



**America's Blood  
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OUR MEMBERS SERVE COMMUNITIES NATIONWIDE

**Food and Drug Administration Public Hearing on the  
Regulations Implementing the Prescription Drug Marketing Act  
October 27, 2000**

**Presented by Jim MacPherson, Chief Executive Officer**

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ABC is the national association of not-for-profit regional and community blood centers that are responsible for providing nearly half of the nation's volunteer donor blood supply. Founded in 1962, ABC, through its members, is committed to ensuring the optimal supply of blood, blood components, and blood derivatives, and to fostering the development of a comprehensive range of the highest quality blood services in communities nationwide.

ABC has been an active participant in FDA's Prescription Drug Marketing Act of 1987 ("PDMA") rulemaking process and welcomes this opportunity to again address the status of blood centers under the final rule.

In our statement today, we will address the specific questions posed by the agency in their Federal Register notice announcing this hearing that pertain to the distribution of blood derivatives by blood centers and other health care entities.

**1. What distribution systems are available for blood derived products? Do these distribution systems differ from those for other types of prescription drugs? If so, how?**

Over 15% of all US plasma derivatives are distributed to hospitals and hemophilia treatment centers by community and Red Cross blood centers. In most instances, these supply relationships date back for 30 to 50 years. Originally, these relationships arose because blood centers provided plasma. As pharmaceutical-based blood derivatives began replacing plasma for transfusion, some blood centers and hospitals allowed these derivatives to be fed into the hospital pharmacy to be distributed like drugs. But many hospitals and hemophilia treatment centers wanted blood centers to maintain their role as neutral and community-based providers of all blood products, whether these products be for transfusion or other therapeutic use by patients. Consequently, hospitals came to rely on the expertise of many blood centers in fulfilling the majority of their blood product, laboratory service and expert medical consultative needs for all licensed blood and plasma products, including Albumin, Immune Globulin (intravenous and intramuscular) and Anti-hemophilic Factor ("Factor VIII").

Of critical value to hospitals is that the blood center, as a neutral and not-for-profit entity, is able to distribute products in short supply equitably throughout the community it serves, preventing hoarding of products by hospitals, preventing gouging in times of shortages, and providing for the smooth transfer of products as needed between hospitals. This role has been especially valuable over the recent past given the critical shortages of IVIG and alpha-1 anti-trypsin.

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It is also important to emphasize that community blood centers have recall, tracking and distribution systems for their blood components and blood derivatives. These are services that many hospitals find to be of great value and that manufacturers of derivatives or commercial distributors do not offer.

**2. What effect would the PDMA final rule, as published, have on the distribution system for blood-derived products? What, if any, adverse public health consequences would result? What would be the economic costs to manufacturers, distributors, and consumers of blood-derived products?**

The blood center-hospital relationships that I outlined in response to the first question have been successful and play a crucial role in scores of communities across America. If the regulations implementing PDMA stand as written, these time-honored relationships would be replaced by untried mechanisms of derivative distribution. For example, PDMA regulations would prohibit a 20 plus-year arrangement between the New York Blood Center and three federally-funded hemophilia treatment centers, which provides products to patients in an efficient and cost-effective way. Through this arrangement, the New York Blood Center supports services such as delivery of the products to the patients' homes and pick up and disposal of biological wastes such as contaminated infusion sets and vials. The patients are extremely happy with the services, and the physicians are pleased with the solid support. Similarly, a hemophilia treatment center program began by the Puget Sound Blood Center in 1974 provides care for some 900 patients with congenital bleeding disorders in Washington, Northern Idaho & Montana. Access to effective treatment for these patients will be similarly disrupted if the PDMA regulations prohibit blood centers from distributing these products. No purpose is served by preventing blood centers that already provide blood and components for use by patients from distributing critical care products to the same patients.

Regarding the direct "health care entity" role of blood centers, which is the reason they would be prohibited from distributing blood derivatives under the PDMA implementation regulations, most blood centers provide a very limited amount (i.e., less than 5% of all activity) of direct health care. However, these services are critical to public health in that they provide patients access to a higher level of expertise than would be possible to obtain or practical to maintain at individual community hospitals. Examples of health care services provided by blood centers include therapeutic phlebotomies, plasma exchanges, and stem cell and cord blood collection and processing. By providing for such services through a centralized blood center, the medical expertise of the blood center can be leveraged in a manner that ensures community wide access to the highest quality blood services available.

ABC also is concerned that forcing blood centers to choose between acting as a health care entity or a wholesale distributor will have a negative economic impact on the provision of blood services and products. The health care services currently provided by blood centers are critical to efforts to contain health costs in that they eliminate the need to duplicate such services at multiple locations. In order for hospitals to extend the same level of medical expertise with respect to blood-related health care services as is currently provided by blood centers, significant additional expenditures would be required to attract and retain qualified medical personnel. This, in turn, would raise the price of these services and blood products to consumers. The current system represents a much more cost efficient approach than will be dictated by FDA's final rule. Last year, for example, the Puget Sound Blood Center's participation in the hemophilia treatment center program saved patients and third-party payers, including Medicaid and Medicare, \$7.6 million.

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Economic costs associated with the distribution of blood-related products will also be negatively impacted if blood centers are not able to act both as health care entities and wholesale distributors. Rather than being able to rely on the current centralized distribution system, hospitals will be required to maintain their own inventories, incurring the attendant costs. Moreover, during periods of shortage of blood-related products, hoarding by individual hospitals is almost certain to occur. Such practices result in artificially inflated prices and will likely leave some hospitals without necessary product. In contrast, the current distribution system in many communities around the US ensures that product distribution is achieved in a fair and efficient manner, and provides an objective mechanism for redistribution on an as-needed basis during times of shortage.

**3. If blood-derived products were excluded from the sales restrictions (i.e., if such products were permitted to be sold by health care entities), would there be an increased risk of distribution of counterfeit, expired, adulterated, misbranded, or otherwise unsuitable blood derived products to consumers and patients? Why or why not?**

We cannot address this issue for all healthcare entities, only for community blood centers. There is no evidence that the current system of derivative distribution by blood centers results in *any* distribution of counterfeit, expired, adulterated, misbranded, or otherwise unsuitable blood derived products to consumers and patients. The legislative history behind PDMA supports this. Indeed, the lead Congressional champion for PDMA, Congressman John Dingell, told FDA that Congress never intended to prohibit blood centers from distributing blood derivatives. In addition:

- Blood centers that purchase and distribute blood-derived products have, since the early 1990's, complied with the State licensing requirements of PDMA by obtaining State wholesale distributor licenses. Thus, they are already complying with the safety tenets of PDMA.
- The health care functions performed by blood centers are carried out under supervision of medical experts in conjunction with the hospital and/or the patient's own physician. Importantly, since all FDA-licensed blood centers must comply with FDA's Good Manufacturing Practices ("GMPs") for the majority of its functions, these health care functions are carried out in a GMP-compliant environment.

The value of the specialized medical expertise that exists in blood centers is critical to community health care, and the ability of the blood center to provide this medical expertise is subsidized by the small margins they earn on the sale of plasma products. Such specialized medical expertise, by and large, does not exist in the majority of local hospitals. Rather than promulgate a rule that weakens a blood center's ability to carry out this function, FDA should be promulgating rules that encourage safer, more medically appropriate and evidence-based uses of blood, blood components and blood derivatives. If the PDMA final rule prohibits community blood centers from simultaneously providing health care services and distributing blood-derived drugs, we believe there actually could be *increased* risk to patients who rely on the current relationships between blood centers and hospitals for the lifesaving drugs they receive.

**4. Do manufacturers of blood-derived products provide these products to health care entities, particularly those that are also charitable organizations, at a lower price when compared to other customers? Do manufacturers sell these products to charitable or for profit health care entities with the understanding that the products will be used for patients of the purchasing health care entity and will not be resold to other health care entities, distributors, or retail pharmacies?**

To the extent blood centers provide blood-derived products to hospitals at lower prices when compared to other vendors, it has nothing to do with the fact that the centers are charitable organizations or healthcare entities. It solely has to do with their abilities to leverage economies of scale on behalf of many hospitals in the areas they serve. Thus, blood centers are not unfairly competing with other distributors of these products, nor are manufacturers granting centers special pricing that would not be available to similarly situated distributors. More importantly, the statutory language of section 503(c)(3) of the PDMA, which states that the term "entity" does NOT include a wholesale distributor of drugs or a retail pharmacy licensed under state law, establishes that entities may simultaneously fulfill these roles. Congress did not intend that this exemption from the resale restrictions would create a loophole for entities participating in any form of prescription drug diversion. Instead we believe that section 503 (c) (3) mandates a regulatory scheme be devised whereby a health care entity *can* operate as a wholesale distributor or retail pharmacy within lawful parameters.

In summary and as described above, there are multiple advantages to patients, to hospitals and to blood centers resulting from the current distribution and shared service arrangements between hospitals and their community blood centers. These benefits will be lost if blood centers are denied the ability to act as both health care entities and wholesale distributors. No downside or adverse effect has been shown from these arrangements. Indeed, adverse effects would result if FDA's final rule were implemented and community blood centers could not simultaneously provide vital medical services and consultation and distribute blood-derived drugs. If FDA forces blood centers to make such a choice, what should they do? Where would the least harm occur? In lieu of forcing such a decision, ABC urges FDA to revise the final rule to allow the dual functions of community blood centers so they may meet the important public health needs of the communities they serve.