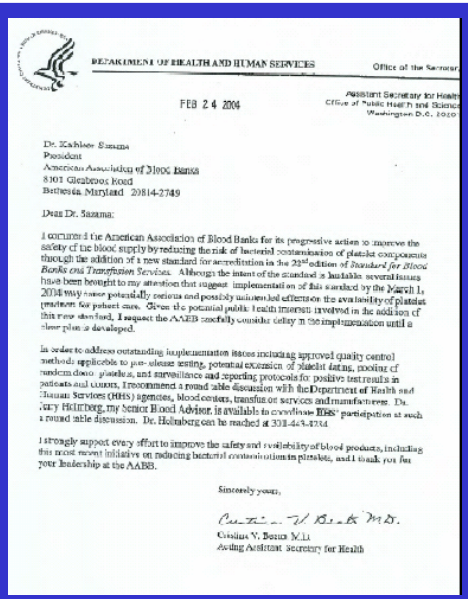
AABB Interorganizational Task Force on Bacterial Contamination of Platelets

UNC Hospitals



DEPARTMENT OF HEALTH AND HUMAN SERVICES — Office of the Secretary

FEB 24 2004

Assistant Secretary for Health
Office of Public Health and Science
Washington, D.C. 20201

Dr. Kathleen Sazama
President
American Association of Blood Banks
8101 Glenbrook Road
Bethesda, Maryland 20814-2749

Dear Dr. Sazama:

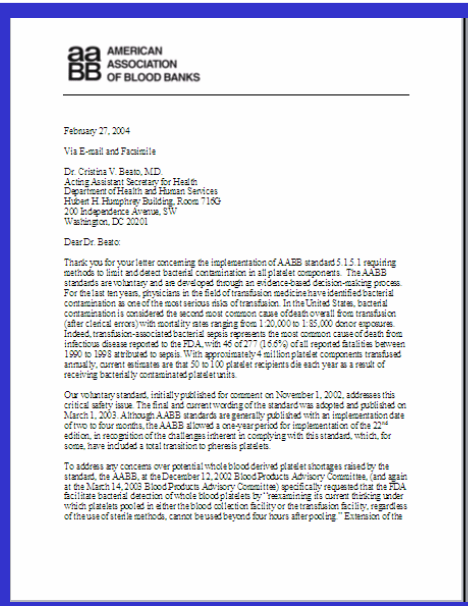
I commend the American Association of Blood Banks for its progressive action to improve the safety of the blood supply by reducing the risk of bacterial contamination of platelet components through the addition of a new standard for accreditation in the 2nd edition of *Standard for Blood Banks and Transfusion Services*. Although the intent of the standard is laudable, several issues have been brought to my attention that suggest implementation of this standard by the March 1, 2004 may cause potentially serious and possibly unintended effects on the availability of platelet products for patient care. Given the potential public health impacts involved in the addition of this new standard, I request the AABB carefully consider delay in the implementation until a clear plan is developed.

In order to address outstanding implementation issues including approved quality control methods applicable to pre-release testing, potential extension of platelet dating, pooling of random donor platelets, and surveillance and reporting protocols for positive test results in patients and donors, I recommend a round table discussion with the Department of Health and Human Services (HHS) agencies, blood centers, transfusion services and manufacturers. Dr. Jerry Holmberg, my Senior Blood Advisor, is available to coordinate HHS participation at such a round table discussion. Dr. Holmberg can be reached at 301-443-4754.

I strongly support every effort to improve the safety and availability of blood products, including this most recent initiative on reducing bacterial contamination in platelets, and I thank you for your leadership at the AABB.

Sincerely yours,

Cristina V. Beato M.D.
Acting Assistant Secretary for Health



AMERICAN ASSOCIATION OF BLOOD BANKS

February 27, 2004

Via E-mail and Facsimile

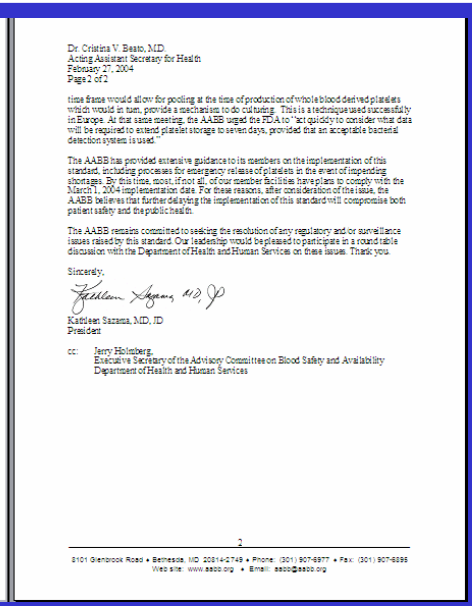
Dr. Cristina V. Beato, M.D.
Acting Assistant Secretary for Health
Department of Health and Human Services
Hubert H. Humphrey Building, Room 715G
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Beato:

Thank you for your letter concerning the implementation of AABB standard 5.1.5.1 requiring methods to limit and detect bacterial contamination in all platelet components. The AABB standards are voluntary and are developed through an evidence-based decision-making process. For the last ten years, physicians in the field of transfusion medicine have identified bacterial contamination as one of the most serious risks of transfusion. In the United States, bacterial contamination is considered the second most common cause of death overall from transfusion (after clerical errors) with mortality rates ranging from 1:20,000 to 1:85,000 donor exposures. Indeed, transfusion-associated bacterial sepsis represents the most common cause of death from infectious disease reported to the FDA, with 46 of 277 (16.6%) of all reported fatalities between 1990 to 1998 attributed to sepsis. With approximately 4 million platelet components transfused annually, current estimates are that 50 to 100 platelet recipients die each year as a result of receiving bacterially contaminated platelet units.

Our voluntary standard, initially published for comment on November 1, 2002, addresses this critical safety issue. The final and current wording of the standard was adopted and published on March 1, 2003. Although AABB standards are generally published with an implementation date of two to four months, the AABB allowed a one-year period for implementation of the 2nd edition, in recognition of the challenges inherent in complying with this standard, which, for some, have included a total transition to pheresis platelets.

To address any concern over potential whole blood derived platelet shortages raised by the standard, the AABB, at the December 12, 2002 Blood Products Advisory Committee, (and again at the March 14, 2003 Blood Products Advisory Committee) specifically requested that the FDA facilitate bacterial detection of whole blood platelets by "maintaining its current thinking under which platelets pooled in either the blood collection facility or the transfusion facility, regardless of the use of sterile methods, cannot be used beyond four hours after pooling." Extension of the



Dr. Cristina V. Beato, M.D.
Acting Assistant Secretary for Health
February 27, 2004
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time frame would allow for pooling at the time of production of whole blood derived platelets which would, in turn, provide a mechanism to do culturing. This is a technique used successfully in Europe. At that same meeting, the AABB urged the FDA to "act quickly to consider what data will be required to extend platelet storage to seven days, provided that an acceptable bacterial detection system is used."

The AABB has provided extensive guidance to its members on the implementation of this standard, including processes for emergency release of platelets in the event of impending shortages. By this time, most, if not all, of our member facilities have plans to comply with the March 1, 2004 implementation date. For these reasons, after consideration of the issue, the AABB believes that further delaying the implementation of this standard will compromise both patient safety and the public health.

The AABB remains committed to seeking the resolution of any regulatory and/or surveillance issues raised by this standard. Our leadership would be pleased to participate in a round table discussion with the Department of Health and Human Services on these issues. Thank you.

Sincerely,

Kathleen Sazama, M.D., JD
President

cc: Jerry Holmberg
Executive Secretary of the Advisory Committee on Blood Safety and Availability
Department of Health and Human Services

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"…implementation…may cause effects on the availability of platelets…I request the AABB carefully consider delay in implementation" C. Beato

"…after consideration of the issue, the AABB believes that further delaying the implementation of this standard will compromise both patient safety and the public health." K. Sazama

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Purposes of task force

- Serve as focal point for all issues related to the AABB bacterial detection standard that took effect in March 2004
- Provide forum for discussion between transfusion medicine community (transfusion services and blood centers), subject matter experts, and PHS agencies (FDA, CDC, HHS, NHLBI) on specific safety/availability issues
- Interact with test manufacturers as appropriate

Purposes of task force

- Provide guidance to AABB membership
  - Issues to be addressed include standardized definitions of test results, follow-up of initially positive tests, identification of organism, what to do if a positive platelet unit has been transfused, notification and possible deferral of the donor, and possible interaction with public health departments
- Survey blood centers/hospitals to assess current practices
  - Data on impact on inventory/transfusion practice

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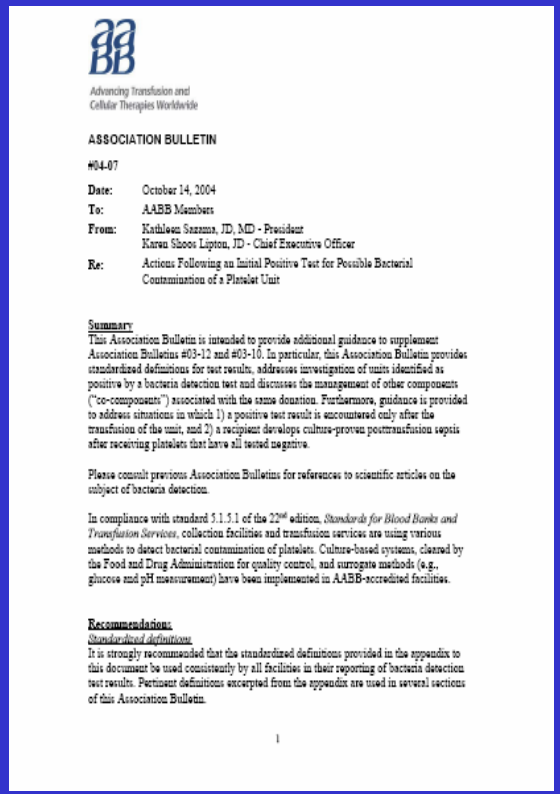

Advancing Transfusion and Cellular Therapies Worldwide

ASSOCIATION BULLETIN

#04-07

Date: October 14, 2004
To: AABB Members
From: Kathleen Sazama, JD, MD - President
Karen Shoos Lipton, JD - Chief Executive Officer
Re: Actions Following an Initial Positive Test for Possible Bacterial Contamination of a Platelet Unit

Summary
This Association Bulletin is intended to provide additional guidance to supplement Association Bulletins #03-12 and #03-10. In particular, this Association Bulletin provides standardized definitions for test results, addresses investigation of units identified as positive by a bacteria detection test and discusses the management of other components ("co-components") associated with the same donation. Furthermore, guidance is provided to address situations in which 1) a positive test result is encountered only after the transfusion of the unit, and 2) a recipient develops culture-proven posttransfusion sepsis after receiving platelets that have all tested negative.

Please consult previous Association Bulletins for references to scientific articles on the subject of bacteria detection.

In compliance with standard 5.1.5.1 of the 22nd edition, *Standards for Blood Banks and Transfusion Services*, collection facilities and transfusion services are using various methods to detect bacterial contamination of platelets. Culture-based systems, cleared by the Food and Drug Administration for quality control, and surrogate methods (e.g., glucose and pH measurement) have been implemented in AABB-accredited facilities.

Recommendations:
Standardized definitions
It is strongly recommended that the standardized definitions provided in the appendix to this document be used consistently by all facilities in their reporting of bacteria detection test results. Pertinent definitions excerpted from the appendix are used in several sections of this Association Bulletin.

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Karen Shoos Lipton, JD - Chief Executive Officer

Re: Actions Following an Initial Positive Test for Possible Bacterial Contamination of a Platelet Unit

UNC Hospitals

Priority action items

7 day platelets

Pre-pooled “random” platelets

Survey on platelet testing

FDA current thinking

- Obtain data on performance of the FDA cleared devices
- Use data as a basis for approval of 7 day platelets provided there is a commitment to perform post market study
- Post market study will consist of an additional culture on outdated products (day 7) to confirm the day 1 negative culture reading
- Size of post market study will be determined by the contamination rate identified by the Q/C testing data

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Day 1/2

Day 8/9

1,500,000 platelet units

50,000 platelet units

Day 1/2

Day 8/9

1,500,000 platelet units

50,000 platelet units

BioMerieux Proposal

UNC Hospitals

The task force reviewed this proposal and does not support the need for the Day 1 anaerobic bottle as a part of the protocol.

However, the task force believes that it is a valid medical/scientific issue as to determine whether bacterial testing of platelets should include the detection of anaerobes and recommends bioMerieux sponsor a protocol to study this issue that is independent of the post-market surveillance study.

The task force has had in-depth discussions with representatives of ARC and BSI about the task force protocol and bioMerieux revisions thereof. The task force recommends that bioMerieux follow-up with these two blood collection organizations (and others) to ascertain their willingness to participate in bioMerieux's proposed protocol.

The task force does not see a further role for itself with regard to the seven day storage issue as it believes it has successfully worked with FDA to clarify what is required for 7 day storage of apheresis platelets to occur. The task force has been influential in providing a roadmap for manufacturers such as bioMerieux to work with FDA-licensed blood collection agencies to achieve this goal.