



America's Blood Centers[®]
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725 15th Street NW Suite 700, Washington, DC 20005
Tel: 202-393-5725 Fax: 202-393-1282

1-888-USBLOOD  www.AmericasBlood.org

August 18, 2014

Dr. Margaret A. Hamburg
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Regulatory parity for apheresis plasma and plasma from whole blood

Dear Commissioner Hamburg,

We are writing today on behalf of the undersigned organizations of the blood community representing the nation's blood centers, transfusion medicine professionals, plasma protein manufacturers, medical technology companies and patients relying on plasma products for life-saving care. Included in this packet is a letter of support that was sent to you by a patient coalition representing 11 rare disease patient groups. We request prompt follow up and agency action on this issue that we have been discussing for over a decade – the most efficient use of apheresis plasma from volunteer (unpaid) donors for further manufacturing, in a fashion consistent with the shipment of recovered plasma from volunteer whole blood donations for fractionation into life-saving derivatives.

Volunteer donor plasma should be regulated consistently, regardless of its method of collection. The *Circular of Information for the Use of Human Blood and Blood Components* makes no distinction between plasma based on the collection method. Clinical indications for plasma are the same regardless of the method of collection, whether from apheresis or whole blood collection, yet the Food and Drug Administration (FDA) requires that the apheresis-derived plasma that is not transfused be left to expire (one year from the date of collection) before it can be relabeled and made available for further manufacturing. Ultimately, this expired plasma cannot be used for fractionation into high value, protein therapy products for patients; instead, it may only be used to manufacture diagnostic products. In contrast, plasma from whole blood donations that is not transfused may be converted at any time prior to outdate into recovered plasma for manufacture into essential patient therapies such as Factor VIII, IgIV and albumin.

We believe that either plasma product is clinically acceptable at any time before expiration for further manufacture into therapeutic products. In Canada and in the European Union, the regulators make no distinction based on collection method. In these countries, plasma collected from whole blood donations and plasma from apheresis can be used either for transfusion purposes or labeled and sent to fractionators for further manufacture at any time after collection. As such, the regulatory

distinction made by the FDA, based on the collection method, is distinction without a difference, is not evidence-based and ought not to be the standard of practice in the US.

Flexibility is necessary to maximize the gift of life. The United States blood supply depends on donors dedicated to providing a consistent source of blood components of the various blood types. Donors intend for their blood to be used, without waste, to save a life or reduce the pain and suffering of others. We have a duty to use every component of blood for this purpose before it expires and not to waste this precious gift, whenever possible. The blood community is looking for maximum flexibility in the use of these products to make the best medical use of the resources that volunteer donors provide. In addition, using all components from one donor to maximum advantage is the most cost-effective method of collecting and processing.

The intent and understanding of our donors is that we make clinically appropriate use of their gift. Accordingly, blood centers should be able to make the labeling decision for apheresis plasma in the same fashion they do for plasma separated from whole blood, based on the community's day-to-day and hour-to-hour needs. The need for transfusable plasma fluctuates, and what is needed for further manufacture vs. transfusion is necessarily often unknown until component manufacturing is underway and even after labeling. As FDA is aware, a single new patient with thrombotic thrombocytopenic purpura can instantly alter plasma collection needs in a facility for many days to weeks. There ought to be no distinction between manually-collected and apheresis plasma in such clinical settings. That is the genesis of our long-standing request for the creation of a single product for further manufacture whether it derives from manual or apheresis collection. This remains our preferred solution from the agency.

Plasma protein therapies are unique, biologic medicines of finite supply that begin with human plasma. Health policy should promote population health via access to needed therapeutics. These unique therapies treat well-defined medical conditions, replacing missing or deficient proteins found in plasma, to allow their recipients to lead healthier and more productive lives. The patient populations that rely on plasma protein therapies generally require regular infusions or injections for the duration of their lives. Additional sources of plasma will help ensure patient access to needed care.

Following the April 2011 Blood Products Advisory Committee meeting, FDA stated that it would continue to work on developing a regulatory pathway for plasma products and then issue a draft guidance document. However, three years later FDA has yet to issue any revised guidance or policy relating to this important topic.

The challenges that lie ahead to improve population health require thoughtful and prompt action and we applaud any efforts that the FDA takes to accomplish this goal. Thank you for the opportunity to provide comments and recommendations on this important issue. If you have any questions, please contact Dr. Louis Katz, ABC Chief Medical Officer at lkatz@americasblood.org.

Sincerely,



Christine Zambricki
Chief Executive Officer



Miriam Markowitz
Chief Executive Officer



J. Chris Hrouda
Executive Vice President



Jan M. Bult
President and CEO



Robert Perry



Stephen J. Ubl
President and CEO



cc: Jay Epstein, MD
Director, Office of Blood Research & Review

Karen Midthun, M.D.
Director, Center for Biologics Evaluation and Research

Richard Davey, MD
Director, Division of Blood Components and Devices