

**AULTMAN HOSPITAL
DEPARTMENT OF PATHOLOGY**

**2600 Sixth Street, S.W.
Canton, OH 44710**

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**Phone: 330-363-6258
Fax: 330-580-5546**

November 10, 2005

Division of Dockets Management (HFA-305)
FDA
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To: Whom it may concern:

This letter is in response to the FDA proposed changes to collect platelets by automated methods (document HFA-305).

FDA's guidance is intended to assist blood collection facilities with methods to insure donor and patient safety. These proposed changes include yearly maximum of 24 apheresis procedures with double apheresis products counting as two and triples as three. Currently no distinction is made amongst the size of pheresis products that an individual donor might provide; all donors are allowed to donate twenty-four times a year.

The current rule allows blood centers to take advantage of the simple biological fact: donors differ. Some donors provide larger pheresis products, often because they are physically larger donors. This is a bonus for the community. These physically generous donors help patients by increasing the availability of platelet products and help the blood center to keep costs down. These larger donors simply have more to offer.

The proposed yearly maximum prevents taking advantage of the physical generosity of our larger donors. If blood centers are no longer aloud to take advantage of donor differences, costs will rise and patients will suffer.

Thank you for allowing blood centers to express our concerns over this potentially serious, but easily remedial situation.

We appreciate the FDA's continuing efforts to maintain the safety of our blood supply.

Sincerely,


Daniel Wasdahl, M.D.
Pathologist

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