



Statement from
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For the U.S. House of Representatives
Energy and Commerce Committee
Subcommittee on Health

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Good afternoon Chairman Pitts, Ranking Member Pallone and Members of the Energy and Commerce Subcommittee on Health. I am John Gray, President and CEO of the Healthcare Distribution Management Association (HDMA). Thank you for the opportunity to discuss with the Subcommittee important legislation introduced by Representatives Blackburn and Marino, the Ensuring Patient Access and Effective Drug Enforcement Act of 2014 (H.R. 4069).

HDMA is the national association representing America's primary pharmaceutical distributors – the vital link between manufacturers, pharmacies and healthcare providers. Our industry's primary mission is to operate the safest and most secure and efficient supply chain in the world. As part of this mission, the pharmaceutical distribution industry is committed to addressing the serious national epidemic of prescription drug abuse. Drug abuse and diversion is a complex and challenging problem that calls for a collaborative effort on the part of doctors, pharmacists, distributors, manufacturers and state and federal authorities.

HDMA's members are committed to working proactively with Drug Enforcement Administration (DEA), local law enforcement and other regulatory agencies to investigate potential cases of diversion and implement protocols to monitor and report suspicious orders.

The healthcare supply chain is a complex system that depends on numerous core components working closely with one another to ensure that patients receive the medicines they need and to prevent diversion to individuals who would abuse these drugs. Physicians see patients and prescribe necessary medicines. Pharmacists receive and dispense prescriptions to the patients. Distributors are tasked with ensuring that pharmacies have the necessary medicines they need to fill legitimate prescriptions. It is sometimes difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications. We hope this legislation will address that need for balance

and encourage cooperation and collaboration between prescribers, dispensers, distributors, manufacturers and regulators, while making sure that legitimate patients continue to receive the medications they require.

All HDMA distributor members take very seriously their obligation to fill only legitimate and appropriate orders for controlled substances. However, in many instances our members struggle with applying the Controlled Substances Act and its accompanying regulations to their specific situation when balancing the need for preventing diversion and ensuring that legitimate patient needs are addressed.

This is one of the reasons why HDMA supports H.R. 4069. This legislation is a timely and thoughtful approach to addressing the prescription drug abuse epidemic. We believe it will foster greater collaboration, communication and transparency between industry stakeholders and regulators, especially the DEA.

HDMA members appreciate the importance of DEA's law enforcement activities in confronting, disrupting and dismantling illegal drug trafficking. However, establishing a collaborative working relationship between DEA and our members will serve as a more effective way to curb diversion of legal medicines. We feel this legislation will improve interaction with the DEA as they engage in their regulatory responsibilities to prevent diversion of controlled substances.

There are several key components of the legislation that I will briefly describe.

This bill brings clarity to the regulatory environment by defining key terms that will facilitate greater compliance with and consistent enforcement of the Controlled Substances Act.

This bill also establishes a corrective action plan for registrants working with DEA. This concept, first raised by Representative Blackburn during a hearing on drug abuse two years ago,

is intended to mirror the way FDA interacts with and regulates pharmaceutical manufacturers. This bill will allow DEA-registered companies to submit corrective action plans to address and mitigate any Agency concerns, creating a more robust, transparent and time sensitive approach to addressing drug diversion. Preventing diversion and drug abuse requires clear understanding of regulations, consistent application of the Controlled Substances Act, and prompt communication between supply chain members and regulators. This provision ensures that law enforcement and registrants will collaborate to achieve these aims.

Finally, the bill will establish a Prescription Drug Abuse Working Group to encourage meaningful dialogue and coordination between supply chain stakeholders, law enforcement, patient advocacy groups, as well as state and federal regulators. Ultimately, this Working Group will provide guidance to Congress on the most effective strategies to curb prescription drug abuse.

HDMA has long been working to improve collaboration among industry stakeholders on this issue. We recently joined the Alliance to Prevent the Abuse of Medicines to bring forth a comprehensive perspective to addressing this problem. The Alliance is comprised of organizations from across the pharmaceutical supply chain, including the American Medical Association, Teva, Cardinal Health, CVS Caremark and Prime Therapeutics. The Alliance is in the process of developing a platform of policy recommendations to address various aspects of drug abuse and diversion and supports H.R. 4069.

There is no one-size-fits-all solution to this problem, but pharmaceutical distributors, along with their supply chain partners, are committed to a more coordinated and transparent approach that provides necessary balance when addressing enforcement, public health and treatment efforts. We are neither seeking to restrict DEA's authority nor increase the regulatory

burden on registrants. What we are seeking is clarity and consistency to ensure that public health needs are adequately addressed in a balanced, collaborative and effective manner. The complexity of this public health challenge will require the entire healthcare supply chain to work together in close partnership with state and federal entities to effectively stem the tide of prescription drug abuse and minimize the potential for unintended consequences.

In the end, we all share the same goal: to ensure patient access to a sufficient, safe and secure supply of medicines for necessary therapies while keeping these drugs out of the hands of individuals who will abuse them. Anti-diversion efforts need to balance the need to reduce abuse and diversion while avoiding disruptions for legitimate patients.

I thank you again for the invitation to participate in this hearing and hope this overview was valuable as the subcommittee evaluates H.R. 4069.