

International Plasma Products Industry Association

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

RE: Comments on FDA Advanced Notice of Proposed Rulemaking on Requirements for Tracking and Notification for Plasma Derivatives and Other Blood Products (Docket No. 98N-0815)

**Submitted by the
International Plasma Products Industry Association**

Introduction

The International Plasma Products Industry Association (IPPIA) is pleased to provide these comments to the Food and Drug Administration (FDA) on the Advanced Notice of Proposed Rulemaking (ANPR) on Requirements for Tracking and Notification for Plasma Derivatives and Other Blood Products. IPPIA is the trade association representing the major commercial producers of plasma derivatives including Alpha Therapeutic Corp., Baxter Healthcare, Bayer, and Centeon. Our comments will first focus on a unique voluntary system developed by the plasma therapeutics industry aimed at providing patient access to withdrawal and recall information. We will then provide more specific comments on the questions posed by the agency in the ANPR.

Existing Framework for Patient Notification

The IPPIA Patient Notification System (PNS) was developed by IPPIA in response to consumer requests for better access to information about plasma product recalls and withdrawals. Lengthy discussions with consumers and their advocates identified a need for better communication of this information to interested individuals. However, these discussions also raised several important privacy, logistical, and legal issues which we believe are addressed by our system.

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Typically, manufacturers do not have direct access to information regarding the identities of patients purchasing their therapies. Information regarding product recalls or withdrawals must therefore flow along the same distribution chain as the products: from manufacturer to distributor to pharmacy or hospital and ultimately to the patient. This chain, which largely remains the same today, hinders the ability of end-users to gain timely access to information on product withdrawals and recalls as the information must be passed from manufacturer to distributor and so on down the chain. Another barrier in this process is that current laws and regulations do not explicitly require that records be kept (including lot numbers) down to the patient level. Without this requirement, direct patient notification through the current system is often not possible. It should be noted, however, that this chain serves a highly important purpose to the patient; it preserves the confidentiality of product administration.

Voluntary Industry Patient Notification System

In order to provide access to withdrawal and recall information for consumers and other interested parties, IPPIA, working in close cooperation with consumer advocacy groups, instituted a voluntary direct to consumer notification system that works around the substantial limitations discussed above. While the word "voluntary" describes the industry participation in this system, it is important to understand that the participation of consumers and other interested parties in this system is also voluntary. With this in mind, the goals of the PNS can be stated as follows:

- 1) To make information on plasma derivative recalls and withdrawals available to all interested parties in one convenient site; and
- 2) To rapidly notify those interested parties *who choose to be so notified* of plasma derivative recalls or withdrawals.

PNS Description

The PNS is divided into two basic areas: outbound notification and dial-in inquiries. Outbound notification requires an individual to confidentially register with the system by providing certain contact information. The individual is able to choose the type of product and the method of notification most convenient: telephone, fax, e-mail, or overnight notification. The system is designed to provide notification to registrants within 24 hours of an event through one of these methods. Additionally, telephone, fax and e-mail recipients receive a first class letter to ensure receipt of this information.

Dial-in notification allows any user to call a toll-free number to hear a list of the most recent recalls or withdrawals. The user may also choose to be directly connected to a manufacturer for additional information on a particular product or recall. A third option under development will allow the user to verify the regulatory status of a particular lot number. This section will enable an individual to check the recall status of a particular vial of product before it is infused.

To ensure the confidentiality of the system, the PNS is operated by an independent organization that has expertise and specializes in pharmaceutical notifications. All registrants' names and contact information are strictly confidential. This confidential information is maintained for the sole purpose of notifying individuals of plasma product recalls or withdrawals through the PNS, and it will not be disclosed to any other party or used for any other purpose.

The PNS is administered by IPPIA, and is supported and funded by all major plasma fractionators and distributors: Alpha Therapeutic Corporation, American Red Cross, Baxter Health Care Corporation, Bayer Corporation, Centeon LLC, Genetics Institute, and Novartis Pharmaceuticals. Participation is free to all consumers, health care providers and other interested parties. Additionally, an advisory panel consisting of consumer representatives and industry participants provides input to the association regarding the current operation and potential improvements to the system.

Effectiveness of PNS

The PNS is a very effective system for meeting the goals discussed above. The dial-in system has been on-line since October 1998 with no down time. It is available 24 hours a day to provide access to recall and withdrawal information. Regarding outbound notification, results from the last five events show that over 90 percent of applicable registrants were notified of an event within 24 hours.

We believe that the IPPIA PNS is a very successful program and will only become more so as patients and other interested parties are made aware of its existence. IPPIA is developing a comprehensive communications plan to provide this awareness in cooperation with interested patient advocacy groups. IPPIA believes that our current voluntary system provides access to important recall and withdrawal information in as effective a manner as possible while still safeguarding patient confidentiality. We do not believe that regulation of this or an alternative system will offer significant improvement over the current, efficient system that is already in place.

Specific Comments Requested by FDA: Concepts of the Proposed Rulemaking

As discussed above, IPPIA believes that no regulatory action regarding patient notification is required at this time. However, the following specific comments are provided in response to the request by FDA:

- A-B. Scope of Regulations – Types of Products, Reasons for Notification
The FDA has suggested that the criteria for notification of recalls should be instances of potential increased risk of communicable disease. It should be noted that while the industry is aware that the risk of viral transmission can never be completely eliminated from therapies produced from human source material, current plasma

derivative formulations have an outstanding viral safety record. Additionally, products made from recombinant technology provide even less viral risk. For these reasons, IPPIA believes it is not necessary to develop notification regulations, especially in light of the voluntary efforts developed by the industry to provide this information.

C. Who Should Be Responsible for Notification and Related Tracking Responsibilities

While the manufacturer is ultimately responsible for its product, the current information systems regarding distribution of product do not always provide adequate means for manufactures to directly notify patients of recalls. Any regulatory requirement must focus on those entities that have direct access to patients, namely pharmacies, home healthcare companies, and others who provide these therapies directly to patients and for whom issues of patient confidentiality are not an issue for consumers.

D. Tracking of the Consignment of Applicable Plasma Derivatives

IPPIA believes that tracking products from manufacturer to consumer raises substantial privacy issues. IPPIA recommends that any regulatory action focus on those entities closest to the patients as discussed above.

E. Initiation of Notification

IPPIA believes that any notification, either under a future regulatory system, or a notification conducted under current guidelines, must be made as a joint decision between a product manufacturer and the FDA.

F. Timing of Notification

IPPIA agrees with the agency that the timing of notification is an important matter, and should be done as soon as possible. However, IPPIA believes that the FDA and the manufacturer need to develop a clear timeline so that the manufacturer has an opportunity to begin its notification process before FDA posts information on its web site. Without further details as to how the agency would mandate notification, we can not provide more specific comments. The agency's suggestion of two days may be reasonable if the notifying entity, such as a pharmacy or hospital, already has the patient information readily available. However, significantly more time will be required if a manufacturer needs to collect patient information for each notification. This is further complicated by the issues raised in section "D", above.

G. Who Should Be Notified

IPPIA believes any rulemaking should only require notification of those individuals who actually received the product in question.

H. Information Included in a Notification of Patients

IPPIA believes the information discussed in the ADPR is adequate. We also suggest that the information for patients should be developed jointly between the manufacturer and the FDA.

I. Adequacy of the Notification Process

IPPIA agrees that any notification system should have a means for evaluating its effectiveness. However, this system must be developed by the entity initiating the notification.

J. Relationship of Notification With Product Recalls and Withdrawals

While the notification envisioned in this ANPR is related to withdrawals and recalls, it is important to define the differences between the two as well. First, the ANPR deals with providing certain notifications to patients, while recalls or withdrawals are a means to remove product from the market. However, it must be clear that only instances that would trigger a product withdrawal or recall should be considered for any type of patient notification, either voluntary or mandated by regulation.

Second, it is unclear at this time how a notification will get to the patient, but unless it comes from the final link in the distribution chain, the processes for recalls and patient notification will be different. For example, in the IPPIA voluntary PNS, the information comes from a manufacturer and flows through a third party to the patient. However, recalled products must be retrieved through the distribution chain, which may not be the notifying entity. The relationship between notification and recalls will therefore depend on the framework of any potential regulation.

K. Informing patients of the Notification Process

IPPIA believes that informing patients of a notification process is an important aspect of any system, voluntary or mandatory. IPPIA would be pleased to work with the agency in developing standardized information for plasma derivatives that would include information on the IPPIA voluntary PNS.

IPPIA appreciates this opportunity to comment on this ANPR. We believe that the voluntary PNS is an adequate system for providing direct to consumer notification for plasma derivatives and that there is no need for additional

rulemaking directed at product manufacturers at this time. Please feel free to contact IPPIA if there are additional questions regarding this letter or if further information is needed.

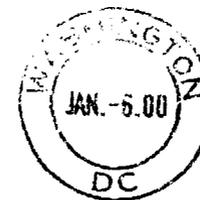
Sincerely,

A handwritten signature in black ink, appearing to read "Jason Bablak", with a long horizontal flourish extending to the right.

Jason Bablak
Director, Regulatory Affairs



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