

Fox, Robert

FAX COVER SHEET

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To: fdadockets@oc.fda.gov
Subject: Docket No. 92N-0297

November 20, 2000

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Hello,

The attached WORD document pertains to Docket No. 92N-0297 regarding the Prescription Drug Marketing Act. A signed copy is being sent simultaneously to FDA fax # 301-827-6870

Thank you for including this document in your process for review. Please contact me directly with any questions or comments.



PDMA Document
Nov00.doc

Robert W. Fox
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TO: FDA Dockets
301-827-6870

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92N-0297

CH 8

November 2000

FDA Docket No. 92N-0297
Position Statement on Proposed Language Amending the
Prescription Drug Marketing Act

RE: Comments Pertaining to the Distribution of Hemophilic Clotting Factor

BACKGROUND

The Mary M. Gooley HemoCenter was founded in 1959 as one of the nation's first hemophilia treatment centers (HTC) and remains one of few freestanding HTCs. The HemoCenter is located in Rochester, NY, adjacent to Rochester General Hospital (RGH, part of the health system "viaHealth"). The hematologists affiliated with the HemoCenter (and with RGH) are recognized across the Rochester region as having expertise for treating people with bleeding disorders. Referrals to the HemoCenter come from throughout the 11-county Rochester region in upstate New York.

Approximately 265 people with bleeding disorders are under the care of the HemoCenter -- including virtually all people with hemophilia in the region. Especially given such a small population, concentrating expertise is an efficient and effective strategy.

Question #1

a. What distribution systems are available for derived blood products?

The HemoCenter purchases clotting factor from pharmaceutical companies, maintaining an inventory (and managing inventory turnover) sufficient to supply a majority of the needs of the region (approximately 12 different products from approximately 7 different vendors). The HemoCenter supplies clotting factor to people with bleeding disorders for outpatient use and to hospitals and other healthcare entities when they need to treat someone for a bleeding episode. Home care agencies also purchase and re-sell clotting factor to patients. Physicians, hospital personnel, and other HTCs recognize the HemoCenter's expertise in the use of clotting factor. Patients are referred for ongoing care and the HemoCenter -or physicians affiliated with the HemoCenter- often receive calls to obtain clotting factor for episodic use (e.g., in the event of trauma or for hospital or dental procedures, or for other infusion needs).

b. Do these distribution systems differ from those for other types of prescription drugs? If so, how?

Yes, inventories of typical pharmaceutical drugs are distributed throughout the region. Most prescription drugs are bought and sold by retail pharmacies, including hospital pharmacies and mail-order pharmacies, and supplied directly to patients or to treating physicians.

Question #2**FDA Docket No. 92N-0297**

a. What effect would the PDMA final rule, as published, have on the distribution system for blood derived products?

The PDMA final rule, as published, may prohibit the HemoCenter from supplying clotting factor to hospitals and other healthcare entities.

b. What, if any, adverse public health consequences would result?

Hospitals and other healthcare entities in the region, not having the HemoCenter's expertise, may not stock clotting factor or may not stock the most appropriate clotting factor products to meet the specialized needs of people with bleeding disorders who need episodic treatment. Use of clotting factor for bleeding disorders without hematology backup can present risks – the HemoCenter has documented instances of our hematologists “clarifying” product and dose issues for providers who contact us for factor. Faced with an urgent or emergency need for clotting factor, patients may not have access to life-saving products (if a hospital chose not to stock these high cost products) or may suffer a delay in getting their optimal product (if a hospital chose to stock only certain products). Scenarios described here would be detrimental to the care of a person with a bleeding disorder, thus, would be an adverse impact on the region's bleeding disorder community.

c. What would be the economic costs to manufacturers, distributors and consumers of blood derived products?

- Economic costs to manufacturers and (non-HTC) distributors – unclear, changing the distribution system as proposed would mean that manufacturers and distributors would sell to and service multiple, lower-volume outlets purchasing clotting factor;
- Economic cost to HTC as a distributor – revenues would decrease by not being able to sell clotting factor to hospitals and other healthcare entities;
- Economic cost to hospital – expenses would increase due to the need to purchase and stock clotting factor, revenue would increase with sale of clotting factor, depending on insurance coverage. Also, expenses (and revenues) may rise due to increased care necessary to treat people with complications resulting from inappropriate or delayed factor use;
- Economic cost to consumers - cost through their insurance coverage would rise, or at least be less predictable, due to probable inconsistency in selling prices across multiple healthcare entities;
- Economic cost to consumers – unknown, would stem from potential medical complications that might arise if providers throughout the region do not maintain a ready supply of clotting factor products in the absence of availability through the HemoCenter.

Question #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?

The HemoCenter has been distributing clotting factor to healthcare entities for decades without the problems described. In the event of such a problem, having a single regional “source” such as the HemoCenter may actually help increase reaction time in the event of a product recall or other potentially adverse situation.

Question #4

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a. 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?

The HemoCenter receives no special treatment or discounts off of market prices aside from the 340B program.

b. Do manufactures 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?

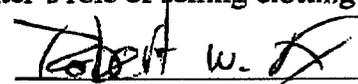
Manufacturers sell clotting factor products to the HemoCenter at two different prices, a 340B price (for outpatient care) and a market price. Pharmaceutical industry representatives also call on hospitals and other healthcare entities, which have the opportunity to purchase clotting factor.

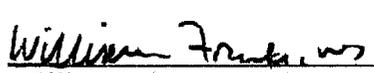
SUMMARY

Care for people with bleeding disorders in the Rochester area evolved based on a rich history of "Comprehensive Care" for people with Hemophilia. The hematologists who practice at the Mary M. Gooley HemoCenter are affiliated with Rochester General Hospital and have faculty appointments at the University of Rochester School of Medicine and Dentistry. The HemoCenter's role as a regional "distributor" of clotting factor stems from the fact that the HemoCenter and its physician-experts have specialized expertise in the use of clotting factor.

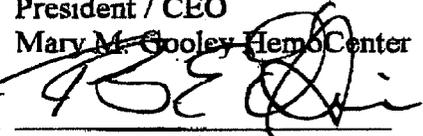
In addition to the HemoCenter, the undersigned represent the two largest local health systems and the pharmaceutical division of the largest health insurer in the Upstate NY region. The current system of distribution of clotting factor serves hospitals and patients well. We would support the continuation of the Mary M. Gooley HemoCenter's role of selling clotting factor to hospitals and other healthcare entities.

November 20, 2000
Rochester, NY

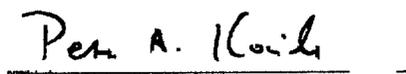
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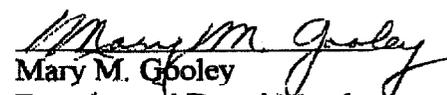

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