



Advancing Transfusion and  
Cellular Therapies Worldwide

04 February 2008

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
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Via Fax

RE: Docket 2007N-0489, 04 January 2008, Request for Comments on the Science and Technology Report; Establishment of Docket

Dear FDA 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, and developing and delivering programs and services to optimize patient and donor care and safety.

AABB appreciates this opportunity to comment on the findings of the Science Board as published in the Report of the Subcommittee on Science and Technology (Report) in the Federal Register on 04 January. The Report appropriately emphasizes the broad scope of responsibilities charged to FDA and the need to leverage public-private partnerships to successfully address FDA's core functions. The following excerpts from pages 47 and 48 represent a common theme of the Report and are reprinted here to emphasize public-private partnership options available to FDA.

The Subcommittee found that the FDA's current critical information supply chains are, at best, inefficient, cost intensive and prone to promote errors in regulatory science due to the inability to access, integrate and analyze data... Furthermore, processes for data information exchange, both internally as well as among external partners, lack clear business processes, information technology standards, sufficient workforce expertise, and robust technology platform, such that the FDA cannot

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credibly process, manage, protect, access, analyze and leverage the vast amounts of data that it encounters. Consequently, the FDA's ability to support industry innovation and regulatory activities is compromised.

The Subcommittee recommends that...FDA should aggressively pursue access to health and public health databases for adverse-event identification and surveillance for risk identification. Similarly, by leveraging standards and access to growing health information exchanges, the FDA should catalyze and participate in the development of efficient pre-market and post-market data exchange networks required to ensure the quality, safety and efficacy of medical and consumer products as defined by its regulatory mandate.

AABB comment: AABB believes that the most effective way to collect adverse event data that can be used to improve patient safety is to take advantage of non-punitive reporting systems. AABB is engaged with the CDC in the public-private development of a national biovigilance system that will provide a mechanism for non-punitive reporting. Furthermore the system is being developed with the ability to mine the data that will reside in this valuable repository.

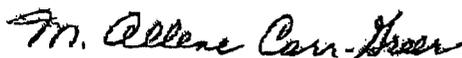
The Subcommittee found that the FDA lacks the capability to leverage technology to assist in the inspection and monitoring of manufacturing sites, transportation vehicles and product...Until the FDA can develop the requirements for these capabilities and work with the private sector so that these capabilities emerge, the manufacture and transportation of its regulated products will not be adequately monitored. The extraordinary number of sites that must be monitored and the dearth of inspectors translate into the FDA's inability to fulfill its quality assurance mandate

AABB comment: The Subcommittee strongly encourages FDA to take advantage of public-private partnerships and AABB encourages FDA to explore options available for third party assessments. AABB has a proven ability to provide third party assessments and has deemed status for CLIA inspections.

AABB strongly supports initiatives that improve the safety of patients and donors and stands ready to interact with FDA as necessary.

Questions concerning these comments may be directed to me at [acarrgreer@aabb.org](mailto:acarrgreer@aabb.org).

Sincerely,



M. Allene Carr-Greer  
Director, Regulatory Affairs