

ONE HUNDRED FIFTEENTH 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

January 26, 2018

J. Christopher Smith  
President and CEO  
H.D. Smith  
3063 Fiat Avenue  
Springfield, IL 62703

Dear Mr. Smith:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee is investigating the opioid epidemic in the U.S. that is taking 91 lives per day, according to the Centers for Disease Control and Prevention.<sup>1</sup> As part of this investigation, the Committee is seeking information to understand your distribution practices for various opioids in West Virginia in light of reports that distributors may have supplied the state with questionably high quantities of drugs. The possible oversupply described in this reporting suggests that such practices may have exacerbated the opioid addiction problem currently facing the state. For example, a December 2016 investigation by the *Charleston Gazette-Mail* reported:

In six years, drug wholesalers showered the state with 780 million hydrocodone and oxycodone pills, while 1,728 West Virginians fatally overdosed on those two painkillers... The unfettered shipments amount to 433 pain pills for every man, woman and child in West Virginia.<sup>2</sup>

In 2015, West Virginia had the highest opioid overdose death rate in the nation.<sup>3</sup> In addition to leading to numerous deaths, the opioid crisis in West Virginia has also caused many social challenges for its residents. The state and federal government have also incurred costs of important social and addiction treatment services.

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<sup>1</sup> Understanding the Epidemic, Opioid Overdose, The Centers for Disease Control and Prevention, August 30, 2017, available at <https://www.cdc.gov/drugoverdose/epidemic/index.html>.

<sup>2</sup> *Drug Firms Poured 780M Painkillers into WV Amid Rise of Overdoses*, The Charleston Gazette-Mail, December 17, 2016, available at <http://www.wvgazette.com/news-health/20161217/drug-firms-poured-780m-painkillers-into-wv-amid-rise-of-overdoses>.

<sup>3</sup> Centers for Disease Control and Prevention, *Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015*, December 30, 2016, available at <https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm>.

The *Gazette-Mail* further cited other examples regarding distribution practices in West Virginia, which if true, cause great concern. For example, in the small community of Kermit, West Virginia, with a population of 406, a single pharmacy received nearly nine million hydrocodone pills over two years. The *Gazette-Mail*'s reporting also cited another example of what they called a "mom-and-pop pharmacy" in the small town of Oceana, West Virginia that received an unusually high level of prescription medicines relative to a nearby pharmacy. In that case, the *Gazette-Mail* reported this single pharmacy "received 600 times as many oxycodone pills" than a Rite Aid drugstore that was "just eight blocks away."<sup>4</sup>

The *Washington Post* has also reported on the heavy distribution of opioids in West Virginia. For example, the *Post* indicated some officials within the state believe the practices of certain distributors may have violated state laws, such as W. Kent Carper, president of the Kanawha County Commission, who stated that, "[t]he impact is beyond words."<sup>5</sup> Citing Carper, the *Post* further reported, "distributors sent 66 million doses of oxycodone and hydrocodone into Kanawha County, population 190,000."<sup>6</sup> CNN similarly reported on drug distribution practices in West Virginia, noting the state "has become ground zero for the opioid epidemic here in the United States."<sup>7</sup>

Data provided to the Committee by the Drug Enforcement Administration (DEA) raises additional questions regarding H.D. Smith's efforts to monitor for, and mitigate controlled substance diversion in West Virginia.<sup>8</sup>

### 1. Family Discount Pharmacy, Mount Gay-Shamrock, West Virginia

DEA data provided to the Committee appear to indicate that in 2008 H.D. Smith supplied Family Discount Pharmacy with over 1.1 million hydrocodone pills, a 1,880 percent increase over the 57,000 pills H.D. Smith provided the pharmacy the year prior.<sup>9</sup> If accurate, this would equal an average rate of approximately 3,000 pills per day in 2008. According to U.S. Census data, Mount Gay-Shamrock's population was approximately 1,779 in 2010.<sup>10</sup> This means that in 2008, H.D. Smith provided Family Discount Pharmacy with 635 doses of hydrocodone for every man, woman, and child in Mount Gay-Shamrock.

- A. Did H.D. Smith perform any analysis to understand why the number of pills that it sent to Family Discount Pharmacy increased by 1,880 percent over a single-year period from 2007 to 2008? Did H.D. Smith have any formal policies or procedures in place to trigger specific reviews if certain threshold amounts (by percentage) were

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<sup>4</sup> See note 2.

<sup>5</sup> *Opioid Distributors Sued by West Virginia Counties Hit by Drug Crisis*, The Washington Post, March 9, 2017, available at [https://www.washingtonpost.com/national/health-science/lawsuits-filed-against-drug-distributors-in-west-virginia/2017/03/09/f9e3165e-0501-11e7-b1e9-a05d3c21f7cf\\_story.html?utm\\_term=.b25a35aa5b92](https://www.washingtonpost.com/national/health-science/lawsuits-filed-against-drug-distributors-in-west-virginia/2017/03/09/f9e3165e-0501-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.b25a35aa5b92).

<sup>6</sup> *Id.*

<sup>7</sup> *The Lead with Jake Tapper*, CNN, December 20, 2016.

<sup>8</sup> Data provided to the Committee pursuant to the Committee's investigatory request.

<sup>9</sup> Source: Data provided to the Committee by the Drug Enforcement Administration (DEA).

<sup>10</sup> U.S. Census Bureau, American FactFinder, *Mount Gay-Smarock CDP, West Virginia*, [https://factfinder.census.gov/faces/nav/jsf/pages/community\\_facts.xhtml#](https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml#).

increased? If so, what were they? If no such threshold policies were in place, why not?

- B. Did H.D. Smith use any analytic tools to assess whether the amount of pills distributed to Family Discount Pharmacy was appropriate for a town of 1,779 in a rural region of West Virginia? If so, what were they and what information did they yield about distribution to this pharmacy? If no such tools were in use, why not?
- C. Did H.D. Smith make any effort to determine the total number of pills sent to Mount Gay-Shamrock, and whether the amount of opioids that H.D. Smith sent to Family Discount Pharmacy was appropriate in light of this overall total?

## 2. Tug Valley Pharmacy and Hurley Drug Company, Williamson, West Virginia

Data provided to the Committee also appears to show that between 2007 and 2008, H.D. Smith provided Tug Valley Pharmacy and Hurley Drug Company, which were located approximately four blocks apart in Williamson, West Virginia, with a combined total of nearly 5 million hydrocodone and oxycodone pills. West Virginia court documents suggest that at one point, H.D. Smith provided the two pharmacies with 39,000 hydrocodone pills over a two-day period in October 2007.<sup>11</sup>

H.D. Smith's shipments of opioids to these pharmacies seem particularly excessive when viewed in context of the geographical area. According to U.S. Census data, Williamson's population was 3,191 in 2010.<sup>12</sup> This means that in 2007 and 2008, for example, H.D. Smith provided approximately 1,565 hydrocodone and oxycodone pills for every man, woman, and child in Williamson. Furthermore, according to market data cited by DEA, "in 2008, a retail pharmacy in rural West Virginia received an average of approximately 22,500 dosage units of hydrocodone per month."<sup>13</sup> However, DEA data seems to indicate that H.D. Smith shipped over 1.2 million dosage units of hydrocodone to each of these pharmacies that year, which would have been more than 4 times what DEA cited a rural pharmacy would be expected to receive.

- A. Is it accurate that H.D. Smith provided these two pharmacies with over 39,000 hydrocodone pills over a two-day period in October 2007? If so, were any red flags raised about potentially suspicious orders, and were any suspicious order reports submitted to DEA? What was the dosage order limit for each of these two pharmacies in October 2007, and how did H.D. Smith set these limits?
- B. Did H.D. Smith use any analytic tools to assess whether the amount of pills distributed to these two pharmacies was appropriate for a town of 3,191 in a rural

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<sup>11</sup> Second Amended Complaint, State of West Virginia *ex rel.* Patrick Morrissey, Attorney Gen., et al. v. Amerisourcebergen Drug Corp., et al., Civil Action No. 12-C-141 (Circuit Ct. of Boone Cnty. W. VA.).

<sup>12</sup> U.S. Census Bureau, American FactFinder, *Williamson city, West Virginia*, [https://factfinder.census.gov/faces/nav/jsf/pages/community\\_facts.xhtml](https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml).

<sup>13</sup> In the Matter of Miami-Luken, Order to Show Cause, U.S. Department of Justice, Drug Enforcement Administration, November 23, 2015. (On file with Committee).

region of West Virginia? If so, what were they and what information did they yield about distribution to this pharmacy? If no such tools were in use, why not?

### **3. Sav-Rite Pharmacy No. 1, Kermit, West Virginia**

H.D. Smith also appears to have been a major supplier to Sav-Rite Pharmacy No. 1 in 2008. DEA data suggests that it provided the pharmacy with over 1.3 million hydrocodone and oxycodone pills, a 1,154 percent increase over the 104,380 pills H.D. Smith provided the pharmacy the year prior. If these figures are accurate, in 2008, H.D. Smith supplied this pharmacy with nearly five times the amount a rural pharmacy would be expected to receive, according to market data cited by DEA in an unrelated case.<sup>14</sup>

Sav-Rite Pharmacy No. 1 was located in Kermit, West Virginia, population 406.<sup>15</sup> The owner of Sav-Rite Pharmacy No. 1, who later spent time in federal prison for violating the Controlled Substances Act, has testified that at one point the pharmacy was dispensing controlled substances at such a volume that it would fill one prescription per minute.<sup>16</sup>

- A. Did H.D. Smith perform any analysis to understand why the number of pills that it sent to Sav-Rite Pharmacy No. 1 increased by 1,154 percent over a single-year period from 2007 to 2008? Did H.D. Smith have any formal policies in place to trigger specific reviews if certain threshold amounts (by percentage) were increased? If so, what were they? If no such threshold policies were in place, why not?
- B. Did H.D. Smith use any analytic tools to assess whether the amount of pills distributed to this pharmacy was appropriate for a town of 406 in a rural region of West Virginia? If so, what were they and what information did they yield about distribution to this pharmacy? If no such tools were in use, why not?

### **4. Westside Pharmacy, Oceana, West Virginia**

DEA data obtained by the Committee seems to indicate that H.D. Smith provided over 369,000 oxycodone pills to Westside Pharmacy in 2009, and over 625,000 pills in 2010. According to market data cited by DEA in an unrelated case, "in 2009, a retail pharmacy in rural West Virginia received approximately 3,750 dosage units of oxycodone per month."<sup>17</sup> This means that, assuming the DEA data is accurate, in 2009 H.D. Smith shipped Westside Pharmacy eight times the amount of oxycodone that a rural pharmacy would be expected to receive. The next year, H.D. Smith's oxycodone shipments to Westside were nearly 14 times the expected amount.

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<sup>14</sup> In the Matter of Miami-Luken, Order to Show Cause, U.S. Department of Justice, Drug Enforcement Administration, November 23, 2015. (On file with Committee).

<sup>15</sup> U.S. Census Bureau, American FactFinder, *Kermit town, West Virginia*, [https://factfinder.census.gov/faces/nav/jsf/pages/community\\_facts.xhtml#](https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml#).

<sup>16</sup> West Virginia Second Amended Complaint, *supra* note 11.

<sup>17</sup> In the Matter of Miami-Luken, Order to Show Cause, U.S. Department of Justice, Drug Enforcement Administration, November 23, 2015. (On file with Committee).

- A. Westside Pharmacy is located in Oceana, West Virginia, which had a population of 1,394 in 2010.<sup>18</sup> Did H.D. Smith use any analytic tools to assess whether the amount of pills distributed to Westside Pharmacy was appropriate for a town of 1,394 in a rural region of West Virginia? If so, what were they and what information did they yield about distribution to this pharmacy? If no such tools were in use, why not?

## 5. Suspicious Order Reporting

According to press reports, H.D. Smith distributed approximately 13.7 million hydrocodone and 4.4 million oxycodone pills to West Virginia between 2007 and 2012.<sup>19</sup> Press accounts further indicate that H.D. Smith did not submit any suspicious order reports to the state for at least a decade, leading up to the time a lawsuit was brought by West Virginia in 2012.<sup>20</sup> That lawsuit alleged, among other things, that H.D. Smith and other distributors contributed to the state's opioid epidemic and contravened state law by failing to report suspicious orders to the state Board of Pharmacy. It is unclear whether H.D. Smith submitted any suspicious order reports to the West Virginia Board of Pharmacy following the state's lawsuit in 2012.

- A. Please provide any suspicious order reports that H.D. Smith submitted to the West Virginia Board of Pharmacy between 2006 and 2017;
- B. Please provide any suspicious order reports that H.D. Smith submitted to DEA for West Virginia between 2006 and 2017 regarding orders from West Virginia pharmacies;
- C. Please provide copies of all hydrocodone or oxycodone orders placed by West Virginia pharmacies between 2006 and 2017 that H.D. Smith refused to ship;

Since 2006, DEA has written at least three letters to wholesale drug distributors regarding their compliance obligations under the Controlled Substances Act. First, on September 27, 2006, DEA reminded distributors of their duty to “design and operate a system to disclose... suspicious orders of controlled substances,” and noted that “[s]uspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”<sup>21</sup>

That letter also reminded distributors that “a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances,” but must “exercise due care in confirming the legitimacy of all orders prior to filling.” Finally, the letter provided a list of possible indications that an order created a

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<sup>18</sup> American FactFinder, *Oceana town, West Virginia* (<https://factfinder.census.gov>).

<sup>19</sup> *Drug wholesaler agrees to pay \$3.5M to settle WV lawsuit*, The Charleston Gazette-Mail, January 3, 2017, available at [https://www.wvgazettemail.com/news/health/drug-wholesaler-agrees-to-pay-m-to-settle-wv-lawsuit/article\\_4e8c7f4c-cec5-5173-a199-c19374a6250c.html](https://www.wvgazettemail.com/news/health/drug-wholesaler-agrees-to-pay-m-to-settle-wv-lawsuit/article_4e8c7f4c-cec5-5173-a199-c19374a6250c.html).

<sup>20</sup> *'Suspicious' drug order rules never enforced by state*, The Charleston Gazette-Mail, December 18, 2016, available at [https://www.wvgazettemail.com/news/health/suspicious-drug-order-rules-never-enforced-by-state/article\\_3c9f1983-9044-5e97-87ff-df5ed5e55418.html](https://www.wvgazettemail.com/news/health/suspicious-drug-order-rules-never-enforced-by-state/article_3c9f1983-9044-5e97-87ff-df5ed5e55418.html).

<sup>21</sup> Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control to DEA Registrants (Sept. 27, 2006).

risk of diversion.<sup>22</sup>

On February 7, 2007, DEA sent another letter to distributors. This letter provided a list of additional "Circumstances That Might Be Indicative of Diversion," such as a pharmacy "[o]rdering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered," and offered a list of questions that a distributor should ask a pharmacy before filling orders from that pharmacy. Suggested questions included, for example, whether a limited number of practitioners were responsible for writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy, and what percentage of the pharmacy's business controlled substance dispensing constituted.<sup>23</sup>

Finally, on December 27, 2007, DEA sent a third letter to all registered distributors. This letter advised distributors that:

[I]f an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a 'normal pattern' to develop over time before determining where a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.<sup>24</sup>

- D. Did H.D. Smith receive the September 27, 2006 letter from DEA? If so, please describe what actions H.D. Smith took in response to this letter.
- E. Did H.D. Smith receive the February 7, 2007 letter from DEA? If so, please describe what actions H.D. Smith took in response to this letter.
- F. Did H.D. Smith receive the December 27, 2007 letter from DEA? If so, please describe what actions H.D. Smith took in response to this letter.

In addition to answers to the above questions, please provide the following:

1. The number of hydrocodone and oxycodone pills sold by H.D. Smith to purchasers in West Virginia each year from 2006 through 2017, broken out by drug;

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<sup>22</sup> *Id.*

<sup>23</sup> Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control to DEA Registrants (Feb. 7, 2007).


<sup>24</sup> Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control to DEA Registrants (Dec. 27, 2007).

2. All documents related to H.D. Smith's due diligence files for Strosnider dba Sav-Rite Pharmacy, located in Kermit, West Virginia, and Sav-Rite Pharmacy #2, located in Crum, West Virginia;
3. All documents related to H.D. Smith's due diligence files for Hurley Drug Company, located in Williamson, West Virginia;
4. All documents related to H.D. Smith's due diligence files for Tug Valley Pharmacy, located in Williamson, West Virginia;
5. All documents related to H.D. Smith's due diligence files for Westside Pharmacy, located in Oceana, West Virginia;
6. All documents related to H.D. Smith's due diligence files for Family Discount Pharmacy, located in Mount Gay-Shamrock, West Virginia;
7. A list of all West Virginia pharmacies H.D. Smith terminated business relationships with since January 1, 2006, and the date of termination. Please describe the reason for the termination and provide copies of any documents or communication related to any pharmacy termination;
8. A copy of any H.D. Smith written protocol regarding identification of suspicious orders, or any memorialization of oral instruction given to employees on this topic;
9. Copies of any letters H.D. Smith received from DEA since January 1, 2006 regarding the responsibilities of controlled substance distributors;
10. All documents since January 1, 2006 related to any H.D. Smith internal review or any external review commissioned by H.D. Smith regarding its compliance responsibilities related to the reporting of suspicious orders of controlled substances;
11. Copies of the meeting minutes for all meetings of the H.D. Smith Board of Directors from January 1, 2006 to the present;
12. Since January 1, 2006, did H.D. Smith take any personnel actions for any reason related to the inadequate performance of DEA compliance responsibilities? If so, please provide the details of these personnel actions, including the name and position of the employee, date of the action, reason for the action, and all documents related to the personnel action.

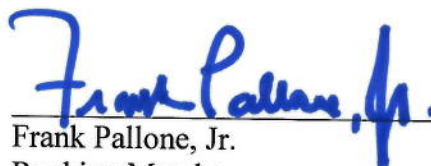
Given the Committee's examination of the opioid crisis, and to evaluate your distribution practices, particularly in West Virginia, we request that you provide the Committee with a briefing and the requested information by February 9, 2018:

An attachment to this letter provides additional information about responding to the committee's request. If you have any questions, please contact Alan Slobodin, Brittany Havens or Christopher Santini of the Majority staff at (202) 225-2927 or Kevin McAloon or Christina Calce of the Minority staff at (202) 225-3641. Thank you for your prompt attention to this matter.

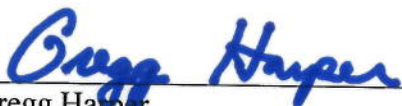
Sincerely,



Greg Walden  
Chairman



Frank Pallone, Jr.  
Ranking Member



Gregg Harper  
Chairman  
Subcommittee on Oversight  
and Investigations



Diana DeGette  
Ranking Member  
Subcommittee on Oversight  
and Investigations



David B. McKinley  
Member of Congress

Attachment