O N

1 WHEREAS, Each year, thousands of Texans depend on plasma
2 protein therapeutics as treatment for life-threatening conditions
3 including shock, severe burns, immune deficiency disorders such as
4 alpha-1 antitrypsin deficiency, and hemophilia and other blood
5 disorders; and

6 WHEREAS, The treatments for these conditions and diseases
7 rely on the safe collection and processing of human source plasma;
8 to ensure the continued quality and safety of these critical
9 therapies, the plasma industry and its global trade association
10 have developed the Quality Standards of Excellence Assurance and
11 Leadership (QSEAL) Program and the International Quality Plasma
12 Program (IQPP); and

13 WHEREAS, The QSEAL and IQPP certification standards include
14 strict criteria for the selection of qualified donors, the use of a
15 60-day inventory hold with provisions for destruction of certain
16 plasma on post-donation information indicating a donor is no longer
17 qualified, the use of state-of-the-art nucleic acid amplification
18 technology to screen donations for human immunodeficiency virus
19 (HIV), hepatitis B and C, and parvovirus B19, and the requirement
20 that plasma used to produce plasma therapies be collected from
21 centers that adhere to strict viral marker standards; and

22 WHEREAS, The QSEAL and IQPP certification standards go well
23 beyond state and federal regulatory requirements to ensure the
24 integrity of human source plasma for the production of plasma

1 protein therapies and encourage use of the latest technological
2 advancements in safety control; these standards have helped drive
3 public health initiatives nationwide and are invaluable to
4 successful treatments for a variety of life-threatening illnesses
5 and conditions; now, therefore, be it

6 RESOLVED, That the Senate of the 78th Texas Legislature
7 hereby express support for the International Quality Plasma Program
8 and the Quality Standards of Excellence Assurance and Leadership
9 Program as important standards of certification that ensure that
10 only the highest quality plasma is collected and used for the
11 manufacture of plasma-derived therapeutic proteins; and, be it
12 further

13 RESOLVED, That the Texas Senate hereby encourage facilities
14 that collect plasma for fractionation into plasma therapeutic
15 proteins to become certified under the IQPP program, encourage
16 manufacturers that fractionate source plasma to become certified
17 under the QSEAL Program, and encourage health care professionals
18 and health plans that purchase or provide plasma proteins for
19 patient care to use products that meet rigorous quality control
20 standards such as those exemplified by the IQPP and QSEAL
21 certification programs.