



America's Blood Centers[®]
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**ABC Comment to
The FDA Science Advisory Board
April 15, 2005**

America's Blood Centers, or ABC, is an association of 78 not-for-profit, community-based blood centers that collect nearly half of the US blood supply from volunteer donors. ABC thanks FDA's Center for Biologics Evaluation and Research for the opportunity to make public comments before the FDA Science Advisory Board.

We want to emphasize the critical need for scientific research to support the development of new knowledge and technologies that will result in increased blood availability blood and transfusion safety. What is urgently needed are major changes in FDA's processes and infrastructure and a focus on the path ahead.

We believe that CBER, the center that regulates blood and blood products needs to enhance substantially the necessary infrastructure for basic research and evaluation of currently- licensed blood components.

We have confronted in recent years a number of incidents that raised serious safety concerns and threatened the availability of blood and components to patients in need. Examples were the discovery of white particulate matter (WPM) in red cells, and the appearance of hemolysis in a large number of red blood cell units subjected to filtration for leukoreduction using filters from one particular manufacturer. What became evident in the investigation of these incidents is that CBER lacks the infra-structure for basic research and evaluation of currently used blood components. They had to rely on the industry and on device manufacturers to generate the data required for science based decision making.

The closure of most research departments at the American Red Cross' Holland Laboratory, the reduced capabilities of the Army Blood Research lab, the closure of Dr. Bob Valeri's Naval Blood Research Laboratory and the aging of the primary investigators in our field should be sending signals to FDA and this country that future regulatory decisions and the available data about collection devices, blood components and modifications to current components will rely solely on data from manufacturers and institutions supported by manufacturers. To prevent this, independent labs must be available for rapid analysis and unimpaired by contractual obligation from revealing that analysis and free from apparent conflicts of interest.

We recommend that FDA fund more adequately its own laboratories and have its own extramural granting mechanism (or through NHLBI) for regulatory or compliance required research. If these are multi-year funds a grant cycle could be developed that would guarantee funds are not wasted but that they would always be available.

Other areas where similar deficiencies can be identified are (a) the quality of lyophilized plasma products and products such as anti-coagulants and collection bags or devices. FDA does not have the ability to characterize these products as far as their basic chemical and molecular content; (b) the quality of donor screening tests particularly when new concerns are raised as in the case of specificity of tests for HBsAg, new variants for HIV and HTLV or the need for individual donor testing for West Nile virus.

We are aware that CBER needs funding and resources to accomplish this. However, the issues are bigger than just money. FDA needs improved and more frequent dialogue with industry on Guidances, Regulations and Memoranda. We are aware that a number of rules restrict FDA's ability to engage in dialogue with industry after the internal decision is made to develop guidance. But we need a mechanism that allows open dialog.

We suggest that CBER hold an annual workshop to discuss the guidance/regulations that it intends to publish during the upcoming year. This might eventually evolve into a review of priorities and an open discussion with stakeholders about what is needed to meet patient needs

first, industry needs second, and regulatory and compliance needs as required. We also recommend that BPAC have at least one meeting per year devoted to strategic planning and advising FDA on the needs of both patients and the regulated industry.

Ultimately, we are looking for greater use of a scientific approach to investigate threats to the blood supply. FDA and CBER need to have the ability to rapidly investigate threats to the blood supply such as WPM, emerging diseases and incidents of hemolysis.

ABC believes that CBER does not have the necessary scientific resources to perform its core functions. Of course, industry needs to be inspected and be responsible to the compliance arm for meeting regulation. But at the same time, the agency must respond rapidly to changes and advances in technology without tying the hands of industry. FDA must have the qualified personnel and laboratories to make science based decisions. CBER scientists must understand blood and blood components in depth.

We need to re-define the relationships and provide a framework that enhances patient care, product advancement and availability and patient safety. We could legitimately claim that US patients are at risk because clear safety enhancements that have been put in place outside of the US (*e.g.*, PRISM, pre-pooled platelets, frozen platelets) others are unavailable because of what manufacturers see as insurmountable roadblocks at FDA. Innovation in the US is being stifled. We need to work together to find a way through this morass.

Thank you for the opportunity to comment. I would be pleased to answer any questions you might have.