

November 15, 2005

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

0068 5 DEC -1 P1:58

Re: Docket number 2005D-0330, Collection of Platelets by Automated Methods

To Whom It May Concern:

Thank you for the opportunity to respond to the draft guidance document cited above. We, the undersigned, are laboratory representatives of hospitals in the Dallas-Fort Worth area. We are dependent upon the community blood center for an adequate platelet inventory and therefore would like to make the following comments:

We are very concerned about the effect of implementation of the draft guidance regarding apheresis platelet collection issued in September 2005. The changes that would occur, should this guidance document be finalized in its current form, will seriously affect the availability of platelets for transfusion in our area.

Specifically:

1) the requirement to limit the number of donor contributions to the blood supply to 24 platelet components per year (versus 24 donations per year) will significantly reduce the number of platelet units available to the community unless a large number of new donors can be recruited. These donors would be needed to replace the products lost from higher donor activity levels in past years. Has FDA considered that the known risk of first time donors may be more significant than a postulated risk of possible harm to donors donating double or triple components at current frequencies?

2) the requirement to have a physician present ("able to arrive at the premises within 15 minutes") is overly burdensome and unnecessary. Platelet donation is a very safe procedure, as proven by years of experience and the very low rate of serious side effects. Requiring a physician will restrict the number of sites at which platelets can be collected by apheresis (there are currently 20 such sites that our local blood center uses).

3) the requirement to defer donors who have taken non-steroidal anti-inflammatory agents in the last 3 days is overly restrictive and will affect large numbers of donors. NSAIDs are reversible inhibitors of platelet cyclo-oxygenase. Platelets from these donors should resume function when transfused to a recipient.

The recent addition of bacterial detection to our platelet inventory has already imposed a significant burden on the blood collection system, requiring larger platelet apheresis draws to offset losses from outdating as well as increased

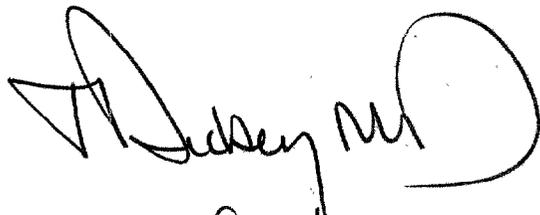
2005D-0330

C5

demand from facilities converting to apheresis platelets from random platelets (which are laborious to bacterially screen).

We urge you to reconsider these proposed changes. The lack of adequate platelet supplies for our community is a real and significant danger. We believe this risk is higher than many theoretical and unsubstantiated risks addressed in the draft guidance document. Thank you for your attention to these comments.

Sincerely,



11-16-05

medical director of lab  
member of Baylor Medical Center

IRB

past CAP inspection + accreditation  
State Chair for Texas

Judy Barnes MT (ASCP) SBB  
Blood Bank Specialist  
Baylor Medical Center at Irving