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Pew finds serious gaps in oversight of US drug safety

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Americans' medicines are increasingly manufactured in developing countries, where oversight is lower than in the U.S., according to a new white paper by the Pew Health Group. The U.S. Food and Drug Administration (FDA) estimates 40 percent of finished drugs and 80 percent of active ingredients and bulk chemicals used in U.S. drugs come from overseas.

The white paper, After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs, finds that increased outsourcing of manufacturing, a complex and globalized supply chain and criminal actors create the potential for counterfeit or substandard medicines to enter the supply chain and reach patients. For economic reasons, the migration of manufacturing abroad is likely to continue. At the same time, industry and government agencies have failed to adapt to the changing environment.

"Today's prescriptions are being produced under last century's oversight," said Allan Coukell, director of medical programs at the Pew Health Group. "Compared with a decade ago, pharmaceutical supply lines stretch around the world and out to a complex web of suppliers. Regulators and industry must modernize supervision of the manufacturing process to ensure the drugs we consume are safe. The After Heparin white paper indentifies links in the supply chain that government and business should strengthen," Coukell added.

Substandard or adulterated pharmaceutical materials from abroad have

entered the U.S. on multiple occasions. In addition, the risks of domestic counterfeiting and diversion of stolen drugs are well documented. The white paper presents several case studies, including incidents involving heparin, a blood thinner adulterated during its manufacture in China, counterfeit vials of the anemia drug Epogen and stolen vials of insulin to illustrate the threats and suggest solutions.

After Heparin is based on public information, including FDA documents, U.S. Government Accountability Office (GAO) reports, congressional testimony, peer-reviewed journals and interviews with more than 50 supply chain experts and stakeholders. The findings and recommendations were discussed during a recent two-day convening on the white paper that included a diverse group of industry representatives, ranging from ingredient manufacturers to community pharmacists.

After Heparin details a number of recommendations for policy makers to remedy drug supply chain problems, including:

- Pharmaceutical companies must have comprehensive systems to ensure quality and safety. This means that companies must take responsibility for the entire supply chain by: improving oversight of contract manufacturers and suppliers; ensuring documentation and transparency of incoming drug ingredients and; developing rigorous testing standards. Drug makers must audit suppliers on-site prior to engagement and institute supplier quality agreements. Company management must be held accountable for implementing these systems.

- The security of drug distribution must be improved. Once manufacturing is complete, medicines may pass through many hands before reaching patients, providing opportunities for stolen or counterfeit products to enter the system. Insufficient tracking

and transparency can prevent industry and regulators from identifying the source of stolen or counterfeit products. Congress should establish national standards and oversight of drug wholesalers and require the private sector to track and verify the authenticity of pharmaceuticals.

- FDA authority and enforcement gaps must be addressed. Despite globalization of manufacturing, U.S. government oversight is largely domestically focused. Overseas inspections by the agency must be significantly increased, along with expanded use of third-party sources of information to supplement FDA inspections. Congress should ensure that FDA can order the recall of an adulterated or substandard drug, similar to the agency's authority for food and medical devices. In addition, the agency needs the authority to subpoena documents and witnesses and an improved set of enforcement tools, such as strengthened penalties for certain violations.

Provided by Pew Health Group

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