FACT SHEET

Safety of Over-the-Counter Drugs

Safety issues affecting over-the-counter drugs

In recent years there have been a number of incidents pointing to the safety concerns of over-the-counter drugs. In 2009, a record 1,742 drugs—including 50 dietary supplements—were recalled, four times the number recalled in 2008.[1] Many of these involved over-the-counter (OTC) medications available without prescription.

On April 30th of 2010, McNeil Consumer Healthcare, a Johnson and Johnson operating unit, announced a recall of over 136 million bottles of children's products, including Children's Tylenol and Motrin Infants' Drops.[2] The recall was initiated due to the presence of particulate matter in multiple products, as well as elevated concentrations of acetaminophen, the active ingredient in Tylenol, in one product. This massive recall is the most recent in a series of concerning events related to drug safety at Johnson and Johnson, including multiple unsatisfactory plant inspections, non-compliance with good manufacturing practices, and recalls that date back to before 2009.[2]

The FDA found that Perrigo Company, a manufacturer of cough and cold medications, had violated standards for good manufacturing practices multiple times starting in 2005.[3] In 2006, Perrigo recalled 11 million bottles of acetaminophen tablets found to contain metal particles.[4] In 2010, the FDA issued a warning letter to Perrigo after it was determined that the company had failed to reject a batch of ibuprofen tablets containing metal shavings.[5]

These and other quality problems that have been discovered at relatively frequently inspected domestic plants indicate that many more quality violations may go undetected. Companies producing products overseas are subjected to less regulatory scrutiny; quality lapses seen domestically may only be the tip of the iceberg.

Americans increasing rely on over-the-counter drugs

Americans today are taking more medicines than ever before. A nationwide survey found that 82 percent of adults in the U.S. took at least one medication in a given week; 29 percent reported taking five or more.[6] OTC medications are those drugs that may be purchased without a prescription. OTC products represent some of the drugs most commonly consumed by Americans. The top three medications Americans reported taking in 2006 were all over-the-counter products,[6] with consumption of some of these products especially widespread. For example, 19 percent of people surveyed reported taking acetaminophen within the last week.[6]

Children are also taking more over-the-counter drugs. A 2009 study found that 56 percent of U.S. children under 12 years old had taken at least one medication, and that OTC products accounted for the majority of these drugs. Twenty-seven percent of children had taken two or more medications in the past week.[7]

Both OTC and prescription drugs are increasingly sourced from overseas. For example, acetaminophen from China accounts for about 50 percent of all acetaminophen imported into the U.S.[8] The U.S. is the number one destination for Chinese pharmaceutical raw material exports, with $2.2 billion of ingredients imported each year.[8]

Regulation and inspections

The Food and Drug Administration (FDA) maintains that there are more than 80 therapeutic categories of over-the-counter drugs that the agency's Center for Drug Evaluation and Research regulates.[9] The FDA requires proof of safety and effectiveness to market new OTC drugs, however, the majority of OTC products, often older molecules, may be marketed in the U.S. without FDA approval.[10] If the OTC product is covered by an existing FDA drug monograph for safe and efficacious products, pre-approval through a New Drug Application is not required.

While the FDA is responsible for regulating the manufacturing and marketing of both prescription and OTC drugs, manufacturing facilities of non-prescription products generally receive less scrutiny than those of prescription drugs.

The FDA conducts preapproval inspections of both domestic and foreign manufacturers before they allow a new drug to be marketed in the United States,[11] but because most OTC products are covered by existing drug monographs, their active ingredients and final products are often produced in manufacturing facilities that are not covered by pre-approval inspections.

The FDA is also tasked with conducting post-approval inspections of manufacturing facilities for drugs it regulates, but because of the large number of sites and strained resources it must use a risk-based approach to determine which facilities to inspect.[12] FDA considers low quality OTC drugs to be of lower risk to public health than problems with prescription drug quality,[11] reducing the frequency with which OTC manufacturing facilities are inspected compared to those manufacturing prescription drugs.

While the FDA inspects domestic manufacturing facilities on average once every 2.7 years, many overseas facilities have never been inspected, and by one estimate it would take over 13 years to inspect every foreign establishment once. Combined with the lower status of OTC products in FDA's risk-based inspection program, this indicates that quality problems may be less likely to be detected at OTC manufacturing sites than at those facilities producing prescription products.

Ensuring the safety of the U.S. drug supply

The safety of drugs in the United States is threatened by an increasingly globalized pharmaceutical manufacturing industry and an under-resourced FDA. The agency's ability to keep pace with industry changes and protect consumers from unsafe drugs has diminished due to lack of funding and an industry shift towards greater outsourcing and reliance on international suppliers for U.S. drugs. More information about the challenges FDA faces in ensuring that drugs manufacturing both domestically and overseas meet quality standards can be found at: http://www.prescriptionproject.org/tools/initiatives_factsheets/files/Safety-Prescription-Drug-Supply-One-Pager-9-15-10.pdf

Legislators, FDA, consumer organizations, and industry have acknowledged the need to strengthen the pharmaceutical supply chain in order to protect patient safety and health. Current legislative proposals and information on efforts to support them can be found here: http://www.prescriptionproject.org/initiatives?id=0003

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[1] Cox, Bowman. Record Drug Recall Totals for 2009 Resulted from GMP Breakdowns. *The Gold Sheet.* Vol.44, No. 5. May 2010.
[2] *Hearings Before the Committee on Government Oversight and Reform of House of Representatives*, 11th Cong, 2nd Sess (2010) (testimony of Joshua Sharfstein, MD, deputy commissioner of the Food and Drug Administration).
[3] FDA Turns Up Heat on Perrigo. *FDA Webview*. 6/21/2010. http://www.fdaweb.com/start.php?sa=v&aid=D5115259&cate=&stid=%241%247N2.Ch3.%24%2F6IOc3SCyR2c3fU4tf4Gf%2F Accessed June 22, 2010.
[4] Rowland, Christopher. Firm recalls pain pills sold at CVS, Wal-Mart, elsewhere. *Boston Globe*. November 10, 2006.
[5] Warning Letter WL: 2010-DT-11. April 29, 2010 To: Joseph C. Papa President and Chief Executive Officer L. Perrigo Company. From: Food and Drug Administration, Detroit District.
[6] Patterns Of Medication Use in the United States 2006: A Report from the Slone Survey Slone Epidemiology Center. Boston University.
[7] Vernacchio L Medication Use Among Children < 12 Years Of Age In The United States: Results From The Slone Survey. *Pediatrics*. 2009;124(2):446-454.
[8] *Potential Health & Safety Impacts from Pharmaceuticals and Supplements Containing Chinese-Sourced Raw Ingredients*. Prepared for the United States China Economic and Security Review Commission by NSD Bio Group. April 2010.
[9] Regulation of Nonprescription Products. U.S. Food and Drug Administration. Center for Drug Evaluation and Research Web Site. http://www.fda.gov/aboutfda/centersoffices/cder/ucm093452.htm Accessed October 13, 2010.
[10] Karst, Kurt R., Hyman, Phelps & McNamara, P.C. Marketed Unaproved Drugs — Overview and FDA Enforcement Policies. Presented at Washington Information Source, Co. Expert Briefing: "FDA's Final Compliance Policy Guide for Marketed Unapproved Drugs. Is Agency Enforcement at a Crossroads, or Stuck in a Traffic Circle?" Washington, D.C. August 10, 2006. http://www.hpm.com/pdf/MARKETED%20UNAPROVED%20DRUGS-%20OVERVIEW.pdf Accessed September 14, 2010.
[11] U.S. Government Accountability Office. Drug Safety: Preliminary Findings Suggest Weakness in FDA's Program for Inspecting Foreign Drug Manufacturers. (Publication No. GAO-08-224T). http://www.gao.gov/new.items/d08224t.pdf Published November 2007. Accessed October 10, 2010.
[12] Risk-Based Method for Prioritizing CGMP Inspections of Pharmaceutical Manufacturing Sites—A Pilot Risk Ranking Model U.S. Food and Drug Administration, "Risk-Based Method for Prioritizing CGMP Inspections of Pharmaceutical Manufacturing Sites—A Pilot Risk Ranking Model." September 2004. http://www.fda.gov/cder/gmp/gmp2004/risk_based_method.htm. Accessed Oct. 21, 2007.