

**House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations**

**Additional Questions for the Record  
Responses Submitted by Mr. James Christopher Smith  
on Behalf of H.D. Smith, LLC**

**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?**

Answer: AmerisourceBergen began its acquisition of H. D. Smith in late 2017, which was consummated on January 2, 2018, before this data was made available, and thus H. D. Smith has had no experience with it. It is true that the DEA added a new feature to its ARCOS Online Reporting System which allows DEA-registered manufacturers and distributors to view the number of competitor companies who have sold a particular controlled substance to a prospective customer in the last six months.

- 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?**

Answer: H. D. Smith had in place a robust diversion control program, continually enhanced and upgraded its program over time, and was in frequent contact with the DEA while developing and then continuously components of the program.

For H. D. Smith, a lack of data sharing and transparency was the primary challenge to our diversion control efforts. We did not have access to information that would allow us to verify whether a particular pharmacy was purchasing from other suppliers, and until very recently did not have access to any prescriber information unless a particular pharmacy voluntarily supplied it.

- 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?**

Answer: Beginning in 2008 when our automated Controlled Substance Monitoring Program (“CSOMP”) system was put in place, orders placed by H. D. Smith’s customers that “triggered” the system were held from shipment and evaluated to determine whether the order was suspicious. For a period of time, orders were reported to the DEA as suspicious as soon as they were held and flagged for evaluation. However, in response to feedback from DEA, we subsequently reported orders to the DEA as suspicious only when a determination was made that an order was suspicious, and was cancelled.

At no time did the DEA ever share any suspicious order reports made by others with respect to orders placed by any West Virginia pharmacy. H. D. Smith does not know whether the DEA shared suspicious order reports made by wholesale drug distributors with drug manufacturers. H. D. Smith did not provide its suspicious order reports to any drug manufacturers.

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H. D. Smith did not have visibility into DEA's internal processes and did not know how the DEA processes, analyzes or uses the suspicious order data the company provided to the agency.

- 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?**

Answer: Congress should focus on issues such as: enhanced supply chain data transparency (including ARCOS data sharing and/or data sharing among distributors), additional resources for education and medication safe storage and disposal, and additional support for e-prescribing and enhancing interoperable prescription drug monitoring programs.

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**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**

Answer: H. D. Smith has always acknowledged its duties pursuant to the applicable laws. We administered a robust anti-diversion program in order to meet, and in fact exceed, the requirements imposed on it as a distributor. H. D. Smith's CSOMP system allowed us to monitor for suspicious orders of controlled substances, and we also maintained complementary programs such as our robust "Know Your Customer" policies and procedures in connection with its regular education and training of personnel in anti-diversion efforts.

2. **Do you agree that the foreseeable harm of a breach of this duty is the diversion of prescription opiates for nonmedical purposes?**

Answer: H. D. Smith operated a system to monitor, detect, block, and report suspicious orders to the DEA. H. D. Smith invested significantly in our efforts to deter diversion, but there were unavoidable limits to our ability to monitor and prevent diversion given our limited role in the supply chain. For example, distributors such as H. D. Smith have no control over, nor input into, the amount of controlled substances that are produced in a given year. Instead, production quotas are set by the DEA with input from manufacturers. Nor are distributors involved in the licensing and regulation of the medical and pharmaceutical professionals who actually prescribe or dispense controlled substances. That responsibility belongs to federal and state governmental agencies, including the DEA. Finally, distributors do not promote opioids to physicians, healthcare providers or patients.

3. **In other words, if you ship a suspicious order, it is likely that prescription opiates will be diverted into the illicit market. Agree?**

Answer: Beginning in 2008, H. D. Smith automatically blocked any pharmacy order that triggered our CSOMP program by appearing "of interest." H. D. Smith maintained that block unless and until our due diligence demonstrated that the particular order was in fact not a suspicious one.

4. **Do you concur that filling suspicious orders is a direct and proximate cause of prescription opiate abuse, addiction, morbidity and mortality?**

Answer: Beginning in 2008, H. D. Smith automatically blocked any pharmacy order that triggered our CSOMP program by appearing "of interest." H. D. Smith maintained that block unless and until our due diligence demonstrated that the particular order was in fact not a suspicious one. H. D. Smith identified and reported suspicious orders, and did not ship any suspicious orders.

Prescription opiate abuse is a multi-faceted problem with many causes. Distributors play a limited role in the distribution chain for prescription opioids. They (1) are not involved in

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obtaining FDA approval for opioids, labeling or warning about opioids, setting guidelines for prescribing opioids, or marketing opioids to pharmacies, physicians, or patients; (2) have no control over the amount of controlled substances that are produced in a given year (instead, production quotas are set by the DEA with input from manufacturers); (3) are not involved in the licensing and regulation of the medical and pharmaceutical professionals who actually prescribe or dispense controlled substances (that responsibility belongs to federal and state governmental agencies, including the DEA); (4) do not receive or have access to any prescription-level information, unless a pharmacy voluntarily supplies that information; and (5) do not have access to any state prescription drug monitoring program information.

**5. Do you agree the United States is in the midst of a prescription opiate epidemic?**

Answer: H. D. Smith has shared the Committee's concern about the tragic epidemic of opioid abuse. H. D. Smith has always desired and tried to be part of much-needed, and unquestionably multi-faceted, solutions to address this public health crisis. For example, our efforts are evidenced in part by the implementation of our robust CSOMP and training programs, particularly with respect to the reporting not just of suspicious orders but also of potentially problematic individual prescribers.

**6. Do you concur that filling suspicious orders is a direct and proximate cause of the prescription opiate epidemic plaguing our country?**

Answer: Beginning in 2008, H. D. Smith automatically blocked any pharmacy order that triggered its CSOMP program by appearing "of interest." H. D. Smith maintained that block unless and until our due diligence demonstrated that the particular order was in fact not a suspicious one.

Prescription opiate abuse is a multi-faceted problem with many causes. Distributors play a limited role in the distribution chain for prescription opioids. Distributors (1) are not involved in obtaining FDA approval for opioids, labeling or warning about opioids, setting guidelines for prescribing opioids, or marketing opioids to pharmacies, physicians, or patients; (2) have no control over the amount of controlled substances that are produced in a given year (instead, production quotas are set by the DEA with input from manufacturers); (3) are not involved in the licensing and regulation of the medical and pharmaceutical professionals who actually prescribe or dispense controlled substances (that responsibility belongs to federal and state governmental agencies, including the DEA); (4) do not receive or have access to any prescription-level information, unless a pharmacy voluntarily supplies that information; and (5) do not have access to any state prescription drug monitoring program information.

**7. Do you believe the prescription opiate epidemic is an immediate hazard to public health and safety?**

Answer: Prescription opiate abuse is a complex problem that affects many aspects of our society. Distributors play a limited role in the distribution chain for prescription opioids. Distributors (1) are not involved in obtaining FDA approval for opioids, labeling or warning about opioids, setting guidelines for prescribing opioids, or marketing opioids to pharmacies, physicians, or patients; (2) have no control over the amount of controlled substances that are produced in a

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**8. Do you believe the prescription opiate epidemic is a public nuisance?**

Answer: Prescription opiate abuse is a complex problem that affects many aspects of our society. Distributors play a limited role in the distribution chain for prescription opioids. Distributors (1) are not involved in obtaining FDA approval for opioids, labeling or warning about opioids, setting guidelines for prescribing opioids, or marketing opioids to pharmacies, physicians, or patients; (2) have no control over the amount of controlled substances that are produced in a given year (instead, production quotas are set by the DEA with input from manufacturers); (3) are not involved in the licensing and regulation of the medical and pharmaceutical professionals who actually prescribe or dispense controlled substances (that responsibility belongs to federal and state governmental agencies, including the DEA); (4) do not receive or have access to any prescription-level information unless a pharmacy voluntarily supplies that information; and (5) do not have access to any state prescription drug program monitoring information.

**9. Are you aware of your company's efforts to detect, address, and report suspiciously large orders in West Virginia?**

Answer: H. D. Smith's CSOMP system was specifically designed to identify potential suspicious orders before the orders are shipped. The CSOMP system was used across all areas of the country that we served, including for customers in West Virginia. The development of H. D. Smith's CSOMP was consistent with DEA's guidance, including the September 2006, February 2007, and December 2007 letters sent by DEA to the distributors.

H. D. Smith reported to the DEA all suspicious orders, including those in West Virginia. Between 2008 and 2009, we reported many suspicious orders to the DEA from West Virginia customers.

Although gathering dispensing and prescribing data from customers was often difficult, if H. D. Smith could obtain it, we were able to analyze such information to great effect along with the data collected by way of CSOMP. For example, in February 2008, we requested, obtained, and evaluated data from West Virginia customers Hurley Drug Company, Tug Valley Pharmacy, and Sav-Rite No.1/Strosnider Pharmacy. We concluded that two physicians were frequently writing prescriptions for hydrocodone, and that their patterns were cause for concern. H. D. Smith reported our analysis and concerns to the DEA on April 25, 2008, and cooperated with additional follow-up requests from the DEA.

**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?**

Answer: No, H. D. Smith did not always report suspicious orders to the West Virginia Board of Pharmacy because we believed it was not required to do so. At the time, H. D. Smith was

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classified as an out-of-state permit holder (as opposed to an in-state licensee), and one of our employees was told by the West Virginia Board of Pharmacy that we were required to comply with the West Virginia Controlled Substances Act, but that the Board of Pharmacy regulations (which include suspicious order reporting to the Board) did not apply to us as a permittee. Additionally, the head of the West Virginia Board of Pharmacy has repeatedly stated publicly, and testified in litigation, that the West Virginia Board of Pharmacy received very few suspicious order reports prior to 2012 and, when it started to receive suspicious orders, took no action in response to those orders. Since then, to the extent H. D. Smith reported a suspicious order to the DEA, it also reported that order to the West Virginia Board of Pharmacy.

It is also worth noting that West Virginia was an “early adopter,” in 1995, of a Prescription Drug Monitoring Program. The program is extremely detailed and comprehensive, and requires every prescriber and every dispenser in the state to report every controlled substance pill prescribed and dispensed at least daily. The DEA, the State Police, all medical licensing boards, etc., have unlimited access to this database. The Legislature charges the Board with several duties, including the duty to capture and report on “abnormal or unusual practices of patients and prescribers.”

**11. Did your company have a policy that orders had to be less than 50% controlled substances to be filled?**

Answer: H. D. Smith did not have such a policy. However, all prospective customers were asked when filling out new customer forms what percentage of their orders they expected would be controlled substances. Additionally, H. D. Smith’s CSOMP system took into account the ratios between purchases of controlled substances and purchases of other prescription and over-the-counter products by its customers. That ratio was closely monitored to identify any issues of concern regarding potential diversion activity.

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**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 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?**

Answer: The primary driver of H. D. Smith's sales is and always has been the orders placed by its customers. There are many factors that could be driving the reduction in orders placed by customers in West Virginia. For example, changes in the number of customers being served could drive changes in shipments. It is possible that the implementation of the automated CSOMP system contributed to the decline in controlled substances being shipped. H.D. Smith used data collected through its CSOMP system to identify, investigate and terminate certain West Virginia customers for suspicious order patterns or other reasons related to diversion control. CSOMP data contributed to H. D. Smith's decision to close West Virginia pharmacy Sav-Rite No. 1's account in April 2009. As a result of CSOMP data and an on-site visit, H. D. Smith terminated another West Virginia pharmacy Tug Valley's account in August 2009. H. D. Smith closed another West Virginia Pharmacy, Westside Pharmacy's account in January 2011. Additionally, H. D. Smith blocked two West Virginia pharmacies, Family Discount and Hurley Drug, from purchasing certain controlled substances in February and March of 2011, respectively.

Moreover, changes in physician prescribing practices could have resulted in reduced ordering by pharmacies.

- 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?**

Answer: It is also worth noting that during the time it was designing and implementing its CSOMP system, H. D. Smith understood that the DEA was very concerned about internet pharmacies and diversion in Florida in particular. But the DEA did not communicate that there were any diversion issues then existing in West Virginia or Appalachia generally. Indeed, Internet pharmacies were the specific topic of a DEA distributor briefing Kyle Wright made to H. D. Smith's head of compliance on January 4, 2007. On October 10, 2007, H. D. Smith met with Wright again for another distributor briefing and agreed to develop what became CSOMP. But before conducting that distributor briefing on October 10, 2007, Wright performed his own detailed analysis of H. D. Smith's national ARCOS data to identify H. D. Smith customers whom

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he believed needed additional scrutiny based on unusual or suspicious ordering patterns. Wright, through his analysis, found that no West Virginia pharmacy warranted additional scrutiny.



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**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?**

Answer: H. D. Smith is now part of ABC as a result of the ABC acquisition and thus defers to ABC on these questions.

- 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)?**

Answer: H. D. Smith is now part of ABC as a result of the ABC acquisition and thus defers to ABC on these questions.

- 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?**

Answer: H. D. Smith is now part of ABC as a result of the ABC acquisition and thus defers to ABC on these questions.