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STATEMENT

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Extension of Platelet Dating

Statement before the Food and Drug Administration's Blood Products Advisory Committee

Louis Katz, MD, President

March 14, 2003 – America's Blood Centers (ABC) is a national network of locally-controlled, non-profit community blood centers that provide nearly half of the U.S. blood supply from volunteer donors. Collectively, ABC total blood collections exceeded 7 million donations in 2001. ABC members operate in 45 states and in Québec, Canada, and serve more than half of the 6,000 hospitals in the U.S.

In the 1970s the platelet outdate period was extended from 5-7 days, and subsequently rolled back to 5 days when it became apparent that an increase in septic reactions to platelets was associated with the longer outdate. This was appropriate. Today ABC's members are pleased to participate in the efforts of the blood community to control septic reactions to platelets using currently approved systems for bacterial detection. It is in this historical context that BPAC and FDA should address both extension of platelet outdates and the regulatory approach to allowing pre-pooling of platelets from whole blood (random donor platelets). The deployment of these detection methods should allow reconsideration of longer platelet outdating.

ABC endorses the comments that primarily address pre-pooling contained in the AABB statement today. We further emphasize the importance of expeditious and non-burdensome attention to extension of platelet outdating to 7 days and beyond as a measure to enhance safety and availability of platelets to patients in need. The optimal use of bacterial detection systems requires a 1-2 day incubation using the licensed quality control systems, and incubation cannot begin until 24 hours after component preparation. This will leave only 1-2 days of shelf life on a 5-day platelet product, and may impair the availability of these products, most critically for blood systems and transfusion services dependent on imports from remote collection facilities.

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The FDA should use the least burdensome approach to allowing extension of outdating for those products subjected to sensitive bacterial detection. We support the need for limited clinical studies of platelet recovery and survival to replicate the data that led to a 7-day expiration in the 1970s using current collection methods. For apheresis platelets, autologous studies will be acceptable; for pooled random donor platelets, studies in thrombocytopenic patients will be required. They should be statistically powered to demonstrate pre-agreed upon recovery and survival in comparison to 1 day old platelets with pre-agreed statistical confidence, and not be unnecessarily large, so as to inhibit the adoption of bacterial detection systems.

Clinical trials using prevention of bleeding as an end point are not needed since recovery and survival are predictive. In vitro studies of platelet function should not be required since their correlation with clinical endpoints is weak.

The voluntary implementation of bacterial detection by the blood community represents a robust approach to the most serious current infectious risk of transfusion. FDA's participation as outlined above is in the best interest of the safety and adequacy of the blood supply.

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