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Safety of the Prescription Drug Supply

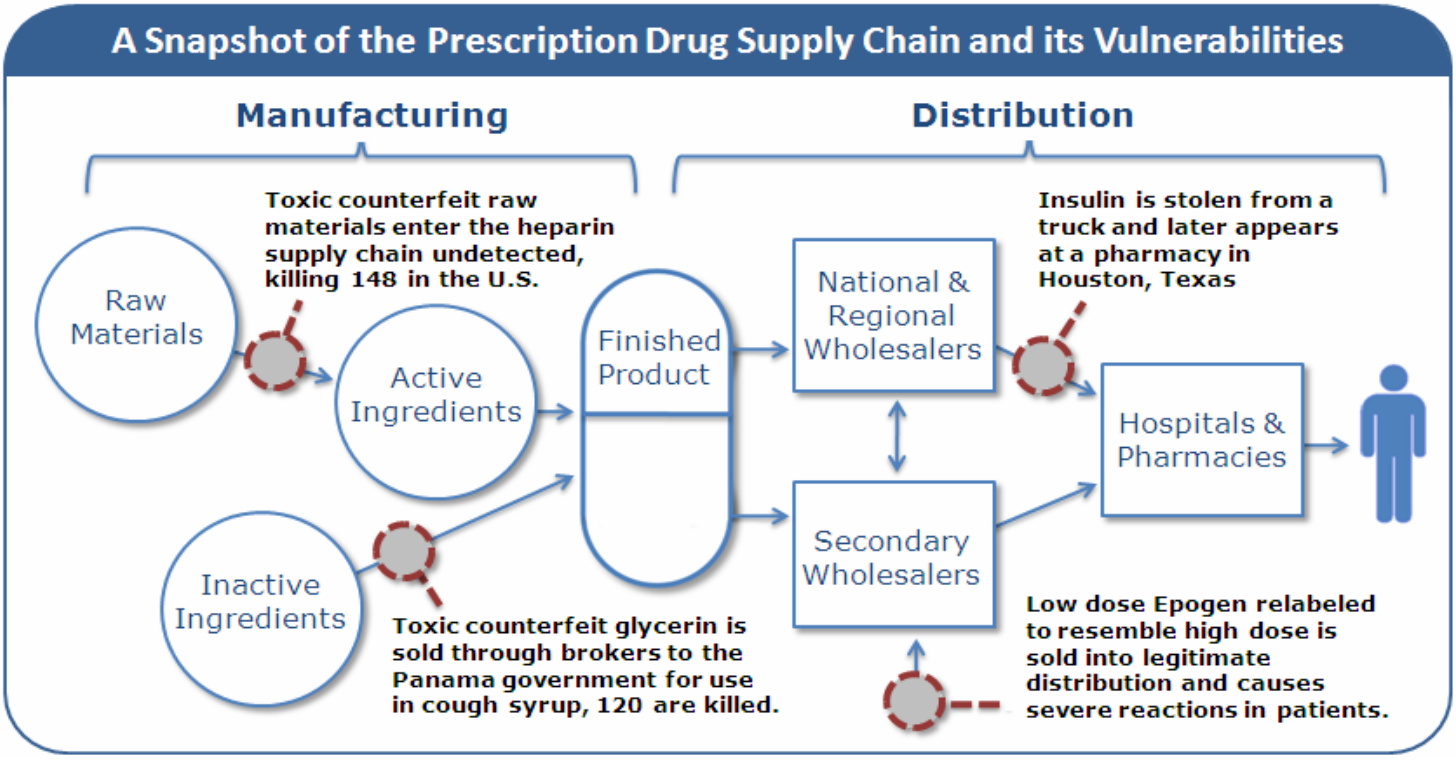
The Pew Prescription Project promotes consumer safety through reforms in the approval, manufacture, and marketing of prescription drugs

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 the safety of the prescription drug supply at risk?

In 2007 and 2008, 149 patients in the U.S. died after they were given contaminated heparin, a widely used blood-thinner.[1] The toxic ingredient was introduced during manufacture in China, and is believed to reflect deliberate use of a low-cost material in place of the pure drug. The contamination was not detected by standard tests, and was discovered only when patients became sick.[2] The heparin was manufactured and distributed by a US-based, Food and Drug Administration (FDA)-regulated company, but the ultimate source of the contamination has never been identified.

The past decade has witnessed rapid growth of overseas pharmaceutical manufacturing,[3] particularly in developing countries. At least 80% of the active ingredients in U.S. prescription drugs now originate overseas,[4] often in countries with weak enforcement of quality standards. Globalization and outsourcing in the pharmaceutical sector is projected to increase further.[5] In addition, drugs may pass through many hands during distribution, often along routes that are poorly tracked. Regulators and industry have failed to adapt to the changing environment, creating the potential for unsafe products to enter the U.S. and harm Americans.



How common are counterfeit or contaminated drugs?

The true prevalence of counterfeit or adulterated drugs is unknown. Estimates in developing countries range as high as 40%.[6] The U.S. domestic prevalence is lower" the FDA puts it at "less than 1%,"[7] but no reliable data exist. Even a rate of one-tenth of one percent would equate to millions of counterfeit, adulterated or substandard prescriptions each year.

How do counterfeit or contaminated drugs enter the US system?

Every year, more and more U.S. drugs are made overseas.[8] Increased outsourcing to contractors has made manufacturing less transparent and more difficult to manage.[9] Strong competition and low risk of inspections or penalties creates a system in which sub-standard drugs and ingredients may be sold to legitimate manufacturers and distributors. FDA lacks the resources and authority to effectively inspect foreign manufacturing sites or assess risk.[10]

The complexity of the domestic drug distribution system also creates risks for consumers. In 2002, U.S. patients across the country received counterfeit vials of the anemia drug Epogen® that were sold by US drug distributors and pharmacies, and reportedly caused painful side effects.[11] Insulin stolen from a truck shipment in June 2009 was stored under unknown conditions before being sold back to legitimate pharmacies and, ultimately, to patients.[12]

The safety of both manufacturing and distribution of drugs is threatened by a weakened FDA. The agency suffers from underfunding that has limited its human, structural, and technological capacities and has prevented it from growing and adapting to an ever-expanding, globalized industry.[13]

- Domestic U.S. manufacturing facilities are inspected, on average, every 2.7 years.[14]
- At current inspection rates, many Chinese facilities producing drugs destined for U.S. consumers might never be inspected.[15]

Indeed, errors and redundancies in FDA databases mean the agency does not currently know how many overseas sites make drugs for U.S. consumption.[16]

What can be done to protect patients?

Legislators, FDA, consumer organizations, and industry alike have recognized the need to strengthen the pharmaceutical supply chain to protect patient safety and health. Congress must pass legislation that:

- Increases FDA oversight of overseas manufacturing
- Holds manufacturers accountable for the security and safety of drug production, particularly when it involves foreign contract manufacturers and suppliers
- Creates national drug tracking standards to protect against counterfeits and allow efficient recall of defective products.
- Gives FDA the resources and authority to require recall of unsafe drugs, subpoena witnesses and documents, and hold and destroy products at the border if they present public safety risks.

What key proposed legislation addresses this issue?

Several bills currently in Congress would give FDA the tools it needs to protect Americans from contaminated and counterfeit medicines.

To increase the safety of drugs manufactured overseas:

H.R.759: The Food and Drug Administration Globalization Act of 2009
Sponsors: Rep. Dingell, Rep. Stupak, Rep. Pallone
Introduced: 1/28/09

S.882: Drug and Device Accountability Act of 2009
Sponsors: Sen. Grassley, Sen. Kennedy
Introduced: 4/23/09

To strengthen domestic drug distribution against diversion and counterfeits:

H.R.5839: Safeguarding America's Pharmaceuticals Act of 2008
Sponsors: Rep. Buyer, Rep. Matheson, Rep. Rogers, Rep. Gene Green
Introduced: 4/7/08

H.R.2726: Counterfeit Drug Enforcement Act of 2009 (Tim Fagan Law)
Sponsors: Rep. Israel, Rep. Ackerman
Introduced: 6/4/09

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[1] The number of reported deaths is from www.fda.gov/Cder/drug/infopage/heparin/adverse_events.htm and includes only patients 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.
[2] Testimony of Robert L. Parkinson, Chief Executive Officer, Baxter International Before Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives. April 29, 2008
[3] Woodcock, Janet. 2008. "The FDA's Response to Biogenerics, QA and Globalization." *Unbranding Medicines: The Politics, Promise, and Challenge of Generic Drugs.* Harvard Interfaculty Initiative on Medications and Society.
[4] U.S. Government Accountability Office. (2007, November). Drug Safety: Preliminary Findings Suggest Weakness in FDA's Program for Inspecting Foreign Drug Manufacturers. (Publication No. GAO-08-224T)
[5] Shahani, Shalini. "Contract Pharmaceutical Manufacturing, Research and Packaging". BCC Research, Wellsley, MA. October 2009.
[6] Data retrieved from a compilation of publicly-available information on country-estimates of counterfeit drug prevalence created by the US Pharmacopoeia. McGinnis, Melissa. Matrix of Medicine Quality Reports Affecting USAID-assisted Countries. Promoting the Quality of Medicines, United States Pharmacopeia. 1/12/10. Rockville, MD.
[7] Rudolph, PM and Bernstein, IBG. "Counterfeit Drugs" New Eng J Med. April 1, 2004. Vol. 350: 1384-1386
[8] Woodcock, Janet. 2008. "The FDA's Response to Biogenerics, QA and Globalization." *Unbranding Medicines: The Politics, Promise, and Challenge of Generic Drugs.* Harvard Interfaculty Initiative on Medications and Society.
[9] Shahani S, 2009
[10] GAO, 2007
[11] Mary Pat Flaherty and Gilbert M. Gaul. "Lax System Allows Criminals to Invade Supply Chain" Washington Post, October 22, 2003. Accesses 12/27/10, Lexis Nexis (cite?)
[12] Hamilton, Reeve. Keep On Trucking. The Texas Tribune. December 18, 2009. http://www.texastribune.org/stories/2009/dec/18/keep-trucking/ Accessed 1/19/10.
[13] GAO, 2007
[14] Ibid

[15] Ibid
[16] Ibid