

**WRITTEN STATEMENT OF JAMES CHRISTOPHER SMITH
FORMER PRESIDENT AND CHIEF EXECUTIVE OFFICER, H.D. SMITH LLC**

BEFORE THE

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

**PRESENTED
MAY 8, 2018**

**Written Statement of James Christopher Smith
Before The Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives
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H.D. Smith was a family-owned wholesaler for more than 60 years. We began by and grew serving an under-served segment of the market – local, independently owned, mostly mom-and-pop pharmacies and rural hospitals in small towns, rural communities, and later in inner cities, taking pride in providing excellent customer service. We recently were acquired by AmerisourceBergen Corporation (“AmerisourceBergen”). I thank the Committee for the opportunity to share my concern about the opioid epidemic plaguing our country, and to explain what H.D. Smith did to prevent diversion during my tenure.

At all times, H.D. Smith has been committed to doing its very best to balance the needs of patients for prescription medications with our efforts to prevent diversion. Fighting the opioid epidemic is unlike fighting other drug abuse. While preventing the abuse of these powerful drugs, we cannot lose sight of ensuring that suffering patients have access to the prescription medications they need when they need them. But H.D. Smith was only one part of a complex supply chain, and we could not see all the information up and down the chain that could flag a potential problem. As a wholesale distributor, H.D. Smith could not second-guess physicians’ prescribing decisions, and could not itself assess the medical needs of the patients of those prescribing physicians. There are difficult policy and medical decisions that are needed to balance access against diversion and we did the very best we could with the limited information to which we had access.

H.D. Smith's Role as a Middleman That Purchased Medicines from Manufacturers and Filled Orders from Licensed Pharmacies

H.D. Smith was a wholesaler. We purchased prescription and generic medicines directly from manufacturers, and distributed them to the licensed pharmacies that ordered them for patients with prescriptions. As a wholesale distributor, H.D. Smith did not interact directly with patients, nor were we in a position to make or second-guess clinical decisions. We also had no way of knowing whether or to what extent our customers were purchasing medicines, including opioids, from other distributors, unless this information was voluntarily disclosed.

H.D. Smith did not manufacture, market or otherwise promote medications, including opioids, to customers, patients or their physicians. We had no control over or involvement with controlled substance manufacturing quotas, which are set by the DEA in consultation with other federal regulators and manufacturers, and which were routinely and significantly increased over the years until recently. The distribution of prescription opioids comprised only a small fraction of our annual revenue.

H.D. Smith's Robust Diversion Control Efforts

H.D. Smith has always strived to do what we could to prevent the diversion of controlled substances, and I am confident it will continue to do so under its new ownership. I can tell you what H.D. Smith did to prevent diversion during my tenure. In addition to taking physical security measures to safeguard against theft and diversion of opioids and other medicines, H.D. Smith developed and maintained a robust anti-diversion program, which was designed to identify potentially suspicious orders. That program came to include, among other components, a controlled substance order monitoring program, focused investigations conducted by an experienced group of former law enforcement and drug diversion investigators, and comprehensive customer and sales force anti-diversion training. We also performed extensive

due diligence on prospective new customers before allowing them to purchase controlled substances, and those due diligence measures continued to evolve over time and continued throughout our relationships with customers.

Before 2006, as was consistent with the DEA's expectations communicated to wholesale drug distributors, H.D. Smith reviewed customer orders manually to detect suspicious orders and to then report them to the DEA. As the DEA's expectations changed, in May of 2008, we implemented an electronic controlled substance order monitoring program (the "CSOMP"), and provided extensive training to our personnel in how best to reliably utilize that system, just as we trained our sales representatives to be alert to any signs of diversion or irregularities at the individual pharmacies we served. H.D. Smith's CSOMP used sales volume data-based algorithms to test orders of controlled substances and blocked the shipment of orders flagged by the system, along with any additional orders for any drug within the same family by that customer. The flagged orders would be placed on the daily CSOMP report, and reviewed by members of the Corporate Compliance and Security Department team. H.D. Smith maintained an ongoing dialogue with the DEA throughout its development of its CSOMP to ensure that the system complied with the DEA's expectations.

For some time after the rollout of CSOMP, H.D. Smith reported to the DEA all orders automatically flagged and blocked – even if only temporarily blocked – by the system as “suspicious.” Then, in 2009, H.D. Smith changed our reporting practices upon learning from the DEA that we were over-reporting and that orders were not “suspicious” simply because they were flagged for initial review by the company's electronic anti-diversion CSOMP. After this time, H.D. Smith reported orders to the DEA only if we determined after further review and due

diligence that the order was indeed “suspicious” and should be rejected. H.D. Smith also reported a number of physicians and pharmacies to the DEA when concerns arose.

H.D. Smith worked to adjust its CSOMP to meet what we understood to be changing instructions from the DEA, including the DEA’s complaints that H.D. Smith was reporting too many orders as suspicious because they exceeded the ordering limitations imposed on a particular customer. H.D. Smith invested substantial resources in improving the program, including by hiring additional personnel for its Corporate Compliance and Security Department. The elements and robustness of our anti-diversion program continued to evolve and improve over time. We experienced some frustration in working with the DEA, however; during some periods of time, the DEA rebuffed the industry and refused to give guidance to help distributors in their efforts to detect suspicious orders. Regardless, I can say with confidence that H.D. Smith used its best efforts to safeguard against diversion.

Combating the Opioid Abuse Crisis Will Require the Cooperation of All Participants in the Supply Chain

Wholesale distributors have statutory and regulatory obligations including to design a system to identify and report suspicious orders to the DEA, but these obligations are, of course, limited by their role in the supply chain. In order to obtain a DEA registration number to sell controlled substances, distributors must report sales of opioids to the DEA, keep the opioids in their possession physically secure, implement a system to detect “suspicious orders,” and report such orders to the DEA. However, distributors are but one link in the heavily federally regulated supply chain. All participants, including manufacturers, pharmacies, and physicians, must fulfill their respective duties to prevent the diversion of controlled substances in the areas within their control.

Physicians are the first line of defense against diversion and abuse, as it is a crime to obtain or dispense prescription opioids without a prescription. Physicians must be state-licensed and DEA-registered and may only prescribe opioids for a legitimate medical purpose and in the usual course of their professional practice. Pharmacists similarly must be duly registered and may only dispense opioids pursuant to legitimate prescriptions. And unlike distributors, pharmacists have access to, and indeed may have the duty to consider, prescription-level information, including the identity and location of the patient and physician, the frequency at which that physician writes prescriptions for controlled substances, and the number of prescriptions presented by the patient.

Additionally, the Prescription Drug Monitoring Programs (PDMPs) in many states require physicians and pharmacists to provide patient and prescription information to state-run databases about the prescriptions they write or fill for opioids. In West Virginia in particular, the DEA and other federal and State law enforcement agencies have immediate and unlimited access to this database, as do various professional licensing boards, but notably distributors do not. Thus, in addition to the ARCOS data that is automatically reported by manufacturers and distributors to the DEA, the DEA has access all the way down to prescriber-specific, pharmacy-specific, and patient-specific data on each and every opioid prescription written and filled and the patient to whom each opioid was dispensed. Wholesale drug distributors, however, cannot access this data.

Conclusion

We fully trust that H.D. Smith's new owner, AmerisourceBergen, will handle its business responsibly. We also strongly believe that the DEA can help distributors be part of the solution to the opioid crisis by collaborating more and sharing information with the industry. Without help from the DEA, and particularly guidance about the reporting of suspicious orders,

distributors cannot make complete assessments about pharmacies' purchasing habits, and are, therefore, limited in their ability to detect suspicious orders. I again thank the Committee for the opportunity to contribute to this important conversation.