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# Congress of the United States

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January 4, 2002

Melinda K. Plaisier  
Associate Commissioner for Legislation  
Food and Drug Administration  
Office of Policy, Planning and Administration  
5600 Fishers Lane, Room 14-89  
Rockville, MD 29857

Dear Associate Commissioner Plaisier:

Thank you for your correspondence with attachments dated December 20, 2001. I appreciate your sending the November 2001 issue of the Journal of the American Academy of Dermatology and the May, 1987 article entitled "Hypervitaminosis A syndrome: A paradigm of retinoid side effects" which we discussed on December 6, 2001. My staff has contacted your office to get a copy of page 1030 from the May, 1987 article, which appears to have been inadvertently skipped in the copying.

While I did not specifically ask for the other articles you sent over, I found them interesting.

Of course I understand that the Food and Drug Administration (FDA) does not conduct actual "clinical research or comprehensive basic science research programs". What the FDA does have is the authority to order drug manufacturers to do clinical research and basic science research both before and after a drug has received FDA approval. In fact, the FDA has the authority to pull a drug from the market until requested research is done, especially when deaths and serious adverse events are related to the drug's use.

The FDA's own Medical Review Officer and others have raised this issue in regard to Accutane, and the FDA has not acted on these perfectly legitimate requests for further research. It would be tragic if the FDA were to ignore its mission of protecting the American public from avoidable consequences connected with a drug the FDA has approved. My family and many others continue to suffer the harmful effects of this dangerous, powerful drug.

Very truly yours,



**BART STUPAK**  
Member of Congress

BTS:lat

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