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Congress of the United States

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Washington, DC 20515-2201

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May 25, 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:

Thank you for your letter date stamped April 25, 2001 and the hand audit that your administration performed on the 38 names that I submitted. I will attempt to get further information on the 22 names not found in AERS. I am not surprised that these 22 individuals probably are not in AERS as I believe no one ever made the possible connection between Accutane and their child's death until they heard about our tragedy. With the passage of time, the information needed to fill out the computerized AERS report becomes impossible for some of these families and their families have not attempted to fill out the AERS report.

Unfortunately, I am enclosing another list of 15 names and relevant information for your AERS report. I would once again request that you do a "hand audit" of these 15 cases to make sure there is no duplication and that each individual is properly reported.

Back on January 4th when we met, you stated that there were 72 suicides reported as of January 2, 2001. My son was not reported, even though I did enter BJ in AERS in October. Of the list of 38 names submitted on March 1, 2001, 22 are new cases. I am now submitting 15 more names. If even a few of these 15 names are new, then we are over 100 suicides, not counting the number of suicides AERS reported to you but not to this office. Plus, it is reasonable to expect that when Roche submits its periodic report covering January to June, 2001, we will see suicides which were not reported to the FDA or this office.

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

PLEASE REPLY TO:

1229 W. WASHINGTON
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616 SHELDEN
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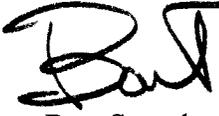
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TOLL FREE: 1-800-950-REP1 (1-800-950-7371)

PRINTED ON RECYCLED PAPER

Sincerely,

A handwritten signature in black ink, appearing to read "Bart", with a horizontal line extending to the right from the top of the signature.

Bart Stupak
Member of Congress
Michigan's First Congressional District

enclosure

cc: Press Conference Members