



VIA EMAIL and U.S. Mail

March 4, 2013

Reference No. SASC 13006 MD SB 746

The Honorable Thomas M. Middleton
3 East Miller Senate Building
11 Bladen Street
Annapolis, MD 21401

RE: Letter of Support for SB 746, Health Insurance – Step Therapy or Fail-First Protocol

Dear Senator Middleton:

The Plasma Protein Therapeutics Association (PPTA) extends its strong support for SB 746, Health Insurance – Step Therapy or Fail-First Protocol, which limits the duration of a fail-first protocol for entities that pay for health benefits. It also allows for physicians to override the fail-first protocol to ensure that a patient gets the therapy that is medically appropriate. This bill is a step in the right direction of placing control of health care decisions in the hands of patients and providers where it belongs.

PPTA is the primary advocate for the world's leading Source plasma collectors and the producers of plasma-based and recombinant biological therapies. The medicines produced by PPTA members 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 α 1-antitrypsin 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 Maryland residents with conditions treated by plasma protein therapies receive the therapy that is most medically appropriate for them. PPTA believes this is a decision best made by the patient and the treating physician. Unfortunately, some health care payers in the private insurance market are usurping that decision and requiring the patients to fail-first on the lowest cost product in a therapeutic class before allowing a patient access to other therapies in that therapeutic class. This, many times, results in less than optimal health outcomes for the patient that may actually increase health care costs.

This is especially important with plasma protein therapies that are not interchangeable. Individuals that rely on plasma protein therapies must have access to their medically

appropriate therapy as determined by the physician. 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 individuals have access to a diverse range of therapies, including those that their provider prescribes. These decisions must be respected and reimbursed.

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 & 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 disorder community has access to a diverse range of therapies and that prescriptions for specific clotting factor concentrates are respected and reimbursed."¹

In fact, the federal Food and Drug Administration (FDA) has approved the various clotting factor therapies for distinct clinical indications. Some are intended to treat an absence of Factor VIII, while others are intended to treat an absence of Factor IX. Some treat von Willebrand's disease, while still others treat the body's resistance to Factor VIII or Factor IX. In addition, some are derived from human plasma, while others are recombinant, created from single cells.

The therapies in other plasma therapy categories are not pharmaceutically or therapeutically equivalent. Each IG therapy has been approved by the FDA for distinct clinical indications and each has distinct contraindications. Each has a very different shelf life, and each is prepared and administered in a distinct manner. Even each product's storage requirements and sugar content varies.

PPTA supports SB 746 because we see this as a step in the right direction towards protecting patients that rely on access to their medically appropriate plasma protein therapy from private health care payers. It is not appropriate for these patients to be put on fail-first or the least costly product before allowing them access to their medically appropriate product. The override language in this bill will help ensure that patients have access to their needed medications and result in positive health outcomes.

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

We thank you for your leadership in supporting this bill. If you should have any questions, comments, or concerns, please let me know. I may be reached at bspeir@pptaglobal.org or 443-433-1110.

Best Regards,



Bill Speir, Director of State Affairs