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ASSISTANT WHIP

May 14, 2008

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
5600 Fisher Lane, Room 1555
Rockville, MD 20857

Dear Dr. von Eschenbach:

On Tuesday, April 29, 2007, the Energy and Commerce Subcommittee on Oversight and Investigations held a hearing entitled "The Heparin Disaster: Chinese Counterfeits and Americans Failure." During the hearing, Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research at the FDA, testified on behalf of the Administration. Accompanying Dr. Woodcock was Ms. Deborah Autor, the Director of the Office of Compliance at the FDA's Center for Drug Evaluation and Research.

The purpose of this hearing was to examine the adequacy of the Food and Drug Administration (FDA) to protect Americans from unsafe drugs. An integral part of ensuring the FDA can protect the American people is equipping the Agency with proper resources and enforcement authority it currently lacks, such as subpoena power. The FDA is one of the few Federal agencies that lack subpoena power. The Department of Agriculture, the Environmental Protection Agency, the Department of Transportation and the Federal Trade Commission all have subpoena power. In some cases, FDA does no testing of its own, and in making decisions it must rely entirely on the test results submitted by manufacturers. Without subpoena power, the only way the FDA can ensure it has the information it needs is to threaten criminal prosecution by the Justice Department if it finds critical data is withheld.

During the April 29 Oversight and Investigations Subcommittee hearing, I questioned Dr. Woodcock and Ms. Autor on the authorities they thought the FDA considered necessary to be able to better serve the American people. I specifically asked Dr. Woodcock and Ms. Autor whether the FDA needs subpoena authority. Ms. Autor replied "I think that would be very helpful," and Dr. Woodcock said "I agree with that. Yes."

For at least six years, Congress has been debating whether to give the FDA subpoena power, without any indication from FDA if they felt it was necessary or whether they would use this authority if it was given to them. Dr. Woodcock and Ms. Autor's

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unfiltered responses during the hearing would indicate that the Agency finally sees the deterrent effect subpoena power will have on unsafe food and drugs. Empowering the FDA with subpoena power will help the Agency ensure they have the tools necessary to investigate any possible withholding of data from companies. This is a needed enforcement tool the FDA can no longer work without.

Do you stand by both Dr. Woodcock's and Ms. Autor's statement that the FDA should be given subpoena power? Would you support this provision if it were included in the FDA Globalization Act that Chairman Dingell, Chairman Pallone and I are working on?

I appreciate your prompt response. Should you have any questions, please do not hesitate to contact Erika Orloff (202-225-4735) in my office.

Sincerely,

A handwritten signature in black ink that reads "Bart Stupak". The signature is written in a cursive, somewhat stylized font. The first letter "B" is large and loops around the start of the name. The "Stupak" part is written in a more fluid, connected script.

BART STUPAK
Member of Congress

BTS/eo