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CDER's Drug Shortages Program

Bikash Chatterjee

Between the years 2005 and 2011 the number of new drug shortages quadrupled to 251, posing a significant risk to public health. President Barack Obama issued a directive to the FDA in 2011 to develop a plan to address the problem. In 2011 the U.S. Government Accountability Office provided testimony to the Committee on Health, Education, Labor, and Pensions, regarding a study to ascertain the true drug shortage situation and to determine whether a formal FDA program would be required.[1] The study concluded that the current regulatory framework was insufficient to prevent drug shortages and the FDA should be given more power in terms of notification of potential or impending drug shortages so a remediation plan could be implemented.

While the drug shortage figure declined to 117 in 2012, there were still more than 300 ongoing shortages at the end of the 2013. Figure 1 illustrates the number of new drug shortages by year from 2005-2012 and shows that shortages predominantly affect sterile injectable products. This reflects the FDA's focus on preventing nationwide shortages of these critical drugs.

In response to this and several other key issues related to the FDA's authority and ability to protect the public, the Food and Drug Administration Safety and Innovation Act (FDASIA) was enacted in July 2012.[2] This legislation has expanded the FDA's authority and strengthened the agency's ability to safeguard and advance public health in a number of ways. FDASIA consists of four directives:

- Giving the authority to collect user fees from industry to fund reviews of innovator drugs, medical devices, generic drugs, and biosimilar biological products
- Promoting innovation to speed patient access to safe and effective products
- Increasing stakeholder involvement in FDA processes
- Enhancing the safety of the drug supply chain

In response to the President's Executive Order[3] and to ensure the safety of the drug supply chain, the FDA issued a Strategic Plan4 in October. The agency broke the action plan into internal initiatives within the agency and external initiatives by key industry stakeholders.

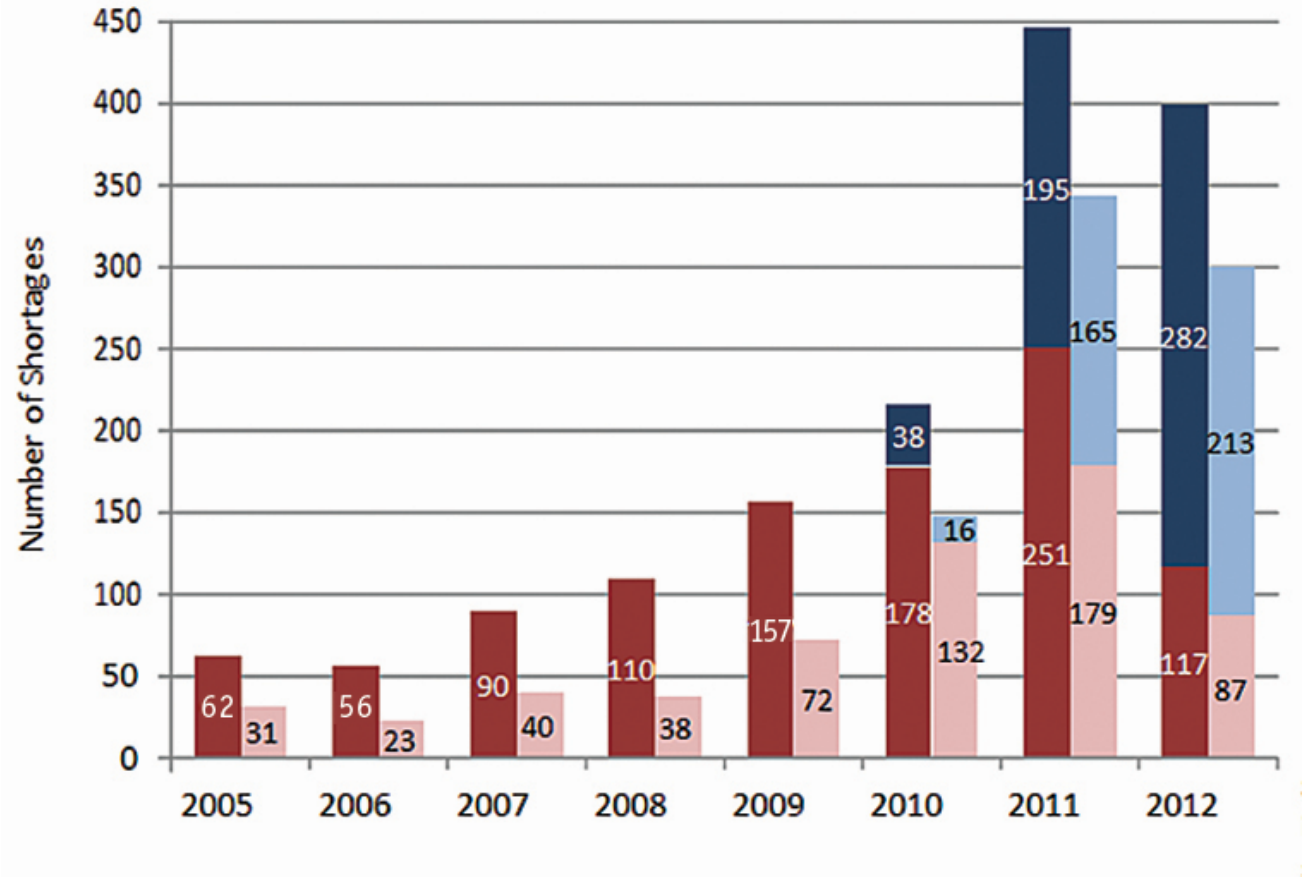

Figure 1. Number of New and Prevented Shortages by Dosage Form, 2005-2012. Source: Date from FDA's internal drug and biologics shortages databases. Key: Light blue = Injectables - Prevented; Light red = Injectables - New; Dark blue = All - Prevented All; Dark red = New

The FDA identified two central internal goals to achieve that address the root causes of both short and long term shortages. The first was to strengthen the FDA's mitigation response, to focus on elements involving better communication with the agency and other chief stakeholders, maximize the agency's ability to respond to a shortage, and improve database tracking to allow better resolution in problem areas. One key element of the initiative was to clarify the role of manufacturers with regard to notifying FDA about supply disruptions, and mitigate impending shortages. If the FDA could be notified earlier of an impending drug shortage, then the agency could not only enhance public communication of the potential drug shortage issue but also begin discussions on countermeasures.

The second program goal was to develop long-term prevention strategies to tackle the underlying causes of supply disruptions and shortages. To achieve this the FDA identified ways to promote and sustain manufacturing and product quality improvements through positive incentives. Organizations such as the International Society of Professional Engineers (ISPE), for example, have created a centralized forum for discussion amongst industry executives called the International Leadership Forum (ILF) that is tasked with addressing industry challenges at a global level. This forum is one example where industry and FDA are working together to develop pragmatic solutions to address drug shortages. One approach being discussed is to use regulatory science to identify early-warning signals of shortages.

These plans can be described as primarily defensive since the FDA has no direct control over drug shortages. The agency outlined key factors for drug manufacturers to consider, such as manufacturing incentives that encourage high-quality manufacturing to help reduce the occurrence and severity of shortages, or the availability of data on manufacturing quality that would help buyers such as hospitals, pharmacies, and other group purchasing organizations make purchasing decisions.

Any disruption in supply is exacerbated if there is limited manufacturing capacity and capability, market concentration, or just-in-time inventory practices that result in minimal product inventory being on hand at any given time. Manufacturers could consider opportunities for building redundant manufacturing capacity, holding spare capacity, or increasing inventory levels to lower the risks of shortages. Other stakeholders might explore how to incentivize such practices.

Price escalation in the face of drug shortages exacerbates the problem. The FDA is asking key stakeholders to explore mitigation activities to minimize gray market activities.

The agency has taken positive steps to address the drug shortages issue. Notification to the FDA by drug manufacturers of potential supply disruptions has increased six-fold since the presidential directive. Now, status of drug shortages can be found on the FDA's website and is searchable alphabetically. It remains to be seen how earnest industry will be in addressing these issues given the public's quality blind spot. The public assumes our drugs are safe and effective regardless of any data to the contrary. The agency is in a difficult position to send a consistent quality message to the industry when it has to deal with potential drug shortage considerations, on a case-by-case basis. However, the strategic plan by FDA is a solid step toward establishing systems that will, if nothing else, provide an early warning so a potential remediation may be identified to avoid the shortage.

References

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Bikash Chatterjee, President and CTO, Pharmatech Associates, has been involved in the biopharmaceutical, pharmaceutical, medical device, and diagnostics industry for over 30 years. His expertise includes site selection, project management, design, and validation of facilities for U.S. and European regulatory requirements.

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Links:
[1] http://digital.cemag.us/controlledenvironments/july_august_2014#pg16