



DRUG SHORTAGES

Drug shortages have increasingly become a major problem for hospitals and health systems across the country, resulting in serious consequences for patient safety, quality of care, and access to essential medications. The growing frequency and prolonged nature of the unavailability of drug therapies has prevented clinician access (and therefore, patient access) to critical medications, which not only delays necessary treatment, but complicates the delivery of care and raises patient safety concerns when clinicians are forced to use unfamiliar alternatives.

According to a March 2011 analysis by Premier Healthcare Alliance, drug shortages have tripled since 2005 with more than 240 drugs either in short supply or completely unavailable, and more than 400 generic equivalents on back order for five or more days¹. Blood thinners, antidotes, anesthetics, and pain medications are often the drugs most frequently experiencing shortages. In 2010, sterile injectibles and older generic drugs were widely reported as most frequently being in short supply.

A confluence of precipitating factors account for medication shortages, but generally they are largely due to factors under the control of drug manufacturers or manufacturers of the raw materials used by drug manufacturers to make drug therapies. These materials are called active pharmaceutical ingredients (APIs) and are regulated by the Food & Drug Administration (FDA).

When shortages occur, providers are forced to either delay treatment or compromise care by using less efficacious or unfamiliar alternative drugs—both of which can have negative consequences. Errors in dosing, administration, and side effects are more likely to occur. The Institute of Safe Medication Practices reported in a recent survey that clinicians expend considerable resources (labor and financial) that would have otherwise been spent on clinical duties to track down and resolve individual shortage issues.² Additionally, hospitals

are often forced to buy from “gray market vendors” that purchase remaining supply and charge hospitals considerably more to procure particular drugs. Premier’s March 2011 analysis found that the financial impact of drug shortages exceeds \$200 million annually for hospitals alone.

Since the FDA lacks the necessary authority to adequately manage shortages, Congress should pass the Preserving Access to Life-Saving Medications Act (S 296), which would significantly improve communication between manufacturers and the FDA about a discontinuation, interruption, or adjustment to the production of a specific drug that would cause a shortage, and impose penalties for failure to provide notice. Additionally, the Health and Human Services (HHS) Secretary should increasingly use her authority to allow the temporary importation of critical shortage drugs. Currently, HHS allows the importation of Propofol, but HHS should deploy this authority with many more shortage drugs.

GNYHA POSITION

Congress should pass drug shortage legislation that would mandate notifications of shortages by manufacturers. HHS should use its authority more broadly to allow for temporary importation of shortage drugs.

CAUSES FOR A SHORTAGE

- **Raw Materials:** When raw materials (80% of which are manufactured abroad) are unavailable
- **Market Exit:** When manufacturers decide to exit the market in the face of increased regulation, decreased profitability through patent expiration or availability of generics, putting sudden higher demand on remaining manufacturers
- **Voluntary Recalls:** When problems with the safety of a product or the manufacturing process are identified
- **Unexpected Demand:** When markets shift resulting from new indication approvals, usage changes from new therapeutic guidance, disease outbreaks, natural disasters, or from rumors of shortages (causing stockpiling)
- **Enforcement Actions:** When an inspection finds non-compliance with FDA-required manufacturing practices
- **Business Decisions:** When manufacturers reformulate their drugs or merge with other companies and narrow their product lines or move plant operations

1. “Navigating Drug Shortages in American Healthcare: A Premier Healthcare Alliance Analysis,” March 2011.

2. Institute for Safe Medication Practices. *Medication Safety Alert*. September 23, 2010; 15(19): 1-4.