

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

COMMITTEE ON ENERGY AND COMMERCE

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February 15, 2018

Mr. George S. Barrett
Executive Chairman of the Board
Cardinal Health, Inc.
7000 Cardinal Place
Dublin, OH 43017

Mr. Michael C. Kaufmann
Chief Executive Officer
Cardinal Health, Inc.
7000 Cardinal Place
Dublin, OH 43017

Dear Messrs. Barrett and Kaufmann:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee is continuing to investigate the opioid epidemic in the U.S. that is taking 115 lives per day, according to the Centers for Disease Control and Prevention.¹

As part of our investigation, the Committee wrote to you on May 8, 2017, regarding your distribution practices generally, and in particular with respect to West Virginia. As we mentioned in that letter, the opioid epidemic has been particularly devastating to West Virginia. For example, in 2015, West Virginia had the highest opioid overdose death rate in the nation.² In addition to leading to numerous deaths, the opioid crisis in West Virginia has also caused many social challenges for its residents, and has devastated its economy. Press reports indicate the

¹ 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>.

² 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>.

epidemic is now estimated to cost West Virginia \$8.8 billion per year.³ Court filings also indicate that Cardinal Health distributed 155,629,101 doses of hydrocodone and 85,493,140 doses of oxycodone, for a total of 241,122,241 doses, to West Virginia between 2007 and 2012.⁴

Your response to our May 8th letter, as well as data and information the Committee obtained from the Drug Enforcement Administration (DEA)⁵, raise a number of additional questions, which are listed below.

I. Family Discount Pharmacy, Mount Gay-Shamrock, West Virginia

The Charleston Gazette-Mail identified Family Discount Pharmacy, located in Mount Gay-Shamrock, West Virginia, as being among the top purchasers of hydrocodone in West Virginia between 2007 and 2012.⁶ According to DEA data, between 2006 and 2016, Family Discount Pharmacy in Mount Gay-Shamrock received a total of 16,591,280 doses of hydrocodone and oxycodone from all distributors. According to U.S. Census data, in 2010, Mount Gay-Shamrock had a population of 1,779.⁷

A. According to DEA data, Cardinal supplied a pharmacy in Mount Gay-Shamrock, WV, with more than six times the amount of hydrocodone that an average pharmacy in rural West Virginia would have been expected to receive

DEA Automation of Reports and Consolidated Orders Systems (ARCOS) data provided to the Committee, and referenced in the chart below, indicate that over a 5-year period Cardinal Health supplied Family Discount Pharmacy with over 6.5 million hydrocodone and oxycodone pills. If accurate, this means that during this period, Cardinal Health shipped an average of 3,561 hydrocodone and oxycodone pills every day to this one pharmacy in rural West Virginia. To put it another way, U.S. Census data indicates that Mount Gay-Shamrock's population was 1,779 in 2010.⁸ This means that Cardinal Health alone shipped an average of approximately 731 opioid pills per year to every man, woman, and child in Mount Gay-Shamrock during this period.

Furthermore, market reports cited by DEA in an unrelated case suggest that an average retail pharmacy in rural West Virginia received approximately 18,000 dosage

³ *Opioid epidemic costs WV \$8.8 billion annually, study says*, *Charleston Gazette-Mail* (Feb. 6, 2018), https://www.wvgazette.com/news/health/opioid-epidemic-costs-wv-billion-annually-study-says/article_1cd8aaa5-78eb-5fd5-8619-3a0a1c086e66.html.

⁴ Second Amended Complaint at ¶ 16, *State of West Virginia ex rel. Patrick Morrissey et al. v. Cardinal Health Inc.*, Civ. No. 12-C-140 (Boone County, WV Circuit Court, Aug. 11, 2015).

⁵ Data provided to the Committee pursuant to the Committee's investigatory request.

⁶ *'Suspicious' drug order rules never enforced by state*, *Charleston Gazette-Mail* (Dec. 18, 2016), https://www.wvgazette.com/news/health/suspicious-drug-order-rules-never-enforced-by-state/article_3c9f1983-9044-5e97-87ff-df5ed5e55418.html.

⁷ American FactFinder, *Mount Gay-Shamrock CDP, West Virginia* (<https://factfinder.census.gov>) (Census 2010 Total Population).

⁸ U.S. Census Bureau, American FactFinder, *Mount Gay-Shamrock CDP, West Virginia* (<https://factfinder.census.gov>) (Census 2010 Total Population).

units of hydrocodone per month in 2010 and 2011.⁹ According to the DEA data provided to the Committee, Cardinal Health appears to have provided Family Discount Pharmacy over 1.3 million dosage units of hydrocodone each year in 2010 and 2011. This seems to indicate that Cardinal Health supplied Family Discount Pharmacy with over 6 times the amount of hydrocodone that an average pharmacy in rural West Virginia would have been expected to receive in each of those two years.

Table 1: Amount of Hydrocodone and Oxycodone Pills Cardinal Health Provided to Family Discount Pharmacy

Year	Hydrocodone Pills	Oxycodone pills
2008	705,600	129,000
2009	1,361,700	170,200
2010	1,358,800	164,500
2011	1,321,300	183,800
2012	975,380	129,800
Total	5,722,780	777,300

Source: DEA data provided to the Committee.

1. What was Cardinal Health's suspicious order threshold for hydrocodone dosage units per month for Family Discount Pharmacy in Mount Gay-Shamrock for each year between 2006 and 2012?
 - a. Did these differ from the thresholds for other pharmacies in rural West Virginia? If so, by how much did they differ?
 - b. Please explain how Cardinal Health established the threshold order limit for Family Discount Pharmacy for each year between 2006 and 2012.
2. Did Cardinal Health 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?
3. Did Cardinal Health make any effort to determine the total number of pills sent to Mount Gay-Shamrock, and whether the amount of opioids that Cardinal Health sent to Family Discount Pharmacy was appropriate in light of this overall total?

⁹ See *In re Miami-Luken*, Order to Show Cause (Drug Enforcement Administration, Nov. 23, 2015). Presumably, even this reference rate reflected overprescribing of opioids. In 2006, CDC conducted an investigation of unintentional drug poisoning fatalities in West Virginia. See CDC memorandum from A. Hall, J. Logan, and R. Toblin to D. Hamilton, "Epi-Aid Trip Report: Investigation of unintentional drug poisoning fatalities --- West Virginia, 2006" (October 12, 2007). Years later, the CDC issued opioid prescribing guidelines to address the over-prescription of opioids throughout the U.S., in part based on findings from such investigations.

4. Cardinal Health's June 30, 2017 response to the Committee noted its "Know Your Customer" program, which Cardinal Health indicated is a process by which it evaluates pharmacies and their use of controlled substances. Was Family Discount Pharmacy evaluated under the "Know Your Customer" component of Cardinal Health's anti-diversion program? If so, please provide all documents related to this evaluation. If not, why not?
5. Please provide all documents related to Cardinal Health's due diligence files for Family Discount Pharmacy, located in Mount Gay-Shamrock, West Virginia.

II. Hurley Drug Company, Williamson, West Virginia

According to DEA data, between 2006 and 2016, distributors shipped a total of 20,827,620 hydrocodone and oxycodone pills to the town of Williamson, West Virginia. DEA data also illustrates that Cardinal Health was one of the major suppliers of hydrocodone and oxycodone for Hurley Drug Company, located in Williamson, West Virginia. In a 2012 Complaint, the West Virginia Attorney General described Hurley Drug Co. and Tug Valley Pharmacy, which were located less than a mile from each other, as "among the most notorious of the pill mill pharmacies in Southern West Virginia."¹⁰ That same Complaint alleges that Hurley Drug Co. "filled hundreds of prescriptions daily" from four particular "pill mill doctors."¹¹

In 2015, the West Virginia Attorney General asserted in a separate complaint that Cardinal Health itself "distributed massive amounts of hydrocodone and other abused controlled substances" to this pharmacy.¹² Indeed, between 2006 and 2016, this single pharmacy in rural West Virginia received over 10.5 million doses of hydrocodone and oxycodone from all distributors.¹³ DEA data show that in 2011 alone, Cardinal Health provided Hurley Drug Company with 537,160 doses of hydrocodone and oxycodone.

According to U.S. Census data, Williamson's population was 3,191 in 2010.¹⁴ Therefore, the amount of hydrocodone and oxycodone shipped to Hurley Drug Company appears to be potentially excessive when compared to the population in that area.

¹⁰ Second Amended Complaint at ¶ 15(g)(ii), *State of West Virginia ex rel. Patrick Morrissey et al. v. Amerisourcebergen Drug Corp. et al.*, Civ. No. 12-c-141 (Boone County, WV Circuit Court, Jan. 2, 2014).

¹¹ *Id.* at ¶ 15(g)(ii)(aa). According to the Complaint, the "pill mill doctors" included Donald Kiser, who was subsequently sentenced to seven years in prison for violating federal drug laws; Diane Shafer, who spent six months in prison after admitting that she negligently prescribed pain pills; William Ryckman, who was convicted of conspiracy to misuse a DEA registration number and was also sentenced to six months in prison; and Katherine Hoover, who had her pain clinic closed and her medical license taken by the West Virginia Board of Medicine. (See, *'It was a conspiracy': recovering addicts wage legal battle over prescription use*, The Guardian (Aug. 28, 2016); *UPDATE: Former Mingo Co. Doctor Sentenced to Prison in Pill Mill Probe*, WSAZ 3 (Sept. 18, 2012); *Former Mingo Pill Mill Office Manager Sentenced to Prison Time*, Federal Bureau of Investigation (Sept. 18, 2013) (press release); *WV Board of Medicine Revokes Doctor's License*, WHSV3 (May 28, 2010).

¹² Second Amended Complaint at ¶ 16(e), *State of West Virginia ex rel. Patrick Morrissey et al. v. Cardinal Health Inc.*, Civ. No. 12-C-140 (Boone County, WV Circuit Court, Aug. 11, 2015).

¹³ Source: data provided to the Committee by DEA.

¹⁴ U.S. Census Bureau, American FactFinder, *Williamson city, West Virginia* (<https://factfinder.census.gov>) (Census 2010 Total Population).

As noted above, market reports cited by DEA suggest that an average retail pharmacy in rural West Virginia received approximately 18,000 dosage units of hydrocodone per month in 2011.¹⁵ According to the DEA data provided to the Committee, Cardinal Health provided Hurley Drug Company 496,060 dosages of hydrocodone in 2011. This means that Cardinal Health supplied Hurley Drug Company with over twice as much hydrocodone than an average pharmacy in rural West Virginia would have been expected to receive in 2011.

Further, according to DEA data, Cardinal Health's distributions to Hurley Drug Company varied considerably between 2006 and 2016. For example, Cardinal Health distributed 739,800 dosages of hydrocodone in 2006, 11,400 dosages in 2007, 585,700 in 2008, and 635,000 in 2009.

6. What was Cardinal Health's suspicious order threshold for hydrocodone dosage units per month for Hurley Drug Company for each year between 2006 and 2016?
 - a. Did these differ from the thresholds for other pharmacies in rural West Virginia? If so, by how much did they differ?
 - b. Please explain how Cardinal Health established the threshold order limit for Hurley Drug Company for each year between 2006 and 2016.
7. How, if at all, did Cardinal Health account for the variances in distribution to Hurley Drug Company between 2006 and 2016?
8. Did Cardinal Health use any analytic tools to assess whether the amount of pills distributed to Hurley Drug Company was appropriate for a town of 3,191 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?
9. Did Cardinal Health make any effort to determine the total number of pills sent to Williamson, and whether the amount of opioids that Cardinal Health sent to Hurley Drug Company was appropriate in light of this overall total?
10. Was Hurley Drug Company evaluated under the "Know Your Customer" component of Cardinal Health's anti-diversion program? If so, please provide all documents related to this evaluation. If not, why not?
11. Please provide all documents related to Cardinal Health's due diligence files for Hurley Drug Company, located in Williamson, West Virginia.

III. Cardinal Health's Suspicious Order Monitoring System

¹⁵ See *In re Miami-Luken*, Order to Show Cause (Drug Enforcement Administration, Nov. 23, 2015).

According to the 2015 Complaint filed by the West Virginia Attorney General, Cardinal Health distributed 155,629,101 hydrocodone pills and 85,493,140 oxycodone pills to West Virginia between 2007 and 2012.¹⁶ In January 2017, Cardinal Health agreed to pay West Virginia \$20 million to settle allegations related to its distribution of controlled substances in that state.¹⁷

Prior to that, in October 2008, Cardinal Health entered into a Settlement Agreement and Release with DEA that resulted in a \$34 million civil penalty related to its failure to report suspicious orders of controlled substances.¹⁸ In 2012, Cardinal Health entered into another Settlement Agreement with DEA regarding allegations that it failed to report suspicious orders as required under the Controlled Substances Act, which ultimately resulted in Cardinal Health paying a \$44 million civil penalty.¹⁹

12. What system did Cardinal Health have in place to monitor controlled substances purchases prior to 2008?
13. Was your suspicious order monitoring program (or any predecessor program) in place in each year between 2006 and 2017?
 - a. Please provide any documents or manual outlining your suspicious order monitoring program for each of these years.
 - b. If Cardinal Health's suspicious ordering monitoring program was not fully implemented in any year(s), please provide an explanation why.
 - c. Please provide any other guidance provided to Cardinal Health employees or contractors related to suspicious order monitoring for each of these years.
14. Given the settlements described above, did Cardinal Health ever conduct an internal investigation or commission an external investigation related to its compliance with suspicious order monitoring requirements? If so, please provide copies of the report(s). If not, why not?
15. Has Cardinal Health assessed the effectiveness of its suspicious order monitoring program for the years between 2006 and 2017? If so, please provide Cardinal Health's findings. If not, why not?

IV. DEA Letters to Distributors

¹⁶ Second Amended Complaint at ¶ 16, *State of West Virginia ex rel. Patrick Morrissey et al. v. Cardinal Health Inc.*, Civ. No. 12-C-140 (Boone County, WV Circuit Court, Aug. 11, 2015).

¹⁷ See, *2 drug distributors to pay \$36M to settle WV painkiller lawsuits*, Charleston Gazette-Mail (Jan. 9, 2017).

¹⁸ *Cardinal Health Inc. Agrees to Pay \$34 Million to Settle Claims That It Failed to Report Suspicious Sales of Widely-Abused Controlled Substances*, Department of Justice (Oct. 2, 2008) (press release).

¹⁹ *Cardinal Health Agrees to \$44 Million Settlement for Alleged Violations of Controlled Substances Act*, U.S. Department of Justice (Dec. 23, 2016) (press release). The parties entered into the Settlement Administrative Memorandum of Agreement in 2012, but did not reach agreement on the actual monetary fine until December 2016.

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.”²⁰

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 risk of diversion.²¹

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.²²

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.²³

²⁰ Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control to DEA Registrants (Sept. 27, 2006).

²¹ *Id.*

²² Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control to DEA Registrants (Feb. 7, 2007).

²³ Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control to DEA Registrants (Dec. 27, 2007).

16. Did Cardinal Health receive the September 27, 2006 letter from DEA? If so, please describe what actions Cardinal Health took in response to this letter.
17. Did Cardinal Health receive the February 7, 2007 letter from DEA? If so, please describe what actions Cardinal Health took in response to this letter.
18. Did Cardinal Health receive the December 27, 2007 letter from DEA? If so, please describe what actions Cardinal Health took in response to this letter.

V. Additional Questions and Requests

19. Please provide all documents related to Cardinal Health's due diligence files for the following pharmacies: Family Discount Pharmacy, located in Stollings, West Virginia; and Tug Valley Pharmacy, located in Williamson, West Virginia.
20. Please provide a list of Cardinal Health's ten largest pharmacy customers in West Virginia, based upon hydrocodone and oxycodone dosage units, between 2006 and 2017.
 - a. For each of those ten customers, please provide the total dosage units of hydrocodone and total dosage units of oxycodone that Cardinal Health distributed to each pharmacy each year from 2006 through 2017.
21. Please provide minutes from all Cardinal Health Board meetings held between 2006 and 2017.
22. Please provide minutes from all meetings of any subcommittee of the Cardinal Health Board of Directors, held between 2006 and 2017, where suspicious order monitoring or diversion of controlled substances was discussed.
23. Did Cardinal Health ever purchase market reports from IMS Health as part of the company's new customer due diligence? If so, in what years did Cardinal Health purchase IMS Health market reports and what specific types of reports did it purchase? If not, were market reports purchased from other sources? If Cardinal Health purchased third party reports or other data to use in its evaluation of existing and potential pharmacy customers from January 1, 2006 until present, please provide the third party vendor as well as the specific types of reports or data Cardinal Health utilized.
24. Cardinal Health's June 30, 2017 response referenced the "Know Your Customer" component of its anti-diversion program. When was this component formally established by the Company? When was it last revised? Did a similar anti-diversion component predate it? If so, please provide the differences between the current "Know Your Customer" component and its predecessor.

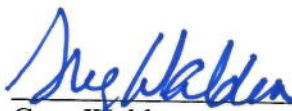
25. Since January 1, 2006 has Cardinal Health received any customer orders from West Virginia for hydrocodone or oxycodone that exceeded either the dosage unit or strength thresholds set by Cardinal Health? If so, please provide details about these orders, and any action taken by the company, including but not limited to, whether the company decided to release the product for shipment.
26. Cardinal Health's June 30, 2017 response to the Committee noted that it "stands by the appropriateness of its distributions in West Virginia" and asserted "based on average prescription sizes, Cardinal Health's distributions to West Virginia pharmacies were sufficient to allow each pharmacy to fill between 4.5 and 6.5 prescriptions for oxycodone and hydrocodone per day."
 - a. What year(s) does this average reference? Please provide documentation on how this average was calculated, and how (if at all) Cardinal Health used this average for purposes of monitoring for suspicious orders in West Virginia.
 - b. DEA data provided to the Committee indicate that Cardinal Health shipped over 1.3 million hydrocodone pills to Family Discount Pharmacy each year from 2009 through 2011, which averages over 3,600 hydrocodone pills shipped to this pharmacy per day. How did Cardinal Health determine that its distribution of hydrocodone and oxycodone to Family Discount Pharmacy was appropriate given its stated average of between 4.5 and 6.5 prescriptions for oxycodone and hydrocodone to each pharmacy per day?
27. Please provide copies of any dashboards and reports since January 1, 2006 of aggregated purchase data by West Virginia customers that Cardinal Health used to identify concerning trends in purchases potentially missed in the review of individual flagged orders.
28. According to its June 30, 2017 response to the Committee, Cardinal Health maintains that its "distributions of oxycodone and hydrocodone to West Virginia pharmacies were never in amounts that exceeded what was reasonably calculated to be necessary for pharmacies to meet the legitimate medical needs of patients." Prior to the Centers for Disease Control and Prevention issuing guidelines on opioid prescribing in March 2016, how did Cardinal Health determine the amounts of oxycodone and hydrocodone that were necessary for pharmacies to meet the legitimate medical needs of patients? Please provide documentation of how those determination were made, and how Cardinal Health used that information to ensure that its distributions never exceeded those amounts.
29. Please provide any suspicious order reports that Cardinal Health submitted to the West Virginia Board of Pharmacy between 2006 and 2017.
30. Please provide any suspicious order reports that Cardinal Health submitted to DEA between 2006 and 2017 regarding orders from West Virginia pharmacies.

31. Please provide copies of all hydrocodone and oxycodone orders placed by West Virginia pharmacies between 2006 and 2017 that Cardinal Health refused to ship.
32. Please provide a list of all West Virginia pharmacies Cardinal Health 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.
33. Please provide a copy of any Cardinal Health written protocol regarding identification of suspicious orders, or any memorialization of oral instruction given to employees on this topic.
34. For each year from 2006 to 2017, please provide the five states with the highest number of suspicious orders reported by your company to DEA.
35. Since January 1, 2006, did Cardinal Health 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.

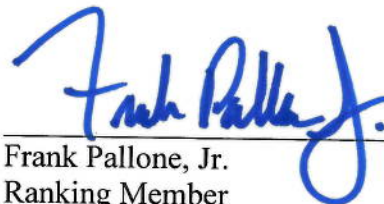
Please provide requested information and documents by March 19, 2018.

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.

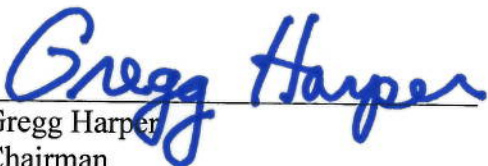
Sincerely,

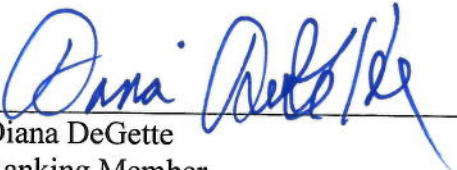


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Chairman
Subcommittee on Oversight
and Investigations


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Attachment