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American Red Cross

BCA/hemerica
Blood Centers of America

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852
Re Docket No. 2005N-0428

Dear Ladies and Gentlemen:

Introduction

These comments are submitted on behalf of AABB (www.aabb.org), America's Blood Centers ("ABC") (www.americasblood.org), the American Red Cross ("ARC") (www.usa.redcross.org), and Blood Centers of America ("BCA") (www.bca-hemerica.com). Together, these organizations represent over 400 FDA-licensed and registered blood establishments and account for virtually all of the nation's volunteer donor blood supply. Our members are responsible for over 80% of the blood transfusions in this country. AABB, ABC, ARC, and BCA submit the following comments on your Notice of Proposed Rulemaking of February 1, 2006 (Docket No. 2005N-0428).

AABB, ABC, ARC, and BCA believe that the Proposed Rule only partially addresses a problem with FDA's original regulations implementing the Prescription Drug Marketing Act. We applaud FDA's decision in the Proposed Rule to allow certain registered blood establishments that qualify as health care entities to distribute blood derivatives. However, to be faithful to Congress's intent in enacting PDMA, and to avoid disrupting the current ability of FDA-licensed blood establishments to perform their core blood-related mission, the exclusion in 21 C.F.R. § 203.22 should be broadened to read as follows: "The sale, purchase, or trade of, or the offer to sell, purchase, or trade any transfusion medicine and cellular and related biological therapy product by a registered blood establishment that qualifies as a health care entity, so long as any health care services that it provides are predominantly related to its activities as a registered blood establishment."

Simply stated, the organizations submitting these comments are concerned that the contemplated exclusion for blood centers from § 203.3(q) in the Proposed Rule may be too narrow. The exclusion should extend to any distribution of drug products used in transfusion medicine and cellular and related biological therapies, not just those that happen to be derived from human blood. That is what Congress intended and it makes sense in the context of allowing blood centers to fulfill their mission to patients. Accordingly, we submit the following comments. Each organization also reserves the right to file additional comments of its own.

Background

As FDA is aware, blood centers across the nation draw blood from volunteer donors, test and process the donations, and then supply various blood products primarily to hospitals in return for service fees that are intended to cover only their costs. Blood centers also perform varying degrees of direct patient care. As noted in the Proposed Rule, these services include “therapeutic phlebotomy, plasma exchange, stem cell and cord blood collection and processing, and medical expertise on the appropriate use of the blood derivatives they distribute.... [T]he majority of local hospitals do not have that kind of medical expertise, and as a practical matter could not obtain and maintain such expertise.” A number of blood centers in effect act as regional centers of transfusion medicine.

Some blood centers, as part of their core blood-related mission, also supply their hospital customers with certain blood-related products. These include blood derivatives, such as anti-hemophilic factor, IVIG, and Albumin, but they also include products that are *not* derived from human blood. For example, blood centers distribute recombinant erythropoietin (EPO), which is used to stimulate the production of red blood cells. Blood centers also distribute blood bags with anti-coagulant. (The presence of the anti-coagulant makes the product a “drug” for purposes of PDMA.) Additionally, blood centers distribute synthetic as well as human-derived coagulation factors (e.g., recombinant Factor VIII) to hemophilia centers and hospitals. In doing so, the centers act as distributors of these products.

A detailed list setting forth the numbers of FDA-licensed and registered blood centers that distribute drug products used in transfusion medicine and cellular and related biological therapies that are *not* blood derivatives, the products distributed, and the value of product distributed is attached hereto and incorporated by reference as Exhibit A.

Furthermore, as biotechnology advances, additional, partial substitutes for human blood are expected to become available. For example, hemoglobin based oxygen carriers derived from bovine blood are in development and may be licensed in the near future. Blood centers would logically be involved in the supply chain of such pharmaceuticals. As in the past, hospitals will be relying on FDA-licensed and registered blood establishments to supply and guide them through the use of these new drugs.

As we read the PDMA, this activity was not intended to be prohibited, so long as the members have state licenses to be wholesale distributors (21 U.S.C. § 353(e)), which in all cases they do. Indeed, in a May 27, 1994 letter (copy attached), Congressman Dingell confirmed to then-FDA Commissioner Kessler that the Subcommittee had not intended in the legislation to prevent community blood centers from operating as both health care entities and wholesalers.

Unfortunately, we understand that Congressman Dingell's letter never made it to the official docket. Thus, in 1999, FDA issued a final rule that would have prohibited blood centers from acting as both health care entities and wholesale distributors of any drugs other than blood and blood components. 64 F.R. 67720 at 67726. This rule resulted in considerable controversy, and as a result, FDA repeatedly postponed its effect for a period of years. 65 FR 25639; 67 FR 6645; 68 FR 4912; 69 FR 8105. Finally, in the Proposed Rule of February 1, 2006, you would allow registered blood establishments to keep distributing blood derivatives, but not other products used in transfusion medicine and cellular and related biological therapies. Moreover, a blood establishment that distributes blood derivatives could not provide any health services that do not relate to its activities as a registered blood establishment.

Blood Centers Should Not Be Prohibited from Distributing Products Used in Transfusion
Medicine and Cellular and Related Biological Therapies

While AABB, ABC, ARC, and BCA appreciate and support FDA's decision to exclude distribution of "blood derivatives," there is no logical reason to limit the exclusion to products that are technically derived from human blood. This is too narrow, is not supported by the underlying legislation or congressional intent, and does not reflect the modern realities of biotechnology. FDA-registered blood centers should be able to continue to act as both health-care entities and distributors of drug products used in transfusion medicine and cellular and related biological therapies.

The current system whereby blood centers offer community hospitals the full range of blood-related products (as well as trained personnel and expertise in handling those products) is cost-effective and makes economic sense. If individual community hospitals were required to maintain their own inventories of these specialized products, duplication of costs and inefficiencies would result. Also, because these are relatively low-use products for hospitals, blood centers and buying groups can negotiate better prices. Blood centers can also offer utilization reviews to hospitals. The current system has emerged in the marketplace because it is sensible, and it should be preserved for the same reason.

Nor are we aware of any complaints or dissatisfaction with the current system. The potential roster of drug products used in transfusion medicine and cellular and related biological therapies is narrow and well-defined. Blood centers do not seek the legal right to compete with pharmacies over the range of non-blood-related drugs. They simply want to keep the existing system in place.

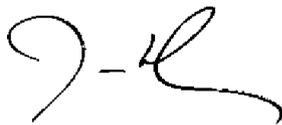
AABB, ABC, ARC, and BCA are concerned that patients may suffer if blood centers are prohibited from distributing blood-related drugs like recombinant Factor VII(a), Factor VIII, and Factor IX. Because of their nonprofit status, their ability to enter into long-term agreements, and their collective buying volume (as indicated on Exhibit A), blood centers are able to negotiate favorable pricing. Patients also benefit from blood centers' commitment to maintaining an adequate supply of blood-related products. Because of their non-profit mission to serve local communities, blood centers can do a better job of assuring a steady supply of these drugs in the face of market fluctuations than profit-oriented hospitals or other businesses. This could change if the existing system were altered.

Lastly, AABB, ABC, ARC, and BCA have concerns about language in the Proposed Rule that would make the exclusion unavailable if the blood center performs *any* health care services not related to blood. From time to time, blood centers may provide incidental services, such as offering flu shots, which in the broader sense further their interest in a healthy blood donor community but may not be strictly related to their activities as a registered blood establishment. We believe that any hypothetical concern about “encourag[ing] hospitals and other health care entities to register as blood establishments” to take advantage of the exclusion can be easily addressed by requiring the health care services to be *predominantly* blood-related. Unless the health care is predominantly blood-related, the registered blood establishment would not qualify for the exception.

Conclusion

As Congressman Dingell’s letter indicates, the impetus behind § 203.3(q) was “not to prevent community blood centers from operating as both a health care entity as well as a wholesaler, but rather to address practices by certain physicians who were abusing the existing system.” AABB, ABC, ARC and BCA respectfully ask that blood centers be permitted to continue to offer their efficiencies and expertise in the field of all products used in transfusion medicine and cellular and related biological therapies. This is a limited field, but to blood centers and the hospitals and patients they serve, an important one. Please consider modifying the Proposed Rule as we have requested.

Submitted by:



Jim MacPherson
CEO
Americas Blood Centers

On behalf of:

AABB
America’s Blood Centers
American Red Cross
Blood Centers of America

Exhibit A

Survey: Non-Plasma-Derived Drugs Distributed by ABC Blood Centers

Survey Period: March 15-May 1, 2006

Number of America's Blood Centers in US: 75

Number Responding to Survey: 67 (89%)

Questions and answers, represented by number and percentage of total responses.

1. Does your blood center distribute blood derivatives?

Yes: 35 (52%) No: 32 (48%)

2. If yes, does your center distribute both plasma derivatives and other drugs?

Yes: 28 (42%) No, just plasma derivatives: 32 (48%) Drugs only: 4 (6%) Did not answer: 3 (4.5%)

3. If yes, what specific other drugs do you distribute (e.g., Recombinant Factor VIII, Recombinant Erythropoietin; empty blood bags with anticoagulants)

Responses: Drug/Number/Percentage of 67 Responses

1. Recombinant Factor VIII: 21 (31%)

2. Recombinant Factor VII(a): 19 (28%)

3. Empty Blood Bags with Anticoagulants: 17 (25%)

4. Recombinant Factor IX: 16 (24%)

Other drugs mentioned: Recombinant erythropoietin, Traysylol, Stimate nasal spray, tetanus diphtheria Td, Rabavert, and Imovax.

From April 16 to May 1, ABC asked those centers that distribute non-plasma-derived drugs to give the dollar amounts they distribute in those drugs. The following table (Table 1.0) gives the total dollar amounts from the 27 respondents.

Exhibit A/Table 1.0

Drug	Average monthly dollar amount (27 ABC blood centers reporting)	Estimated average annual dollar amount (27 ABC blood centers reporting)
Rec. Factor VII	3,353,049	40,236,588
Rec. Factor VIII	4,343,460	52,121,520
Rec. Factor IX	822,643	9,871,716
Empty blood bags with anticoagulants	8,069	96,828

MAY-31-94 TUE 17:58 Porter/Novelli

P.02

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0-01 04 : 4:10PM :

-Porter/Novelli

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OUR MESSAGE INTO CONGRESS

FORM 1244
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U.S. House of Representatives
Subcommittee on Oversight and Investigations
of the
Committee on Energy and Commerce
Washington, DC 20515-6116

May 27, 1994

The Honorable David A. Kessler, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Kessler:

The Food and Drug Administration recently published a proposed rule on the Prescription Drug Marketing Act of 1987 and the amendments to this statute enacted in 1992 (59 Fed. Reg. 11842, March 14, 1994). That proposed rule covers certain requirements regarding the definition of wholesale drug distributors and health care entities.

There are some instances where community blood centers function as full-service blood centers, providing therapeutic apheresis, therapeutic phlebotomies, and diagnostic blood tests for HIV and Hepatitis, as well as providing care for hemophiles. Where these full-service community blood centers are distributors of blood products, they have presumably complied with FDA regulations by registering with their respective states as wholesalers.

Nevertheless, in the FDA's recent Federal Register notice, proposed section 203.3(n) states that:

" a person cannot simultaneously be a 'health care entity' and a retail pharmacy or wholesale distributor."

This suggests that full-service blood centers that provide legitimate health care, and that have registered with their respective state as a wholesaler, would be prohibited from either providing blood components or plasma derivatives as part of their service, or providing health care or diagnostic service. This could create obvious difficulties for the community blood centers in this position.

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P.03

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5-31-94 : 4:11PM :

-Porter/Novelli

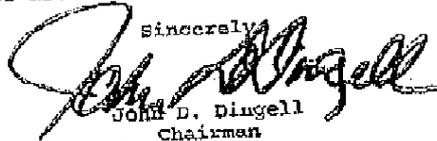
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The Honorable David A. Kessler, M.D.
May 27, 1994
Page 2

The Subcommittee understands that the Agency included this prohibition not to prevent community blood centers from operating as both a health care entity as well as a wholesaler, but rather to address practices by certain physicians who were abusing the existing system. Specifically, both the Department of Justice and the FDA had determined that there were practitioners operating as health care entities that were purchasing drugs at a discount and reselling them, rather than using them to treat patients.

The Subcommittee understands that the FDA intends to address this issue in order to avoid disrupting the supply of biologics sold as prescription drugs to individuals such as hemophiliacs and individuals with compromised autoimmune systems. The Subcommittee will work with you to resolve this issue so that important services are not disrupted.

Sincerely,



John D. Dingell
Chairman
Subcommittee on
Oversight and Investigations

cc: The Honorable Dan Schaefer