

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

February 15, 2018

Mr. Steven H. Collis  
Chairman, President and Chief Executive Officer  
AmerisourceBergen Corporation  
1300 Morris Drive  
Chesterbrook, PA 19087

Dear Mr. Collis:

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.<sup>1</sup>

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.<sup>2</sup> 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 epidemic is now estimated to cost West Virginia \$8.8 billion per year.<sup>3</sup>

According to a Complaint filed by the Attorney General of West Virginia, over five years, AmerisourceBergen distributed 60,937,584 doses of hydrocodone and 29,406,680 doses of oxycodone, for a total of 90,344,264 total doses, to the state.<sup>4</sup> According to the Complaint, these amounts “are far beyond the number of distributions of controlled substances as would be

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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> 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>.

<sup>3</sup> *Opioid epidemic costs WV \$8.8 billion annually, study says*, Charleston Gazette-Mail (Feb. 6, 2018).

<sup>4</sup> Second Amended Complaint at ¶ 15a (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).

reasonably distributed to a population of 1.85 million.”<sup>5</sup> In January 2017, AmerisourceBergen agreed to pay West Virginia \$16 million to settle allegations related to its distribution of controlled substances in that state.<sup>6</sup>

These numbers, as well as your response to our May 8<sup>th</sup> letter and data and information the committee obtained from the Drug Enforcement Administration (DEA)<sup>7</sup>, raise additional questions, which are listed below.

1. Did AmerisourceBergen ever purchase market reports from IMS Health as part of the company’s new customer due diligence? If so, what years did AmerisourceBergen purchase IMS Health market reports and what specific types of reports did it purchase? If not, were market reports purchased from other sources? If AmerisourceBergen 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 AmerisourceBergen utilized.
2. Did AmerisourceBergen 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?
3. Please provide minutes from all AmerisourceBergen Board meetings held between 2006 and 2017.
4. Please provide minutes from all meetings of any subcommittee of the AmerisourceBergen Board of Directors, held between 2006 and 2017, where suspicious order monitoring or diversion of controlled substances was discussed.
5. AmerisourceBergen’s June 30, 2017 response to the Committee referenced a Diversion Control Advisory Committee. When was this committee established and why? Please provide a list of the members by name and position as well as any meeting minutes from January 1, 2006 until present.
6. Since January 1, 2006, have there been any customer orders from West Virginia that exceeded either (1) the Cumulative Volume Parameter and the Order Size Parameter, or (2) the Fail-Safe Parameter? If so, please provide details about these orders and whether the company decided to release the product for shipment.
7. Please provide copies of on-site customer investigations since January 1, 2006 conducted by The Pharma Compliance Group (or any other investigative group) of any customer located in West Virginia that resulted in a company decision to refuse to service.
8. AmerisourceBergen’s June 30, 2017 response referenced the “Know Your Customer” component of its anti-diversion program. When was this component formally established

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<sup>5</sup> *Id.*

<sup>6</sup> *2 drug distributors to pay \$36M to settle WV painkiller lawsuits*, Charleston Gazette-Mail (Jan. 9, 2017).

<sup>7</sup> Data provided to the Committee pursuant to the Committee’s investigatory request.

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.

9. Please provide copies of any dashboards and reports since January 1, 2006 of aggregated purchase data by West Virginia customers that AmerisourceBergen used to identify concerning trends in purchases potentially missed in the review of individual flagged orders.
10. 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>8</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 risk of diversion.<sup>9</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>10</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.

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<sup>8</sup> Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control to DEA Registrants (Sept. 27, 2006).

<sup>9</sup> *Id.*

<sup>10</sup> Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control to DEA Registrants (Feb. 7, 2007).

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>11</sup>

- a. Did AmerisourceBergen receive the September 27, 2006 letter from DEA? If so, please describe what actions AmerisourceBergen took in response to this letter.
  - b. Did AmerisourceBergen receive the February 7, 2007 letter from DEA? If so, please describe what actions AmerisourceBergen took in response to this letter.
  - c. Did AmerisourceBergen receive the December 27, 2007 letter from DEA? If so, please describe what actions AmerisourceBergen took in response to this letter.
11. Please provide all documents related to AmerisourceBergen's due diligence files for Westside Pharmacy, located in Oceana, West Virginia.
  12. Please provide all documents related to AmerisourceBergen's due diligence files for Family Discount Pharmacy, located in Mount Gay-Shamrock, West Virginia.
  13. Please provide all documents related to AmerisourceBergen's due diligence files for Tug Valley Pharmacy, located in Williamson, West Virginia.
  14. Please provide a list of AmerisourceBergen'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 AmerisourceBergen distributed to each pharmacy each year from 2006 through 2017.
  15. Please provide any suspicious order reports that AmerisourceBergen submitted to the West Virginia Board of Pharmacy between 2006 and 2017.
  16. Please provide any suspicious order reports that AmerisourceBergen submitted to DEA between 2006 and 2017 regarding orders from West Virginia pharmacies.
  17. Please provide copies of all hydrocodone or oxycodone orders placed by West Virginia pharmacies between 2006 and 2017 that AmerisourceBergen refused to ship.
  18. Please provide a list of all West Virginia pharmacies on AmerisourceBergen's "Do Not Ship List," referenced in the Company's June 30, 2017 response.
  19. Please provide a list of all West Virginia pharmacies AmerisourceBergen terminated business relationships with since January 1, 2006, and the date of termination. Please

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<sup>11</sup> Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control to DEA Registrants (Dec. 27, 2007).



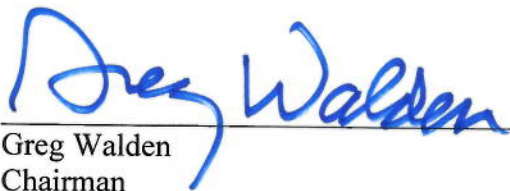
describe the reason for the termination and provide copies of any documents or communication related to any pharmacy termination.

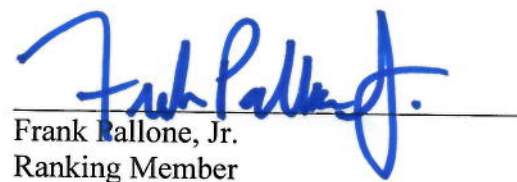
20. Was your suspicious order monitoring program (or any predecessor program) in place in each year between 2006 and 2017?
  - a. Please provide any documents or manual outlining your suspicious order monitoring program for each of these years.
  - b. Please provide any other guidance provided to AmerisourceBergen employees or contractors related to the suspicious order monitoring program in each of these years.
21. 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.
22. Since January 1, 2006, did AmerisourceBergen 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 the Committee with the 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,

  
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

Letter to Mr. Collis  
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David B. McKinley  
Member of Congress

Attachment