AHA
Advancing Health in America

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February 14, 2001

Bernard Schwetz
Acting Principal Deputy Commissioner
Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane – Room 1061
Rockville, MD 20852

Re: [Docket Number 99–2337, 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 HCV infection ("Lookback")], (65 *Federal Register* 69378), November 16, 2000

Dear Mr. Schwetz:

On behalf of our nearly 5,000 member hospitals, health systems and other providers of care, the American Hospital Association (AHA) welcomes this opportunity to comment on the proposed "current good manufacturing practice" for blood and blood components pertaining to notification of patients who may have received transfusions of blood infected by hepatitis C virus (HCV).

The proposed rule requires hospitals that transfuse blood and blood products to follow written procedures when it is determined that those products in the hospital's possession are at increased risk of transmitting HCV. The regulation establishes both a retrospective review and notification (or targeted "lookback") process to evaluate blood products, and a prospective duty to inform patients of possible infection. The proposal requires hospitals to: 1) establish notification agreements with blood establishments that provide blood products to the hospital; 2) quarantine prior collections that came from a donor who is identified as at-risk for HCV; and 3) notify all patients who received a transfusion that may be HCV-infected.

AHA supports the general aim of the proposed rule: to notify patients who received transfusions of blood that may have been HCV-infected. We worked with the Food and Drug Administration (FDA) as it developed guidance pertaining to the HCV lookback and have communicated that guidance to our members. We have one specific concern, however, about the requirement that three attempts be made to contact the patient. We believe that requiring three attempts is unnecessary, and we request that hospitals be permitted to satisfy this provision by making one attempt using a traceable method, such as certified mail, return receipt requested. A signed returned receipt means the patient was successfully notified. A returned letter should be proof that notification was attempted and was unsuccessful, meaning further attempts will be similarly

unsuccessful. In addition, if the record retention requirement is increased to 10 years, then using information available in the patient record (e.g., last known address or telephone number) should be acknowledged as a good-faith effort by a hospital to contact the patient. Should the FDA disagree, we would be very concerned about the tremendous costs of locating patients who are untraceable to their last known address.

The AHA appreciates the opportunity to submit our comments on FDA's proposed HCV lookback rule. The hepatitis C virus is an important public health concern, and we share your goal of improving public trust in the nation's blood supply. We look forward to working with the agency to resolve our concerns.

If you have any questions regarding our comments, please contact me, Mary Beth Savary Taylor, director of executive branch relations, (202) 626-2270, or Aarti Shah of our policy staff, (202) 626-2327.

Sincerely,

Rick Pollack

Rick Pollack
Executive Vice President