

## **Drug Shortage Announcement Q and A from HHS:**

### **Q. How will these modest announcements help prevent drug shortages?**

The problem of drug shortages is complex and stems from economic, legal, regulatory, policy, and clinical decisions that are deeply interconnected. While many of the root causes of drug shortages are outside of FDA's purview, each component of today's announcement will aid FDA in mitigating and even preventing shortages and ideally motivate stakeholders to continue to collaborate in developing approaches that might serve to prevent, ameliorate, and resolve this significant public health problem.

### **Q. Why does early notification of potential shortages help prevent shortages?**

Early notification from manufacturers to FDA can help to prevent drug shortages in certain circumstances since FDA may be able, for example, to:

- work with the company on the issues causing the shortage before the supply is depleted, and
- contact other manufacturers of the drug to encourage them to increase production.

For example, such efforts have prevented 99 shortages so far in 2011 due to early notification from the manufacturers.

It's important to note that not all shortages can be prevented. For example, natural disasters, or unforeseen manufacturing shutdowns could imperil anyone's ability to prevent a shortage.

### **Q. What will FDA and DOJ do to investigate price gouging?**

Following the manufacture of prescription drug, they are typically further distributed by wholesalers, who then distribute the drugs to hospitals and pharmacies, often facilitated by GPOs. In some cases, a wholesaler will sell drugs to another wholesaler. Because of vulnerabilities in the drug distribution system in the U.S., drugs can be diverted and leave the legitimate supply chain. In such instances, the diverted drugs circulate in the "gray market" and, when the product is in shortage, they are often offered for sale at significantly higher prices.<sup>1</sup> It is unknown how these drugs are stored and handled or whether they are expired, counterfeit, or otherwise substandard.

Per the President's Executive Order, FDA will communicate to the Department of Justice (DOJ) any information we obtain that shortages have led market participants to accumulate available quantities of the affected drugs or charge excessive markups. The public can make reports through FDA's Office of Criminal Investigation website. The Department of Justice will review the information from FDA to determine whether such activities may violate applicable laws.

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<sup>1</sup> Institute for Safe Medication Practices. Gray Market, Black Heart: Pharmaceutical Gray Market Finds a Disturbing Niche During the Drug Shortage Crisis. ISMP Medication Safety Alert, August 25, 2011. Available at: <http://www.ismp.org/Newsletters/acutecare/showarticle.asp?ID=3> (accessed September 28, 2011).

Investigations for additional follow-up at the following link:  
<http://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm><sup>4</sup>

**Q. Do you have any examples of price gouging when a drug shortage was reported?**

A 2011 report by the Institute for Safe Medication Practices examined gray market activities associated with drug shortages in an online survey of hospital purchasing agents and pharmacists. Of 549 respondents (response rate not calculable), 56% reported receiving daily solicitations from gray market vendors and 52% reported purchasing drugs from gray market vendors in the last two years. Many respondents provided examples of egregious price gouging, including propofol that was marked up by over 1500%.

We are also aware of a report that the Cytarabine Injection, a leukemia drug whose typical contract price is about \$12 per vial was being sold at \$990 per vial - 80 times higher.

In addition, FDA often receives copies of faxes and e-mailed advertisements forwarded by pharmacists that offer drugs that are in shortage at high price mark-ups. Pharmacists continue to report their concerns that these drugs are from an unknown distributor, the source of the drugs is not known, and the drugs could be stored or handled incorrectly.

**Q. What reason do you have to believe that gray market profiteers are hoarding drugs or gouging consumers? And what laws could they be violating?**

FDA is aware from communications it has received from pharmacists that there are distributors that acquire drugs in shortage and offer them for sale to pharmacies at high price mark-ups. Pharmacists share faxes and e-mails from these distributors with FDA and we share the concerns the pharmacists have about the source of these drugs, as well as potential storage, handling and other concerns. Under the Executive Order, we will share these reports with DOJ for follow up.

**Q. Doesn't FDA create drug shortages through cumbersome regulatory processes that prevent medications from coming to market?**

No, the federal requirements for manufacturing quality have been in place for more than four decades and there have been no recent changes to these manufacturing standards. It is a fundamental aspect of FDA's public health mission to ensure that drugs produced for the U.S. market meet these high standards for quality, purity and potency in order to safeguard the health and safety of the American public. For example, patients need injectable drugs that are sterile and uncontaminated with fungal, viral, or bacterial contaminants, or with metal or glass filings. When a quality issue occurs, FDA works with the manufacturer to resolve the issue while keeping the drug available as long as there is not a risk for patients.

Companies sometimes voluntarily stop production or suspend production of critical drugs when manufacturing problems occur so that they can resolve the root cause of product quality problems. Some of these issues are complex and companies may need to take significant time to correct the underlying cause of the problem.

**Q. What will the increased staff at FDA's Drug Shortages Program do and how will you pay for these activities?**

FDA is making sure that everything that the Agency can do to help mitigate and prevent drug shortages is being done. In order to keep up with the anticipated increase in workload from increased early notification by manufacturers, FDA will secure additional staff from across HHS.

FDA Drug Shortage coordinators will examine the reports of shortages or potential shortages received from healthcare professionals, associations, patients, patient groups, industry, and other FDA components; research their roots and coordinate activities within the agency to prevent shortages. We will also add 2 dedicated staff in FDA's Office of Compliance to enhance collaborative planning across FDA to address shortages, including their prevention, while maintaining quality manufacturing standards. The additional staff will also help track shortages and analyze trends and work to establish clear guidelines and procedures to enhance internal collaborations and communications.

**Q. How will you pay for all of the activities you have outlined today?**

Additional staffing will be tapped from across the Department to ensure that the drug shortages program has enhanced resources and expertise to help them deal with additional workload from increased early notification by industry of potential shortages. Because these staff currently exist within the Department, there are no additional costs at this time. As we implement the action steps announced today, we will assess the need for additional resources.

**Q. Do you think Congress has any chance of passing this legislation this year?**

Drug shortages represent a real and urgent challenge to our health care system and there is no such thing as a partisan solution to the problem. In fact, both the House and Senate bills enjoy co-sponsorship from both Democrats and Republicans. The President urges Congress to make this legislation a priority for passage as soon as possible.

**Q. Why has the House held a hearing on the legislation backed by the President, while the Senate has not? Isn't this an example where Republicans are ahead of Democrats?**

There has been significant bi-partisan interest in this topic and both the House and Senate bills enjoy support from Democrats and Republicans. We urge both the House and Senate to move forward with these bills as expeditiously as possible, and look forward to their consideration and passage.

**Q. Some are suggesting that the way Medicare pays for drugs, particularly cancer drugs, is preventing the free market from working to help alleviate shortages. Is this true?**

There is little economic support for this view. Medicare does not purchase drugs from manufacturers, but rather reimburses physician offices and hospitals when they provide services to Medicare beneficiaries. Medicare reimburses at the average sales price of a drug plus a 6 percent margin. The actual market prices for these drugs are determined by contractual

agreements between drug manufacturers and group purchasing organizations, which negotiate on behalf of providers. Medicare changed to the current payment system effective in 2005 because under the previous system Medicare was overpaying for drugs administered in physicians' offices and hospital outpatient settings. Following the Medicare payment change in January 2005, the Medicare Payment Advisory Commission found that providers could still purchase most drugs at below the Medicare payment rate.<sup>2,3</sup> Increasing Medicare reimbursement to providers for drugs they are already purchasing at prices below the reimbursed rate will financially benefit providers but will not increase revenues for drug manufacturers. Likewise, increasing Medicare reimbursement rates to providers would not necessarily result in changes in future contract terms between purchasers and manufacturers that would increase revenues for manufacturers beyond what would occur under current law.

**Q. Would raising reimbursement for Medicare oncology drugs help alleviate or prevent drug shortages?**

Increasing reimbursement for oncology drugs is unlikely to help alleviate or prevent drug shortages, because Medicare already reimburses providers at the average sales price of a drug plus a 6 percent margin. Increasing reimbursement to providers above the market prices for oncology drugs will benefit providers but will not increase revenues for drug manufacturers. Similarly, increasing Medicare reimbursement rates to providers would not necessarily result in changes in future contract terms between purchasers and manufacturers that would increase revenues for manufacturers beyond what would occur under current law.

**Q. If it's not Medicare reimbursement that's preventing the free market from fixing this problem, what is?**

The current class-wide shortages in the sterile injectable drug industry appear to be a consequence of a substantial expansion in the scope and volume of products produced by the industry that has occurred over a short period of time, without a corresponding expansion in manufacturing capacity. The current shortages will likely be resolved when new supply sources come on line as the manufacturing industry increases its capacity.

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<sup>2</sup> Medicare Payment Advisory Commission, *Report to the Congress: Effects of Medicare Payment Changes on Oncology Services*, January 2006.

<sup>3</sup> Medicare Payment Advisory Commission, *Report to the Congress: Impact of Changes in Medicare Payments for Part B Drugs*, January 2007.