

# **REPORT TO CONGRESS**

Third Annual Report on Drug Shortages  
for Calendar Year 2015

Required by Section 1002 of the  
Food and Drug Administration Safety and Innovation Act

Public Law 112-144

Department of Health and Human Services  
Food and Drug Administration

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## **EXECUTIVE SUMMARY**

This third annual report to Congress summarizes the major actions taken by the Food and Drug Administration (FDA) during the first three quarters of 2015 to prevent or mitigate drug shortages in the United States. Because drug shortages can pose a significant public health threat that can delay, and in some cases even deny, critically needed care for patients, shortages remain a top priority for FDA. As a result of actions by the President, Congress, and FDA, manufacturers are notifying FDA about potential shortages earlier than in the past. Early notification of potential shortages gives FDA additional time to work with sponsors and other stakeholders to identify ways to maintain treatment options and prevent a shortage. Using a range of available tools, including regulatory flexibility and discretion when appropriate, FDA's Center for Drug Evaluation and Research (CDER) worked with manufacturers to successfully prevent 128 shortages from January 1 to September 30, 2015. In addition, the number of new shortages tracked by CDER for this same time period is 22, compared with the 33 new shortages during the same time period for 2014.

Based on our experience to date and the data on drug shortages presented in this report, FDA believes that the requirements related to early notification of potential shortages and FDA's own actions are helping to reduce the threat and impact of drug shortages. FDA will continue to prioritize this important public health issue, working to ensure the availability of necessary drugs for the American public.

## **INTRODUCTION**

The Food and Drug Administration Safety and Innovation Act (FDASIA) was enacted on July 9, 2012. Title X of FDASIA, which addresses drug shortages, took effect on the date of enactment and, among other things, amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355) by updating section 506C. Section 506C sets forth the requirement that manufacturers notify FDA of a permanent discontinuance or interruption in the production of certain prescription drugs that are lifesaving, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition. In addition, section 1002 of Title X of FDASIA added section 506C-1 to the FD&C Act, requiring FDA to file a report to Congress at the end of each calendar year on drug shortages. FDA is submitting this annual report to fulfill its obligations under section 506C-1. The report provides background about drug shortages and FDA efforts to address them to date. FDA also responds to the specific issues listed under section 506C-1. The analyses reflect data collected and evaluated by CDER from January 1, 2015, through September 30, 2015. To provide a more comprehensive view of CDER's efforts to manage drug shortages, this report includes data for all products tracked by

CDER's Drug Shortage Staff (DSS).<sup>1</sup> This report also summarizes some important ongoing activities FDA believes will help to address drug shortages in the future. A list of definitions and the statutory language regarding annual reporting on drug shortages is included at the end of this report.

## **BACKGROUND**

Drug shortages can have serious and immediate effects on providing needed therapies to patients, and preventing shortages is a priority for FDA. At the height of the drug shortage crisis, the number of new shortages tracked by CDER quadrupled from approximately 61 shortages in 2005 to more than 250 in 2011. Although that number significantly decreased in 2012 to 117 shortages and 44 new shortages in 2013 and 44 new shortages in 2014, shortages continue to pose a real challenge to public health. This is especially the case when a shortage involves a critical drug to treat cancer, to provide parenteral nutrition, or to address another serious medical condition, such as the current shortage of intravenous saline solution. These shortages can delay or deny needed care for patients, creating a potential lapse in medical care. Shortages can also lead prescribers to use second-line alternatives, which may be less effective or pose additional risks. To prevent these from occurring, FDA has used a variety of methods to prevent shortages, working within the confines of the statutory and regulatory framework in place and in partnership with manufacturers and other stakeholders. FDA helped prevent 282 drug shortages in 2012, 170 shortages in 2013, 101 shortages in 2014, and 128 in the first three quarters of 2015.

Several actions have been taken in recent years that have helped FDA address drug shortages.

### **1. Executive Order 13588 – Reducing Prescription Drug Shortages**

In response to a dramatic increase in shortages, on October 31, 2011, the President issued Executive Order 13588, recognizing that “shortages of pharmaceutical drugs pose a serious and growing threat to public health...endanger patient safety...burden doctors, hospitals, pharmacists, and patients...and increase health care costs.”<sup>2</sup> The Executive Order acknowledged the need for a “multifaceted approach” to address the many different factors that contribute to drug shortages. The Executive Order directed FDA to take steps to help prevent and reduce current and future disruptions in the supply of lifesaving medicines, including through notifications and expedited reviews, as appropriate.

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<sup>1</sup> Such products include all drugs within the meaning of section 506C(h)(1), as well as other products tracked by CDER's Drug Shortage Staff, such as biological products approved under section 505 of the FD&C Act. In the future, FDA's annual reports on shortages may include data on biological products licensed under section 351 of the Public Health Service Act and tracked by the Center for Biologics Evaluation and Research, including vaccines and blood products.

<sup>2</sup> Executive Order 13588, available at <http://www.whitehouse.gov/the-press-office/2011/10/31/executive-order-reducing-prescription-drug-shortages>.

## **2. FDA Safety and Innovation Act**

With the passage of FDASIA, FDA was given important new authorities related to drug shortages. For example, section 1001 of FDASIA broadened the scope of the early notification provisions by requiring manufacturers of *all prescription drugs* that are life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition (whether approved or unapproved) to notify FDA of a permanent discontinuance or temporary interruption in manufacturing. FDASIA also allowed FDA to require, by regulation, early notification of discontinuances or interruptions in manufacturing of biologics. FDASIA requires FDA to send a non-compliance letter to firms that fail to notify FDA in accordance with section 506C, as amended by FDASIA. FDA sent the first two letters last year and posted the letters and the responses from the manufacturers on its website. No non-compliance letters were sent during the first three quarters of 2015. Section 506C also authorizes FDA to expedite reviews of drug applications and supplemental applications and to expedite inspections that could help mitigate a shortage. Other FDASIA requirements include improving FDA's internal and external communications about shortages, improving communication between FDA and the Drug Enforcement Administration (DEA) regarding shortages of controlled substances, and developing a strategic plan to enhance FDA's response to preventing and mitigating drug shortages.

## **3. FDA Strategic Plan to Prevent and Mitigate Shortages**

On October 31, 2013, FDA issued its *Strategic Plan for Preventing and Mitigating Drug Shortages*.<sup>3</sup> The plan contains details on the origin of drug shortages, FDA's processes and procedures for helping to prevent or mitigate shortages, and FDA's strategy for strengthening those processes and procedures. The plan also recommends actions that other stakeholders can consider to help prevent shortages.

## **4. Final Rule – Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products**

On July 8, 2015, FDA published a final rule to implement certain drug shortages provisions of section 506C, as amended by FDASIA.<sup>4</sup> Among other requirements, the rule requires all applicants of covered approved drug or biological products, including certain applicants of blood or blood components for transfusion, and all manufacturers of covered drug products marketed without an approved application to notify FDA electronically of a permanent discontinuance or an interruption in manufacturing of the product that is likely to lead to a meaningful disruption in supply (or a significant

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<sup>3</sup> To view the Strategic Plan and related information, visit <http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM372566.pdf>.

<sup>4</sup> 21 CFR §§ 310.306, 314.81, 600.82

disruption in supply for blood or blood components) of the product in the United States. The rule became effective on September 8, 2015.<sup>5</sup>

## **DATA SOURCES USED IN THIS REPORT**

The data used to fulfill the reporting requirements of section 506C-1 are collected by several program areas within FDA, sometimes for reasons that are broader than the FDA response to drug shortages. Tracking the data for reporting requirements related to drugs (the number of drugs in shortage) is within the purview of DSS. Similarly, DSS tracks information about notifications and their source (and, therefore, the number of reporting manufacturers). In contrast, reporting requirements related to expedited review are tied to specific *submissions* by manufacturers that are experiencing production disruptions or manufacturers that are adding or expanding their production capabilities to address a specific shortage. CDER offices reviewing these submissions track which reviews and related inspections they expedite as a part of a larger set of activities related to their review of submissions. Other reporting requirements for this report relate to instances of regulatory flexibility and discretion. These specific cases, all requiring separate regulatory and scientific evaluation and justification, are tracked by CDER's Office of Compliance (CDER/OC).

## **ANNUAL REPORT REQUIREMENTS PER 506C-1**

Section 1002 of Title X of FDASIA added section 506C-1 to the FD&C Act, requiring FDA to file a report to Congress on drug shortages at the end of each calendar year.

The statutory requirements for the report are as follows.

***Requirement 1: Specify the number of manufacturers that submitted a notification to the Secretary under section 506C(a) during such calendar year***

For the first three quarters of calendar year 2015, FDA was notified of 131 potential shortage situations by 47 different manufacturers.<sup>6</sup>

***Requirement 2: Describe the communication between FDA field investigators and CDER's Office of Compliance and Drug Shortage Program, including FDA's procedures for enabling and ensuring such communication***

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<sup>5</sup> To view the final rule and related information, visit <https://www.gpo.gov/fdsys/pkg/FR-2015-07-08/pdf/2015-16659.pdf>

<sup>6</sup> As noted above, this report includes data on all products tracked by CDER's Drug Shortage Staff.

CDER/Office of Compliance (OC) and the FDA field investigators in the Office of Regulatory Affairs (ORA) are crucial to FDA's prompt response to a drug shortage. These two groups have separate functions with respect to drug shortages. Consistent with sections 506D(b) and (c) of the FD&C Act, CDER/OC communicates with DSS on warning letter and enforcement action recommendations being reviewed within CDER/OC. FDA field investigators in ORA typically conduct inspections at manufacturing facilities and report on their findings. For example, if the investigators identify actions or activities during an inspection that may have a detrimental impact on product availability, information regarding the observations and the products manufactured can be relayed to CDER immediately so that DSS can begin to assess the supply situation for those products. These procedures are critical to FDA's efforts to prevent and mitigate a potential drug shortage.

To facilitate communications between ORA and CDER/OC, ORA issued Field Management Directive, Product Shortage Communication (FMD #15), in July 2012. FMD #15 established drug shortage coordinators in ORA, and now each FDA field district has a District Drug Shortage Coordinator who serves as the point of contact between ORA and FDA's medical product centers. The District Drug Shortage Coordinator is responsible for notifying the relevant FDA center of any issue that has the potential to lead to a product shortage (e.g., information obtained during an inspection or other field activities). FMD #15 clarified communication roles, responsibilities, and expectations related to potential and current product shortage situations between ORA and the centers.

### ***Requirement 3: List the major actions taken by the Secretary to prevent or mitigate drug shortages***

Mitigation efforts begin once FDA has confirmed that a shortage exists or could occur. The actions FDA can take to prevent or mitigate a shortage include, as appropriate:

- Identify the extent of the shortfall and determine if other manufacturers are willing and able to increase production to make up the gap;
- Expedite FDA inspections and reviews of submissions from manufacturers attempting to restore production;
- Expedite FDA inspections and reviews of submissions from competing manufacturers who are interested in starting new production or increasing existing production of products in shortage;
- Exercise temporary enforcement discretion for new sources of medically necessary drugs;
- Work with the affected manufacturers to ensure adequate investigation into the root cause of the shortage; and
- Develop risk mitigation measures for a batch(es) of product initially not meeting established standards.

FDA can use one or more of these mitigation tools, or seek to develop other options, depending on the severity of the potential shortage and the surrounding circumstances.



When selecting specific tools, FDA continues to work with the manufacturer to tailor its response to the specific situation. As a part of these actions, FDA also frequently communicates available information about a potential shortage or existing shortage to affected stakeholders and monitors the shortage until it has been resolved.

- **List the number of applications and supplements for which the Secretary expedited review under section 506C(g)(1) during such calendar year<sup>7</sup>**

CDER expedited the review of 116 applications in the first three quarters of 2015, as described below:

- CDER's Office of Generic Drugs (OGD) expedited the review of 102 applications, including 62 abbreviated new drug applications and 40 supplemental abbreviated new drug applications.
  - CDER's Office of Pharmaceutical Quality (OPQ) expedited 14 applications: 10 supplemental new drug applications and 4 BLA supplemental applications.
- **List the number of establishment inspections or reinspections related to mitigation or prevention of a shortage that the Secretary expedited under section 506C(g)(2) during such calendar year<sup>8</sup>**

Eleven inspections occurred that were prioritized to address a drug shortage.<sup>9</sup>

#### ***Requirement 4: Describe the coordination between FDA and DEA to prevent or alleviate drug shortages***

If a drug at risk of shortage is a controlled substance, FDA works closely with the DEA in efforts to prevent or mitigate its shortage. Among other issues, DEA is responsible for setting aggregate limits on the amount of each controlled substance that may be manufactured and for allocating to each manufacturer a specific percentage of the aggregate limit (a quota). This tight control over controlled substance products requires FDA and DEA to coordinate when a shortage of a controlled substance is looming. For example, FDA may work with DEA to enable a manufacturer to increase its allotted quota if this step would help avoid a shortage of the product.

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<sup>7</sup> Includes submissions for abbreviated new drug applications, as well as prior approval supplements (PAS) for new drug applications (NDAs). In some cases, changes being effected (CBE) supplements are also included for NDAs, where FDA determined that it was appropriate for a CBE to be submitted for a less significant change instead of as a PAS. FDA's answer to requirement 3 includes data on all products tracked by CDER's Drug Shortage Staff.

<sup>8</sup> Includes prioritized inspections or site reviews for new applications or supplements, which were granted expedited review due to drug shortage.

<sup>9</sup> Note that not all submissions to OGD and OPQ require inspections, but that some submissions can involve multiple sites, which may require inspections.

Recognizing this need, FDASIA included provisions on improved coordination and communication between FDA and DEA regarding a potential shortage of a controlled substance. To help streamline and improve communications, FDA and DEA developed a memorandum of understanding (MOU). The MOU sets forth steps and procedures, including identifying contacts, for efficiently tracking and exchanging relevant information<sup>10</sup>.

***Requirement 5: Identify the number of and describe instances in which FDA exercised regulatory flexibility and discretion to prevent or alleviate a drug shortage***

FDA's standards of safety, efficacy, and quality do not change in a shortage situation. FDA's preferred solution to a shortage is a supply of approved drugs, sufficient to meet patient demand, as well as meet the appropriate quality, safety, and efficacy standards. However, FDA recognizes that there can also be risks to patients if treatment options are not available for critical conditions and understands the importance of using appropriate tools for a given situation to prevent or mitigate a shortage. In appropriate cases, the temporary exercise of regulatory flexibility and discretion has proven to be an important tool in ensuring access to treatment options for patients in critical need.

During the first three quarters of calendar year 2015, FDA has exercised regulatory flexibility and discretion in 19 instances, affecting 37 products.<sup>11</sup> Examples of situations in which FDA has exercised regulatory flexibility and discretion to prevent or mitigate a shortage are listed below:

- FDA has used temporary regulatory flexibility and discretion for medically necessary products that present quality issues through the use of measures to mitigate the risks associated with those products when weighed against the risk to patients of not receiving the drug, as follows:
  - Filters are supplied with a product to remove particulate matter,
  - Extra testing for product quality or identity is done at the manufacturing facility before releasing the product into the marketplace,
  - Third-party oversight of production is instituted to monitor quality issues, and
  - Special instructions are provided to health care professionals/patients.
- FDA has used temporary regulatory flexibility and discretion with regard to continued distribution of a drug product to mitigate or resolve a drug shortage

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<sup>10</sup> The MOU can be found at <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm440091.htm>

<sup>11</sup> One instance of regulatory flexibility may affect more than one product. Conversely, a shortage of one product may involve multiple instances of regulatory flexibility.

while FDA reviews a supplement/proposed change to address a problem with the drug product.

- FDA has used temporary regulatory flexibility and discretion with regard to new sources of medically necessary drugs, including FDA-registered foreign sources, in rare instances when all alternative approaches have been exhausted.

***Requirement 6: List the names of manufacturers issued letters under section 506C(f)***

Under section 506C(f) of the FD&C Act, if a manufacturer fails to provide notification of a discontinuance or interruption in manufacturing as required by section 506C, FDA must issue a letter to that manufacturer stating that the notification requirement was not met. The manufacturer is required to respond to FDA's letter within 30 calendar days, providing the reason for noncompliance and the required information on the discontinuance or interruption. Within 45 calendar days of its original letter to the manufacturer, FDA is required to post that letter and any response received on FDA's website,<sup>12</sup> with appropriate redactions to protect trade secrets or confidential commercial information, unless FDA determines that the original notification was issued in error or, after review of the manufacturer's response, that the manufacturer had a reasonable basis for not notifying FDA as required.

To date, FDA has issued two non-compliance letters under section 506C(f). The first letter was sent on May 22, 2014, to Bristol-Myers Squibb Company and Corden Pharma Latina S.p.A, and the second letter was sent on August 26, 2014, to Mylan Institutional LLC and Agila Specialties Private Limited. The letters sent by FDA and the responses received from the manufacturers are available on FDA's website. During the first three quarters of 2015, no non-compliance letters have been sent.

***Requirement 7: Specify the number of drug shortages occurring during 2015 (the first three quarters of 2015)***

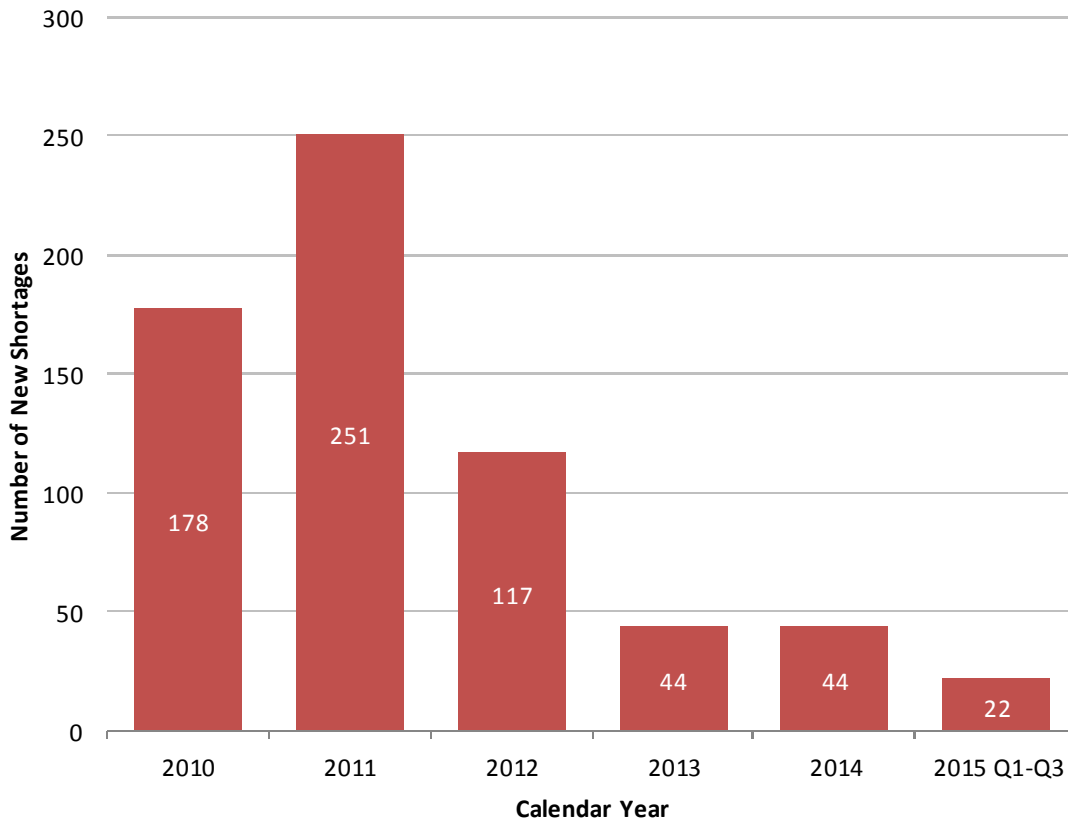
Analysis of the data from CDER's drug shortage database<sup>13</sup> shows that the number of new shortages significantly decreased, from 117 in 2012 to 44 in 2013, and 44 in 2014. Data indicate that this trend is continuing into 2015. As of September 30, 2015, 22 new drug shortages have been identified. The following graph shows the number of new drug shortages identified by year from 2010 through September 30, 2015.

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<sup>12</sup> Links to letters of Non-Compliance With Notification Requirement can be found at <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm403902.htm>.

<sup>13</sup> CDER's drug shortage statistics can be found at <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm>.

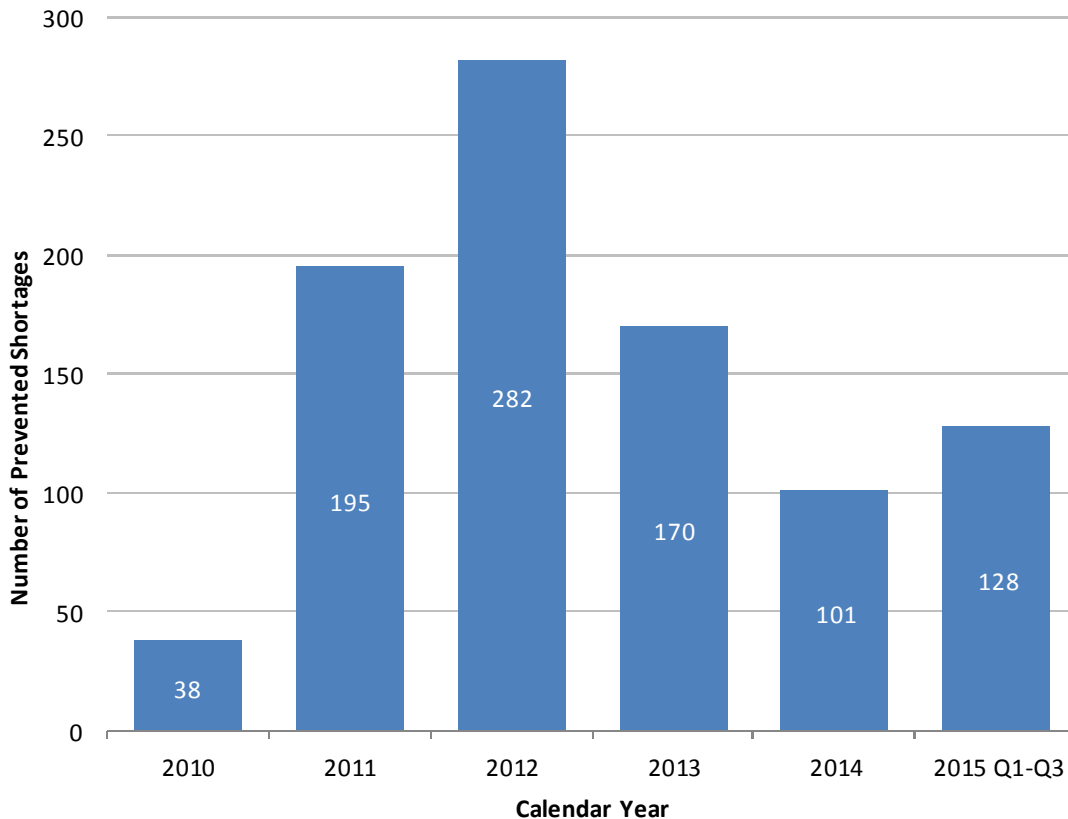
Figure 1. Number of New Drug Shortages Per Year, 2010 Through September 30, 2015



Source: FDA, Drug Shortage Staff

This graph illustrates the results of the work FDA and its partners are doing to prevent drug shortages. For example, in the first three quarters of 2015, we have prevented 128 shortages. The next graph shows the number of prevented drug shortages identified by year from 2010 through September 30, 2015.

**Figure 2. Number of Prevented Drug Shortages Per Year, 2010 Through September 30, 2015**



Source: FDA, Drug Shortage Staff

Another important piece of data is the number of ongoing or persistent shortages yet to be resolved from previous years. FDA identified 97 ongoing shortages at the end of calendar year (CY) 2013, and 74 ongoing shortages at the end of CY 2014. As of September 30, 2015, there were 48 ongoing shortages.

## **HIGHLIGHTS OF FDA WORK IN 2015 ON DRUG SHORTAGES**

### **1. Drug Shortage Data System**

FDA continues to improve its system for data tracking and analysis for drug shortages and last year put into place a system called the Drug Shortage Data System (DSDS). This system was responsive to the Government Accountability Office (GAO) report on drug shortages,<sup>14</sup> which made recommendations to further enhance the tracking of drug shortage data. The primary function of the DSDS is to streamline day-to-day work to identify and mitigate shortages, including research, data entry, and data management for

<sup>14</sup> GAO's report can be found at <http://www.gao.gov/assets/670/660785.pdf>.

DSS. DSDS is not designed to predict whether a manufacturer or product is at risk of shortage.

Ongoing work is focused on integrating DSDS with other CDER data systems, such as the FDA Drug Shortage website database, the Document Archiving, Reporting, and Regulatory Tracking System, Panorama, and the Compliance Management System. While this work is being done, certain processes, such as receiving notifications under section 506C of the FD&C Act and updating the FDA Drug Shortage website, still require manual input spanning multiple platforms. A longer-term goal for DSS is to integrate DSDS into a new system that is currently under development, called Shortage Tracker, which interfaces with other CDER data systems to improve its drug shortage tracking and reporting capabilities.

## **2. FDA Public Communications Regarding Drug Shortages**

In March 2015, FDA launched its first mobile application (app) that provided the public with easier and faster access to important information about drug shortages. The free mobile app is an innovative tool designed to identify current drug shortages, resolved shortages, and the discontinuations of drug products. The app provides health care professionals and pharmacists with real-time information about drug shortages to help them make treatment decisions. Users of this app can search or browse by a drug's brand name, generic name or active ingredient, and also by therapeutic category. The app can also be used to report a suspected drug shortage or supply issue to FDA. The mobile app was further enhanced in August for Android devices. Android device users are able to receive notifications when there is new or updated information about a shortage of a drug product or about a drug within selected therapeutic categories. As of September 30, 2015, there have been almost 22,000 installs of the Drug Shortage App.

This year DSS partnered with CDER/OC to publish a blog<sup>15</sup> about the Unapproved Drugs Initiative and how CDER/OC works closely with DSS to ensure that the Initiative does not lead to an increase in drug shortages. Prescribers and their patients may sometimes think there is a shortage of product because once the manufacturer can produce an approved drug in sufficient quantities to meet market demand, the unapproved versions transition out of the market. To help allay such concerns, CDER/OC works closely with DSS to share information about the availability of the newly-approved product from the manufacturer, information that is then conveyed to patients and providers.

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<sup>15</sup> FDAVoice Blog, "Reducing the number of unapproved drugs while working to prevent drug shortages: a job that calls for strong collaboration in FDA" can be found at <http://blogs.fda.gov/fdavoiced/index.php/2015/04/reducing-the-number-of-unapproved-drugs-while-working-to-prevent-drug-shortages-a-job-that-calls-for-strong-collaboration-in-fda/>

DSS also partnered with American Society of Health-System Pharmacists to publish a joint piece that was featured on the Health Affairs Blog,<sup>16</sup> to clarify any misconceptions on how each partner defines a drug shortage.

The FDA Drug Shortage website enhancements provide a searchable database for stakeholders to obtain easy access to information about drugs in shortage, such as product availability, supply, and anticipated duration of shortage. This website remains a valuable resource to the public, with over 3.2 million page views during the first three quarters of 2015.

Further outreach during the first three quarters of 2015 included eight presentations given to professional and patient advocacy organizations, industry and trade associations, as well as stakeholder groups. Additionally, the peritoneal dialysis solution shortage prompted FDA to publish an article in the Clinical Journal of the American Society of Nephrology.<sup>17</sup>

### **3. FDA Internal Communications Regarding Drug Shortages**

In addition to efforts to continue to improve communication among DSS, CDER/OC, and ORA, new policies and procedures are being implemented regarding communications involving the newly created Office of Pharmaceutical Quality (OPQ) within CDER. The establishment of OPQ creates a single unit dedicated to product quality by improving FDA's oversight of quality throughout the lifecycle of a drug product. DSS has important and frequent interactions with OPQ and works closely with OPQ on shortage mitigation and prevention efforts.

## **CONCLUSION**

Drug shortages remain a significant public health issue in the United States and a top priority for FDA. To address them, FDA works with manufacturers to help prevent shortages from occurring and to mitigate the impact of shortages that cannot be prevented. Early and open dialogue between FDA and manufacturers is critical to our success. Because of important actions taken by the President and Congress, FDA has been able to learn of possible shortages before they occur and take steps to prevent or mitigate them. During the first three quarters of 2015, CDER helped prevent 128 potential new shortages. As a result of the Agency's work in preventing shortages, as

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<sup>16</sup> Health Affairs Blog, "Are Shortages Going Down Or Not? Interpreting Data From The FDA And The University Of Utah Drug Information Service" can be found at <http://healthaffairs.org/blog/2015/04/08/are-shortages-going-down-or-not-interpreting-data-from-the-fda-and-the-university-of-utah-drug-information-service/>

<sup>17</sup> Clinical Journal of the American Society of Nephrology: Jensen, Valerie E., and Throckmorton, Douglas C "Shortage of Peritoneal Dialysis Solution and the Food and Drug Administration's Response." CJASN August 07, 2015 vol. 10 no. 8 1484-1486

well as efforts by industry and other partners, there were 22 new shortages for the first three quarters of 2015, which is 11 fewer new shortages than in the same period in 2014. This report reflects FDA's commitment to continue our work to prevent or mitigate drug shortages. While important progress has been made in preventing drug shortages from occurring, and decreases have been seen in the total numbers of shortages, FDA continues to work to ensure that patients in the United States will have access to the medicines they need.



## KEY DEFINITIONS USED IN THIS REPORT

**Drug Shortage:** A *drug shortage* or *shortage*, with respect to a drug, means a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug.

**Meaningful Disruption:** A *meaningful disruption* is a change in production that is reasonably likely to lead to a reduction in the supply of a drug by a manufacturer that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product. A meaningful disruption is not an interruption in manufacturing due to matters such as routine maintenance and does not include insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

**Life Supporting or Life Sustaining:** *Life supporting* or *life sustaining* is used to describe a drug product that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

## APPENDIX

### SEC. 506C–1. ANNUAL REPORTING ON DRUG SHORTAGES.

(a) ANNUAL REPORTS TO CONGRESS.—Not later than the end of calendar year 2013, and not later than the end of each calendar year thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on drug shortages that—

(1) specifies the number of manufacturers that submitted a notification to the Secretary under section 506C(a) during such calendar year;

(2) describes the communication between the field investigators of the Food and Drug Administration and the staff of the Center for Drug Evaluation and Research’s Office of Compliance and Drug Shortage Program, including the Food and Drug Administration’s procedures for enabling and ensuring such communication;

(3) (A) lists the major actions taken by the Secretary to prevent or mitigate the drug shortages described in paragraph (7);

(B) in the list under subparagraph (A), includes—

(i) the number of applications and supplements for which the Secretary expedited review under section 506C(g)(1) during such calendar year; and

(ii) the number of establishment inspections or reinspections that the Secretary expedited under section 506C(g)(2) during such calendar year;

(4) describes the coordination between the Food and Drug Administration and the Drug Enforcement Administration on efforts to prevent or alleviate drug shortages;

(5) identifies the number of and describes the instances in which the Food and Drug Administration exercised regulatory flexibility and discretion to prevent or alleviate a drug shortage;

(6) lists the names of manufacturers that were issued letters under section 506C(f); and

(7) specifies the number of drug shortages occurring during such calendar year, as identified by the Secretary.