



Community Blood Center
Community Tissue Services

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COPY

OFFICE OF THE CHIEF EXECUTIVE OFFICER / MEDICAL DIRECTOR

MAIN OFFICE

349 South Main St.
Dayton, Ohio 45402-2715
1-800-388-4483
(937) 461-3450
FAX (937) 461-9217

DONOR CENTERS

105 South D St.
Hamilton, Ohio 45013
(513) 894-6966
FAX (513) 894-4901

3990 Roosevelt Boulevard
Suite C
Middletown, Ohio 45044
(513) 727-1995
FAX (513) 727-0006

4821 Old National Rd. East
Richmond, Indiana 47374
(765) 962-6329
(FAX) (765) 966-3957

2200 North Limestone St.
Suite 106
Springfield, Ohio 45503
(937) 399-2611
FAX (937) 399-5044

TISSUE CENTERS

349 South Main St.
Dayton, Ohio 45402-2715
1-800-684-7783
(937) 222-0228
FAX/4TH FL (937) 461-4237
FAX/ADMIN (937) 461-9217

708 South Henderson St.
Suite A
Fort Worth, Texas 76104
1-800-905-2556
(817) 882-2556
FAX (817) 882-2557

2801 N. Gantenbein Ave.
Room 2122
Portland, Oregon 97227
1-800-545-8668
(503) 288-4899
FAX (503) 288-8430

3445 North First St.
Suite 105
Fresno, California 93726
1-800-201-8477
(209) 224-1168
FAX (209) 229-7217

June 27, 2000

Jay S. Epstein, MD
Director
Office of Blood Research and Review (HFM-300)
Center for Biologics Evaluation and Research
1401 Rockville Pike
Room 400N
Rockville, MD 20852-1448

Dear Dr. Epstein,

Community Blood Center (CBC) appreciates the delay of the effective date, the reopening of the administrative record, and the opportunity to comment on the provisions of the Prescription Drug Marketing Act (PDMA). I am writing to explain why CBC considers it vital to the public health needs of our community to remain both distributors of blood derivatives as well as a health care entity. This dual status has been our role for decades and is important to our continuing role as a hospital-shared service organization.

Founded in 1964, CBC is a quality, comprehensive provider of blood components, laboratory services, transfusion medicine, and therapeutic blood services in the Miami and Whitewater Valleys. CBC is a not-for-profit, charitable organization, servicing the blood needs of twenty-seven hospitals. The Dayton Headquarters is open to donors five days a week and additional days based upon need. The Center delivers blood to all hospitals served and handles emergencies on a seven days per week, twenty-four hours a day basis. CBC operates four branch blood collection centers for the convenience of donors in Middletown, Hamilton, and Springfield, Ohio, and Richmond, Indiana. The Apheresis department operates at the Dayton Headquarters and the Springfield branch. Mobile blood drives are scheduled throughout fifteen counties to help assure that donations will be sufficient to meet patient blood needs. CBC is accredited as a Regional Marrow Donor Center, and operates Reference and Stem Cell Laboratories accredited by the American Association of Blood Banks. The principal role of CBC is service to the patients.

The following is a list of critical health care services CBC provides to the community. Because of these services, CBC falls within the definition of a health care entity, as defined by 21 CFR § 203.3.

- Therapeutic phlebotomies
- Therapeutic hemapheresis
- Collection, processing, and storage of stem cells

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- Transfusion services (out of hospital only)
- Consultative services regarding the proper use of blood derivatives
- Distribution of products in short supply

These services are carried out under the supervision of medical experts in conjunction with the hospital and/or the patient's own physician. Since CBC can carry out these activities for an entire or large section of its community, it provides an opportunity to share a higher level of medical expertise than may be possible for an individual hospital. Indeed, because CBC provides this service, hospitals do not have to duplicate the medical expertise necessary for these types of blood-related activities, nor do patients have to seek such expertise outside their own communities. Importantly, since all blood centers must comply with FDA's Good Manufacturing Practices (GMP) for the majority of its functions, these health care functions are carried out in a GMP-compliant environment.

In addition to providing blood, blood components, and the health care services listed above, CBC also distributes blood derivatives, namely Factor VIII, Factor IX, and Anti-thrombin III, throughout our service area. CBC is licensed by the state of Ohio (Identification Number 01-1071500) and the state of Indiana (License Number 100623) as a Wholesale Distributor of Dangerous Drugs. CBC is also licensed by the state of Ohio (Identification Number 02-0071300) as a Terminal Distributor of Dangerous Drugs, which allows CBC to purchase and utilize the Albumin needed for certain therapeutic hemapheresis procedures.

As presently structured, CBC's ability to carry out both its role as a wholesale distributor of blood derivatives and a health care entity will end pursuant to the final rule implementing the Prescription Drug Marketing Act ("PDMA") which takes effect on December 4, 2000. The requirement of the final rule, which provides that a licensed wholesale drug distributor cannot also be a health care entity for purposes of PDMA (21 C.F.R. § 203.3(q)), is unfortunate. This is clearly contrary to the public health of the local community served by CBC.

The following table indicates the blood derivatives CBC shipped to area hospitals from January 1, 1998 through June 9, 2000.

	Factor VIII	Factor IX	Anti-Thrombin III
1998	60,327 iu	102,510 iu	11,800
1999	259,887 iu	31,815 iu	⊖
2000	42,211 iu	7,610 iu	⊖

Many of our hospitals choose to routinely purchase derivatives from CBC. They find that they cannot stock them efficiently. A hospital's use of blood derivatives is sporadic and when purchased and stored at the hospital, they often expire prior to use. In November 1998, a survey was sent to the hospitals in our service area to see if they preferred to maintain their own inventory of blood derivatives or rely on CBC. 12 of the 21 hospitals responding to the survey indicated that they would rather depend on CBC to provide them with these products.

When the hospitals order derivatives from CBC, it is usually for an acutely bleeding patient. Any delay in treatment may mean that the patient's health will decline quickly, possibly even leading to the patient being put on a respirator. Frequently, the derivatives are in short supply and unobtainable by the hospitals. Due to the fact that CBC purchases the products on a fairly regular basis, we are usually able to obtain them and make them available to the patients in need.

CBC's role as a distributor and healthcare entity is often intertwined. Recently, CBC performed a therapeutic apheresis procedure at a hospital for a patient with Guillain Barre syndrome. The treatment called for 3 liters of albumin to be used every other day for 2 weeks. The hospital pharmacy chose to provide the albumin for the procedure. However, in the middle of the 4th procedure, it was discovered that the hospital's supply of albumin was depleted. Fortunately, the CBC Apheresis department maintains an inventory of albumin and carries a supply with them to each procedure. Had CBC not provided the remaining albumin needed, the patient's care would have been compromised.

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Therapeutic hemapheresis is an emergency procedure that is sporadic in nature. As with the blood derivatives, hospitals have a difficult time maintaining an adequate in-date supply of albumin for use as the need arises. Since CBC provides therapeutic hemapheresis services to their entire service area, albumin is ordered in larger quantities and utilized more frequently, which means that less of the product is wasted due to expiration.

In 1993, an area hospital solicited CBC to provide assistance in developing a new autologous bone marrow transplant program. CBC agreed, and provided highly trained and competent staff to collect and process bone marrow and peripheral stem cell products. Since that time, the program has expanded to include pediatric peripheral stem cell collections as well as allogeneic collections for the National Bone Marrow Registry. Under the supervision of knowledgeable medical directors, CBC's Stem Cell Laboratory processes, freezes, and stores autologous bone marrow and peripheral stem cell products.

It must be noted that the hospital who initially requested that CBC provide these services could have hired the appropriate staff and performed these functions internally. However, they realized that CBC could readily provide a higher level of medical expertise than they would be able to provide themselves. Also, because CBC provides this service, patients requiring bone marrow and peripheral stem cell transplants can remain in the Dayton area, close to home and family, rather than having to travel outside the community. This is much less burdensome for the patients and may aid in their recovery.

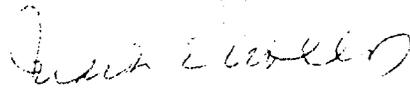
While neither the distribution of blood derivatives nor the provision of health care services as described above is the principal role of CBC, each of these activities provides a vital public health service to our community. Having all blood-related products distributed by a blood center allows the hospital to manage its own inventories more carefully and to reduce storage needs. Also of critical value is that CBC, as a neutral party, is able to distribute products in short supply equitably, preventing hoarding of products by hospitals and providing for the smooth transfer of products as necessary between hospitals. This function has been especially valuable considering the critical shortages of blood derivatives

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seen in the recent past. Further, CBC's specialized medical expertise provides valuable consultative services with regard to the proper use of blood derivatives.

CBC requests that FDA revise its regulations to allow blood centers to provide health care services and act as wholesale distributors. To serve our community, CBC must remain able to distribute blood derivatives and utilize the materials necessary for therapeutic hemapheresis procedures under appropriate pharmaceutical licenses as required by the PDMA.

Sincerely yours,



Judith E. Woll, MD
CEO/Medical Director
License #394
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JEW:pam
6/22/00

bc. America's Blood Centers