

December 19, 2007
Reference No.: SASC07073

VIA FIRST CLASS MAIL

Mr. William Powers
President
California Board of Pharmacy
1625 N Market Blvd, N219
Sacramento, CA 95834

Dear Mr. Powers,

On behalf of the Plasma Protein Therapeutics Association (PPTA), I am writing to request that you exercise your statutorily granted discretion as codified in the California Business and Professions Code and delay implementation of the substantive aspects of California's Pedigree requirements until January 1, 2011. Patients that rely upon life-saving plasma-derived and recombinant analog therapies (collectively, "plasma protein therapies") cannot risk any disruption to their access to care. In this instance erring on the side of caution by delaying implementation and putting access to care first for the chronically ill patient populations treated with plasma protein therapies should be paramount.

PPTA is the primary advocate for the world's leading producers of plasma-derived and recombinant analog therapies. Plasma protein therapies, which include albumin, blood clotting factor, alpha-1 proteinase inhibitors and intravenous immunoglobulin, among others, are lifesaving therapies used to treat a variety of rare diseases and serious medical conditions for a very small, often compromised patient population in the United States. The complexity of biologics must be taken into account when considering a law directed at comprehensive prescription drug distribution. PPTA members are committed to ensuring the safety and availability of these medically needed life-sustaining therapies.

The California Business and Professions Code defines Pedigree as "a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer through acquisition and sale by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. The pedigree shall be created and maintained in an interoperable electronic system ensuring compatibility throughout all stages of distribution." CAL BUS. & PROF. CODE § 4034(a). We would like to note at the outset that as the primary association representing the leading manufacturers of plasma protein therapies, PPTA is committed to maintaining the integrity of the distribution channel in California and, more broadly, globally. We take the potential of counterfeit therapies very seriously and individual companies have taken numerous concrete steps to guard against such threats as patient safety. PPTA manufacturers view patient safety as their highest priority.

PPTA is concerned, however, that the interoperability requirements, as codified in Section 4034 might lead to disruptions in the supply channel should the January 1, 2009 implementation date be maintained. Specifically, we believe that many downstream providers, particularly those in

rural parts of the state will not be able to comply with the pedigree requirements resulting in difficulties accessing therapies for patients who depend upon them to lead normal healthy, productive lives. Therefore, an adverse impact on patients who utilize plasma protein therapies may be an unintended consequence of attempting to ensure the integrity of the distribution channel. PPTA respectfully requests that the Board keep this issue in mind when considering the January 1, 2009 implementation date.

Section 4034 defines “interoperable electronic system” as “an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture, contained within a standardized nonproprietary data format and architecture that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug.” CAL BUS. & PROF. CODE § 4034(i). We believe that downstream providers, such as some individual pharmacies referenced in the statute may not be able to comply with these requirements resulting in potential disruptions to access. It should be noted that we believe that interoperable system is essential to ensuring the integrity of the channel. Our concern is that such a system may not feasibly be in place 12 months from now.

For the purpose of a standard for product serialization, PPTA supports a requirement for manufacturers to apply a unique numerical identifier 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. PPTA believes that the timing for compliance with this requirement must take into account the technological hurdles including engineering changes, and emerging labeling technologies.

While there are several counterfeit-resistant technologies successfully employed by the Bureau of Engraving and Printing as well as radio frequency technology, nanotechnology, and encryption technology available for manufacturers to use, PPTA believes the technologies used to identify and track prescription drugs must be selected at the discretion of the manufacturers in order to best ensure the safety and efficacy of the drug. The selected technology should eventually be linked to an interoperable health information technology system database by its numerical identifier. The timing of such linkage must be consistent with the engineering changes required for implementation.

PPTA greatly appreciates the opportunity to comment on the implementation of the California pedigree law. PPTA hopes to be part of the dialog with the Board as it continues to work with the issues associated with implementation of this important law for the residence of California. Should you have any questions, or if you require additional information, please do not hesitate to contact me at (202) 789-3100 or by email at rfaden@pptaglobal.org.

Very truly yours,

Ryan M. Faden, JD, MPH
Assistant Director, State Affairs