



NATIONAL ASSOCIATION OF  
CHAIN DRUG STORES

Statement  
Of  
The National Association of Chain Drug Stores  
For  
U.S. House of Representatives  
Committee on Energy and Commerce  
Subcommittee on Health

Hearing on:

“Securing Our Nation’s Prescription Drug  
Supply Chain”

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2322 Rayburn House Office Building

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The National Association of Chain Drug Stores (NACDS) thanks Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee on Health for consideration of our statement for the hearing “Securing Our Nation’s Prescription Drug Supply Chain.” We look forward to our continued work with you on issues related to the security and integrity of the U.S. prescription drug supply chain.

NACDS commends the Committee for their efforts. This statement addresses the following matters:

- The necessity of enacting a national approach to securing the Nation’s drug distribution supply chain now.
- The chain pharmacy industry support for the work of the Pharmaceutical Distribution Security Alliance (PDSA).
- Chain pharmacy policies for the security of the U.S. drug distribution supply chain.
- Chain pharmacy comments on the recent discussion draft released by the Committee.

### **U.S. DRUG DISTRIBUTION SUPPLY CHAIN IS SAFE**

The United States prescription drug distribution system is recognized as one of the safest and most secure in the world, if not the safest. The Food & Drug Administration (FDA) has stated that drug counterfeiting is rare in the U.S. drug distribution system due in large measure to the extensive scheme of federal and state regulatory oversight, and steps already taken by pharmacies, drug manufacturers, and wholesale distributors to prevent counterfeit drugs from entering the U.S. drug supply.<sup>1</sup>

NACDS and the chain pharmacy industry are committed to partnering with policymakers and supply chain stakeholders on viable, effective strategies to further enhance the safety and security of the U.S. prescription drug distribution supply chain. Our members have invested significant resources and efforts towards this goal, including changes in purchasing practices

<sup>1</sup> See <http://www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM272150.pdf>; *FDA Preliminary Report: Review of Counterfeit and Diversion Criminal Case Information*, September 2011.

and actively supporting legislation enacted in a number of states that strengthened the U.S. supply chain integrity. We have also supported increased fines and penalties for violations of these state laws. Our members have seen marked improvements in the security of the drug distribution supply chain since the adoption of these initiatives and state laws. Nothing is more important to our industry than the health and safety of our patients.

We urge policymakers to consider approaches to enhance supply chain integrity that are feasible and workable for the supply chain, and that recognize the importance of allowing a stepwise approach that uses feasible and tested approaches for adding enhancement to supply chain integrity. We do not support approaches that mandate the use of untested, costly requirements that would disrupt, rather than enhance, supply chain security. These proposals would add billions in additional costs to the healthcare system and take time and resources away from pharmacies' ability to provide care to their patients.

### **NACDS' POLICIES**

We believe that the security of the U.S. prescription drug distribution supply chain requires the commitment of all supply chain stakeholders working together to ensure the security and integrity of the supply chain; any measures must be tested, implementable, feasible and achievable. To that end, NACDS is a member of the *Pharmaceutical Distribution Security Alliance* (PDSA), a coalition of supply chain stakeholders including drug manufacturers, wholesale drug distributors, third party logistics providers, their national associations, as well as pharmacies and their national associations. NACDS is pleased to be a member of PDSA and to work with other supply chain stakeholders on efforts to enhance supply chain integrity.

NACDS supports measures that include providing uniform federal requirements for wholesaler drug distributor licensure that is implemented by the states, evaluation and pilot projects to inform and phase in any changes to supply chain security, and federal preemption to establish a uniform national solution for supply chain security. These policies will lead to a national uniform supply chain integrity platform rather than the current patchwork of state laws. A patchwork of state requirements is unworkable and has the potential to hinder the timely and

efficient distribution of drugs across the nation. Moreover, a national approach provides the benefits of blocking unscrupulous entities from “gaming” the system by moving across state lines in search of less stringent laws.

### **COMMENTS ON DISCUSSION DRAFT**

We applaud Representatives Latta and Matheson, as well as the full Committee, for the comprehensive discussion draft legislation. In particular, we support one national standard as promoted by PDSA and recognized by Congressmen Latta and Matheson. A comprehensive, practical approach would enhance safety and efficiency, and minimize inconsistencies among the states.

Along with PDSA, we support enhancing the licensing standards of wholesale distributors. To ensure that bad actors are not allowed to enter the prescription drug supply chain by becoming licensed in the state with the least stringent requirements, we agree with the Committee draft with the establishment of a national floor for rigorous state wholesale licensure requirements. As a member of PDSA, we support their proposal for lot-level identification of prescription drug packages. We are pleased that you have included all of these elements in the Committee’s discussion draft.

As proposed by the discussion draft, the next phase of supply chain security would be best informed by pilot projects, routine public meetings, and well-designed studies. Without the critical information that would be gleaned from these projects, meetings, and studies, there would be a great risk of mandating systems and technologies that are not feasible, mature, or scalable. We must ensure patient access to critical lifesaving medications without imposing unnecessary or unworkable burdens on the mechanisms that deliver those medications to patients.

### **CONCLUSION**

NACDS thanks the Subcommittee for consideration of our comments. We look forward to working with policy makers and stakeholders on these important issues.