

## **Importation of Plasma Therapies is Not Practical and Will Not Improve Patient Access and Choice**

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### **Background**

In searching for ways to curb the rising cost of prescription drugs, a number of state and local governments are exploring the possibility of allowing consumers, and requiring beneficiaries in state-run health programs, to directly import drugs from Canada or other countries. While importation may result in consumer/state savings on traditional pharmaceuticals, there are a number of issues that make importation of plasma-derived and recombinant analog therapies (collectively, "plasma therapies") impossible and impractical. Additionally, there is no evidence that importation of plasma therapies would significantly improve patient access to and choice of therapies. The member companies of the Plasma Protein Therapeutics Association (PPTA) believe that importation of plasma therapies from foreign countries is not a practical cost-cutting model for consumers and state run health care programs.

### **About PPTA**

PPTA is the primary advocate for the world's leading producers of plasma therapies. Plasma therapies treat unique, life threatening diseases and disorders. Life-saving therapies produced by PPTA members include clotting factor therapies for individuals with bleeding disorders, intravenous immunoglobulins (IVIG) to treat complex diseases in persons with immune deficiencies and neurological disorders, and therapies for individuals who have alpha-1 anti-trypsin deficiency which typically manifests as Chronic Obstructive Pulmonary Disease (COPD) and substantially limits life expectancy. PPTA's member companies produce 80 percent of the plasma therapies used in the United States.

### **Quality and Safety**

Plasma therapies are unique, infused therapies. They are produced in adherence to a myriad of regulatory requirements and international industry standards. Direct to consumer importation of plasma therapies bypasses a critical component in the distribution chain, mainly a US-licensed pharmacy that is responsible for ensuring the authenticity of therapies that are provided to consumers.

In addition, plasma therapies have specific storage and shipping requirements, many of which are mandated by U.S. regulatory authorities. If consumers of plasma therapies have the ability or are required (in the case of state-run health care programs) to purchase their self-administered therapies directly from foreign countries, there can be no assurance that the distributing pharmacy will comply with

shipping and storage requirements. Further, a detailed report on the chain of custody is especially important. Failure to adhere with any of these shipping or storage requirements could negatively impact the effectiveness or safety of plasma therapies.

### **Access and Choice**

PPTA supports any initiative designed to improve patient access to and choice of plasma therapies. While on the surface it would appear that importation would increase patient access, in fact it may not. Questions about the authenticity of imported therapies may discourage patients from choosing certain therapies. The possibility of therapies being detained or delayed during the importation process could leave patients who rely on life-saving therapies without the therapy they need, when they need it. All of the proposed importation of traditional pharmaceuticals are designed for "maintenance" drugs that a consumer takes on a regular schedule and has advance notice of the need to refill the prescription. Plasma therapies are life-saving and life-sustaining therapies for those who rely on them. Any delay in patient receipt of plasma therapies could have significant consequences, including death.

### **Not Practical Cost Cutting Measure**

Plasma therapies are different from traditional pharmaceuticals. States looking to use importation of plasma therapies as a tool to decrease Medicaid spending should understand that Medicaid spending on all plasma therapies nationwide was just 1.5 percent of the total Medicaid prescription drug spending in 2001. The limited savings states may derive from the importation of plasma therapies will be vastly outweighed by quality, safety, access and choice issues Medicaid recipients may face.

### **Conclusion**

Importation of certain pharmaceutical products is a potential solution to reducing prescription drug costs for consumers and state and local governments. However, quality and safety concerns make importation of plasma therapies impossible. Additionally, there is no guarantee importation will improve patient access and choice to plasma therapies, or produce significant patient or Medicaid cost savings. In short, importation is not the cost containment answer for plasma therapies.