America's Blood Centers

OUR MEMBERS SERVE COMMUNITIES NATIONWIDE

725 15th Street, NW ♦ Suite 700 ♦ Washington, DC 20005 ♦ 202-393-5725 ♦ 1-888-USBLOOD ♦ FAX 202-393-1282
Web Site: http://www.americasblood.org ♦ e-mail: abc@americasblood.org

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

Re: Docket No. 99N-2337
Current Good Manufacturing Practice for Blood and Blood Components; Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting Hepatitis C Infection ("Lookback")

To Whom it May Concern:

America's Blood Centers is pleased to have the opportunity to comment on the Center for Biologics Evaluation and Research's proposed regulations on HCV lookback.

General Comment. We found this document to be very difficult to follow in many cases, with the many cross-references and repetition, and the tables only compound this problem. We strongly recommend that the final document include a flow diagram of the process.

Products for Fractionation. The preamble to the proposed rule states that "the proposal would not require quarantine of products that have already been pooled for further processing because the process of fractionation inactivates or removes HCV." However, the body of the proposed regulation does not appear to address this policy. This statement should be included both in section 610.46 (with respect to HIV) and in section 610.48 (with respect to HCV).

610.46(a). Changes to HIV Lookback Regulations. The proposed rule is intended to harmonize the requirements for HIV and HCV lookback. However, this section states that lookback and quarantine should be conducted for "all such prior collections," while section 610.48(a) states that such action take place for "in-date blood and blood components." We urge FDA to revise section 6510.46(a) to clarify that it applies specifically to "in-date blood and blood components."

610.48(a). Quarantine and Consignee Notification. Three calendar days for notification for quarantine is insufficient time, especially if the quarantine action is based on the collection facility being notified from an outside source. We believe that seven calendar or five business days is more appropriate.

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610.48(d)(3-4). Review of historical testing records and identification of donors tested using a single antigen screening test prior to effective date of final rule (third and fourth instances). It is our understanding, based on previous FDA statements, and more specifically on the recommendation of the HHS Advisory Committee on Blood Safety and Availability that with signal to cutoff (S/CO) ratio less than 2.5 on a single antigen assay, there would be no consignee notification or lookback. The provisions in (3) (third instance) conflict directly with this understanding, and would require that "blood establishments . . . identify previously distributed blood and blood components from such donors" when any single antigen test was repeatedly reactive and there was "no record of a supplemental test or multi-antigen screening test for HCV performed on the repeatedly reactive sample or on a later sample from the same donor." The whole point of the use of S/CO was to minimize the need for consignee notification and lookback or recall for further phlebotomy of a large population of probable false positives with no supplemental results on record. We request that 610.48(d)(3), and all similar references in the document be deleted.

610.48(g). Exemption from Quarantine. This provision exempts from quarantine products meeting certain criteria. We request that FDA clarify the intent of this exemption to make it clear that blood collection facilities should not be required to notify consignees of units for which appropriate supplemental testing is available that would exempt them from quarantine.

610.49. Notification of transfusion recipients. This section describes requirements for lookback. FDA has solicited comment on the appropriateness of requiring concurrent notification of the physician of record and the transfusion recipient. We believe *requiring* concurrent notification to be inappropriate for two reasons. First, the most common reason for direct recipient notification is the refusal of the physician of record to do so. Second, in many cases the "physician of record" at the transfusing facility has no ongoing relationship with the recipient to justify their involvement in the process.

Specifying a minimum of three attempts to notify recipients is unnecessarily inflexible. Three is a reasonable number under most circumstances, but transfusion services should be given the flexibility to stop after fewer, if they have solid information suggesting further attempts will not be fruitful. For example, a transfusion service may make a single attempt, find the recipient no longer at the address they have available, and with no other source of information available should be allowed to stop if documentation is maintained.

Nucleic Acid Testing. We urge FDA to consider nucleic acid testing (NAT) for HCV, if performed under an FDA-approved IND, adequate to initiate consignee notification and lookback, in lieu of licensed supplemental testing (such as RIBA).

Cost Estimates. We believe that the prospective lookback cost estimates are flawed by restriction of the calculations to components of the current donation, which has been discarded. In fact, it is past donations that generate lookback and its resultant cost. ABC members' experience with seroconverting donors suggests that there will be between 2 and 10 prior components and that the cost is 3 to 5-fold higher than FDA estimates.

Thank you for the opportunity to comment. If you have any questions, please don't hesitate to contact me.

Yours truly,

Celso Bianco, MD
Executive Vice President