

Food and Drug Alert

House Committee Issues Report on FDA Contribution to Drug Shortage

June 22, 2012

On June 15, 2012, the Committee on Oversight and Government Reform issued a staff report titled “FDA’s Contribution to the Drug Shortage Crisis.” The report was issued as part of the Committee’s ongoing investigation of the FDA and its enforcement policies under the leadership of Commissioner Margaret Hamburg.

The report addressed the shortage of oncology medicine, focusing on generic injectables. According to the report there is a shortage of over 200 drugs, 80 percent of which are generic injectables. The report observes that shortages threaten the lives of thousands of patients, stop beneficial clinical trials, and lead to rationing of health care. The document identified the sources of the problem as growing market concentration perpetuated by certain provisions of the Medicare Modernization Act (MMA) and increased numbers of production lines shut down due to “overzealous” inspections by the FDA.

MMA Frustrates Economic Forces. According to the report, the MMA’s provision governing the reimbursement rates to suppliers of injectable generic drugs hamper economic forces. This provision only applies to drugs administered in outpatient settings. Specifically, the report states that after a drug becomes generic, its price can drop by up to 90 percent causing manufacturers to exit the market. If a shortage of the drug develops, prices should rise to attract manufacturers. However, the MMA limits drug price increases to 6 percent semiannually on top of already low prices and the minimal profit margin removes incentive to produce these key drugs. Because oncology drugs tend to be administered in an outpatient setting, manufacturers of oncology drugs are disproportionately impacted and a few reported to the Committee that they were producing these drugs at a loss.

FDA Policies.¹ The staff report points to a number of FDA policies that it believes are further contributing to the drug shortage crisis, including:

- **FDA’s Philosophy.** According to the report, Commissioner Margaret Hamburg has emphasized the focus on compliance and prompt corrective action. The FDA has sought to limit the potential for harmful products at the cost of interfering with the production of beneficial drugs.
- **Warning Letters.** The number of warning letters increased 250 percent between 2009 and 2011. Every drug company that has ceased manufacture of generic injectable medications has received one of these letters.

¹ FDA has claimed that the complexity of producing sterile generic injectables and often outdated nature of the facilities that produce them is to blame. Sandra Kweder, Testimony before Senate Committee on Health, Education, Labor and Pensions Hearing, “Prescription Drug Shortages: Examining a Public Health Concern and Potential Solutions,” December 15, 2011. Available at <http://www.fda.gov/NewsEvents/Testimony/ucm282956.htm>. Hearing, “Prescription Drug Shortages: Examining a Public Health Concern and Potential Solutions,” December 15, 2011. Available at <http://www.fda.gov/NewsEvents/Testimony/ucm282956.htm>.



- **Outdated Means.** FDA requires plants to perform major overhauls of their facilities instead of using targeted approaches to address the problems found. According to the report, insider sources reveal this may be due to the lack of communication among those at headquarters, scientists and inspectors in the field.

Simultaneous Shut-downs. Manufacturers of the same product are shutting down production at the same time. Four² [2]of the five largest generic injectable manufacturers have been forced to divert resources to remediation and the industry is running at only 70 percent capacity. Fifty-eight percent of all drugs on the shortage list are undergoing the same remediation process. Not a single person was harmed by products from any of these facilities.

Recommendations

- Congress should reform the price system under MMA to reflect market conditions.
- FDA must consider the consequences of remedial action on nation's drug supply and use a more common sense approach to instituting inspections.
- Drug companies should consider sharing information about capacity to manage a shortage. However, there is a potential issue of collusion amongst large manufacturers.

Next Steps

The Generic Pharmaceutical Association responded to the report that additional collaboration between the industry and the FDA was clearly needed. The organization stated that it was in that vein that they developed the Accelerated Recovery Initiative. This initiative calls upon an independent agency to gather drug supply information and determine gaps as well as a SWAT team within the FDA to coordinate with existing bodies to stop shortages.³

Major legislation that reforms the FDA has passed both the House and the Senate with provisions that require manufacturers to report shortage related information to the FDA. Currently such reports are voluntary.⁴

Groups with diversified interests such as the Government Accountability Office, Pharmaceutical Research and Manufacturers and American Medical Association have endorsed mandatory reporting to FDA.⁵

Similar issues have been reported to members and staff of the Committee as well as to other Committees and subcommittees, relative to the Centers for Food Safety and Applied Nutrition (CFSAN) and the Center for Radiological Devices and Health (CDRH). While there is no indication that similar reports are in preparation regarding these

² Bedford Laboratories, Hospira Pharmaceuticals, Sandoz Pharmaceuticals and Teva Pharmaceuticals.

³ Generic Pharmaceutical Association, "GPha reveals Accelerated Recovery Initiative: An Unprecedented Multi-stakeholder Proposal to Address Drug Shortages," May 11, 2010. Available at <http://www.gphaonline.org/media/press-releases/2011/gpha-reveals-accelerated-recovery-initiative-unprecedented-multi-stakehold>.

⁴ FDA Safety and Innovation Act, S.3187; FDA Reform Act, H.R. 5651.

⁵ Joyce Frieden, "House Report Blames FDA for Drug Shortages," June 19, 2012. Available at <http://www.medpagetoday.com/PublicHealthPolicy/FDAGeneral/33364>.

Centers, there have been numerous expressions of concern from industry regarding increasing enforcement actions, including more frequent inspections and Import Alerts.

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