The Pew Prescription Project — an initiative of the Pew Health Group — promotes consumer safety through reforms in the approval, manufacture, and marketing of prescription drugs

Drug Safety and Accountability Act of 2010

The Drug Safety and Accountability Act of 2010 (S.3690) seeks to strengthen industry standards to ensure the quality and safety of drugs made for the U.S. market, and to improve the U.S. Food and Drug Administration's (FDA) oversight abilities through modernized information systems and new authorities, such as the power to order a drug recall.

Introduced: August 3, 2010, by Sen. Michael Bennet (D-CO)

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

Why is this legislation needed?

In recent years, a marked increase in drug recalls and FDA warnings to companies regarding manufacturing quality problems has exposed gaps in the safety and oversight of drugs for the U.S. market.[1;2] The globalization and increased outsourcing of drug manufacturing has made ensuring quality and safety particularly challenging. Up to 80 percent of the active and chemical ingredients in drugs made for U.S. consumers are now manufactured abroad, many in countries where regulatory oversight does not meet U.S. standards.[3]

The dangers of these gaps were highlighted when Americans died in 2007 and 2008 after taking heparin, a blood thinner, contaminated during its production in China.[4] Later, in 2010, consumers faced the recall of more than 130 million bottles of over-the-counter (OTC) children's medicines because of manufacturing quality issues.[5]

Congress must take steps now to protect American patients and ensure drugs in the U.S. are safe and effective no matter where they are manufactured.

Quality management plans

The bill would require manufacturers to have plans in place to ensure the quality and safety of their drugs and active ingredients, including those that are manufactured, prepared, processed, or compounded by another person. The plans would include assessment by the manufacturer of suppliers prior to contracting, as well as ongoing oversight through periodic site audits and component testing.

Under the legislation the FDA would be permitted to inspect quality management plans and when necessary require revisions to them, including updating testing methods.

Manufacturing supply chain documentation

The bill requires drugmakers to be able to produce, upon request, documentation of every entity involved in the production, processing or transport of a drug and its active ingredients. Under some circumstances drugmakers will also document entities involved in the manufacture, processing or transport of materials used in the creation of an active ingredient. The documentation will include the name, address, phone numbers and Global Positioning System coordinates for every documented entity.

FDA tracking systems for manufacturing sites

The bill would require the U.S. Secretary of Health and Human Services to develop systems to adequately track facilities that manufacture drugs or active ingredients for the U.S. market.

The oversight systems would also include a Duns and Bradstreet Data Universal Numbering System (D-U-N-S) identification number for each site. D-U-N-S is a widely-used system for identifying business entities; using D-U-N-S as a unique identifier for manufacturing facilities could help reduce error and duplicate entries in the FDA's tracking systems. Companies would be required to submit this number when registering with the FDA.

New FDA authorities

The FDA would be given certain essential authorities to ensure the safety of drugs in the U.S., beginning with improved enforcement options including mandatory recall authority for drugs (a power the agency already has for medical devices) and the ability to assess civil penalties for violations of the Federal Food, Drug and Cosmetic Act (FFDCA).

The bill would give the agency better tools to investigate threats to drug quality and safety, such as subpoena authority for documents and witnesses. It also provides the FDA with the ability to share information relevant to the public's health with other regulatory bodies in a protected manner, which will improve the data the agency receives. In addition, the bill would also protect whistleblowers within industry who inform the FDA of violations of the FFDCA or other statutes relating to the safety and effectiveness of a drug, biological product or medical device.

Other provisions

- The FDA has traditionally focused supply-chain oversight on manufacturers of prescription drugs rather than OTC products. However, the bill requires the FDA to make risk assessments independent of prescription or non-prescription status.
- The bill would also require the FDA to provide a report on agreements it enters into with foreign regulatory authorities to mutually recognize assessments of industry compliance with manufacturing standards.
- The FDA's authority to enter and inspect non-U.S. plants making drugs for the U.S. market would be made explicit under the legislation.

[1] Bowman Cox, "Record Drug Recall Totals for 2009 Resulted from GMP Breakdowns," *The Gold Sheet* 44, no. 5 (2010).
[2] Joanne S. Eglovitch, "Enforcement on Steroids: FDA Delivers Twice the Drug GMP Warning Letters," *The Gold Sheet* 44, no. 4 (2010).
[3] U.S. Government Accountability Office, *Drug Safety: Preliminary Findings Suggest Weakness in FDA's Program for Inspecting Foreign Drug Manufacturers*, GAO-08-224T (Washington, DC: 2007).
[4] The FDA published information only on reported deaths of patients taking heparin with symptoms consistent with those caused by the contaminant. This represents a marked increase in deaths over the previous year, but some reports may have been stimulated by public awareness, and causality cannot be determined precisely. "Information on Adverse Event Reports and Heparin," U.S. Food and Drug Administration, http://www.fda.gov/Cder/drug/infopage/heparin/adverse_events.htm (accessed July 26, 2010).
[5] Sharfstein, Joshua. Principal Deputy Commissioner, United States Food and Drug Administration. Testimony before the Committee on Oversight and Government Reform, United States House of Representatives. May 27, 2010. htttp://oversight.house.gov/images/stories/Hearings/Committee_on_Oversight/2010/052710_JandJ_Recall/TESTIMONY-FDA.pdf (accessed August 2, 2010)