



# Indiana Blood Center

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December 29, 2005

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Docket Number 2005D-0330

Dear Docket Officer:

The Draft Guidance for Industry and FDA Review Staff on Collection of Platelets by Automated Methods published in the Federal Register October 3, 2005 by the Food and Drug Administration contains proposed changes we feel could have a significantly negative impact on our ability to provide Platelet, Pheresis products in our community, and thus adversely effect patient care. Although as a member organization we concur in whole with the response to the proposed guidance forwarded to you by America's Blood Centers, we would like to take this opportunity to share concerns specific to our organization, and provide our own data.

Indiana Blood Center (IBC) serves 46 member hospitals throughout Central and Southern Indiana, supporting approximately 2,000,000 Indiana residents. As the largest blood center in Indiana, we collect 135,000 whole blood units and almost 15,000 apheresis platelets yearly to supply a hospital demand of more than 3,000 blood products per week. In addition, we offer a number of specialized services, including an AABB accredited reference laboratory and an ASHI and AABB accredited HLA-DNA laboratory providing paternity and relationship testing. Important to this discussion, we provide HLA and SPRCA cross-matched platelets as well as platelet products from mothers of infants with neonatal alloimmune thrombocytopenia. As stewards of the community's blood supply, we are licensed by the FDA and Indiana State Department of Health, as well as accredited by the AABB and a member of America's Blood Centers.

We would like to address some specific recommendations found in the Draft Guidance, and discuss their projected impact within our organization. The following summarizes these recommendations and our concerns.

- **Determining frequency of platelet apheresis donation based on number of products, including double and triples, rather than on number of donation procedures** (Page 6, Section III B, 2). IBC has many regular platelet donors whose products consistently yield split products (doubles and triples) with no indication of adverse effects. If donation frequency is determined as suggested, a projected 10% of products will be lost from inventory. In light of the status of platelets as one of the most perishable of products, these periods of ineligibility

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for some of our most dedicated donors could result in serious shortages in our community. We fail to understand how this proposed change will improve donor safety, and fear it will result in dire patient consequences secondary to product shortages.

- **Requiring a physician on donation premises, or able to arrive within 15 minutes** (Page 7, Section III D). In order to better meet the demand for Platelet, Pheresis product, we collect apheresis platelets at 7 fixed sites in addition to our main branch. This strategy not only enables us to provide the sheer number of products demanded by our member hospitals, but also allows us to obtain phenotypic diversity by collecting among several different populations, and aids in the provision of our specialized HLA and SPRCA cross-matched platelets, when needed for alloimmunized patients. All of our fixed sites would require transit time greater than the proscribed fifteen minutes, even under the best traffic conditions, and would thus be eliminated from eligibility as Platelet, Pheresis collection facilities under the proposed change. This would result in a loss of **8623 (56%)** products yearly. We also feature extended hours for Platelet, Pheresis donation, and limiting those hours to those the Medical Director is in-house would result in **an additional projected loss of 1859 (12.5%) products**. Please consider, according to a recent Marion County (Indiana) Commission meeting, *paramedic* response time is an average of four minutes. This rivals potential response time of the Medical Director when present in the same building. In our estimation, in an emergency situation, the donor/patient is better served by prompt arrival of ACLS personnel and speedy transport to definitive care, without the interposition of a requirement for the Medical Director, which may only result in delay of appropriate care. As you are aware, the frequency of adverse reactions among apheresis donors is lower than that of whole blood donors. Our data for moderate and severe reactions indicate a frequency of **0.26%** among whole blood donors, but only **0.12%** among our apheresis donors. In reviewing apheresis reactions, these incidents are limited to hematomas or needle infiltrations and have not required advanced medical care. In light of the above, we again predict a failure to improve donor safety while dangerously reducing available supply of Platelet, Pheresis products, and ask that this proposed requirement be struck.

In summary, we feel the aforementioned requirements would severely impair our ability to provide both routine and specialized Platelet, Pheresis products in this community, resulting in severe product shortfalls with dire consequences for patient care. In light of similar projections from many of the ABC facilities, it is unlikely we would be able to meet demands during such shortfalls by importing Platelet, Pheresis products. We thank you for your consideration of our arguments, and for the opportunity to provide our

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comments. We look forward to working with the FDA to ensure the consistent provision of safe and effective products to the patients of our community.

Yours truly,

A handwritten signature in black ink, appearing to read "Dan Waxman". The signature is written in a cursive style with a large initial "D".

Dan A. Waxman, M.D.  
Executive Vice President/Chief Medical Officer

/nkw