

February 26, 2010

Reference No. SASC 10005-CA

The Honorable Fran Pavley
California State Senate
State Capitol, Room 4035
Sacramento, California 95814

Re: SB 971 (Pavley) - SUPPORT

Dear Senator Pavley:

The Plasma Protein Therapeutics Association (PPTA) extends its strong support for your bill (SB 971), the Standards of Service for Providers of Blood Clotting Products for Home Use Act, which would set treatment standards for persons with hemophilia and other bleeding disorders. People with bleeding disorders require access to high quality care in order to live long, productive lives. This bill would ensure that residents of California affected by bleeding disorders have access to their medically appropriate care.

The Plasma Protein Therapeutics Association (PPTA) represents the world's leading manufacturers of plasma-derived and recombinant biological therapies, collectively known as plasma protein therapies. These critical therapies are infused or injected by more than 1 million people worldwide to treat a variety of rare, life threatening diseases and serious medical conditions. PPTA members produce in excess of 80 percent of the plasma protein therapies used in the United States today and more than 60 percent worldwide. PPTA is a global trade association that administers international, voluntary standards programs to help ensure the highest quality and safety of plasma protein therapies and the plasma collected to manufacture them. Additionally, PPTA works in partnership with the patient community and consumer advocates to help ensure continued access to lifesaving plasma protein therapies.

Plasma protein therapies treat rare, life-threatening diseases and disorders. Lifesaving therapies produced by PPTA members include clotting factor therapies for individuals with bleeding disorders, immunoglobulins (IG) to treat complex diseases in persons with compromised immune systems and neurological disorders, and therapies for individuals who have alpha-1 anti-trypsin deficiency, which typically manifests as adult onset chronic obstructive pulmonary disease and substantially limits life expectancy.

As a matter of public policy, it is crucial that individuals in California are not denied timely access to the treatments they need to keep them functioning as productive members of society. Delayed access to clotting factor can cause painful and crippling injury to the joints and organs of someone living with hemophilia. Such complications often lead to increased costs for hospital, skilled nursing and other specialty services. This bill would ensure that Californians will have timely access to their medically appropriate therapy.

An individual with hemophilia should have access to the full range of FDA licensed clotting factor concentrates from the most medically appropriate provider. Specifically, the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF)—a leading patient organization for persons with bleeding disorders in the United States—has stated that, “Clotting factor therapies are neither pharmacologically nor therapeutically equivalent and vary based upon purity, half-life, recovery, method of manufacture, viral removal and inactivation processes, potential immunogenicity, and other attributes. The characteristics of each product and the resultant product choice for an individual patient require a complex decision making process with the ultimate product being agreed upon by the patient and their respective healthcare provider. It is critical that the bleeding disorders community has access to a diverse range of therapies and that prescriptions for specific clotting factor concentrates are respected and reimbursed.”¹>

SB 971 would ensure that individuals with bleeding disorders have unrestricted access to the full range of clotting factor therapies and ancillary infusion equipment and supplies. This access is essential for optimal treatment, because plasma protein therapies are distinct sole source products that have no generic biological equivalents and are not interchangeable. Furthermore, individual patients will react differently to therapies depending upon their unique health care needs.

SB 971 would also allow individuals to select providers that are familiar with the treatment of bleeding disorders. For example, many patients self-infuse clotting factor in their homes. The types of home supportive services that are required is a decision best made by the patient in consultation with his or her physician. Patients need options when selecting such services to ensure that they will receive the highest possible level of service and care.

We thank you for your great work on this important issue. If you should have any questions, comments, or concerns, please let me know.

Best Regards,



Bill Speir
Assistant Director, State Affairs

cc: Terri Cowger Hill

¹ MASASC Recommendation #159 (last visited August 14, 2008), available at <http://www.hemophilia.org/NHFWeb/MainPgs/MainNHF.aspx?menuid=57&contentid=179>