



Drug Shortages

The Issue

Drug shortages have become a critical issue effecting patient care. While there has always been a cyclical nature to drug shortages, the shortages we have been experiencing in the past 4 years have been more severe with more significant detrimental effects. The number of active drug shortages has increased from 154 in 2007 to a high of 456 in 2012. While the number of new shortages is starting to decrease, the total number of active drug shortages remains high.

The Research

There are a number of potential causes for the recent resurgence of drug shortages. These include decreased manufacturing capacity, quality problems, few manufacturers, an increase in the number of generic drugs, and the unavailability of raw materials.

Infants in the NICU have been at an increased risk for harm due to these recent shortages. The lack of sterile injectables to make TPN for our infants has resulted in known zinc deficiencies, metabolic acidosis, osteopenia, and has the potential for unknown long term effects. We have also seen shortages in a number of other drug classifications including pain medications and saline.

In a 2013 survey of NANN members, 65.9% viewed the problem of drug shortages as extremely serious. In this same survey, 95.6% of members' units have experienced drug shortages. Seventy six percent of members reported the problem of drug shortages as getting worse.

Current Legislation

The Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law in July 2012. FDASIA was one of the first pieces of legislation passed to address drug shortages. While the FDA cannot mandate drug companies to produce drugs, FDASIA allowed for more oversight. Specifically it required the FDA to create a task force and create a strategic plan. It also required manufacturers to notify the FDA of impending interruption or discontinuation of drugs. It allowed the FDA to expedite importation of drugs and reviews of new drug applications. The FDA must now write an annual report and distribute information regarding drug shortages.

Recommendations

There is no current legislation addressing drug shortages. Despite this fact there is an opportunity for you to remain informed on current drug shortages and to report shortages directly to the FDA.

To stay abreast of current shortages please view the [FDA's Website](#). You can also [subscribe to receive emails](#) with updates from the FDA.

To report a shortage of a drug product by email please use drugshortages@fda.hhs.gov or to make a report by phone, please call (888) INFOFDA or (888) 463-6332.

If you are experiencing drug shortages that are affecting your ability to care for patients you can also write directly to the pharmaceutical companies that make the drugs. Your stories are powerful and it is important to share our experiences.

References

1. Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability. GAO-14-194. Washington, D.C: February 2014
2. Food and Drug Administration. (2013). Strategic plan for preventing and mitigating drug shortages. Retrieved on June 27, 2014. <http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM372566.pdf>
3. Hamburg, M. (2013, July 8). Looking back and looking ahead: FDASIA's one year anniversary. Retrieved from blogs.fda.gov/fdavoices/index.php/tag/drug-shortages
4. Jensen, V. (2013, May 29). Importing drugs to address shortages. Retrieved from blogs.fda.gov/fdavoices/index.php/tag/drug-shortages
5. Johnson, P. The ongoing drug shortage problem affecting the NICU. Neonatal Network. 2012; 31(5); 323-327.
6. Norton, S. Zinc deficiency dermatitis in cholestatic extremely premature infants after a nationwide shortage of injectable zinc. Morbidity and Mortality Weekly Report. 2013; 62(7); 136-137.
7. United States. Congress. House of Representatives. Committee on Oversight and Government Reform. (2012). FDA's Contribution to the Drug Shortage Crisis, June 15th, 2012. Washington: Government Printing Office.