

AABB Support of HHS Gap Analysis and Update on Hemovigilance

Statement Before the

Advisory Committee on Blood Safety and Availability

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AABB appreciates the opportunity to provide the Advisory Committee on Blood Safety and Availability with a brief update regarding hemovigilance activities and in the broader context, the efforts of the Interorganizational Task Force on Biovigilance to establish the US Biovigilance Network. AABB commends the Department of Health and Human Services for its work in preparing a gap analysis of biovigilance activities within the federal government. The paper offers important background and analysis of the existing government programs touching upon blood, organ and tissue safety monitoring.

However, because this paper focuses mainly on government activities up to a certain time, it does not provide an entirely complete, up-to-date picture of hemovigilance efforts.

Today, I would like to focus on the considerable progress that the public and private sectors, working together, have made in advancing hemovigilance efforts in the United

States as well as the challenges that remain to realizing a robust system which can best lead to improvements in patient care and donor health.

AABB is extremely pleased that the hemovigilance module of the National Healthcare Safety Network (NHSN) will open to all interested participants beyond its current nine pilot sites in January 2010. Over the past year, AABB has worked closely with CDC to recruit and educate the nine hospitals participating in the pilot and worked to improve the system to address issues raised by the pilot participants. AABB has also expended considerable effort in promoting the hemovigilance module to hospitals across the country with the intent that significant numbers of hospitals will join the system when it becomes fully operational in January. We have held regional recruitment meetings in eleven cities, spoken at numerous regional blood bank meetings in 2008 and 2009, published articles, hosted audio conferences and offered related programs and educational opportunities during our annual meetings in Montreal and New Orleans. Stemming from these efforts, over 60 hospitals have indicated that they will join once the pilot is completed.

In addition, with the support of HHS and strong participation from the private sector, the donor hemovigilance system has been piloted with small, medium and large blood centers. Preparations are underway for full implementation of this system in early 2010.

While this progress is notable, significant challenges remain before a robust, high quality program can lead to meaningful patient care advancements. In today's economic

environment, funding for both public and private sector efforts continues to be uncertain. On the private sector side, AABB and our members (many of whom have already contributed generously to the initial funding for this initiative) cannot afford to financially support biovigilance to the degree we have to date. Increased federal funding to support the program, including the essential private sector role, is absolutely critical. AABB would like to highlight for the committee the following areas where committed, sustained funding from the federal government is needed to support the private sector role:

- **Recruitment:** Considerable effort is needed to inform and educate hospitals about the significant value of this program.
- **Education:** As hospitals begin to participate in the hemovigilance module, their staffs will need to be educated about the myriad definitions and issues that may arise, so that standardized reporting is assured.
- **Quality Control:** Funds need to be dedicated to data review to assure that data reported into the system meet the protocols.
- **Analysis:** Finally, considerable funding will be needed to support the analyses of the data to identify optimum interventions to improve transfusion safety.

We recognize that today the committee is focused primarily on organ and tissue safety. AABB supports expansion into these important areas for patient safety and notes that a robust and financially sound hemovigilance system is a key first step to expansion into tissues and organs. Without a strong private-public collaborative network, including

infrastructure of electronic systems and qualified experts working towards the desired patient safety improvements, there is no solid base to expand into these next arenas.

Therefore, AABB urges the committee to continue to be vigilant about hemovigilance. Your previous recommendations have led directly to the progress that has been made to date in advancing blood safety surveillance. AABB hopes that the committee and HHS will promote increased, sustained funding for both the public and private sector roles to support the ongoing collaboration to advance hemovigilance and improve patient care and blood donor health