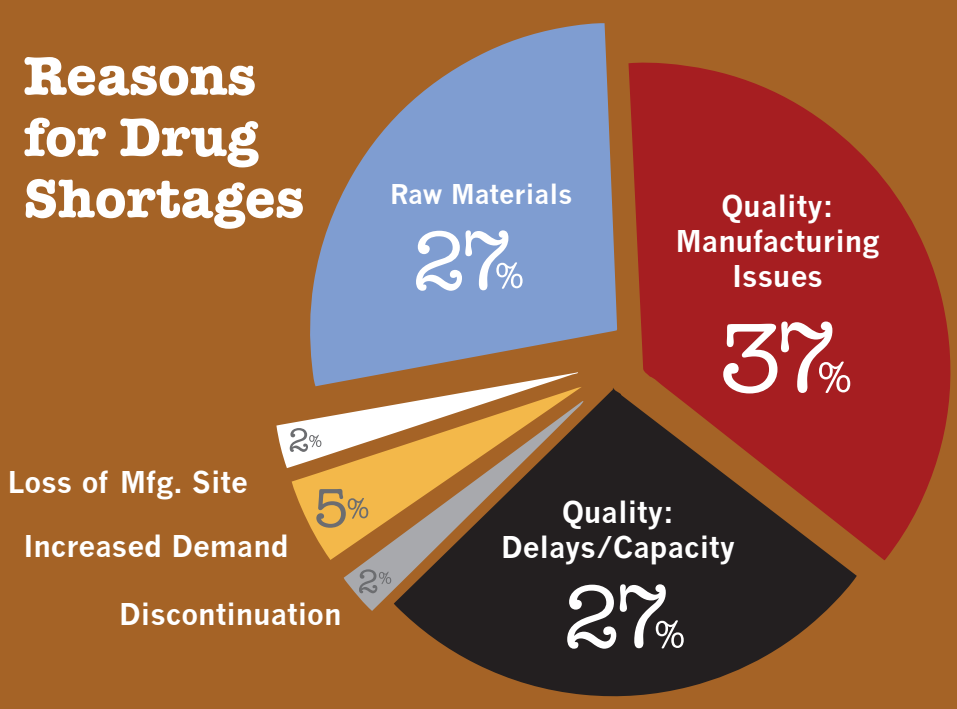
DRUG SHORTAGES

Patient care is our primary concern.
Since 1999, FDA has worked with the pharmaceutical industry and stakeholders to address this critical issue that impacts health care delivery in the United States.

Types of Drugs FDA Considers for Drug Shortages

FDA prioritizes drugs that are medically necessary. A medically necessary drug product is a product that is used to treat or prevent a **serious disease or medical condition** for which there is no alternative drug, available in adequate supply, that medical staff has determined to be an acceptable substitute. Although the agency focuses on medically necessary drugs, all potential shortages are evaluated to help determine the possible public health impact.

Reasons for Drug Shortages



117 shortages reported in **2012**

FDA Works to Prevent Drug Shortages

FDA works to find ways to mitigate drug shortages. However, there are a number of factors that can cause or contribute to drug shortages that are outside of FDA's control. Sometimes manufacturers have an unforeseen breakdown in manufacturing line that affects their production. Other times, shortages are caused by longstanding quality manufacturing issues.

FDA cannot require a pharmaceutical company to:

1. make a drug, even if it is a medically necessary drug,
2. make more of a drug,
3. change how much and to whom the drug is distributed.

FDA issued a long-term **strategic plan** to outline the agency's priority actions, as well as actions drug manufacturers and stakeholders can take to prevent drug shortages by promoting and sustaining quality manufacturing.

FDA Responds to Drug Shortages

44 shortages reported in **2014**

FDA responds to potential drug shortages by taking actions to address their underlying causes and to enhance product availability. FDA determines how best to address each shortage situation based on its cause and the public health risk associated with the shortage.

FDA works to maintain availability of a drug in a variety of ways, while minimizing the risk to patients.

For manufacturing/quality problems, **FDA works with the firm** to address the issues. Problems range from very low risk, such as the wrong expiration date on package, to high risk, such as particulate in product or sterility issues.

FDA also works with other pharmaceutical companies making the drugs that are in shortage to determine if they have the capacity to assist and if they are willing to do so.

When the U.S. manufacturers are not able to resolve a shortage immediately and the shortage involves a critical drug needed for patients, **FDA may look for a pharmaceutical company that is able to redirect product into the U.S. market to address a shortage**. FDA considers a list of criteria to evaluate the product to ensure efficacy and safety, including the formulation and other attributes of the drug, as well as the quality of the manufacturing site where the drug is made.

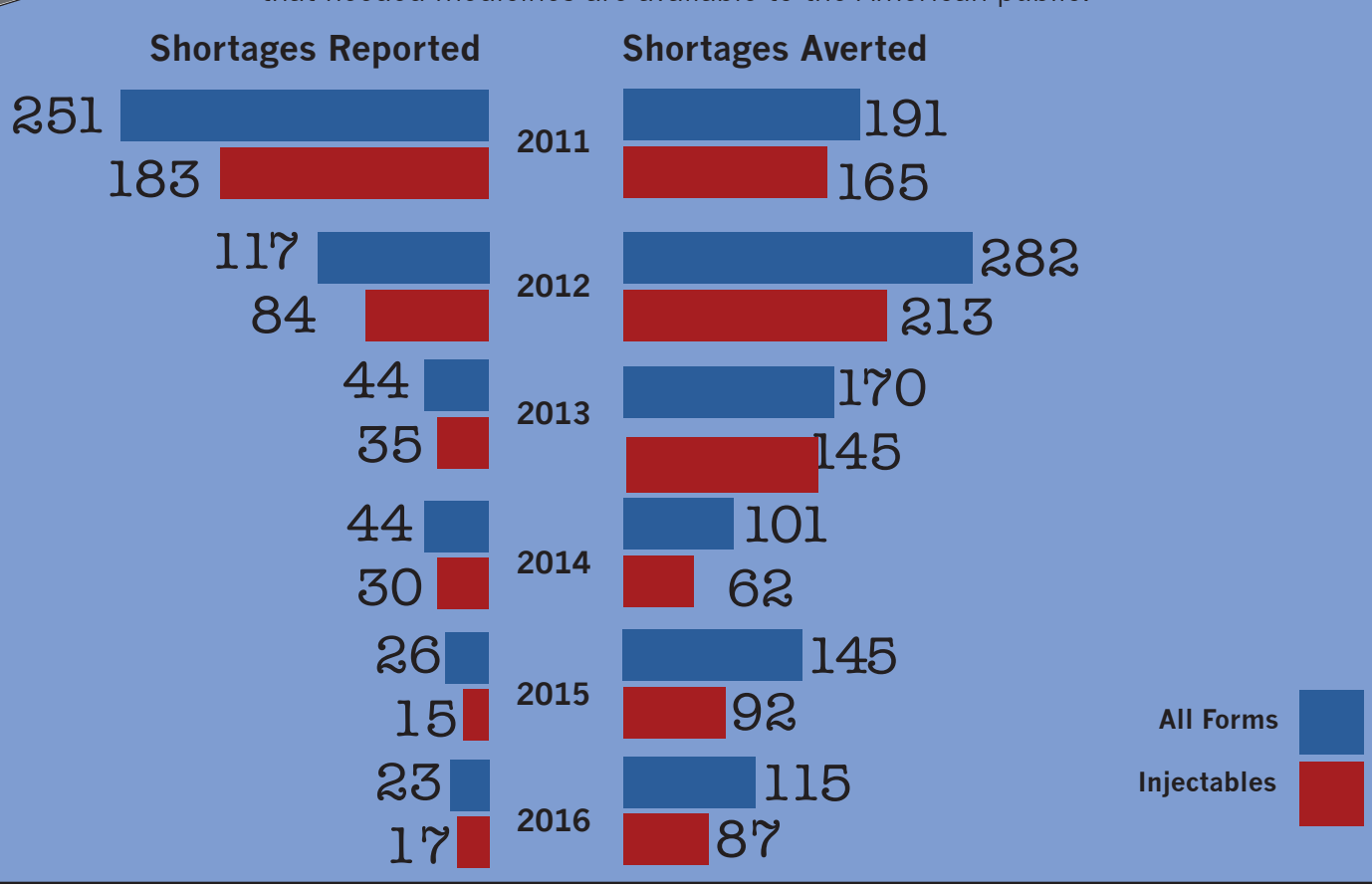
The Pharmaceutical Industry Can Help Prevent Drug Shortages

Notifying FDA early is critical to helping prevent or mitigate a drug shortage. Through the Food and Drug Administration Safety and Innovation Act (FDASIA), **pharmaceutical companies are required to notify FDA, when manufacturing interruptions or production changes could lead to a supply disruption or discontinuation.**

23 shortages reported in **2016** down from **26** in 2015

Progress Has Been Made

While FDA and industry has made progress, patients are still experiencing drug shortages that impact their care. **A high percentage of drug shortages have been, and continue to be, sterile injectables, including chemotherapy, anesthesia and other acute drugs.** When there are quality or production problems for sterile injectables, it is not uncommon for a shortage to occur. FDA will continue to work with manufacturers and other stakeholders to ensure that needed medicines are available to the American public.



U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration
Center for Drug Evaluation and Research
www.fda.gov/drugs

For more information on drug shortages visit the FDA Drug Shortages web page
http://www.fda.gov/drugshortages