Texas Children's Hospital
www.texaschildrenshospital.org

Department of Pathology

Located in the Texas Medical Center

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February 13, 2001

Dockets Management Branch (HFA_305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville MD 30852

RE: 21 CFR Parts 606 and 610 ; 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 HCV Infection ("Lookback")

To whom it may concern:

As Medical Director of the Transfusion Service for a large pediatric hospital, I read your proposed lookback rules with great interest. Most of the provisions we find acceptable, and in keeping with our mission to provide the best possible health care to children.

We are concerned with one aspect of the proposed rules. We would like to state our strong support of the proposed FDA rule 21 CFR 610.49(c), which specifically does NOT require notification efforts to continue if the recipient is deceased because, "...as previously discussed, direct percutaneous exposure to infectious blood, particularly in the setting of drug abuse, accounts for the majority of HCV infections acquired in the United States. Secondary transmission of HCV to sexual partners, care providers or others with close contact is very unlikely." The specific proposed rule reads, "If the transfusion recipient is deceased, the transfusion service or physician, as described in this paragraph, may discontinue the notification process." [p. 69411]

The HCFA rules accompanying this, published in the same issue of the Federal Register, state that they propose to "adopt as our requirements for hospitals the procedures for HIV and HCV proposed by the FDA published elsewhere in this issue of the Federal Register [p. 69418, under heading II]." However, in 482.27, Conditions of participation for hospitals, laboratory services, (10), they specifically state "If the patient is deceased, the physician or hospital must continue the notification process and inform the deceased patient's legal representative or relative." [p. 69424]

The HCFA rule is not, of course, your immediate concern. I would like to express my strong support for the FDA's proposed rule, which does not require notification of family members of deceased individuals. This notification seems to have minimal medical justification. Most of our children were transfused as neonates or as young cardiac or oncology patients. For those who died, the risk of familial transmission is virtually nil. In our population, the "lookback" notification of families of children who had died years previously could only contribute to emotional distress and confusion, without meeting any medical need.

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If it is felt that family members of deceased recipients need to be notified, an exception should be made for pediatric recipients, for whom family transmission risk would be negligible.

Thank you for the opportunity to comment on the proposed rule. Any questions or comments may be addressed to me at the above address and phone number, or I may be contacted at snrossma@texaschildrenshospital.org.

Sincerely,

Susan N. Rossmann, M.D., Ph.D.
Medical Director
Microbiology, Serology, Blood Bank
Department of Pathology
Texas Children's Hospital

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