

The Honorable Gregg Harper

1. Does your company request dispensing data from both prospective and existing pharmacy customers as part of its due diligence efforts to mitigate controlled substance diversion? If so, at what frequency does your company request this information and how is the dispensing data utilized? If no, why not?

As part of its comprehensive anti-diversion program, Cardinal Health periodically requests and receives aggregate dispensing data and total number of prescriptions filled for both controlled and non-controlled substances from prospective and existing pharmacy customers. Cardinal Health requests total number of prescriptions filled for certain controlled substances from prospective customers as part of its initial Know Your Customer account set up process. In addition, outside of the account set up process, requests for aggregate dispensing data or total number of prescriptions filled may be made by Cardinal Health professionals working in Cardinal Health's anti-diversion program when they determine such a request is appropriate pursuant to the monitoring, inspection, and escalation protocols of the company's anti-diversion policies and procedures. That aggregate dispensing data and total number of prescriptions filled, along with Cardinal Health's complete data about its own distributions to each customer, is utilized to set and evaluate customer thresholds for controlled substance distributions.

Also, Cardinal Health reports all distributions of controlled substances to the DEA, which receives similar reports from every distributor through its ARCOS data reporting system. These reports, taken together, provide DEA with contemporaneous data reflecting all opiates purchased by every pharmacy in the United States.

2. In its contracts with pharmacy customers, is your company able to require that a pharmacy produce dispensing data upon request? If so, does your company include such a requirement in the contracts it enters into with its pharmacy customers? If your company doesn't include such a requirement in its contracts, why not?

Cardinal Health will not distribute opioids to a pharmacy customer without receiving sufficient information about its dispensing to allow the company to evaluate the pharmacy customer and its orders under Cardinal Health's anti-diversion program, nor will Cardinal Health distribute opioids to pharmacy customers who refuse to provide such information upon request.

3. As part of your company's due diligence efforts related to prospective and existing customers, does your company review and maintain a list of the number of pharmacies that are located in the prospective/existing customer's service region? If so, how long has that been your company's practice and how does your company determine what a pharmacy's potential service region is?

Among the many factors Cardinal Health considers when evaluating customers are the pharmacy's size, business model, location, historical volume of controlled substance purchasing, and its ratio of controlled substance purchasing to non-controlled substance purchasing. This multifaceted analysis is performed because appropriate thresholds for a pharmacy are not necessarily reflective of the size of the community where the pharmacy is located or how many pharmacies are located in a particular geographic area. Other relevant factors include the volume

of patients served as reflected by the volume of non-controlled substances dispensed, and the pharmacy's proximity to or affiliation with hospitals, clinics, surgery centers, hospice facilities, and long-term care facilities.

4. Does your company request dispensing data from both prospective and existing pharmacy customers as part of its due diligence efforts to mitigate controlled substance diversion? If so, at what frequency does your company request this information and how is the dispensing data utilized? If no, why not?

Cardinal Health refers the Committee to the response to Question 1 above.

5. In its contracts with pharmacy customers, is your company able to require that a pharmacy produce dispensing data upon request? If so, does your company include such a requirement in the contracts it enters into with its pharmacy customers? If your company doesn't include such a requirement in its contracts, why not?

Cardinal Health refers the Committee to the response to Question 2 above.

6. As part of your company's due diligence efforts related to prospective and existing customers, does your company review and maintain a list of the number of pharmacies that are located in the prospective/existing customer's service region? If so, how long has that been your company's practice and how does your company determine what a pharmacy's potential service region is?

Cardinal Health refers the Committee to the response to Question 3 above.

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?

On February 14, 2018, DEA announced that it added a feature to the ARCOS Online Reporting System that would allow distributors and manufacturers the opportunity to “view the number of competitors who have sold a particular controlled substance to a prospective customer in the last six months.” Cardinal Health has been able to access this data, but its usefulness is limited because it does not reflect specific products within drug families and because it reflects only the number of distributors who shipped to the customer within the prior six months, but not the volume of controlled substances shipped. Many if not most pharmacies purchase controlled and non-controlled substances from multiple distributors for a variety of business reasons, including price and product availability. The fact that a particular pharmacy purchased controlled substances from more than one distributor is not necessarily indicative of a risk of diversion.

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?

As an intermediary in the pharmaceutical supply chain, Cardinal Health does not ultimately control either the supply of or the demand for opioids. The demand for legal opioids is generated by licensed physicians prescribing medications for individual patients, and the supply of legal opioids is controlled by the annual DEA procurement and manufacturing quotas. The company's role as a distributor is to provide a secure channel to deliver medications of all kinds, from the hundreds of manufacturers who make them, to the thousands of hospitals and pharmacies authorized by the DEA to dispense them. Cardinal Health has a dual responsibility—to ensure that prescription medications are available for prescribers and their patients when needed, while working to limit the potential for those prescription medications to fall into the wrong hands. Cardinal Health shares the judgment of policymakers at the Department of Health and Human Services, the Food and Drug Administration, the Surgeon General, the Centers for Disease Control and Prevention, and others that there have been too many prescriptions for too many pills across the country. However, other participants in the healthcare delivery system have greater access to information than distributors. For example, many individual states have taken enormous strides in improving data sharing amongst licensed healthcare providers and pharmacies through prescription drug monitoring programs (“PDMPs”). DEA also has access to comprehensive data through ARCOS.

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?

Cardinal Health generally does not have knowledge of what actions DEA may take in response to suspicious order reporting, nor can it speak to the role of drug manufacturers. As a distributor, Cardinal Health has reported to DEA hundreds of thousands of opioid orders that exceeded the company's conservative thresholds and that we have refused to ship. The company also has terminated or refused to distribute controlled substances to over a thousand pharmacies.

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?

Cardinal Health supports appropriate prescribing limits on opioid pain medications, the creation of a national prescription drug monitoring program through collaboration with industry participants, and state and federal regulations and legislation that would require prescriptions to be issued electronically. Cardinal Health also supports legislation aimed at illegal street narcotics interdiction that target the supply of heroin and illicit fentanyl within communities. Finally, Cardinal Health shares the Committee's view that all parties in the health care community have a responsibility to help prevent opioid abuse and diversion, and the company is committed to doing its part to help ensure opioids are not diverted from the distribution channels within which Cardinal Health operates. In this regard, Cardinal Health supports legislative solutions that would harness the power of modern data analytics to strengthen oversight of the entire supply chain by encouraging greater data sharing and visibility among industry

participants and with regulators. Cardinal Health also supports and encourages increased communication between distributors and the federal and state regulators responsible for licensure of prescribers and dispensers.

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.

As a licensed pharmaceutical distributor, Cardinal Health is subject to regulatory oversight by the Drug Enforcement Administration, including pursuant to the laws cited above. Cardinal Health has a dual responsibility—to ensure that prescription medications are available for prescribers and their patients when needed, while working to limit the potential for those prescription medications to fall into the wrong hands. Cardinal Health takes its regulatory obligations to the DEA seriously, and has worked continuously to improve its anti-diversion program to address the ever-changing diversion landscape and to account for changing regulatory expectations.

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

Cardinal Health's dual responsibility is to ensure that prescription medications are available for prescribers and their patients when needed, while working to limit the potential for those prescription medications to fall into the wrong hands. Licensed pharmacies order medications from Cardinal Health. As a distributor, Cardinal Health is not licensed to engage in the practice of medicine, never sees or examines the patient, and cannot second guess the professional judgments of licensed prescribers, pharmacists and pharmacies, FDA, DEA, or state Boards of Pharmacy. The medications Cardinal Health supplies should never be dispensed by a pharmacy unless the pharmacy receives a lawful prescription from a licensed prescriber.

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

Licensed pharmacies order medications from Cardinal Health. As a distributor, Cardinal Health does not write prescriptions to patients (doctors do that), and does not transact directly with customers of a pharmacy seeking to fill those prescriptions (pharmacists do that). The medications Cardinal Health supplies never reach a patient unless a doctor prescribes them and the pharmacy dispenses them. The fact that a particular pharmacy places large orders to fill prescriptions by licensed doctors can be reflective of the practice of medicine and pharmacy and not necessarily reflective of diversion. Cardinal Health maintains and continuously improves robust anti-diversion controls to prevent the shipment of opioids to customers that it believes present a substantial risk of diversion, and does not ship orders it determines are suspicious.

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

Cardinal Health refers the Committee to the response to Question 3 above.

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

There is a public health crisis involving drug abuse including both legal and illegal opioid drugs. Cardinal Health is committed to doing its part to fight opioid abuse and misuse. For over a decade, Cardinal Health has funded education and prevention programs in communities across the country through Generation Rx, which the Cardinal Health Foundation developed in partnership with the Ohio State University School of Pharmacy. Generation Rx is a national prescription drug misuse prevention program that has been used in every state, at more than 100 colleges of pharmacy, and has provided more than a million people with tools and educational resources to prevent and address the issues that drive opioid abuse. More recently, Cardinal Health launched its Opioid Action Program (OAP), which has four elements, each of which has been cited by leading experts as essential to the fight to reduce opioid abuse and casualties. The OAP includes: 1) partnership with a leading school of medicine to refine and share medical school curricula that address opioid abuse and treatment through a collaboration with over 20 medical schools nationwide; 2) increased support of drug take back efforts to ensure excess medications are not available for abuse; 3) grants for community organizations engaged in youth prevention education, prescriber opioid awareness and reduction efforts, and community responses to the epidemic; and 4) the distribution of overdose reversal drug Narcan free-of-charge to first responders and law enforcement. Cardinal Health piloted OAP in four of the nation's hardest-hit states across Appalachia—Ohio, Kentucky, Tennessee, and West Virginia—to help alleviate the opioid epidemic.

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

Cardinal Health refers the Committee to the response to Question 3 above.

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

Cardinal Health refers the Committee to the response to Question 5 above.

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

Cardinal Health refers the Committee to the response to Question 5 above.

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

Cardinal Health has invested significant resources to develop and operate a rigorous anti-diversion system. Through its anti-diversion program, Cardinal Health employs technology and analytics to evaluate its customers and scrutinize orders to identify potentially suspicious orders.

Cardinal Health reports potentially suspicious orders to federal and state authorities, including the West Virginia Board of Pharmacy.

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?

Cardinal Health produced documents to the Committee identifying over 1,900 potentially suspicious orders that were reported to West Virginia regulatory authorities. See CAH_HOUSE-000024 and CAH_HOUSE-002299.

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

Cardinal Health processes orders on a line item basis, meaning each order is for a single pharmaceutical product. As part of its anti-diversion program, Cardinal Health evaluates the controlled substance purchasing and non-controlled substance purchasing across a pharmacy's total orders, not within a particular order or subset of orders. Every Cardinal Health customer has an individualized threshold limit for all drug families of controlled substances Cardinal Health distributes. The thresholds are based on various factors specific to the customer as well as analysis of third-party data detailing dispensing volumes of pharmacies nationwide.

The Honorable Frank Pallone, Jr.

1. Cardinal's responses to the Committee do not appear to include any suspicious orders submitted by Cardinal to DEA prior to 2012. But the opioid crisis was exploding during the mid-2000s, and West Virginia has the highest death rate in the country from opioids. In retrospect, what could Cardinal have done to more proactively monitor its orders and help spot diversion?

Cardinal Health has had a suspicious order monitoring process in place going back decades. From at least the late 1980's through approximately 2007, Cardinal Health used the DEA's mandated algorithm to identify excessive purchases that were reported to DEA. See Drug Enforcement Administration, Office of Diversion Control Suspicious Order Task Force, Report to the U.S. Attorney General, October 1998, Ex. II. Cardinal Health's system has been continually enhanced and improved as the diversion landscape has changed over time, and as DEA provided letters to industry and undertook enforcement actions. Cardinal Health takes its regulatory obligations seriously: on Cardinal Health's own initiative and in response to regulators, Cardinal Health has increased the size of its anti-diversion team, including bringing in personnel with additional regulatory, pharmaceutical, and law enforcement experience to further enhance the anti-diversion program. The company developed an analytical model to evaluate customers, assigned threshold ordering volumes, created a centralized database to store and track data on customers and orders, and designed new policies and procedures for anti-diversion personnel. No program can be perfect, which is why Cardinal Health is so focused on continuous improvement.

The Honorable Jan Schakowsky

1. According to the DEA records, Cardinal Health paid \$34 million in civil penalties to the DEA regarding allegations that you failed to report suspicious orders, as required by the Controlled Substances Act. Do you accept and admit to this Committee that your company repeatedly shipped and failed to report suspicious orders?

As was stated in Mr. Barrett's written testimony, despite the development of a quality anti-diversion system, Cardinal Health has not always gotten every decision right, and in the past has entered into settlements with regulators to address aspects of its anti-diversion program. The company has learned and improved from each of them. While no program can ever be perfect, the company's goal is always to get it right, and Cardinal Health has stopped suspicious orders for the shipment of hundreds of millions of dosage units of controlled substances over the last decade. Cardinal Health does not ship opioids to customers that it believes present a substantial risk of diversion, and does not ship orders it determines are suspicious.

2. 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?

In the vast majority of cases, Cardinal Health buys medications from manufacturers, taking title to the product. Cardinal Health generally does not sell medications on a consignment arrangement.

3. 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)?

Cardinal Health negotiates a variety of different pricing arrangements with its pharmacy customers depending on their needs and preferences.

4. 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?

Cardinal Health refers the Committee to the response to Question 3 above.