American Hospital Association

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April 26, 2017

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

Re: Docket No. FDA–2014–D–1814, "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services To Enhance the Safety and Availability of Platelets for Transfusion" Draft Guidance, March 15, 2016.

Dear Dockets Manager:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) on the draft guidance, "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services To Enhance the Safety and Availability of Platelets for Transfusion." The guidance details specific requirements for bacterial testing of all apheresis and whole blood derived platelets on Day 4 and 5, or the use of pathogen reduction (PR) technology as an alternative approach.

The AHA understands that the FDA is considering finalizing the draft guidance in the near future. However, we have recently heard serious concerns from hospitals and blood collection organizations about the possible unintended consequences that the draft requirements will have if FDA finalizes them unchanged. Specifically, we fear the testing requirements, which are intended to improve safety by reducing the chance of infection, will actually put patients at greater risk. As we discuss further below, the national supply of platelets is already constrained, and the proposed changes to the processes will further reduce that supply by limiting the number of products that can be obtained from a single donor collection and forcing hospitals and other care providers to discard more platelets that become outdated. Such shortages could force hospitals to cancel some surgeries, and patients would be forced to wait longer for needed services. Rural communities may be put at particular risk if they are no longer able to rotate their stock of platelets, trying to ensure a fresh supply is available when needed.

We believe FDA needs to consider the full ramifications and potential unintended consequences of its proposed change and determine whether the processes it proposes will have a positive effect on patient safety before proceeding. Therefore, the AHA does not support finalizing the draft guidance at this time. We understand that three major blood organizations have recently submitted a joint letter to FDA raising similar concerns. We share their concerns. **We urge the FDA not to finalize this guidance until it has addressed concerns including**:

- Using the current PR technology, it is not possible to inactivate bacteria for all platelet products. Multiple options need to be developed. Due to content and volume limitations, current PR processes are not a complete solution. Further, PR processes diminish the number of products that can be obtained from a single donor collection, which reduces overall production efficiency and the supply of platelets. The use of PR will also be very costly to hospitals; blood collectors in one state estimate an additional $100 to $120 per platelet unit, cost which will then be passed on to hospitals, insurers, and ultimately to patients. One health system estimates it uses 10,000 platelets per year, which would increase their costs between $1 million and $1.2 million per year.

- The option to PR offered by FDA – requiring hospital transfusion services to conduct bacterial testing – is unworkable at this time. There are significant challenges to implementing the testing and relabeling of platelets beyond Day 3 of dating. The testing is labor intensive, requiring additional trained staff, who may not be readily available. Further, compliance with this testing will require significant training, equipment and information technology adjustments. Many hospitals do not yet have the operational structure in place to support such complex manufacturing-like processes. Transfusion services will need adequate time after the final guidance is released to make these changes.

- The requirements for either PR or bacterial testing will have a significant impact on the supply of platelets to patients, with possible delays in care and treatment. Currently, many blood collection organizations meet the demand for platelets by allowing returns of unused platelets from hospitals for distribution elsewhere. This process minimizes wastage and helps ensure adequate supplies of this critical product. We are concerned that the guidance requirements will disrupt blood collection organizations' ability to enter into such consignment arrangements with hospitals in which they accept returns and rotate platelets to higher volume users on Days 4 and 5 of dating. The resulting increase in outdating of platelets could lead to shortages. It may also inhibit the ability of rural hospitals to keep an emergency stock of platelets on hand through rotation of their inventory.

- A constrained platelet supply will put even more recruitment pressure on existing donors, which could reduce the number of willing donors.

With such critical concerns about the ability of hospitals and blood collection organizations to comply with the requirements as well as the potential impact on platelet supply, it is premature for the FDA to finalize its recommendations. Additional time, information and resources are needed to address these concerns. Furthermore, as the new administration works to decrease the cost of health care and reduce regulatory burden, we encourage the agency to re-examine this proposed guidance.

If, nevertheless, the FDA decides to move forward to finalize the guidance, then it should impose these changes in a manner designed to minimize the unintended consequences. Consistent with the recommendations from the blood industry, the AHA strongly recommends that FDA delay the release of final recommendations and also allow at least an 18-month implementation period once the final guidance is issued in order to give blood collectors and hospitals adequate time to comply.

Thank you for your consideration of these comments. Should you have any questions concerning this letter, please contact me or Roslyne Schulman, director of policy, at rschulman@aha.org.

Sincerely,

/s/

Ashley Thompson
Senior Vice President Public Policy Analysis and Development