

2186 7 MAY 24 2007



Your Liver. Your Life.

STATEMENT OF

JAMES L. BOYER, M.D.
BOARD CHAIR

ON BEHALF OF
THE AMERICAN LIVER FOUNDATION

PROVIDED TO

FOOD AND DRUG ADMINISTRATION, HHS

DOCKET NO. 1977N-0094L
RIN 0910-AF36

MAY 24, 2007

1977N-0094L

C5

On behalf of the American Liver Foundation, I thank you for the opportunity to provide this comment to FDA. My name is Dr. James L. Boyer, and I am Board Chair of the American Liver Foundation. I also am Ensign Professor of Medicine and Director of the Liver Center at Yale University School of Medicine in New Haven, CT.

The American Liver Foundation (ALF) is the nation's leading non-profit organization promoting liver health and disease prevention. ALF provides research, education and advocacy for those affected by liver disease, including hepatitis.

At ALF, we are dedicated to liver health and the prevention of liver disease. Clearly, one element of our work concerns the use of drugs by Americans – both prescription and OTC. We are honored to be a voice for Americans in this area, helping to ensure that their need for new and increasingly effective treatments and drug uses is addressed in the context of safe guidelines for usage.

Today, we can reassert a statement that we made to an FDA Advisory Committee several years ago: “Acetaminophen is a good drug, proven so over decades.” Healthcare providers with whom we work do suggest acetaminophen as one of the drugs that can be appropriate for liver patients. For example, our medical experts tell us that acetaminophen is the antipyretic and analgesic of choice for patients with chronic non-alcohol related liver disease.

We are acutely aware that this drug (like all other drugs) must be taken in appropriate doses and in the right circumstances. Acetaminophen does have a well-known association with hepatotoxicity, particularly in alcoholics. Usage above the usual doses can have tragic results. We also are concerned about the possibility of unintended high dosing, for patients who may take two or more different medications that may contain acetaminophen, without being aware of the “double-dosing” possibility. And there are specific considerations that need to be taken into account by parents and healthcare providers alike to properly dose for infants and children.

Given the issues involved, though, acetaminophen is normally a safe drug. It is in the patients’ best interests to continue its safe marketing and use. ALF has been and will continue to be involved in educating consumers to follow the most appropriate and safest ways of using this drug. We will continue to encourage patients to ask their healthcare providers about individual needs and precautions, based upon their unique medical situations. We will continue to advocate for full and user-friendly disclosure of all appropriate information about drugs. We will continue to underscore the need for the knowing use of multiple drugs and awareness of best practices in the area of drug dosing at all ages.

At ALF, we encourage an active approach to these issues by all involved: consumers, pharmacists, physicians, other healthcare providers and advisers, drug manufacturers, the government, and the not-for-profit sector.

ALF is a full participant in this activity and looks forward to continuing efforts to educate consumers, encourage safe drug marketing and dissemination, and help reach a responsible balance between the public's need for new drugs and new drug uses and its need for product safety.

We thank you for the opportunity to address these issues.