



American Academy of
Orthopaedic Surgeons®

AAOS

American Association of
Orthopaedic Surgeons

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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

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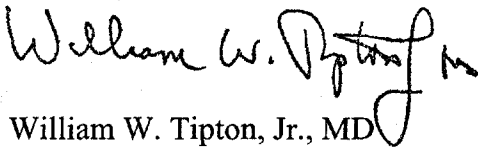


through the receipt of blood. Once these patients are identified and tested, the medical community needs to be prepared to provide quality care. The AAOS cautions that currently available treatments are not efficacious enough to provide such care.

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,

A handwritten signature in black ink that reads "William W. Tipton, Jr." with a stylized flourish at the end.

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

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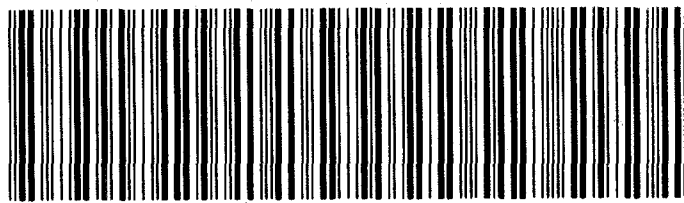
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