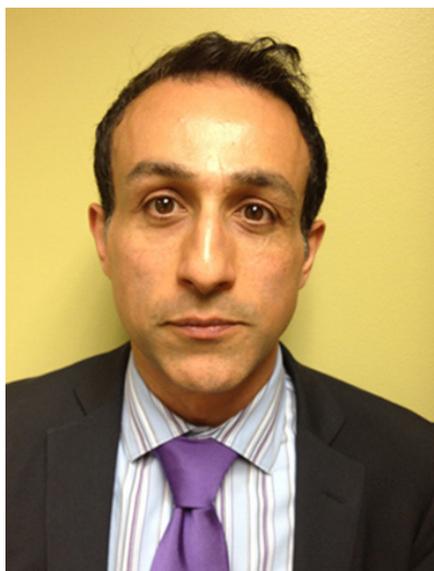
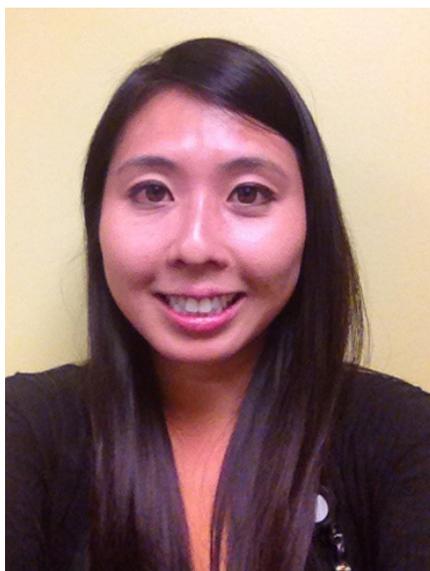


The Root Cause of Drug Shortages

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Drug shortages have increased in frequency and severity in recent years, and are now considered a national crisis. The number of reported prescription drug shortages in the United States nearly tripled between 2005 and 2010 from 61 to 178 medications. In 2011, the number of drug shortages reached 267, the record high in a single year.

Why drug shortages occur

Drug shortages occur for a multitude of reasons. According to

the U.S. Food and Drug Administration (FDA), the major reasons for shortages in 2010 were manufacturer quality issues (54%) and manufacturing delays (21%). Manufacturers may suffer from an unanticipated increase in demand or a shortage of raw materials. Others have experienced quality control and other manufacturing problems that take time to correct. There are a limited number of production firms, and therefore when one company has a problem or discontinues, it is difficult for the remaining manufacturers to rapidly

increase production. Discontinuations are another contributing factor to the shortages, as some manufacturers have made the business decision to stop producing older generic drugs when they become less profitable.

Impact on patient care

When shortages occur, health practitioners are forced to find therapeutic alternatives. However, this produces multiple concerns:

Increase in costs

Alternatives are often more expensive, particularly when brand-name substitutes are used in the setting of generic shortages. There are also costs in added time for management and safety issues as pharmacists and hospitals cope with shortages. A 2011 study conducted by Kaakeh, et al, found that managing drug shortages has cost the US health care system \$216 million annually in labor costs alone.

Increase in errors

Errors can occur when less familiar drugs are used in place of the drug of choice. The Institute for

Safe Medication Practices (ISMP), a nonprofit organization devoted entirely to medication error prevention and safe medication use, conducted a national survey of healthcare practitioners revealing serious impact on patient safety due to growing drug shortages. Approximately 35% reported their facility experienced an error that could have led to patient harm during the past year due to a drug shortage. In November 2011, an Associated Press article reported 15 deaths in the prior 15 months that were related directly to drug shortages. Deaths and patient harm have been linked to situations in which the preferred drug wasn't available, or dosing, administration and preparation errors occurred with the unfamiliar alternative medication.

Compromise in therapy

Alternatives are often not a treatment drug of choice, and may lead to suboptimal management. In some cases, an alternative is not available or on shortage itself, re-

sulting in non-treatment or delayed treatment of the patient. The drug shortage has had a particularly immense impact on cancer treatment, in which the short supply of key chemotherapy agents have forced oncologists to change regimens to those which are less familiar, less effective, and may cause more adverse effects. The FDA and American Hospital Association report drug shortages have resulted in delayed treatment for thousands of cancer patients and have caused nearly every hospital to ration supplies or turn away new patients.

Government Initiatives

The impact of drug shortages has now caught attention at the government level. In late October 2011, President Obama signed Executive Order 13588 in an effort to reduce and prevent prescription drug shortages. The executive order directed the FDA and Department of Justice to expedite reviews of new manufacturing facilities, encouraged drug manufacturers to report shortages earlier, and in-

creased staffing resources for the FDA's drug shortage program.

The FDA reported improvements immediately following the implementation of the Executive Order. At the six-month mark, the FDA was able to prevent 128 drug shortages and saw fewer numbers of shortages occur overall.

Future congressional fixes will likely aim to tackle the fundamental drivers of shortages, including the limited number of manufacturing lines and the economic issue of low profits for generic drugs.

Drug shortages have changed clinical practice and compromised patient care. The management of this continuing burden will require united efforts and communication between the government, drug manufacturers, health care providers, and patients.

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