A LOOK INTO U.S. DRUG SUPPLY SAFETY

The Pew Health Group's report *After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs* addresses the implications of a U.S. pharmaceutical supply that has become increasingly globalized, outsourced and complex. Medicines originate in factories all over the world, moving into the American marketplace through networks that can involve numerous processing plants, manufacturers, suppliers, brokers, packagers and distributors.

The number of drug products made **OUTSIDE** of the United States **DOUBLED** from **2001** to **2008**.[1]

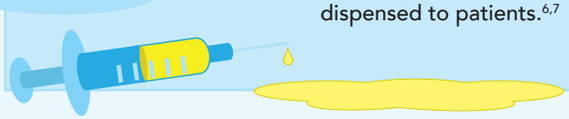
The United States imports the most pharmaceuticals and medicines[2] by weight from China: **188 MILLION POUNDS** in 2009.[3]

Chinese pharmaceutical raw material exports to the U.S. represent a $2.2 billion business **EACH YEAR.**[4]

94% of the pharmaceutical executives who responded to a 2010 survey consider raw material sourcing from foreign suppliers to be a **SERIOUS OR MODERATE RISK.**[5]

Of the **129,000** vials of insulin stolen in 2009, only 2 percent were recovered.

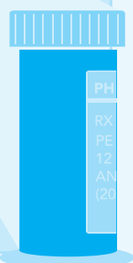
Some of the stolen product, which was stored under uncertain conditions, was sold to pharmacies and dispensed to patients.[6,7]



How often, on average, the Food and Drug Administration inspects drug manufacturing plants:[8]

DOMESTIC SITES **EVERY 2-3 YEARS**

FOREIGN SITES **EVERY 9 YEARS**

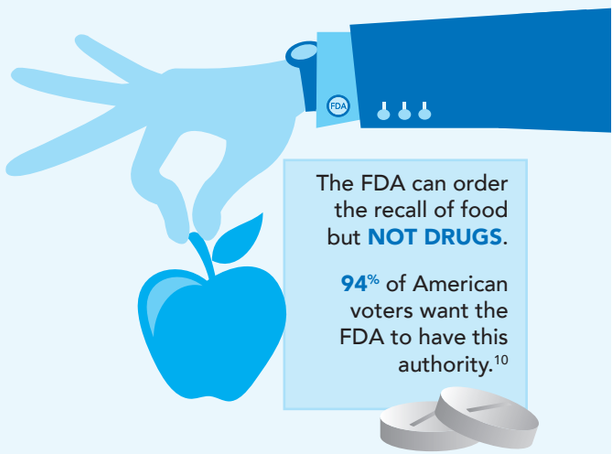


40% INDIA

10% U.S.

ONLY 10% of the active pharmaceutical ingredient factories listed in generic drug applications are in the United States.[9]

40% are located in India.



The FDA can order the recall of food but **NOT DRUGS.**

94% of American voters want the FDA to have this authority.[10]

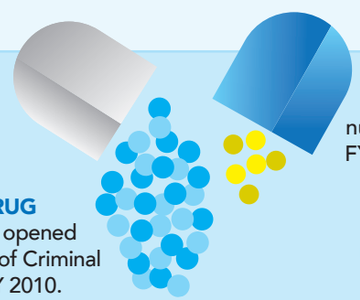
Active ingredients and bulk chemicals **80%**

80 PERCENT of active ingredients and bulk chemicals used in U.S. drugs come from foreign countries,[11]

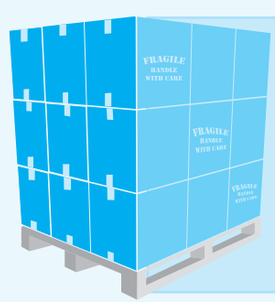
and **40 PERCENT** of finished drugs used by U.S. patients are manufactured abroad.[12,13]

Finished drugs **40%**

72 The number of **COUNTERFEIT DRUG INVESTIGATIONS** opened by the FDA Office of Criminal Investigations in FY 2010.



The number in FY 2000:[14] **6**



Manufacturer → Wholesaler → Wholesaler → Pharmacy

The shipment of your birthday present can be tracked from distribution to delivery, **BUT** there is no comprehensive national system to track a package of drugs from the manufacturing plant to your pharmacy.

PEW PRESCRIPTION PROJECT
pewtrusts.org/drugsupply

PEW HEALTH GROUP

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[3] Source of original data: United States Census Bureau, Foreign Trade Division

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[8] U.S. Government Accountability Office (September 2010). Drug Safety: FDA Has Conducted More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but More Progress Is Needed. Appendix 1: Comments from the Department of Health and Human Services (Publication No. GAO-10-961).

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