

# Morgan Lewis

**Amanda B. Robinson**

+1.202.739.5579

amanda.robinson@morganlewis.com

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**VIA HAND DELIVERY  
VIA EMAIL**

The Honorable Claire McCaskill  
Ranking Member, Committee on Homeland Security and Governmental Affairs  
340 Dirksen Senate Office Building  
Washington, D.C. 20510-6250

Dear Ranking Member McCaskill:

As set forth in detail in our September 29, 2017 letter, AmerisourceBergen Drug Corporation ("ABDC") is deeply committed to the safe and efficient delivery of medications to meet legitimate patient needs across the United States and desires to be part of much-needed and multi-faceted solutions to the opioid public health crisis. ABDC takes very seriously its legal and regulatory obligations in connection with the distribution of controlled substances, and has had in place for many years a robust diversion control program that not only meets but exceeds these requirements. ABDC has never paid any fine or penalty and has not had any enforcement action in connection with its controlled substance distribution in the last 10 years. ABDC is proud of the controls it has in place and the significant and meaningful enhancements it has made and continues to make since ABDC's diversion control program was first implemented in the 1980s.

Under ABDC's diversion control program, ABDC only delivers controlled substances to DEA and state licensed pharmacies. ABDC has rejected, refused to ship and reported to DEA thousands of suspicious orders. Over time, as more data-driven analytical tools have come available, ABDC has refined the algorithms it uses to identify orders that should be held for additional scrutiny and has worked hard to more precisely identify suspicious orders which it reports to DEA. Further, ABDC endeavors to supply only trusted customers who share ABDC's commitment to diversion control. ABDC believes its due diligence and monitoring efforts help eliminate problematic orders from the start, with ABDC ultimately refusing to contract with certain customers, terminating customers, and limiting customers' ordering - thereby resulting in fewer suspicious orders to be reported.

The diversion control systems and operations to detect and report suspicious orders vary across distributors as there has been limited guidance from regulators.<sup>1</sup> Those differing system

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<sup>1</sup> For example, a year after the U.S. Government Accountability Office ("GAO") 2015 recommendation that DEA "provide guidance around best practices in developing suspicious orders monitoring systems" GAO found that DEA "had not made any plans to develop and distribute additional guidance for distributors." U.S. Government Accountability Office, *Drug Enforcement Administration: Additional Actions Needed to Address Prior GAO*

**Morgan, Lewis & Bockius LLP**

1111 Pennsylvania Avenue, NW  
Washington, DC 20004  
United States

+1.202.739.3000  
+1.202.739.3001

The Honorable Claire McCaskill  
July 3, 2018  
Page 2

approaches may result in a number of differences in operation, including distributors reporting different numbers of suspicious orders. There are a number of reasons why the number of suspicious orders may be different. For example, a distributor may not even allow certain customers to purchase controlled substances or may otherwise limit a pharmacy's ability to order controlled substances, all of which may result in a lower number of reported orders. Thus, the number of suspicious orders alone is not indicative of compliance or lack thereof with respect to effective controls to prevent diversion. Factors that may indicate effective controls to prevent diversion, other than suspicious orders reported, include, for example, the characteristics of customers being serviced by a distributor, the pharmacies a distributor declines to permit to purchase controlled substances, the pharmacies a distributor restricts from purchasing controlled substances, and the quality of on-going monitoring of pharmacy customers.

Despite critical challenges, including the limited information to which ABDC has access regarding the overall market and supply chain for opioid products, ABDC remains committed to providing access to the medications that many patients need and at the same time doing everything it can to prevent the abuse of such treatments. ABDC has designed and built a robust diversion control program, strives to continually improve and refine its processes, and welcomes guidance from and the opportunity to collaborate with DEA to achieve the shared goal of combatting this public health crisis.

ABDC looks ahead to working with all relevant stakeholders, including DEA, and seeks to leverage its expertise and position in the supply chain to help address the opioid abuse epidemic.

Respectfully,



Amanda B. Robinson

c: Chairman Ron Johnson

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*Recommendations*, GAO-16-737T: Published: Jun 22, 2016. Publicly Released: Jun 22, 2016. GAO 2015 recommendation found at U.S. Government Accountability Office, *Prescription Drugs: More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access*, GAO-15-471: Published Jun. 25, 2015. Publicly Released: Jun. 27, 2015.