



**America's Blood
Centers**

O U R M E M B E R S S E R V E C O M M U N I T I E S N A T I O N W I D E

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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December 22, 1999

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

RE: Docket No. 98N-0607: Notification of Deferred Donors

Dear Dockets Management Staff:

America's Blood Centers (ABC) is pleased to comment on FDA Docket N 98N-0607: Notification of Deferred Donors. We support the Food and Drug Administration's stated goal of reducing the risk of infecting blood product recipients and individuals handling blood or blood products with communicable disease agents by converting guidelines, understandings, verbal expectations and compliance observations into rules and by codifying general current industry practice.

However, we submit that much of this current practice—such as supplemental testing, donor notification and donor education—is outside the purview of FDA.

These activities do not materially affect the safety, potency or purity of blood components and fall largely into the categories of practice of medicine and customer service. As such, they vary from one establishment to another and require flexibility as to approach, not necessarily rulemaking and other regulatory activity. The proposed rule imposes upon blood establishments a public health function. We are interested in the derivation of statutory authority for this activity.

Donor Notification Based on Test Results

We agree that donors deferred on the basis of test results must be notified of their deferral status—including, as applicable, results of confirmatory testing, information concerning disease associations and appropriate medical follow up and counseling, and any possibility of future reinstatement. Most blood establishments already perform this service.

However, the rule should allow blood establishments the flexibility to perform this notification in the manner they have determined to be most effective by long experience. Such donor communication falls in the realm of medical practice and FDA should not micromanage details. In many cases, state laws dictate infectious disease notification requirements; for FDA to impose a different set of criteria will be confusing at best.

98N-0607

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With respect to the very detailed proposed requirements spelling out specific shipping methods and timing of donor notification, **we believe that requiring certified, registered or restricted delivery mail as well as specifying acceptable time intervals is intrusive.** The experience of many of ABC's members suggests that these special types of mail may, in fact, be less effective than the standard mail and telephone notification strategies used for initial attempts at notification that are standard at most blood centers.

Moreover, for the vast majority of donors such notification vehicles are inappropriate—for example, a donor being notified for antibody to HBc or a false positive RPR may be unnecessarily alarmed by receipt of a certified letter. For test results of a more serious nature (confirmed HCV, HBV, HIV and HTLV), many blood center physicians or their designees strongly prefer notification in person, and take concerted steps to contact and see affected donors.

Notification of Autologous Donors

We concur with FDA that notification of autologous donors of medically relevant test results resulting in their subsequent deferral as allogeneic whole blood donors is important. However, in the case of autologous donation, the patient is under the care of a prescribing physician and the provision of autologous units is clearly a medical procedure. As such, it is perfectly reasonable that reports of abnormal results and deferral be addressed to the patient's physician rather than to the patient directly. In virtually all other medical settings, reports of laboratory tests or procedures that are ordered by a physician go to the physician rather than the patient. One could reasonably argue that direct notification of the patient could constitute interference with the role of the patient's physician.

We strongly urge FDA to allow flexibility in this matter.

Donor Notification Based on Donor Suitability

Donors deferred for suitability criteria are informed at the time of attempted donation of the reason for their deferral and its duration. There is no need to further regulate this process. Additional regulations regarding the details of this process are not needed. A number of our members have read the proposed rule as requiring additional written notification of such donors.

We request that you clarify this issue. If it is, in fact, FDA's intention to prescribe specific methods of notifying donors deferred for suitability criteria, we will vigorously disagree.

Except for specific donor suitability criteria codified by FDA, most decisions regarding donor suitability criteria are made by each blood establishment's medical director and encompass practice of medicine. Even with deferrals required by FDA, the collection facility is the only repository of information and understanding of its import and follow up. For example, to whom will a collecting facility refer a donor with six months residence in the United Kingdom during the relevant time frame?

We strongly request that such referral and counseling decisions be left to the collection facility's medical direction. They are the practice of medicine, not material to the safety, purity or efficacy of blood components and are therefore beyond the purview of FDA.

Notification of donors upon first repeat reactive anti-HBc or anti-HTLV test result

We support maintaining flexibility in determining when and if to notify donor found to be repeat reactive for anti-HBc and/or anti-HTLV. The specificity and predictive value of these tests is low enough that a one-time positive is not grounds for deferral. For the same reason, notification should not be required.

We strongly maintain that requirements for notification must be tied to a requirement for deferral.

Requirement for proof of a permanent address

We strongly recommend that the issue of "permanent" addresses be deleted from the final rule.

Although it seems reasonable that the blood establishment obtain a donor's "permanent" address, it must be recognized that "permanent" addresses change, and that "permanent" could be variably defined. In rural areas many donors receive their mail via a post office box; does a street address reflect a "permanent" address more so than a post office box, especially since many persons maintain the same box over many years while moving from residence to residence? A university student may give what is obviously a "temporary" college address; should this student be turned down as a donor? Similarly, if a notification we sent to a college student at his "permanent", home address, the letter would reach the parents rather than the student, which is a breach of confidentiality.

The requirement for "proof" of permanent address is unnecessary. What is acceptable as "proof?" It makes no sense to believe a donor's response to our various personal and pointed questions about high risk behavior and yet refuse to believe he or she is providing an accurate address.

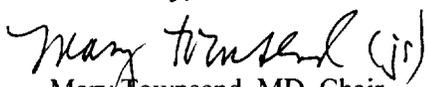
Methods of Notification to Assure Donor Confidentiality

The only method of notification that assures complete donor confidentiality is person-to-person contact. Anyone can answer a telephone or open a letter. Not all donor notification messages are equal.

The blood establishment must be able to exercise flexibility and medical judgement in determining the best manner to notify given the specific message. For test results with more serious health implications, the level of confidentiality may be stricter.

Once again, thank you for the opportunity to comment. If you would like to discuss ABC's recommendations and comments further, I can be reached at (806) 358-4563.

Yours truly,



Mary Townsend, MD, Chair
Scientific, Medical and Technical Committee
America's Blood Centers