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Summary of Statement
Before
United States House of Representatives Energy and Commerce Committee
Subcommittee on Health
Hearing on
FDA User Fees 2012: Issues Related to Accelerated Approval, Medical Gas, Antibiotic
Development and Downstream Pharmaceutical Supply Chain
March 8, 2012

NCPA appreciates the opportunity to share the community pharmacy perspective on issues relating to securing the pharmaceutical supply chain. NCPA represents America's community pharmacists, including the owners of more than 23,000 community pharmacies, pharmacy franchises and chains.

National, Uniform Federal License Standards for Wholesale Distributors and Logistics Providers

NCPA recommends the development of national, uniform, federal license standards for wholesale distributors and logistics providers (3PLs). At present, wholesale distributors are licensed at the individual state level, which has resulted in a patchwork of conflicting requirements. By setting a high bar nationwide, we could further safeguard the supply chain by making sure that only appropriately credentialed and legitimate entities are able to participate in the drug distribution aspect of the pharmaceutical supply chain. These new federal standards would preempt existing state requirements.

Other Measures to Secure the Supply Chain

S. 1002, the *Safe Doses Act*, would expand the penalties for pharmaceutical cargo theft. In addition, H.R. 4095, the *Online Pharmacy Safety Act* would create a publicly available "white list" of legitimate internet pharmacies to be managed by the FDA or its contracting organization. This list would help educate consumers and crack down on the "rogue" internet pharmacies that currently exist and are used by consumers looking for "bargain" prescription medications.

Pharmaceutical Distribution Security Alliance and Use of RxTec Act

NCPA is currently a member of the Pharmaceutical Distribution Security Alliance (PDSA), a working group comprised of representatives of all sectors of the pharmaceutical supply chain, which together has worked to develop the RxTec Act. This draft legislation would create a registry of legitimate on-line pharmacy websites, increase penalties for counterfeiters and provide for the tracking of prescription medications at the lot level. Independent community pharmacists have had reservations in the past due to concerns about the cost of the hardware and software that would be required to set up such a system as well as the significant time and labor costs associated with it. The RxTec proposal specifies that the encoded information on each finished prescription drug unit must be in both machine readable and human readable form. The proposal would also enable independent community pharmacists to rely upon the records of their trusted wholesaler if needed to double check the lot numbers in question.

Conclusion

Community pharmacists take seriously our role in ensuring the safety of the medications that we personally dispense to our patients. We remain committed to working with our colleagues in the supply chain—other pharmacy organizations, wholesalers and manufacturers—as well as with state and federal authorities to make any needed improvements. It is essential that all stakeholders make a concerted effort to keep the lines of communication open so that consumers can continue to trust the integrity of the medications that they depend upon.