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**Congress of the United States**  
**House of Representatives**  
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March 1, 2001

Dr. Janet Woodcock  
Director  
Center for Drug Evaluation and Research  
Food and Drug Administration  
1451 Rockville Pike  
Room 6027  
Rockville, MD 20852

Dear Dr. Woodcock:

At our January 4, 2001 meeting, I stated that I would be providing you a list of deaths related to Accutane that were reported to my office. Most of these deaths were not reported to the Food and Drug Administration (FDA), even though the reporter received written correspondence from my office urging them to report any adverse event to the FDA.

I also sent an e-mail to the reporting party of each of these deceased individuals. Plus, I have followed up with a telephone call to most of these families who lost a child.

With this information, I would request a "hand audit" of these 38 cases to make sure there is no duplication and that each individual is properly reported. Many of these deaths occurred before October of 2000, but these families did not realize that there may be a connection between Accutane and their child's death until after the airing of the *Today Show*. Once your hand audit is completed, I would like to know the results as to whether these are first time reported suicides since the *Today Show*. I did not include my son on this list as I believe he is now properly reported as I received notification from MedWatch.

In addition, I would like to receive a copy of the Adverse Event Reports from August 1, 2000-February 1, 2001. Previous Adverse Event Reports were provided to Congressman Waxman. I would like these reports to ensure the accuracy of my records.

PLEASE REPLY TO:

1229 W. WASHINGTON  
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Finally, there was an internal memo written in February of 1988 warning of, among other things, the effects of Accutane on the adult human brain. This memo seems to be the basis for the increased warnings issued by the FDA in May of 1988 on birth defects. I would like a copy of the memo.

Again, thank you for your prompt attention to this issue. If you have questions, please do not hesitate to contact either me or Matt Berzok on my staff at (202) 225-4735. I look forward to your reply.

Sincerely,

A handwritten signature in cursive script that reads "Bart".

Bart Stupak  
Member of Congress  
Michigan's First Congressional District

enclosure