Two recently released reports from the U.S. Department of Health and Human Services (HHS) and the U.S. Government Accountability Office (GAO), respectively, focus on the impact of prescription drug shortages, their potential causes and the role that HHS, particularly the Food and Drug Administration, plays in identifying, tracking and alleviating these problems.

In recent years, an increasing number of drug shortages have threatened public health by reducing—if not eliminating—patient access to critical pharmaceuticals. As such, drug shortages have been the subject of considerable federal activity, including an October 2011 Executive Order that directed the U.S. Food and Drug Administration (FDA) to “take steps that will help to prevent and reduce current and future disruptions in the supply of lifesaving medicines” (e.g., requiring broader reporting of manufacturing discontinuances and expediting regulatory reviews), and a December 2011 interim final rule issued by the FDA that amended the FDA’s early notification requirements.
FDA Safety and Innovation Act

Perhaps most importantly, however, the FDA Safety and Innovation Act, Pub. L. No. 112-144, 126 Stat. 993 (2012) (FDASIA), significantly enhances the FDA’s ability to identify and mitigate the effects of drug shortages by:

- Requiring all manufacturers of all covered prescription drugs (i.e., drugs that are life-supporting, life-sustaining or intended for use in the prevention or treatment of debilitating disease or condition, including any such drug used in emergency medical care or during surgery (except for radiopharmaceuticals and other products designated by the agency)) to notify the FDA of permanent discontinuation or temporary interruption in manufacturing (previously, the notification requirement applied only to sole product manufacturers)

- Authorizing the FDA to require (by regulation) that biological product manufacturers be included among those manufacturers required to provide notice of permanent discontinuation or temporary interruption

- Requiring the FDA to send a non-compliance letter to firms that fail to provide the required notice of permanent discontinuation or temporary interruption

- Expressly permitting the FDA to continue expediting reviews and inspections that may mitigate a shortage

- Requiring the improvement of internal and external communications by the FDA regarding shortages

- Mandating the development and implementation of a strategic plan for enhancing the FDA’s response to preventing and mitigating shortages

- Triggering the initiation of a new rulemaking process (which will replace the December 2011 interim final rule) to incorporate the new requirements set forth in FDASIA

FDA Report

The FDASIA also requires the Department of Health and Human Services to submit an annual report on drug shortages to the U.S. Senate Committee on Health, Education, Labor & Pensions and the House Energy and Commerce Committee. On February 5, 2014, the FDA submitted its first report, in which it discussed actions it has taken to identify and prevent or mitigate prescription drug shortages, and described the impact drug shortages have on the health care system, particularly on patients and health care providers. With respect to the efficacy of the agency’s activities, the report states that the total number of actual drug shortages decreased from 250 in 2011 to 117 in 2012, with 280 other drug shortages prevented in 2012. The FDA attributes these results to the above-described presidential, congressional and agency activity, which has resulted in manufacturers providing the FDA with earlier notice of potential shortages and the agency having additional time to work with sponsors and other groups to maintain patient access to critical medication.
The report also highlights the mitigation efforts that the FDA can implement when faced with a potential shortage. Mitigation efforts may include allowing other manufacturers to increase production to make up for the shortfall; expediting reviews and inspections relating to manufacturers attempting to restore production, competing manufacturers interested in starting new production and competing manufacturers interested in increasing existing production of products in shortage; and exercising temporary enforcement discretion for new sources of drugs. The FDA also notes that it exercised its regulatory flexibility in order to prevent 140 drug shortages in the first nine months of 2013.

**GAO Report**

The FDASIA also requires the Government Accountability Office (GAO) to issue a report that examines the causes of drug shortages and formulates recommendations to prevent or minimize them. On February 10, 2014, the GAO released this analysis. To create this report, the GAO reviewed data, interviewed stakeholders and performed a meta-analysis of 20 different studies as well as FDA data.

The GAO found that, despite the efforts of the FDA, the number of drugs shortages remained high. The GAO report notes that 44 percent of the shortages were sterile injectable generic drugs, 17 percent were sterile injectable brand name drugs and the remainder were oral drugs. Even more disturbing, the GAO found that during the period from 2007 to 2012, nearly half of the reported shortages were for drugs that were in shortage multiple times. According to the report four categories of drugs, anesthetics, anti-infectives, cardiovascular agents and nutritive drugs accounted for 53 percent of all drug shortages.

The GAO’s analysis indicates that the majority of drug shortages (70 percent) are related to manufacturing quality, delays or capacity issues. While the report identified additional underlying factors, such as payer-related issues, particularly Medicare Part B pricing, and market-based price competition, the report does not present any of these factors as being significant causes of shortages.

Providers indicated to the GAO that drug shortages can affect patient care beyond just the inability to access drugs in short supply. Provider groups highlighted the risks stemming from the inability to find suitable and effective alternative drugs, rationing care when drugs have limited availability and the increased cost of short supply drugs. Provider groups also noted that their practices were required to devote additional staff and provider time and costs on managing drug inventory instead of providing direct patient care.

The GAO report lauds the FDA’s efforts to identify and mitigate drug shortages. However, it notes that many contributing factors are beyond the FDA’s control. The GAO recommends that the FDA streamline its existing processes by better and more consistently using the information it collects to further enhance its ability to identify, track and prevent drug shortages.

**Implications**

Patients, providers, manufacturers and payers alike will be encouraged by the FDA’s
report of reductions in and the prevention of drug shortages. Nevertheless, the GAO’s report and remaining shortage concerns suggest that significant progress remains to be made. Therefore, where required to more fully address shortage-related issues, the FDA’s regulatory policy may evolve over time—at least to the extent required and permitted under the FDASIA.

For example, as mentioned above, the FDA intends to replace the 2011 interim final rule with regulations consistent with the FDASIA’s requirements. The comment period for the proposed replacement rule closed in early January 2014, so the FDA could promulgate the final regulations as soon as later this year. Therefore, interested entities—especially manufacturers—should carefully monitor communications regarding the final rule from the FDA, as well as other FDA activities under its drug shortage program.

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