

February 26, 2010  
Reference No. SASC 10005-MO

Honorable Ron Richard  
Speaker of the House of Representatives  
201 West Capitol Avenue  
Room 308  
Jefferson City, MO 65101

**RE: Letter of support for HB 1525, Standards of Care for People with Bleeding Disorders**

Dear Speaker Richard:

The Plasma Protein Therapeutics Association (PPTA) extends its strong support for HB 1525, sponsored by Representative Schaaf, 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 Missouri 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 Missouri 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 will ensure Missouri citizens received their therapies in a timely manner.

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,

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"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."<sup>1</sup>

HB 1525 would ensure that individuals with bleeding disorders have unrestricted access to the full range of clotting factor therapies and ancillary infusion equipment and supplies. These standards are 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.

We thank you for your consideration of 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: Representative Rob Schaaf  
Mary Fleming, Gateway Hemophilia Foundation

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