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ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

April 24, 2014

Mr. D. Linden Barber
Partner and Director
DEA Compliance Practice
Quarles & Brady LLP
1700 K Street, N.W., Suite 825
Washington, D.C. 20006

Dear Mr. Barber:

Thank you for appearing before the Subcommittee on Health on Monday, April 7, 2014, to testify at the hearing entitled "Improving Predictability and Transparency in DEA and FDA Regulation."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Thursday, May 8, 2014. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to **Sydne.Harwick@mail.house.gov**.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachment

Attachment—Additional Questions for the Record

The Honorable Joseph R. Pitts

1. We have been hearing from pharmacies that their wholesalers are cutting them off for ordering above the "normal" amount. Will you describe your expectations of wholesalers and what guidance has been provided to wholesalers in the last year to help them conduct due diligence on their customers?

2. Does DEA conduct an investigation on pharmacy registrants when wholesalers have reported suspicious orders for a particular pharmacy? Can other wholesalers continue to serve that pharmacy?

3. Does DEA conduct due diligence on an initial application for DEA registration (pharmacy, wholesaler, physician, etc.)? What does that involve?

4. Despite efforts by industry and the government, the prescription drug abuse epidemic continues to increase and it is clear we need to do something different than the track we are on now. Do you have any suggestions as to how industry, DEA, and Congress could better address this epidemic?

5. Does DEA use an escalation of enforcement approach?

6. Just because a registrant has stopped its bad conduct does not mean they will not start again. How can DEA address those situations?

7. The bill I introduced with Mr. Pallone, H.R. 4299, the "Improving Regulatory Transparency of New Medical Therapies Act" requires the DEA to schedule new molecular entities within in a timely manner. Based on your experience working at the DEA, is this approach a safe and effective way to get patients medications faster?