



Advancing Transfusion and
Cellular Therapies Worldwide

November 15, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 2004S-0233, “Stimulating Innovation in Medical Technologies”

Dear Dockets Manager:

AABB is an international association dedicated to advancing transfusion and cellular therapies worldwide. Our members include more than 1,800 hospital and community blood centers and transfusion and transplantation services as well as approximately 8,000 individuals involved in activities related to transfusion, cellular therapies and transplantation medicine. For over 50 years, AABB has established voluntary standards for, and accredited institutions involved in, these activities. AABB is focused on improving health through the advancement of science and the practice of transfusion medicine and related biological therapies, developing and delivering programs and services to optimize patient and donor care and safety.

The AABB commends the Department of Health and Human Services (HHS) for convening a high level panel to examine ideas on ways in which HHS can coordinate its efforts to help stimulate medical innovation. AABB has been involved in several initiatives with HHS agencies and can attest to the value of interaction and coordination among the HHS agencies as well as with the private sector. Several recent blood-related public-private sector initiatives may serve as models for addressing issues facing the medical and scientific community with regard to safety and efficacy of blood, transfusion therapy and cellular therapies. However, the AABB believes even greater coordination among HHS agencies is needed to promote the introduction of new technologies aimed at promoting transfusion safety. Most notably, AABB believes that enhanced coordination between the Food and Drug Administration (FDA) and Centers for Medicare and Medicaid Services (CMS) and more timely reimbursement of blood products and services is essential to ensure suppliers invest in technologies designed to provide patients with the safest possible blood supply.

8101 Glenbrook Road
Bethesda, MD 20814-2749
301.907.6977 MAIN
301.907.6895 FAX
www.aabb.org

Recent Models of Agency Collaboration

The AABB commends both the FDA and the Centers for Disease Control and Prevention (CDC) for their interaction with the blood banking community with regard to West Nile Virus. As a result of close cooperation and communication, testing of the blood supply in 2003 and 2004 was initiated using nationwide INDS, and the CDC was able to obtain valuable epidemiological information as well. Such cooperation should serve as a model for identification and resolution of emerging pathogens that might impact the blood supply, as well as for further exploration of existing and newly proposed blood donor suitability requirements.

The CDC and FDA have been active participants with the AABB Interorganizational Uniform Donor History Task Force to develop a uniform donor history questionnaire that is intended to simplify and improve blood donor history screening materials. The ground-breaking and innovative work of the Task Force resulted in a very different type of questionnaire which will make the pre-donation qualifying process more effective in capturing relevant donor information and, in turn, enhancing blood safety. In particular, the National Center for Health Statistics (NCHS) of the CDC provided invaluable advice in question development as well as performing cognitive interviews to verify that the questions were well understood. Funding from the National Heart, Lung and Blood Institute (NHLBI) supported the initial cognitive interview studies, and FDA provided additional funding for new questions that were required after the initial testing had been completed. CDC and NIH scientists also provided additional information concerning hepatitis and other disease transmission. After extensive review, FDA published a draft guidance recognizing the questionnaire and accompanying materials. Approval of an abbreviated history questionnaire for use by frequent donors is also under review. Continued involvement of HHS agencies, especially NCHS, will be critical as the questionnaire is a very dynamic document and continued review and revision will be essential.

HHS, FDA and CDC have also been active in an AABB Interorganizational Task Force on Bacterial Contamination in Platelets. AABB convened this Task Force in an effort to promote the development and implementation of technologies aimed at reducing the risk of bacterial contamination of platelets – the most significant infectious risk associated with receiving a blood transfusion today. The Task Force has developed standardized definitions, recommendations for investigation of units identified as positive by a bacterial detection test, recommendations for management of co-components associated with the same donation, and policies related to donor and patient notification. HHS, FDA, and CDC have provided invaluable insight to the Task Force, and the HHS Advisory Committee on Blood Safety and Availability has requested and received reports from the Task Force. In particular, FDA has been involved in an effort to develop a mechanism to increase the expiration date of platelets and provide for pre-storage pooling of whole blood derived platelets. FDA has demonstrated a willingness to consider new and innovative approaches to reaching these goals, and we look forward to continued exploration of these ideas. Such innovative approaches are essential to encourage medical technology suppliers to invest in this important, but limited, area of patient safety. We anticipate that

resolution of the issues and availability of platelets with a longer expiration time will have a positive impact on platelet supply in the U.S., as well as enhance safety of platelet transfusion.

Enhanced Coordination between CMS and FDA Needed

AABB believes it is imperative that there be better coordination between FDA and CMS to ensure that patients have access to the best possible blood products and services. Today, Medicare payments for blood components lag far behind the actual costs of these products, which continue to rise significantly with the introduction of new FDA-approved and/or required blood safety measures. Non-profit blood centers and the hospitals that provide life-saving blood technologies cannot afford to absorb these increased costs for the years between the time blood safety technologies are introduced and the time Medicare actually reimburses for them. Furthermore, absent a fair return on their significant investments, medical technology companies will not dedicate resources to researching and developing new life-saving blood-related technologies.

HHS' Advisory Committee on Blood Safety and Availability has recognized this problem, adopting several resolutions urging the Department to take steps so that Medicare payments are based on the actual, current costs of blood products and services. AABB is pleased to note that CMS now has a representative serving on this advisory committee and appears to be paying greater attention to blood-related issues. However, more action is needed. AABB strongly urges HHS to act on these recommendations, which will help to provide Medicare recipients, and in turn other Americans, with improved access to the safest possible transfusion therapies.

Greater Attention to Technologies Aimed at Reducing Mistransfusions

As HHS and its various agencies work to alleviate errors in the healthcare arena, **particular attention should be given to transfusion-related errors. The most common non-infectious risk of a transfusion involves the mis-transfusion of a unit of blood intended for another patient. Today, a patient receiving blood in the United States is at least 100 times more likely to receive a misdirected unit of blood than to be exposed to HIV or hepatitis by transfusion.** AABB urges the government to address the need to promote technologies to ensure the right patient gets the right unit of blood. Because blood represents only a very small percentage of healthcare dollars, this issue is not necessarily a priority for hospitals. But because blood safety is a national public health priority, HHS should take steps to promote this critical area of transfusion safety.

Coordinated Regulation of Tissue Practices Needed

AABB also has concerns about the lack of coordination among government agencies charged with overseeing human tissues and the effect this confusion may have on the development of innovations in tissue-related therapies. There continues to be a disconnect between some federal agencies in the protection of recipients of organs and tissues from infectious risks. The AABB

Division of Dockets Management
Page 4
November 15, 2004

has established a Task Force, including a CDC liaison, to address issues relative to storage and distribution of tissues including traceability. The identification of multiple infectious risks in the last few years has provided the impetus to bring agencies together to solve this problem. Coordination between the Health Resources and Services Administration, FDA, HHS, CDC and NIH along with organizations such as AABB, the American Association of Tissue Banks and the Association of Organ Procurement Organizations to discuss improved communications and better management of resources could address these issues.

AABB appreciates the opportunity to comment on this important inter-departmental initiative. We welcome the opportunity to continue to work with HHS and all of its agencies, and recommend use of methods that encourage communication and interaction, not only across governmental agencies, but also with outside stakeholders. The safety and availability of new technologies related to blood and other health care arenas depend on the coordination of all such agencies.

Questions regarding these comments may be referred to Kay Gregory at kayg@aabb.org.

Sincerely,

Karen Shoos Lipton
Chief Executive Officer