



Carolina-Georgia Blood Center

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20857

Re: Docket Nos. 92N-0297 and 88N-0258

Carolina-Georgia Blood Center (CGBC) must retain its ability to distribute blood derivatives under appropriate wholesale pharmaceutical licenses as required by the Prescription Drug Marketing Act (PDMA). Therefore, CGBC requests that the Food and Drug Administration (FDA) revise its regulations to allow dual classification as a health care entity and a wholesale drug distributor under the PDMA. Our Blood Center functions with a single goal in mind: the best interests of the public health of our local communities. By revising its regulations, the FDA would encourage, not discourage, this goal.

CGBC considers it vital to the public health needs of the communities in our service area that we remain both distributors of blood derivatives (also known as "blood products"), as well as a health care entity. This dual status has been part of the role of many blood centers for decades and is important to our continuing role as a hospital-shared service organization in our local communities.

As presently structured, CGBC's ability to carry out its role as a wholesale distributor of blood derivatives and a health care entity will end pursuant to the final rule implementing the PDMA, which takes effect on December 4, 2000. As discussed fully below, this is clearly contrary to the public health of the local communities we serve.

Even more troubling is the fact that 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 not an explicit requirement of the statute itself. Rather, it is an administrative expansion of the FDA's authority presumably intended to further congressional intent. Yet the principal Congressional author of that legislation, Representative John Dingell (D-MI), wrote to the FDA on May 27, 1994 urging the FDA to address the issue since the FDA's proposed rule "... could create obvious difficulties for the community blood centers in this position." Representative Dingell concluded his letter to the FDA by saying, "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." The final rule unfortunately left in place the ban on being both a state-licensed wholesale drug distributor and a health care entity.

88N-0258

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CGBC and other blood centers are hospital shared-services organizations. By design, our organization centralizes multi-faceted blood related and health services for the hospitals in our service area so that such services do not have to be duplicated at each hospital. Thus, a higher quality of blood service is provided to all hospitals. In this context, blood centers like ours collect, process, store and ship blood and blood components to hospitals. Blood and blood components are exempt from the state wholesale drug distribution requirement of PDMA. However, blood centers like ours also purchase blood derivatives from manufacturers and distribute them to hospitals along with blood and blood components. Many of these derivatives are manufactured from plasma that we, and other blood centers like us, provide. As the market for such derivatives has grown, safer and more specific derivatives have replaced many of the plasma transfusions that formerly were used to treat patients in need of plasma factors. (Indeed, to help assure a community's supply for derivatives, blood centers often link the amount of derivatives from a pharmaceutical manufacturer to the amount of plasma that they supply.) Blood derivatives, such as anti-hemophilic factors and other blood coagulation factors, albumin, intravenous immune globulin and alpha-1 anti-trypsin, are not exempt from PDMA. This means, for purposes of PDMA, that blood centers that ship blood derivatives in interstate commerce must be state-licensed wholesale drug distributors.

Additionally, CGBC and blood centers like CGBC provide health care services to patients, which places blood centers under the definition of a health care entity. Simultaneous provision of these two services (distribution of blood derivatives and certain health care services) are not allowed by a not-for-profit blood center under the final rule.

The prohibition on being a health care entity and a wholesale drug distributor under the PDMA regulations impacts a relatively small, but a growing and vitally important set of services provided by blood centers. Many hospitals rely on blood centers to carry out several critical health care functions. For CGBC these service include:

1. therapeutic phlebotomies (for patients with hemachromatosis and other polycythemias);
2. the processing and storage of stem cells (for treatment of a variety of malignancies); and
3. transfusion services (such as crossmatching services, and home and outpatient transfusions).

CGBC offers these health care functions under supervision of medical experts in conjunction with the hospital and/or the patient's own physician. Because CGBC 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, especially in smaller communities. Because of such expertise, area 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 CGBC must comply with the FDA's Good Manufacturing Practices ("GMPs") for the majority of its functions, these health care functions are carried out in a GMP-compliant environment.

Also of critical value to hospitals is that CGBC, as a neutral entity, is able to distribute products in short supply equitably throughout the community it serves, preventing hoarding of products by hospitals and providing for the smooth transfer of products as necessary between hospitals. Further, CGBC's specialized medical expertise provides valuable consultative services with regard to the proper use of blood derivatives.

The collection, processing, and distribution of blood components is CGBC's central mission, while the distribution of blood derivatives and the provision of health care services provide vital public health services to local communities. The value of the specialized medical expertise that exists in this and other blood centers is critical to community health care, and the ability of each blood center to provide this medical expertise is subsidized by the small margins earned on the sale of plasma products. Such specialized medical expertise, by and large, does not exist in the majority of local hospitals. Especially for smaller hospitals, this type of expertise is often not available.

Once again, we urge the FDA to revise its regulations to allow dual classification as a health care entity and a wholesale drug distributor under the PDMA.

Sincerely,

A handwritten signature in cursive script, appearing to read "Gregory Hart".

Gregory Hart
Chief Executive Officer