

Principles for the Establishment of Prescription Drug Pedigree Requirements for Plasma Protein Therapies

Plasma protein therapies, which include albumin, blood clotting factor, alpha-1 antitrypsin, and intravenous immunoglobulin, among others, are lifesaving therapies used to treat a variety of orphan diseases and serious medical conditions for a very small, often compromised patient population in the United States. These therapies are biologics, which require special handling, storage, and shipping conditions. Congress and the Food and Drug Administration (“FDA”) must consider the complexity of these lifesaving therapies when considering a law directed at comprehensive, national prescription drug distribution, and the subsequent regulations promulgating such law.

PPTA member companies are committed to protecting the public health against counterfeit, misbranded, or adulterated versions of their therapies. As such, PPTA supports the following principles with respect to the establishment of a federal prescription drug pedigree requirement:

- The establishment of a uniform, national prescription drug pedigree standard that preempts existing and future State laws and regulations with regard to pedigree.
- The implementation of a manufacturer generated unique numerical identifier applied to each prescription drug package, as defined as the unit of sale in which a drug may be received by a pharmacy or other entity authorized to acquire or possess prescription drugs.
- Manufacturer discretion in the development and implementation of product identity and tracking technologies.
- The creation of a federal prescription drug wholesaler licensing requirement that preempts existing and future State laws and regulations with regard to wholesaler licensing. Any entity distributing plasma protein therapies must not only maintain a wholesale license in good standing, but also be an authorized distributor of the manufacturer for whose product it is distributing.

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PPTA urges Congress and the FDA to give consideration to the technological hurdles associated with manufacturer compliance with both product serialization and tracking technologies, including the eventual linkage of such technologies to an interoperable health information technology system database. In transitioning toward full compliance, PPTA believes a national standard may be satisfied with a manufacturer’s packing list, invoice, or comparable document at the start of the pedigree, subsequent distributor electronic or paper pedigree, and manufacturer maintenance and Web site publication of its list of authorized distributors.

PPTA member companies are committed to ensuring the safety and efficacy of the therapies they produce, and remain vigilant and dedicated to anti-counterfeiting and product tracking initiatives in the distribution channel.