PPTA
Plasma Protein Therapeutics Association

October 29, 2003

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VIA USPS AND E-MAIL

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

SUBJECT: Docket No. 2003N-0361, Federal Register: August 26, 2003 (Volume 68, Number 165, p. 51270); FDA Counterfeit Drug Task Force: Interim Report, "Safe and Secure."

Dear Sir or Madam:

PPTA is pleased to provide these comments on the Food and Drug Administration's (FDA's) Counterfeit Drug Task Force Interim Report, entitled "Safe and Secure" (hereinafter "Interim Report"). The Plasma Protein Therapeutics Association (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 would like to congratulate FDA in initiating action on this important topic and in assembling the Counterfeit Drug Task Force (hereinafter "Task Force.") FDA has shown commendable initiative and foresight in creating the Task Force, marshaling preliminary data, providing an early public hearing, and moving quickly and with resolve to combat the growing number of counterfeit therapies.

PPTA agrees with FDA that the counterfeiting arena is a fluid one, with ever-changing methods and shifting endpoints. A number of presenters at the Public Hearing of

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October 15, 2003 stated that there is no "magic bullet" solution to the counterfeit problem, and a multi-prong approach must be used to address it. Those who presented at the October 15 Hearing showed many interesting methods of combating counterfeiting at different levels, while others demonstrated the importance of containing counterfeiting.

PPTA believes that FDA's first steps in identifying the counterfeit medication problem are crucial. Already, FDA has presented data showing that counterfeit medications are rampant in certain countries. These same data show that, currently, the United States faces only a small –but growing—amount of counterfeit pharmaceuticals. Further data gathering should be geared toward increasing government and industry perspective on the issue, and allow a more comprehensive view of the counterfeiting problem and tailor solutions accordingly. FDA should liaise with other government agencies, such as the Bureau of Customs, to increase its database and focus on enforcement targets. After more data have been gathered and analyzed, the FDA can determine an appropriate level of safety.

PPTA is not convinced that the "high-tech" solution is always the best or permanent one. In many cases, a "low-tech" solution may provide complete anti-counterfeiting coverage. The difficulty at this point in time is that we simply do not know what will work, and it is important to allow the solutions to be as fluid and easily adjusted as the problem itself. After more data have been gathered and the FDA identifies a level of safety, it should be left to industry to determine the methods of achieving this goal. Manufacturers are closest to the product in terms of its chemical construction, its ability to be handled, dosage forms, and so on. Armed with robust FDA data, the manufacturer will be in an ideal position to partner with FDA and combat the counterfeiting problem through a variety of modalities.

PPTA urges FDA to increase its oversight over re-packaging, which, as the Task Force noted in its Interim Report, contributes to the so-called "gray-market." PPTA member companies supply predominantly injectable or infusible products that may not be inherently subject to the same re-packaging concerns as other pharmaceuticals, but PPTA understands that the current re-packaging system is essential for efficient pharmaceutical distribution. Thus, complete elimination of the system is neither currently feasible or in the interest of patient care. PPTA would like to point out that drug re-importation, as has been initiated in some form or another by a number of states, opens an entirely new realm of gray market and may also open the door for an onslaught of counterfeit pharmaceuticals.

PPTA will gladly work with FDA on finding both immediate and long-term solutions to the public health threat that counterfeit prescription medications present. As stated

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above, PPTA applauds FDA's actions to date in this regard and is eager to make a meaningful contribution to the anti-counterfeiting effort. We believe that it will be a productive relationship, with FDA's enforcement capabilities and widespread knowledge over products in the global marketplace, and with industry's help in ensuring practical, feasible solutions which benefit the patient populations at risk.

PPTA appreciates the opportunity to comment on the Interim Report and looks forward to working with FDA in the future 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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Plasma Protein Therapeutics Association