



American Red Cross

National Headquarters

December 21, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers lane, rm. 1061
Rockville, MD 20852

**RE: Plasma Derivatives and Other Blood-Derived Products;
Requirements for Tracking and Notification; Advance Notice of
Proposed Rulemaking [(August 19, 1999) (Docket No. 98N-
0815)]**

Dear Docket Officer:

On behalf of the American Red Cross (ARC or Red Cross), this letter is to provide public comments concerning the Food and Drug Administration's (FDA or Agency) Advanced Notice of Proposed Rulemaking (ANPRM) published on August 19, 1999.

The ANPRM outlines FDA's intentions to propose regulations "requiring that certain blood-derived products, including certain plasma derivatives, be tracked from a U.S. licensed manufacturer, through the distribution network, to any patient having custody of the product." FDA further explains that they intend "to require notification of consignees and patients having custody of a blood-derived product or an analogous recombinant product in the event the product is associated with a potential increased risk of transmitting a communicable disease, as determined by FDA or by a U.S. licensed manufacturer. The regulations would also apply to any blood-derived product which, in the future, may be routinely dispensed to the patient and held by the patient prior to administration."

The Red Cross is an independent non-profit corporation and the largest provider of blood services in the United States. Each year, the Red Cross collects almost 6 million units of whole blood from volunteer donors, representing approximately 45 percent of the nation's blood supply.

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Approximately 1,000,000 liters of plasma recovered from Red Cross volunteer blood donors are processed annually, or fractionated, into plasma derivatives. These plasma derivative products are distributed under the Red Cross label to hospitals, hemophilia treatment centers, group purchasing organizations, pharmacies, home care companies, insurance companies, and third-party distributors.

Because of its role in providing blood products and services including the plasma-derived derivatives that would be subject to the rulemaking, the Red Cross has a considerable interest in the proposed regulation and appreciates the opportunity to provide public comments to the FDA.

Industry-wide Patient Notification System

Red Cross agrees with the Agency that a system to notify patients in the event of a product recall is appropriate. However, there are certain circumstances surrounding a mandated patient notification system that may add considerable complexity given patient confidentiality and other considerations.

Currently, the Red Cross participates in a voluntary, industry-wide patient notification system along with other plasma derivative manufacturers. The industry-wide system was modeled after the Red Cross patient notification system allowing voluntary registrants (both patients and healthcare professionals) to learn about product recalls/withdrawals from their method of choice (email, phone, fax, overnight express mail, etc.) The industry-wide system officially launched at the National Hemophilia Foundation Annual Meeting in Orlando in October 1998. The Red Cross feels that this industry-wide system meets the intentions of FDA's ANPRM and we believe is likely to be as effective in the long run in reaching the intended patients as the alternative program that FDA is considering.

Below, ARC will describe this program and our views on its value to patients, manufacturers, and FDA. We will also describe suggestions for FDA's consideration for future activities in terms of patient notification.

Voluntary Efforts

In recognition of the need to develop a system for informing patients of product withdrawals, ARC developed a nationwide system in January 1998. This system then rolled into an industry-wide system led by the International Plasma Products Industry Association (IPPIA) on behalf of most all plasma manufacturers in the United States. This system provides recall/withdrawal notifications to voluntary registrants (patients, families, and healthcare professionals) who might be in possession of a product that has been recalled or withdrawn.

This industry-wide system is managed by a confidential, third-party organization called the National Notification Center (NNC). Therefore, no manufacturer has access to the registrants' information. During the development of the system, patient advocacy groups indicated that patients wanted a third-party to manage the system so that manufacturers would not be privy to their personal information (address, product usage, etc.).

As a result of this input from the patient groups, the system is managed by NNC. NNC maintains a database containing manufacturers' products that have been withdrawn/recalled, the lot numbers, and names and locations of patients and healthcare providers who have voluntarily agreed to participate.

The participating patients who have enrolled in the system are typically patients who have hemophilia A, hemophilia B, immune deficiencies, alpha antitrypsin deficiencies to name a few. Many of these patients self-administer their plasma product as they are all typically chronic users of plasma derivatives. Patients have learned about the industry-wide patient notification system via their physician, nurse coordinator, home care company, awareness campaign launched by the IPPIA and the participating manufacturers, articles and support from the patient groups, direct mail, and trade show promotion.

The participating patients provide NNC, their mailing address, an indication of the patients they wish to receive notifications for, and choose a notification method, such as fax, phone, email, or overnight express letter. At the time of a product recall/withdrawal, the manufacturer contacts NNC and NNC then notifies the individual patients to inform them of the product withdrawal or recall.

Participating manufacturers are continuing efforts to keep potential participants informed of the notification system. Given the industry-wide system's ability to reach out to the patients the FDA is trying to cover, the Red Cross asks FDA to reconsider the need for a regulated system. Specifically, the Red Cross believes that there are several risks and issues that would ensue if a new, regulated system were mandated.

First, a regulated system may not be as effective as the existing voluntary program. The current voluntary program is well established; and, patients and physicians are familiar with it. Changing to a regulated may not achieve the level of effectiveness of the current voluntary one. For example, there is no guarantee that a regulated system will reach all patients, since many patients will not want to divulge their personal information to a manufacturer or even an independent, third-party handling the notification process. It is critical to point out that many patients do not want to share their personal information, (name, address, product they use, etc.) for confidentiality reasons. Many patients will be resistant to sharing the information necessary to be able to contact them during a withdrawal or recall. Thus, we would be substituting a known system that is effective for one an unknown and untested one.

Second, there may be some confusion on the part of patients and physicians, and possibly on the part of the fractionators and distributors, as to which system was required versus which was voluntary. The need to avoid misunderstandings, or potential duplication, coupled with the resource constraints that would be entailed by maintaining two systems, we anticipate that most manufacturers and distributors would discontinue the current voluntary program. Manufacturers and distributors would probably not want to pay for two systems that perform the same functions.

More importantly, the patients and the patient groups would most likely want only one notification system so as to avoid confusion. In fact, the reason the industry-wide system was launched was so to minimize confusion for the patients. Having one system would require patients and their healthcare providers to enroll in one system, memorize one phone number, and rely on one system to inform them of all withdrawals/recalls in their category of choice. We believe that ending the current voluntary program would not be in the best interest of the parties involved, particularly the patients.

Safety Concerns

Red Cross believes that the initial concerns that may have given rise to the ANPRM a few years ago have been somewhat alleviated since then. The safety of the blood supply is increasing over time as evidenced by a decrease in the number of transfusion transmitted disease cases. Also, there is an increase in the sensitivity and specificity as of tests available to detect transmissible diseases. Implementation of the new Nucleic Acid Test (NAT) is a good example of these improvements.

Red Cross is not implying that we should relax our vigilance. FDA and all blood and plasma establishments should support research and investigate other methods for continuously improving the blood and plasma derivative supply. However, these improvements, along with the voluntary system described above, help strengthen the industry's and FDA's ability to reassure patients that multiple mechanisms for ensuring their safety continue to be identified and implemented.

Patient Issues

First, as indicated above, patient confidentiality is a very serious consideration in the decision to launch a mandatory notification system. Many patients will refuse to provide their personal information and we are unaware of any mechanism that would force a patient to comply so that they learn about product withdrawals and recalls.

Second, FDA does not have regulatory authority over hospitals and other distribution channels, so that they cannot mandate compliance. Without an ability to ensure full compliance, the value of such a requirement is limited.

Recommended Alternatives to the ANPRM

(1) Working with the IPPIA and the other participating manufacturers/distributors in the industry-wide system, the Red Cross is willing to expand advertising and information dissemination about the current voluntary system.

(2) If FDA believes it still must regulate patient notification, we suggest the regulation require all manufacturers to participate in the voluntary program. We also recommend that the regulated system be built upon the current industry-wide system so as to maximize efficiencies, benefit from the learning experience for developing an effective system, and to prevent "recreating the wheel."

In closing, the Red Cross appreciates the opportunity to submit its views on the ANPRM to the FDA. If there are any questions on this letter, please contact Anita Ducca, Director, and Regulatory Relations, at 703-312-5601.

Sincerely,



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