May 8, 2003

The Honorable James C. Greenwood
Chairman, Oversight & Investigations Subcommittee
House Energy and Commerce Committee
2125 Rayburn HOB
Washington, D.C. 20510

Dear Chairman Greenwood:

Thank you for holding the December 11, 2002 hearing on the safety of Accutane. Almost everyone I have talked with thought it was an "excellent" hearing, and the public was "mesmerized" by the members' questioning.

I have spent considerable time reviewing the 19 boxes of materials voluntarily provided by the FDA and Hoffman LaRoche (HLR). A review of the committee document requests shows that some critical documents were never produced and/or were redacted by the FDA and HLR.

The Accutane investigation and hearing demonstrates why the Energy and Commerce Committee should overhaul the FDA's drug review and approval process, give the FDA the authority to rein in exaggerated claims by manufacturers, and strengthen FDA's post-marketing surveillance of prescription drugs. The hearing also magnified the FDA's inability to control the flow of prescription drugs at our borders, over the internet, and through the mail.

Accutane is a dangerous drug that causes birth defects and adverse psychiatric injuries and warrants further investigation by the Oversight and Investigations Subcommittee. At our hearing, our colleague Ted Strickland said it best when he asked, "Is it possible that this medication has an effect, an action that results in spontaneous, impulsive, self-destructive behavior that is different from that which occurs from a clinical depression"? I believe that answer to Mr. Strickland's questions is YES! This committee should immediately seek to have Accutane and all generic versions of Accutane removed from the market until a number of life-threatening questions are answered and true safeguards are implemented to prevent the horrific birth defects, psychiatric injuries and suicides caused by Accutane. While additional hearings may be necessary, I am submitting additional documents with this request

It is my understanding that the December 11, 2002 hearing record is still open. I am requesting that this correspondence with the following statement and documentation be made part of the hearing record. I understand that all documents contained in this review are from the documents voluntarily submitted by the FDA and HLR to the committee on or prior to December 11, 2002. This review is to supplement our hearing and to aid the committee in its evaluation of the safety issues relating to Accutane and the FDA's drug approval process, post marketing surveillance, control and distribution of prescription drugs at our borders, and sale and distribution of Accutane via the internet and through the mail.

I am not sure if the FDA is unwilling, unable, or simply incompetent in its attempt to fulfill its mission of protecting the American public from unsafe drugs. The public policy issues presented transcend this one drug, but it is this drug, Accutane, which highlights the weakness, flaws and need to overhaul the FDA's drug approval process in America.

I am submitting this review and documentation for the record and in support of my request that the committee seek the withdrawal of Accutane from the market.

Sincerely,

Bart Stupak

cc: Ranking Member

Enclosure: Review with Exhibits