



725 15TH STREET, NW ♦ SUITE 700 ♦ WASHINGTON, DC 20005

202-393-5725 ♦ 1-888-USBLOOD ♦ FAX: 202-393-1282

Web Site: <http://www.americasblood.org> ♦ e-mail: abc@americasblood.org

OUR MEMBERS SERVE COMMUNITIES NATIONWIDE

BLOOD BAGS FOR DIVERSION OF INITIAL COLLECTION

STATEMENT OF AMERICA'S BLOOD CENTERS

BEFORE THE FDA BLOOD PRODUCTS ADVISORY COMMITTEE

March 15, 2001

**Presented by Celso Bianco, M.D.
Executive Vice President**

America's Blood Centers, or ABC, is an association of 75 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 Blood Products Advisory Committee.

ABC members commend CBER for bringing up the discussion of practical solutions to the rare but serious problem of bacterial contamination of whole blood and apheresis collections. Despite the procedures used to sterilize bags and to decontaminate the donor skin prior to blood collection, bacterial contamination occurs with a measurable frequency and may lead to fatal complications.

Experimental evidence published in the literature and presented to the Committee suggests that the diversion of the first few milliliters of blood into a side pouch attached to the collection tubing contributes to the reduction of bacterially contaminated units of whole blood. The actual benefit of introduction of such bags will be hard to determine, because of the low frequency of clinically-significant bacterial contamination events. Consequently, we recognize that licensure of the newly configured bags cannot be based on actual clinical data. ABC members support the introduction of these modified collection bags, provided that the issues below are adequately addressed. In fact, ABC members believe that, in the short-term, addressing bacterial contamination may do more for the safety of the blood supply than low specificity deferrals (*e.g.* malaria, history of hepatitis) and the introduction of additional tests for viral diseases transmissible by transfusion.

ABC members request that CBER and the Committee take into account the following important issues:

1. Current manufacturers of licensed blood collection bags in the US have never manufactured whole blood bags with a side pouch in large scale. We know that these companies will resolve the complex manufacturing issues raised by the modifications. Besides being effective, the added tubing and seals must be appropriately placed in the collection system

and simple enough to use, in order to prevent increases in failed collections and human error. The modified bags must be field tested in actual collection settings before their introduction for routine use in more than 13 million whole blood collections a year. We also expect adequate training materials and technical support.

2. In the proposed scenarios, the side pouch will be used as the source of specimens for donor screening. Thus, it must hold enough blood for all required testing. Sample quality must also be appropriate. A recent survey of ABC members shows that many collect 4 tubes—each with a volume of between 7 and 10 ml. Thus, the pouch must hold at least 35 ml of blood.
3. According to the same survey, there is no consistent approach to the sequence of types of tube collected. Some centers collect first the dry tubes for serology; others collect first the EDTA tubes for NAT and red blood cell typing. Currently, this sequence is irrelevant because the venous blood is only exposed to a short segment of tubing. With the proposed collection systems, the technician must seal the tubing between the needle and the pouch and initiate blood flow into the collection bag prior to the start of sample collection, in order to prevent obstruction of the needle by clots. This may affect the sequence of specimen collection: which tubes should be collected first? The specimen for NAT? The dry tubes or the anticoagulated tubes? We hope that this will be clearly addressed in the package insert and training materials.
4. We request that CBER consider allowing the collection of an alternate sample obtained from a different venipuncture site on the same donor, in case the filling of the pouch, or the collection of samples from the pouch are unsuccessful.
5. Finally, we believe that package inserts and training materials must acknowledge that there are sources of accidental contamination of transfusable blood and blood products that are not associated with the venipuncture of the donor (*e.g.* contamination during platelet pooling, contamination of the bag ports and contamination of transfusion sets and catheters).

In conclusion, ABC member centers wholeheartedly support the introduction of measures to prevent bacterial contamination of blood. ABC members are committed to blood safety. ABC members are also committed to the preservation of the supply of safe volunteer donor blood for all patients in need, because no blood is a real risk, not a theoretical risk, and it threatens patient care.

Thank you again for the opportunity to comment.