American Academy of Orthopaedic Surgeons® | AAOS American Association of Orthopaedic Surgeons

6300 North River Road Rosemont, IL 60018-4262
Phone 847/823-7186, 800/346-2267 Fax 847/823-8125 Fax-on-Demand 800/999-2939 Internet www.aaos.org

February 14, 2001

Bernard A. Schwetz, D.V.M., Ph.D.
Acting Principal Deputy Commissioner
Food and Drug Administration (FDA)
5630 Fishers Lane
Rockville, Maryland 20852

The American Academy of Orthopaedic Surgeons (AAOS), representing over 16,000 Board certified orthopaedic surgeons, welcomes this opportunity to comment on the FDA's proposed rule: 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. (Published in the Federal Register on Thursday, November 16, 2000. [Docket No. 99N-2337]).

AAOS members frequently use allogeneic blood during surgery and thus share the FDA's concern over the safety and integrity of the nation's blood supply. The AAOS acknowledges the importance of identifying and notifying recipients of blood who may have been exposed to HCV and supports the efforts of the FDA to this end. However, any plan to identify patients at risk for HCV infection must take into account not only the benefits, but the limitations and drawbacks associated with such efforts as well.

The AAOS would like to call attention to two areas of concern. These include potential problems associated with the testing of patients and subsequent treatment issues that were not addressed in the proposed rule.

There is some question over the degree of benefit a patient will receive by being tested for HCV infection before the onset of clinical illness. The extent that a person is likely to change high-risk behaviors based solely on the knowledge of his or her test results is unknown. Even if a patient tests positive for the HCV antibody, the absence of clinical symptoms may create a perceived absence of illness and fail to invoke a change in detrimental behavior, such as drinking alcohol. Additionally, there can be far-reaching implications to testing, including disrupted personal relationships and possible discriminatory action (e.g. loss of employment or insurance).

Furthermore, our understanding of HCV infection and treatment is in its infancy. Indication for treatment is ambiguous in many patient groups, including those with acute infection or with certain histologic profiles, and sustained response rates are variable. Moreover, approximately 15-25% of HCV-infected patients spontaneously resolve the infection without treatment. We face a great amount of uncertainty when treating HCV infection. There are an unknown number of patients who may have been exposed to HCV

through the receipt of blood. Once these patients are identified and tested, the medical community needs to be prepared to provide quality care. The AAOS cautions that currently available treatments are not efficacious enough to provide such care.

Although there is no easy solution to these potential problems, the AAOS urges the FDA to be mindful of the potential for adverse consequences to those patients who are diagnosed with HCV infection.

The AAOS appreciates the opportunity to express these areas of concern. We support the FDA's goal in this matter and will continue to work with your agency in order to provide the greatest possible care to our patients and the community as a whole.

Sincerely,

William W. Tipton, Jr., MD
Executive Vice President

Align top of FedEx PowerShip Label or Astra Label here.

TIM WILLIAMS
AMER. ACADEMY ORTHO SURGEONS
6300 N. RIVER ROAD
ROSEMONT IL 60018-4262
(847)823-7186

SHIP DATE: 16MAR01
ACC # 0606634130
ACTUAL WGT: 1 LBS SCALE

TO: DOCKETS MANAGEMENT BRANCH HFA-(301)827-6210
FDA/DOCKET # 99N-2337
5630 FISHERS LANE
ROOM 1061
ROCKVILLE MD 20852

4172 6542 3674 FedEx®

REF: B. DUSZINSKI

STANDARD OVERNIGHT MON

cad # 0044269 16MAR01

TRK# 4172 6542 3674 FORM 0201

Deliver by: 19MAR01

IAD AA

20852 -MD-US 19 GAIA

153078-077 RIT 03/99

World Talk®