

### Why GAO Did This Study

In recent years, nationwide shortages of prescription drugs have increased, preventing patients from accessing medications essential to their care. The Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), established a Drug Shortage Program with a mission of helping to prevent, alleviate, and resolve shortages. FDA receives information about shortages from manufacturers, though this reporting is generally voluntary, as well as from the American Society of Health-System Pharmacists (ASHP). ASHP tracks nationwide shortages for its members through a partnership with the University of Utah Drug Information Service (UUDIS).

GAO was asked to review trends in shortages and examine FDA's response. In this report, GAO (1) reviews trends in drug shortages, (2) describes FDA's response, and (3) evaluates FDA's ability to protect public health through its response to drug shortages. GAO analyzed UUDIS data, interviewed officials from FDA, health care professional associations, and industry, and also examined relevant statutes, regulations, information, and documents.

### What GAO Recommends

Congress should consider establishing a requirement for manufacturers to report to FDA any changes that could affect the supply of their drugs. In addition, FDA should enhance its ability to respond to drug shortages, for example, by developing an information system to manage data about shortages. HHS outlined actions it plans to take that are consistent with GAO's recommendations.

View [GAO-12-116](#) or key components. For more information, contact Marcia Crosse at (202) 512-7114 or [crossem@gao.gov](mailto:crossem@gao.gov).

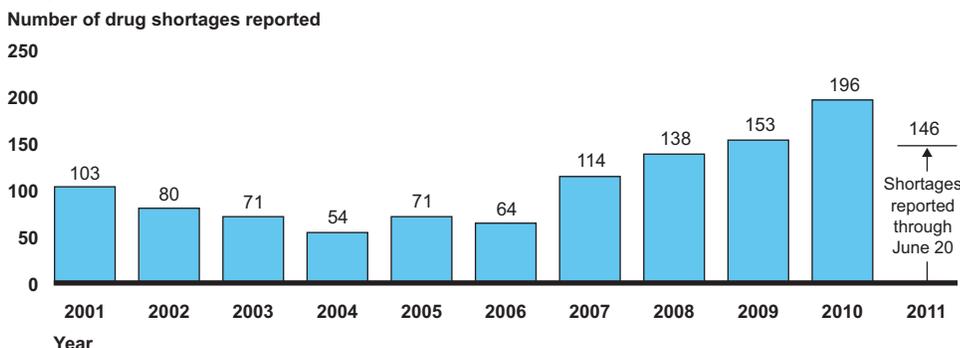
## DRUG SHORTAGES

### FDA's Ability to Respond Should Be Strengthened

### What GAO Found

The number of drug shortages has grown substantially since 2006. In total, 1,190 shortages were reported from January 1, 2001, through June 20, 2011, according to UUDIS data. From 2006 through 2010, the number of drug shortages increased each year. A record number of shortages were reported in 2010, and 2011 is on pace to surpass 2010's record. Sixty-four percent of shortages involved drugs that were in short supply more than once. On average, shortages lasted 286 days (over 9 months). Over half of shortages reported from January 1, 2009, through June 20, 2011, that UUDIS identified as critical—because, for example, alternative drugs were not available—involved generic injectable drugs. Certain therapeutic classes (such as anesthetic, oncology, and anti-infective drugs) were among those most often in short supply.

**Drug Shortages Reported January 1, 2001 through June 20, 2011, by Year**



Source: GAO analysis of University of Utah Drug Information Service data.

FDA responds to drug shortages by taking actions to address the underlying causes and to enhance product availability, for example by providing assistance to manufacturers to resolve manufacturing or quality problems that can result in a shortage. When informed of the possibility of a shortage in advance, FDA has increasingly been able to prevent potential drug shortages from occurring. FDA prevented 50 potential shortages during the first half of 2011. As part of its response, FDA provides general information about drug shortages to the public via its website.

FDA is constrained in its ability to protect public health from drug shortages due to its lack of authority to require manufacturers to report actual or potential shortages to the agency or the public, or to require manufacturers to take certain actions to prevent, alleviate, or resolve shortages. As a result, the agency's approach to managing drug shortages is predominately reactive. FDA's ability to protect public health is also constrained by management challenges that weaken its ability to respond to drug shortages. For example, FDA does not systematically maintain data on drug shortages, without which it is unable to monitor trends and enhance its ability to address the causes of drug shortages. In addition, FDA has provided limited resources to manage its response to drug shortages and lacks related performance measures and priorities.