



July 2, 2009

Bill Summary

The Pew Prescription Project promotes consumer safety through reforms in the approval, manufacture, and marketing of prescription drugs

*"FDA needs additional tools to move our oversight capabilities into the 21st century. FDA needs to access regulatory information quickly, hold all parties responsible for the quality of products in the supply chain, and have reasonable and reliable options for enforcement."
(Principal Deputy Commissioner Joshua M. Sharfstein, 2010)*

*At least 80% of the active ingredients in U.S. prescription drugs now originate overseas.
(US Government Accountability Office, 2007)*

*Regulatory demands placed on the Food and Drug Administration far exceed its ability to respond.
(FDA Advisory Board, Subcommittee on Science and Technology, 2007)*

H.R.2726: Counterfeit Drug Enforcement Act of 2009 (Tim Fagan Law)

Introduced: 6/4/2009 by Rep. Steve Israel (D,NY), Rep. Gary Ackerman (D-NY)

Increases penalties

- Sale or trade of Rx drugs knowingly adulterated or misbranded, or misrepresented as approved. Fines in accordance with Title 18 USC, prison term up to life

Tracking the distribution supply chain

- Drugs that do not comply with distribution tracking/technological requirements are misbranded
- Authorized distributors are no longer exempt from supply chain tracking requirements
- Secretary shall establish new supply chain tracking requirements (covering chain from manufacturer to pharmacy) if they will better track the supply chain than existing requirements, and if they are technically feasible. They may include standardized anti-counterfeiting or track and trace technologies.
- Each manufacturer shall maintain a list of authorized distributors for their products

Inspections

- \$60,000,000 for each fiscal year, 2010-2014 is authorized to be appropriated for inspections with respect to violations concerning sale of adulterated or misbranded product.

Other provisions

- Secretary shall educate public on counterfeits
- Recall authority, with provisions for informal hearings
- Subpoena authority