

AmerisourceBergen Corporation
WRITTEN STATEMENT
OF STEVEN H. COLLIS
CHAIRMAN, PRESIDENT, AND CHIEF EXECUTIVE OFFICER
AMERISOURCEBERGEN CORPORATION

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES

PRESENTED
MAY 8, 2018

**Written Statement of Steven H. Collis
Chairman, President, and Chief Executive Officer
AmerisourceBergen Corporation
Before the Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives
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I am Steven H. Collis, Chairman, President, and Chief Executive Officer of AmerisourceBergen Corporation (“AmerisourceBergen” or “the Company”). I thank the Committee for the opportunity to express my concern, and the Company’s concern, about the tragic epidemic of opioid abuse, as well as our desire to be part of much-needed, and unquestionably multi-faceted, solutions to address this public health crisis.

The epidemic raises many complex problems. AmerisourceBergen associates and I see firsthand the struggles of individuals impacted by the opioid epidemic. Like so many others, the AmerisourceBergen family is impacted by opioid addiction in many ways. We have seen our families and friends struggle with addiction and we have been touched personally by harrowing stories of the devastation it has caused in communities throughout this country. But we also know that FDA-approved opioid medications play an important role for many Americans who struggle with debilitating pain and severe sickness, such as cancer. We cannot forget that opioids are approved as safe and effective treatments to ease the pain and suffering of many patients who need them, and they can be vital in end-of-life care. Opioids also allow others to function in spite of medical conditions and pain that would otherwise make life unbearable.

The critical challenge we face lies in finding the appropriate balance: preventing the abuse of these treatments, while providing clinically appropriate access to the medications that many patients need. AmerisourceBergen Drug Corporation is a distributor – a logistics provider that purchases pharmaceutical products from manufacturers and supplies Drug Enforcement Administration- (“DEA”) and state-licensed pharmacies, hospitals, and clinics that dispense to

patients based on prescriptions written by board-certified physicians. Our place in the supply chain provides AmerisourceBergen Drug Corporation with neither the information nor the expertise to override clinical decisions by trained doctors and pharmacists or to determine the appropriate supply of medications. While we believe it is important to recognize our limited but vital role in the supply chain, we are committed to working with the Committee and all stakeholders on ways that all distributors, and AmerisourceBergen in particular, can leverage our expertise and position in the supply chain to help address this crisis. We welcome an ongoing dialogue on how to move forward expeditiously and effectively.

AmerisourceBergen Drug Corporation Is a Logistics Provider That Distributes Legal, FDA-Approved Products to DEA-Licensed Customers

The wholesale pharmaceutical distribution business is not well known to the American public. The lack of awareness and understanding of a distributor's limited but vital role in the healthcare supply chain has led to significant misunderstandings about what AmerisourceBergen Drug Corporation does and does not do.

AmerisourceBergen Drug Corporation facilities do not manufacture pharmaceuticals. We are a wholesaler that plays a critical role in ensuring the safety and security of America's pharmaceutical supply chain. We purchase some 15 million innovative brand and generic medicines, the vast majority of which are non-controlled substances, directly from manufacturers. We are responsible for getting those medicines to tens of thousands of sites of care every day, including pharmacies, hospitals, and clinics, which administer or dispense the medicines on prescriptions written by licensed health care providers. By acting in this logistics role, AmerisourceBergen Drug Corporation contributes to a secure supply chain and an efficient

distribution system that has been estimated to save the United States health care system \$42 billion a year.¹

AmerisourceBergen Drug Corporation's distribution role in the system is vital, yet limited in many ways. Prescription opioids represent less than 2% of AmerisourceBergen's annual revenue. AmerisourceBergen Drug Corporation delivers the products that our customers order from us, but does not promote the prescribing or use of medications, including opioids. We do not offer our sales representatives special compensation or incentives of any kind that target opioid orders in particular. We have no ability, and no desire, to encourage the prescribing or dispensing of pain medicines.

Further, as a wholesale distributor, AmerisourceBergen Drug Corporation does not control how any medications we deliver are prescribed, dispensed, or ultimately used. Strict statutory privacy requirements (including HIPAA) prevent us from obtaining information about the particular patients for whom medicines are prescribed, the specific medical purpose for which medicines are prescribed, or how they are used by the patients. This is true for all medicines AmerisourceBergen Drug Corporation distributes, including opioids. AmerisourceBergen Drug Corporation has absolutely no role in the clinical decisions made between a doctor and a patient.

The number of opioids shipped by AmerisourceBergen Drug Corporation was and is driven by the number of pills ordered by our customers. Until very recently, AmerisourceBergen Drug Corporation has never known (unless a customer discloses that information voluntarily) whether a pharmacy customer buys opioids from other distributors. Even with the DEA's new rules for sharing information on a pharmacy's other distributors, AmerisourceBergen Drug

¹ See Center for Healthcare Supply Chain Research, *The Role of Distributors in the U.S. Healthcare Industry: A 2011 study prepared by Booz & Company*. Arlington, VA: The Center, 2011.

Corporation does not know what types of opioids or how many opioids its customers order from other distributors. AmerisourceBergen Drug Corporation only has access to its own distribution data. This is in fact why we have been a vocal advocate for increased data transparency across the supply chain, including the sharing of scrubbed ARCOS (Automation of Reports and Consolidated Order System) data. Such data, which is only visible to the DEA, would allow us to make more informed decisions when evaluating orders of controlled substances as well as the customers who are placing those orders.

All Participants in the Supply Chain of Prescription Opioids Are Closely Regulated by the DEA and Must Safeguard Against Diversion, Within the Areas They Control

Federal law regulates prescription opioids at every link in the closed system of distribution. All prescription medicines, including opioids, are evaluated and approved as safe and effective by the FDA based on their ability to effectively and safely treat a medical condition, such as cancer, diabetes, high cholesterol or chronic pain. The DEA sets annual quotas for the manufacture of opioids, based on the anticipated legitimate medical need, which is informed in part by the number of prescriptions written the previous year. AmerisourceBergen has never had any involvement in the evaluation and determination of these quotas. All participants in the closed system of distribution of prescription opioids and other controlled substances (other than the end user/patient) must be registered with the DEA. All participants – manufacturers, distributors, pharmacies, hospitals, and physicians – have different roles and responsibilities within the closed system and must safeguard against diversion and abuse in the areas within their control.

Physicians and other authorized practitioners must be licensed by their state board of pharmacy and the DEA in order to prescribe opioids. Any prescriptions they write for opioids must be issued for a legitimate medical purpose and in the usual course of their professional

practice. Most states (including West Virginia) operate Prescription Drug Monitoring Programs (“PDMPs”) that require physicians to provide information to a state-run database about the prescriptions they write for opioids. Unlike distributors, physicians have the right (and state law may require them) to search the PUMP database to determine if a patient has “doctor-shopped” and sought opioids from multiple sources.

Pharmacists also play a critical gatekeeping role in ensuring that opioids are prescribed for a legitimate medical purpose. A pharmacy may dispense opioids only if it is registered with the DEA and has a valid state license to dispense controlled substances. The pharmacy may dispense opioids only pursuant to a prescription from a licensed medical practitioner who is registered with the DEA. Pharmacists are prohibited from dispensing opioids based on illegal or falsified prescriptions, and must act diligently in determining whether a prescription is issued for a legitimate medical purpose based on their education and training. Unlike distributors, pharmacists are required to know the practitioner who issued the prescription, the number of other prescriptions the practitioner wrote that the pharmacy filled, and whether the patient has presented prescriptions obtained from more than one doctor. Pharmacists can also observe the demeanor of the patient who presents the prescription.

Like physicians and pharmacists, distributors have duties to help prevent diversion, within the areas in which we have some visibility and control. We must maintain the physical security of controlled substances in our possession, distribute controlled substances only to DEA-registered customers, and report all opioid sales to the DEA. Distributors must also design and implement systems to detect the “suspicious orders” we receive and report those suspicious orders to the DEA.

AmerisourceBergen Drug Corporation's Rigorous Anti-Diversion Controls

AmerisourceBergen Drug Corporation's obligation to safeguard controlled substances and prevent their diversion is one we take very seriously. AmerisourceBergen Drug Corporation has refused to service and has terminated service to hundreds of pharmacies that it identified as problematic, including some of the pharmacies in West Virginia that news reports have claimed were diverting opioids. We are licensed with the DEA to buy, possess, and distribute controlled substances. We have invested heavily in physical security to ensure that our facilities have the best possible protocols and technology to minimize the risk of theft or diversion of any controlled substances from the time they enter AmerisourceBergen Drug Corporation facilities to the time they are delivered to our customers. We also devote significant resources to our anti-diversion program. AmerisourceBergen Drug Corporation employs a team of diversion-control experts who perform the many aspects of its diversion control program.

AmerisourceBergen Drug Corporation's diversion control team performs due diligence to determine whether prospective new customers are suitable purchasers of controlled substances. The procedure to review prospective customers has varied over time but since 2007 has generally included the following elements: the completion of a Retail Customer Questionnaire; site visits; verification of the pharmacy's DEA registration and state licensure; review of the pharmacy-provided information; and online investigation (including internet licensing and disciplinary searches) for the identified pharmacy, owner, and pharmacist-in-charge. The questions on the questionnaire are based on guidance from the DEA.

Since at least the 1980s, AmerisourceBergen Drug Corporation has had in place a system to monitor the orders it receives (the "Order Monitoring Program," or "OMP"). We worked with the DEA to enhance the system in 1998, and again in 2007, and have continually reviewed and improved it, including a comprehensive 2015 revision to build on current data, respond to trends

in prescription drug abuse, and adopt improved technological capabilities, including data-driven analytical tools. The OMP's innovative program uses sophisticated technology to test every order of controlled substances that AmerisourceBergen Drug Corporation receives. Orders that the system identifies as "of interest" are held electronically and investigated, and shipment is automatically blocked until the investigation is complete and the order is determined to be appropriate. If the order is deemed suspicious after that review, the order is reported to the DEA and is not shipped. Using the OMP, AmerisourceBergen Drug Corporation reported and refused to ship more than 800 such orders for oxycodone and hydrocodone from West Virginia from 2008 to 2016. AmerisourceBergen Drug Corporation ends relationships with customers that it determines have an increased potential for diversion. In addition, the AmerisourceBergen Drug Corporation maintains a "Do Not Ship" list, which includes customers that the diversion control program has identified through its order monitoring program and other ongoing diversion control efforts.

On a daily basis, for every order of opioid-based medication we ship, AmerisourceBergen Drug Corporation provides the DEA with detailed information about the order, including the type of opioid, quantity, and the recipient. On a monthly basis, AmerisourceBergen Drug Corporation also reports to the DEA's Automation of Reports and Consolidated Orders System ("ARCOS") all sales of Schedule II and reportable Schedule III controlled substances.

AmerisourceBergen Drug Corporation uses analytical tools to review aggregate purchase data for trends that are not captured in the review of flagged individual orders. AmerisourceBergen Drug Corporation conducts on-site investigations of customers when issues or concerns are identified by its monitoring activities, the OMP, personnel at its distribution centers throughout the country, or external bodies such as the DEA or state agencies. AmerisourceBergen Drug

Corporation also provides substantial training in diversion control: It trains its dedicated diversion-control teams, all associates in compliance-sensitive positions at its distribution centers throughout the country, and its sales associates, and also offers anti-diversion training to its pharmacy customers.

AmerisourceBergen Is Committed to Fighting the Opioid Crisis

AmerisourceBergen is and has been committed to ensuring a pharmaceutical supply system that is safe, secure, and marked by integrity. As such, we want to be part of the solution to the opioid crisis, which we believe can be conquered while keeping opioids available for patients who legitimately need them. But in order to conquer this problem, it is imperative that the DEA come to the table and work with all stakeholders in the supply chain in a more cooperative and collaborative manner. The Controlled Substances Act (“CSA”) under which the DEA operates was enacted and the regulations promulgated in 1970. We would recommend updating the regulations and guidance implementing this important law to standardize suspicious order monitoring programs across the 900+ distributors that are regulated under this system to ensure the highest standards across the board for all distributors’ suspicious order programs.

In addition, AmerisourceBergen Drug Corporation reports all opioid orders daily, submits ARCOS data monthly, and reports suspicious orders to the DEA. If the DEA could utilize this data to alert those of us in the supply chain who have no “real time” visibility to customers that may be receiving shipments from multiple sources, this could help prevent what has occurred in West Virginia from happening in the future. AmerisourceBergen supports a number of other proposed solutions including revision of prescribing guidelines, which will likely reduce the number of opioids prescribed. Indeed, AmerisourceBergen funded a grant to the Health Care Improvement Fund to support prescriber education for post-surgical procedures.

AmerisourceBergen also supports mandatory e-prescribing, which would generate real-time

information on opioid use and reduce the number of opioids obtained through fraudulent prescriptions or doctor shopping. We support policies to make state PDMPs interoperable, which would allow physicians and regulators to determine if patients are obtaining prescriptions from physicians in more than one state. We are also the only distributor member of the Collaborative for Effective Prescription Opioid Policies (“CEPOP”), which supports policies to reduce prescription opioid abuse and promote treatment options.

AmerisourceBergen is also eager to collaborate with policymakers and stakeholders throughout the pharmaceutical supply chain to improve distributors’ ability to assess and act on possibly suspicious orders of prescription opioids. As part of the National Association of Drug Diversion Investigators, AmerisourceBergen has presented on effectively combatting drug diversion at the distribution level and collaborating with law enforcement. AmerisourceBergen also supports increased fees for DEA registration to help support such enhanced data capabilities.

AmerisourceBergen believes that education about opioids and the safe storage and disposal of opioids are equally critical to resolving the opioid crisis. To this end, AmerisourceBergen participates in, and funds, numerous industry, non-profit and policy group initiatives that support the fight against opioid abuse. For example:

- AmerisourceBergen Foundation has partnered with The Prevention Action Alliance and Everfi to launch the Prescription Drug Safety Network, an interactive online educational platform designed to teach high school students to make informed decisions about prescription medications.
- AmerisourceBergen is a member of the Anti-Diversion Industry Working Group which, working with the National Association of Boards of Pharmacy, funded production of the “Red Flags of Diversion” educational video that many state

pharmacy boards, including West Virginia's, use to educate pharmacies about diversion control.

- AmerisourceBergen has partnered with Walgreens, Pfizer, Prime Therapeutics and Blue Cross Blue Shield to install safe disposal kiosks for medication in hundreds of Walgreens stores across the country and near military bases and other areas where the opioid epidemic has challenged communities. This partnership has already collected 155 tons of unused medications and is expected to collect an additional 300 tons.
- AmerisourceBergen Foundation launched a Municipal Support program that has provided drug deactivation pouches to 17 municipalities and non-profit organizations in six states, and also sent resources to Americares, a health-focused relief and development organization that responds to people affected by poverty or disaster. Americares distributes the deactivation pouches to free clinics and community health centers nationwide that serve low-income and uninsured patients in need. To date more than 60,000 pouches that allow consumers to dispose of unused medications at home, safely and in an environmentally friendly manner, have been distributed.
- AmerisourceBergen Foundation provided a grant to The Moyer Foundation to support community programs that serve youth who have been affected by a family member's substance abuse.
- AmerisourceBergen recently launched the AmerisourceBergen Foundation Opioid Resource Grant Program, which will provide funding to efforts to address opioid abuse with direction from an external advisory council.

- AmerisourceBergen Foundation announced a grant to Thomas Jefferson University to hold a substance abuse symposium.

Conclusion

I and AmerisourceBergen share Congress's concern, and indeed the entire nation's concern, about the tragic abuse of opioids. AmerisourceBergen is committed to the continuous analysis and ongoing improvement of our programs and policies. We look forward to additional ideas and guidance from this Committee, industry regulators, and other experts about how we can continue to improve our efforts and help alleviate the crisis while supporting clinically appropriate access to opioid medications for legitimate medical needs. On behalf of AmerisourceBergen, I thank the Committee for this opportunity to share more information, our views and our eagerness to help address this crisis.