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ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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May 31, 2018

Mr. J. Christopher Smith
Former President and CEO
H.D. Smith
C/o AmerisourceBergen Corporation
1300 Morris Drive
Chesterbrook, PA 19087

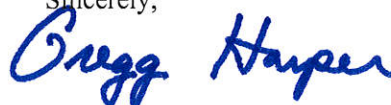
Dear Mr. Smith:

Thank you for appearing before the Subcommittee on Oversight and Investigations on May 8, 2018, to testify at the hearing entitled "Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion."

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. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Thursday, June 14, 2018. Your responses should be mailed to Ali Fulling, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Ali.Fulling@mail.house.gov.

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

Sincerely,



Gregg Harper
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

Attachment—Additional Questions for the Record

The Honorable Michael C. Burgess

1. While your companies seem to have put forth effort to improve your system of flagging possible drug diversion, there remains work to be done. In February, the Drug Enforcement Administration announced that it would begin sharing select data it collects on controlled substance prescriptions with drug distributors. Have your companies been able to access that data, and if so, has it been useful?
2. What is the largest hurdle you face as your companies scale up your diversion prevention activities? Is data-sharing, or lack thereof, the primary challenge?
3. Throughout each of your written testimonies, you mentioned your efforts to report suspicious orders to the DEA, and in cases that exceed the volume threshold, you stop the orders entirely. Where is the line drawn between drug manufacturers and the DEA in responding to suspicious orders? Does the DEA take enforcement action after you report the suspicious order?
4. Distributors and other pieces of the drug supply chain have a responsibility to help prevent diversion. What can Congress do legislatively to strengthen oversight of that supply chain?

The Honorable David B. McKinley

1. As a Wholesale Distributor of prescription opiates, do you agree that you owe a duty under federal law to monitor, detect, investigate, refuse and report suspicious orders? 21 U.S.C. § 823, 21 CFR 1301.74
2. Do you agree that the foreseeable harm of a breach of this duty is the diversion of prescription opiates for nonmedical purposes?
3. In other words, if you ship a suspicious order, it is likely that prescription opiates will be diverted into the illicit market. Agree?
4. Do you concur that filling suspicious orders is a direct and proximate cause of prescription opiate abuse, addiction, morbidity and mortality?
5. Do you agree the United States is in the midst of a prescription opiate epidemic?
6. Do you concur that filling suspicious orders is a direct and proximate cause of the prescription opiate epidemic plaguing our country?
7. Do you believe the prescription opiate epidemic is an immediate hazard to public health and safety?

8. Do you believe the prescription opiate epidemic is a public nuisance?
9. Are you aware of your company's efforts to detect, address, and report suspiciously large orders in West Virginia?
10. Are you aware that for years your company never followed West Virginia's law by reporting all suspicious orders to the West Virginia Board of Pharmacy?
11. Did your company have a policy that orders had to be less than 50% controlled substances to be filled?

The Honorable Frank Pallone, Jr.

1. In one of the documents H.D. Smith provided to the Committee, you list the total hydrocodone and oxycodone pills sold by H.D. Smith to purchasers in West Virginia from 2006 through 2017. According to that information, H.D. Smith sent over 17 million hydrocodone and oxycodone pills to West Virginia between 2007 and 2011. That includes 6 million pills sent to the state in 2008 alone. But H.D. Smith's shipments to West Virginia plummeted in later years. For example, H.D. Smith provided 583,400 hydrocodone pills to purchasers in West Virginia in 2017. Back in 2008, H.D. Smith had shipped almost 10 times that amount, or about 5.4 million hydrocodone pills, according to the company's data. The next year, 2009, H.D. Smith also shipped a very high amount, which was about 2.8 million pills. I understand that prescribing went down in recent years, but did additional due-diligence or recognition of the unfolding opioid crisis lead to far fewer pills in these later years than in the earlier years?
2. Did H.D. Smith attempt to look at these trends both rising and falling to determine if something problematic was happening regarding the company's distribution in West Virginia?

The Honorable Jan Schakowsky

1. Does your company buy the drugs from the manufacturers, take title and move pallets to and from your warehouse? Or are you like brokers, working on consignment, arranging sales to pharmacies and then taking a percentage of the sale price?
2. In setting prices to pharmacies, is your markup more like a flat rate (for example, selling \$5 more than the price at which you bought), or is your markup more like a percentage (for example, selling for 5% higher than the price at which you bought)?
3. Is it possible that even if your company pays a higher price to get those drugs in stock, you end up making more money on those sales where your acquisition prices are higher? And would the same be true for your consignment/broker sales?