May 6, 2020

Ms. Christina Vert
Dr. Prabhakara Atreya
Division of Scientific Advisors and Consultants
CBER/FDA
10903 New Hampshire Avenue
White Oak, Bldg. 71
Silver Spring, MD 20993-0002

Dear Ms. Vert and Dr. Prabhakara,

AABB, America's Blood Centers, Blood Centers of America and Plasma Protein Therapeutics Association served on the selection group for the nonvoting member to represent industry on the Blood Products Advisory Committee (BPAC) as instructed in your March 20, 2020 letter. The selection group met for two hours on April 16th to identify well-qualified individuals from the list of nominees provided in your letter.

While we recognize and appreciate the appointment of a primary and an alternate nominee, we continue to believe that BPAC would be best served by appointing a representative from each sector of the industry to address the scientific and medical aspects under discussion and the practical implications that must also be considered. Our February 20, 2020 letter, attachment 1, was a joint communication supported by AABB, ABC, BCA, ACTS (Alliance for Community Transfusion Services), PPTA, and AdvaMed (Advanced Medical Technology Association). Our joint letter details the importance of updating the model for industry representation to ensure the BPAC is fully informed before they are asked to provide advice and opinions on complex issues to assist the FDA in its mission.

Following the agency's current limited model, we have fulfilled our responsibility to identify two well-qualified industry experts. Our consensus nominees for the nonvoting member and alternate to represent industry on the BPAC are:

Susan N. Rossmann, MD, PhD, Gulf Coast Regional Blood Center – Primary Representative
Mark A. Becker, MD, Grifols – Alternate Representative

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Please notify the selection group when Drs. Rossmann and Becker are formally appointed to serve on the BPAC. Thank you for providing guidance during the nomination process.

Sincerely,

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ATTACHMENT 1

February 20, 2020

Christina Vert
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave
Bldg. 71, Rm. 628
Silver Spring, MD 20993-0002

Re: Blood Products Advisory Committee Non-Voting Industry Representative(s) Position

Dear Ms. Vert:

AABB is submitting this joint request on behalf of the undersigned organizations, representing the blood, plasma, and medical device industries. We respectfully request that you consider strengthening the support available to the Blood Products Advisory Committee (BPAC) by establishing positions for multiple non-voting industry representatives to ensure a broad range of expertise is available for all issues addressed by BPAC.

The BPAC serves as a key resource to assist the Food and Drug Administration (FDA) in accomplishing its mission to protect the public health, assuring a safe and adequate blood supply. As described in the BPAC charter, "[t]he Committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood, products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases, and, as required, any other product for which the Food and Drug Administration has regulatory responsibility, and advises the Commissioner of Food and Drugs of its findings regarding screening and testing (to determine eligibility) of donors and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or

revocation of biological products licenses, and on the quality and relevance of FDA's research program which provides the scientific support for regulating these agents." The broad scope of the work of the BPAC is further demonstrated by the wide field of knowledge encompassed on the seventeen member committee "in the fields of clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, and other related professions."

Currently, this large, diverse committee has only one non-voting member to provide expertise on issues and considerations that are unique to regulated industry. Through diligent work from all of the blood industry, this one representative has generally been able to represent the information and expertise of the entire industry. However, the issues facing this industry have grown more complex, and are now more accurately described as multiple industries diverging in both technical and operational requirements and challenges.

The remarkable contributions to public health made possible by innovative products are a direct result of the diversity and complexity of this growing industry, and also make it increasing problematic for a single individual to embody the necessary expertise to represent the broad array of regulated products and manufacturing processes that are now today's blood industry. Furthermore, the blood industry now faces an increasing number of issues where diverse manufacturers have key differences on important public health concerns. Many years ago, the agency recognized a similar challenge with growing divergence through the naming of an alternate BPAC industry representative. At this time, we believe the changes within our industry necessitate a change in the composition of the supporting roles to allow non-voting representation to cover all aspects of the blood industry.

The rules for membership[1] on an advisory committee state that committee membership depends on several factors including "[t]he types of specific perspectives required, for example, such as those of consumers, technical experts, the public at-large, academia, business, or other sectors;" and "[t]he need to obtain divergent points of view on the issues before the advisory committee." While many committees only have one industry representative, there are examples of committees where the industry diverged enough to justify multiple industry representatives. For example, the Tobacco Products Scientific Advisory Committee has 3 non-voting industry representatives; one from the tobacco manufacturers, one from the tobacco growers and one from small business tobacco manufacturers industries. Similarly, the Pharmaceutical Science and Clinical Pharmacology Advisory Committee can have up to three non-voting and pharmacy compounding can have one or more. The Risk Communication Advisory Committee resolved a similar issue by creating a panel of individuals nominated to serve temporarily based on the topic(s) being discussed.

Based on these precedents and the current scope of manufacturing and product safety requirements facing the blood industry, we respectively propose FDA consider strengthening the expertise to improve the support to BPAC. We recommend FDA consider the following to improve the current model:

[1] 41 CFR Parts 101-6 and 102-3 Federal Advisory Committee Management, Appendix A to Subpart B

1. Increasing the number of non-voting industry representatives on BPAC for the reasons described earlier.

   We believe representatives from each of the three major arms of the industry - blood collection and transfusion medicine; plasma protein therapies, including plasma for manufacturing use; and the medical devices used in support of the blood industry - would more fully inform the BPAC when making critical decisions on the broad array of public health issues.

OR

2. Using a panel of experts to strengthen support to BPAC, if industry was systematically consulted on the range of expertise needed to inform BPAC on complex topics facing the industry.

We look forward to working with FDA to bring the most capable and informed industry representation to better support the BPAC with its responsibility to advise FDA.

Sharon Carayiannis, MT(ASCP)HP
Director, Regulatory Affairs
AABB

Submitting on behalf of ABC, ARC, ACTS, PPTA, AdvaMed and BCA:

AABB is an international, not-for-profit association representing individuals and institutions involved in the fields of transfusion medicine and cellular therapies. The association is committed to improving health through the development and delivery of standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. AABB membership includes physicians, nurses, scientists, researchers, administrators, medical technologists and other health care providers. AABB members are located in more than 80 countries and AABB accredits institutions in over 50 countries.

Founded in 1962, **America's Blood Centers** is North America's largest network of community-based, independent blood programs. Recognized by the U.S. Congress for its critical work in patient care and disaster preparedness and response, the federation operates more than 600 blood collection sites providing close to 60 percent of the U.S., and a quarter of the Canadian blood supply.

The **American Red Cross** shelters, feeds and provides emotional support to victims of disasters; supplies about 40 percent of the nation's blood; teaches skills that save lives; provides international humanitarian aid; and supports military members and their families. The Red Cross is a not-for-profit organization that depends on volunteers and the generosity of the American public to perform its mission. About 5.6 million units of whole blood are collected from roughly 3.3 million Red Cross volunteer donors, separated into 8 million transfusable blood products and supplied to approximately 2,700 hospitals and transfusion centers across the country for patients in need.

The **Alliance for Community Transfusion Services** (ACTS) is an affiliation of 12 independent blood centers that annually collect, process, and distribute more than 1.5 million blood products to help patients in more than 750 hospitals and healthcare facilities throughout the United States. Members also provide various technical services, therapeutic treatments, and cellular therapy procedures. ACTS members collectively meet ongoing challenges through shared resources, initiatives, and expertise. Through this unique collaboration, ACTS members achieve the economic benefits typically associated with large centralized operations without sacrificing the qualitative benefits of independent, community blood banking.

The **Plasma Protein Therapeutics Association** (PPTA) is a dynamic trade and standards-setting association that represents a unique sector of the biologics and biotechnology industry. PPTA represents the private sector manufacturers of plasma-derived and recombinant analog therapies, collectively known as plasma protein therapies, and the over 800 collectors of Source Plasma used for fractionation. Our members produce approximately 80 percent of the plasma protein therapies in the U.S. and 60 percent of those manufactured in Europe. Plasma protein therapies are primarily used in the treatment of a set of rare diseases. These diseases are often genetic, chronic, life-threatening conditions that require patients to receive regular infusions or injections of plasma protein therapies for the duration of their lives. These therapies include blood clotting factors for individuals with bleeding disorders, immunoglobulins (IG) to treat a complex of diseases in persons with antibody deficiencies and severe autoimmune disorders, therapies for individuals who have alpha-1 anti-trypsin deficiency, which typically manifests as adult-onset emphysema and substantially limits life expectancy, and albumin, which is used to treat individuals with severe liver diseases and, in emergency-room settings, shock, trauma, burns, and other conditions. PPTA members are committed to assuring the safety and availability of these medically needed, life-sustaining therapies.

The **Advanced Medical Technology Association** (AdvaMed) is the world's largest trade association representing medical device and diagnostics manufacturers. AdvaMed's member companies produce the innovations that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed has more than 400 member companies, ranging from the largest to the smallest medical technology innovators and manufacturers. AdvaMed advocates for a legal, regulatory and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. The Association promotes policies that foster the highest ethical standards, rapid product approvals, appropriate reimbursement, and access to international markets.

Blood Centers of America (BCA) is a member-owned organization comprised of over 50 independent blood centers throughout the North America, representing nearly 40% of the U.S. blood supply. Along with their core business of providing a substantial portion of U.S. blood supply, other BCA member services transfusion services, immunohematology testing, therapeutic apheresis and tissue and cord blood banking. In addition, BCA members provide a variety of human blood products, cells and tissues to the therapeutic, diagnostic and cell therapy industries. Through the Foundation for Blood Centers of America, BCA also manages blood4me.com a patient oriented website aimed to educate patients, families and health care professionals about the vital role of transfusions in patient care. Learn more at www.bca.coop and blood4me.com.