
Dear Ms. Destro:

The Healthcare Distribution Alliance (HDA) thanks the Department of Health and Human Services (HHS) for the opportunity to provide comments regarding the Federal Register notice of July 26 with respect to implementation of Section 3 of the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 ("EPAEDEA" or "the Act"), Public Law 114–145. To support fulfilling its obligations under the Act, HHS seeks information from stakeholders on “ensuring legitimate access to controlled substances, including opioids, while also preventing diversion and abuse, as well as how federal, state, local, and tribal entities can collaborate to address these issues,” 84 Fed. Reg. at 36,111. HDA commends HHS for reaching out to the stakeholder community.

HDA represents primary pharmaceutical distributors — the vital link between the nation’s pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics, and others nationwide. Since 1876, HDA has helped educate members about the regulatory environment and advocated for policies serving the interest of supply chain safety, innovation, and efficiency.

While distributors do not prescribe, dispense, market, or manufacture prescription opioids, they do communicate and work with a range of supply chain trading partners, as well as federal and state regulatory agencies, to help prevent the diversion of prescription drugs. They do this by operating sophisticated anti-diversion systems and reporting data on orders,
distributions, and suspicious orders to federal and state authorities responsible for regulating the nation’s closed supply chain.

Distributors are dedicated to helping prevent prescription painkillers from falling into the hands of people who may use them for purposes other than those for which they are intended. To help address this threat, distributors support policy measures to reduce the over-prescribing of opioids and to prevent misuse and abuse before it happens. We also strongly support the Drug Enforcement Administration (DEA) having the tools it needs to undertake appropriate enforcement actions.

To that end, HDA applauds the efforts of Congress and the Administration to protect Americans by advancing meaningful solutions to address the opioid epidemic. One important aspect in this multi-faceted effort is to facilitate communication among federal agencies and registrants handling controlled substances; a key provision of EAPADEA. Further, the passage and enactment of the SUPPORT for Patients and Communities Act, Public Law 115-271, offers a comprehensive response to the complex public health crisis that our country faces. HDA strongly supports the implementation of these two measures as they will enhance compliance and data sharing as well as improve coordination and communication among healthcare supply chain stakeholders, regulators, public health authorities, and law enforcement.

We commend the DEA for its recent efforts to implement the SUPPORT Act. Pursuant to the SUPPORT Act, DEA has taken steps to make data from the Automation of Reports and Consolidated Orders System (ARCOS) more available to DEA registrants to assist them in fulfilling their statutory and regulatory obligations. DEA recently developed the Retail Buyer Statistics Lookup Tool (ARCOS Tool) to enable DEA registrants to better access and use ARCOS data and has sought input from stakeholders on how to improve the functionality and utility of the ARCOS Tool.

In the spirit of the EAPADEA and the SUPPORT Act, DEA also recently convened a meeting with representatives from the various registrant stakeholder trade organizations, including groups representing manufacturers, distributors, and pharmacy. To combat diversion and abuse, techniques must constantly evolve to stay ahead of those intent on breaking the law and harming the public health. The stakeholder meeting was an excellent opportunity for DEA to speak to regulated industry about its expectations for compliance, coordinating efforts to stem the tide of opioid abuse and misuse, and refining the ARCOS Tool to achieve these ends. HDA supports continued events such as this one, to help improve coordination, collaboration, and communication between the DEA and the pharmaceutical supply chain.

Support for public health authorities and state regulators, such as boards of medicine and pharmacy, is also essential. We commend the Department of Justice’s Bureau of
Justice Assistance for its support for and coordination of Prescription Drug Monitoring Programs (PMPs). Such programs empower doctors and pharmacists – who have regulatory responsibility to exercise professional judgment in preventing prescription drug misuse and abuse – to help stop this threat to public health, even on a patient-by-patient basis.

HDA and its distributor members look forward to continued collaboration with other stakeholders, Congress, the Administration, law enforcement, and public health officials in advancing a comprehensive approach to reversing the opioid abuse epidemic in our country. We appreciate this comment opportunity and welcome further dialogue.

If you have any questions, please feel free to contact me at pkelly@hda.org or by phone at 703-885-0233.

Sincerely,

Patrick M. Kelly
Executive Vice President, Government Affairs

cc: John Martin
   Assistant Administrator, Diversion Control Division
   U.S. Drug Enforcement Administration