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Dockets Management Branch, HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

VIA E-Mail & USPS

SUBJECT: Docket No. 2005N-0510, Anti-Counterfeit Drug Initiative Workshop and Vendor Display

Dear Sir or Madam:

The Plasma Protein Therapeutics Association (PPTA) is pleased to provide these comments on the Food and Drug Administration's (FDA) Anti-Counterfeit Drug Initiative Workshop and Vendor Display [hereinafter, "Workshop"]. PPTA is the international trade association and standards-setting organization for the world's major producers of plasma-derived and recombinant analog therapies. Our members provide 60 percent of the world's needs for Source Plasma and protein therapies. These include clotting therapies for individuals with bleeding disorders, immunoglobulins to treat a complex of diseases in persons with immune deficiencies, therapies for individuals who have alpha-1 anti-trypsin deficiency which typically manifests as adult onset emphysema and substantially limits life expectancy, and albumin which is used in emergency room settings to treat individuals with shock, trauma, burns, and other conditions. PPTA members are committed to assuring the safety and availability of these medically needed life-sustaining therapies.

PPTA applauds FDA on its unrelenting efforts to combat the counterfeit drug problem in America. FDA's guidance coupled with work initiated by manufacturers, distributors, and others have made America's drug supply one of the safest in the world. These efforts have significantly decreased the chance of counterfeit drugs entering the U.S. market. However, vigilance by all parties is necessary to ensure patients continue to receive safe and efficacious therapies. By holding this Workshop, FDA demonstrates that it is committed to working with industry to solve this problem.

PPTA agrees with many of the opinions expressed at the Workshop. For example, that there is no single solution for solving the counterfeit problem and a multi-layered approach with many different components must be used to address it. We specifically support statements made by companies that place patient safety as their highest priority. As a result, PPTA evaluates FDA's recommendation of widespread adoption for Radio Frequency Identification (RFID) in the U.S. drug supply chain by 2007, from the perspective of whether RFID will assist or inhibit access for consumers to safe and efficacious therapies.

A tremendous amount of evidence supports the view that RFID, if fully implemented from the manufacturer to the pharmacist, would reduce the number of counterfeit drugs that enter the supply chain. However, complete implementation by 2007 of RFID presents a number of

problems that may result in inadvertent, detrimental consequences. The following are some issues that need to be examined and resolved before implementation.

- Limitations of RFID technology – many questions remain regarding the impact certain surrounding environmental conditions may have on tag readability. Any inaccuracies in readability would decrease efficiency, increase processing time, and ultimately prolong a consumer's ability to obtain therapies.
- Uniform adoption of RFID technology – RFID technology will only be successful if all members of the supply chain are participants. In theory, it may seem plausible to require all companies to use RFID but due to individual business limitations this may not be feasible. Without full participation, the benefit of this track and trace technology will be lost.
- Cost – to implement RFID, companies would have to invest a large amount of capital. PPTA represents only a small specialized portion of the drug manufacturing industry. Furthermore, many of these companies' therapies are distributed through small specialty distribution channels. Due to the uniqueness of our members and their supply chains any increase in cost the manufacturer or distributor incurs may be passed directly on to the patient. PPTA requests careful consideration of any initiative that would place a further burden on the patients who need life-saving therapies.
- Repackaging – PPTA in previous comments urged FDA to increase oversight on repackaging; we reiterate such sentiments today. Even though PPTA companies supply predominately inject-able or infusible products that may not be inherently subject to the same repackaging concerns as other pharmaceuticals, we remain concerned about the opportunities repackaging offers to counterfeiters. A clear plan must be developed to make certain RFID technology is not discarded during repackaging, which may enable a counterfeiter additional chances to infiltrate the supply chain.
- Lastly, effects of RFID technology on biologics – PPTA is particularly concerned with the possible effects RFID technology may have on biologics. In 2005, FDA updated its final report titled, "Combating Counterfeit Drugs, A Report of the Food and Drug Administration". In addition, to voicing continued support for efforts made toward the development of an "electronic safety net" by 2007, the report recognized the effects of RFID on biologics were uncertain. FDA stated to obtain a better understanding, studies were currently being conducted by the Product Quality Research Institute and FDA's Center for Devices and Radiological Health. PPTA commends FDA for recognizing the uniqueness of biologics and looks forward to reviewing these results.

Due to the uncertainty of RFID on biologics and the lack of answers available regarding issues raised above, PPTA can not endorse the implementation of RFID technology by 2007. Moreover, FDA should leave the decision to the manufacturers, who know their products and business practices best, to determine the correct counterfeit technology to implement. However, PPTA does believe FDA should continue to foster programs that encourage the use of RFID technology and guide the industry in making their decisions. PPTA is committed to working on this issue and looks forward to FDA's assistance in finding solutions to the counterfeit problem.

In addition to requesting opinions regarding RFID, FDA sought additional information about the Prescription Drug Marketing Act (PDMA) and the use of e-pedigree. While PPTA cannot speak directly to all the questions posed in this section of the Federal Register, published on January 11, 2006 (Vol. 71, No. 7 pg. 1761), we do reiterate the overwhelming view expressed at the Workshop – there is a clear need for federal guidance. In the absence of appropriate federal guidelines, some states, including California, Florida, and Indiana have begun to enact pedigree legislation. At the workshop, the panel on state efforts illustrated the substantial variation in state approaches to pedigree legislation. If states continue to enact such distinct legislation, an undue burden will be placed on America's drug supply chain, potentially compromising consumer access to therapies. PPTA encourages FDA to provide a uniform pedigree standard, which would function as a model to be utilized in crafting state legislation. This will help avoid inconsistent, costly, and onerous requirements being placed on the drug supply chain.

As stated above, PPTA commends FDA's continued efforts to combat the proliferating counterfeit problem. We know that, with FDA's guidance and enforcement capabilities along with industry's continued vigilance and use of new technologies, America's drug supply will remain the safest in the world. PPTA appreciates the opportunity to comment on the Workshop and looks forward to working with FDA on this important issue. Should you have questions regarding these comments or would like to discuss these issues further, please contact me at the Association. Thank you for your consideration.

Respectfully submitted,



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