



August 19, 2009

Fact Sheet

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)*

Prescription Drug Supply Chain: Overview of 2009 Bills

Overseas manufacturing

H.R.759: The Food and Drug Administration Globalization Act of 2009 (Drug Safety Provisions)

Sponsors: Rep. Dingell, Rep. Stupak, Rep. Pallone

Introduced: 1/28/09

It aims to: Increase the safety of drugs manufactured overseas for sale in the US

By: Increasing cGMP compliance via FDA inspections of foreign sites (every 2-4 years); requiring manufacturers to trace manufacturing supply chain and have quality/risk management plans for the manufacturing process; improving FDA IT systems for tracking cGMP compliance and inspections; giving FDA recall and subpoena authority.

S.882: Drug and Device Accountability Act of 2009

Sponsors: Sen. Grassley, Sen. Kennedy

Introduced: 4/23/09

It aims to: Increase the safety of drugs manufactured overseas for sale in the US

By: Increasing cGMP compliance via FDA inspections of foreign sites (every 2-5 years); identifying and revising weak assays; requiring manufacturers to trace manufacturing supply chain; giving FDA recall and subpoena authority.

Domestic distribution

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

Sponsors: Rep. Israel, Rep. Ackerman

Introduced: 6/4/09

It aims to: Strengthen domestic drug distribution against counterfeits

By: Removing language exempting authorized distributors from pedigree requirements, enabling the Secretary to establish new supply chain tracking requirements; appropriating funds for inspections of distribution sites; giving FDA recall and subpoena authority.

Reimportation

S. 525 and H.R. 1289: The Pharmaceutical Market Access and Drug Safety Act of 2009

Sponsors: Sen. Dorgan, Sen. Snowe; Rep. Berry, Rep. Burton

Introduced: 3/4/09

It aims to: Establish legal and safe commercial (and personal) reimportation of prescription drugs

By: Registering all exporters and importers and inspecting them 12x/year; limiting imports to drugs with equivalent US label drugs, and only from permitted countries; requiring statements identifying complete chain of custody of a product; requiring drug packaging have a standard numerical identifier and anti-counterfeiting technology.