

THIRD QUARTER 2013

ExpertRECALL

QUARTERLY RECALL INDEX

Recall Index – Third Quarter 2013

Stericycle ExpertRECALL™ helps our partners minimize risk to the public and to their company brand by executing and planning for product recalls efficiently, effectively, and compliantly. Each quarter, we analyze cumulative recall data across five product categories to help our partners stay abreast of the latest trends in product recalls and the regulatory environment.

Our clients include some of the world's leading pharmaceutical, medical device, consumer goods, juvenile product, and food and beverage companies that have relied on us to manage more than 3,000 recalls from the largest withdrawal in U.S. history to smaller consumer product and medical device recalls.

ExpertRECALL service offerings include the following:

- » **Consulting**
- » **Affected Party Identification**
- » **Notification/Communication**
- » **Response, Product Processing**
- » **Remedy Management**
- » **Resolution Management**
- » **Retrieval**
- » **Technology**

Overview

The ExpertRECALL Index tracks recall activity and trends in five product categories: food, consumer products, children's and infant products, medical devices, and pharmaceuticals. Highlights of recall activity in the third quarter of 2013 include:

7
million

7 million units of food products were recalled by the FDA in the third quarter, more than double the previous quarter.

86
percent

86 percent of USDA recalls were classified as Class I recalls, the USDA's most serious classification, representing the highest percentage in seven quarters.

2,676
incidents

2,676 product safety incidents were attributed to consumer products recalled in the third quarter, nearly three times the number of incidents in the previous quarter.

63
injuries

63 injuries were attributed to children's and infant products recalled in the third quarter, up from zero injuries in the previous quarter.

171
companies

Of the 171 medical devices that faced recalls in the third quarter, two recall events comprised nearly half of all recalled units in the third quarter.

60
percent

More than 60 percent of pharmaceutical recalled units were attributed to just three companies in the third quarter.

Recall Index – Third Quarter 2013

How the ExpertRECALL Index is Compiled

The ExpertRECALL Index gathers and tracks cumulative data from the three primary federal agencies that oversee recalls in the United States: the Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA), and the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA). Recall trends are calculated from FDA enforcement reports and news releases published on agency websites.

FDA Data

To track trends in food, pharmaceutical, and medical device recalls, the ExpertRECALL Index uses information publicly available in news releases posted on the FDA website. For additional insight into recalls governed by the FDA, ExpertRECALL collects and analyzes data from the agency's weekly enforcement reports, which provide additional details including recall class, quantity of units affected and number of reported incidents.

CPSC Data

For further insight into consumer product recall trends, ExpertRECALL analyzes data from CPSC recall announcements. When compiling statistics and analyzing trends for consumer product recalls, the ExpertRECALL Index uses standard product categories and hazards recognized by the CPSC.

USDA Data

For additional insight into food recall trends involving meat, poultry, and egg products, the ExpertRECALL Index collects and analyzes data from recall announcements posted on the USDA's FSIS website. Statistics and trends are compiled using standard product categories, classifications, and reasons for recalls as recognized by the USDA.

Terminology

Announced recalls represent those recalls documented in news releases published on agency websites. Enforced recalls refer to those recalls documented in weekly FDA enforcement reports. Their documentation can lag behind announced recalls by weeks or even months because the recall process may take time to complete.

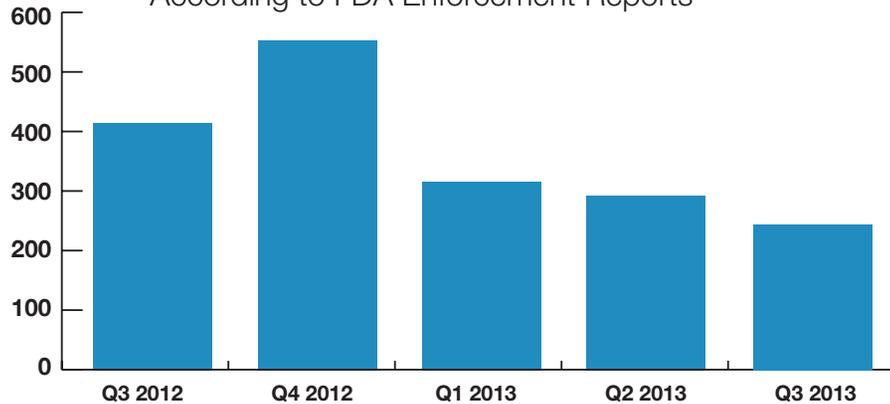
A Class I recall, according to the FDA, is a situation in which there is a reasonable probability that the product will cause serious adverse health consequences or death. A Class II recall is a situation in which the product could cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. The FDA defines a Class III recall as a situation in which the product is not likely to cause adverse health consequences.

Trend Report

This quarter marked a significant increase in the volume of international recalls. Thirty-three percent of all FDA-regulated recalls tracked by the index affected the U.S. and at least one other country, a ten percent increase from the previous quarter. With this growth in mind, companies must take proactive measures to understand the nuances of regulations in all countries where their products are distributed and be prepared to handle the challenge of multi-country recall events.

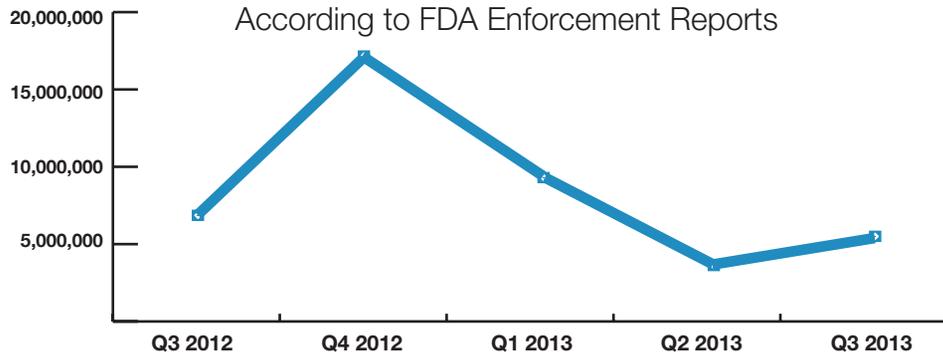
Food Recalls by Quarter

According to FDA Enforcement Reports



Pounds of Food Recalled by Quarter

According to FDA Enforcement Reports



Regulatory Update:

This August, the FDA issued a final rule defining “gluten-free” for food labeling that mandates items labeled “gluten-free” meet a defined standard.¹ Undeclared allergens, such as gluten, continued to be a primary concern for food manufacturers during the third quarter. As the FDA approves new regulations relating to allergen labeling, food manufacturers must remain ever vigilant in adhering to these more rigorous standards. Manufacturers that fail to closely monitor and abide by these new regulations as well as modify their labels may confront a recall event.

¹<http://www.prweb.com/releases/2013/8/prweb11066216.htm>

Recall Index – Third Quarter 2013

Food Recalls

FDA Enforcement Reports documented 252 food recalls in the third quarter of 2013, representing a 14 percent decline over the previous quarter. Recalls in the third quarter affected approximately seven million units, twice as much compared to the previous quarter. According to FDA documentation, one recall affected 2.5 million units, three recalls affected between 500,000 and one million units, and eight recalls affected between 100,000 and 500,000 units. The remaining recalls affected fewer than 100,000 units.

Of the recalls documented in FDA Enforcement Reports during the third quarter, 44 percent were classified as Class I recalls, 47 percent were categorized as Class II recalls and nine percent as Class III.

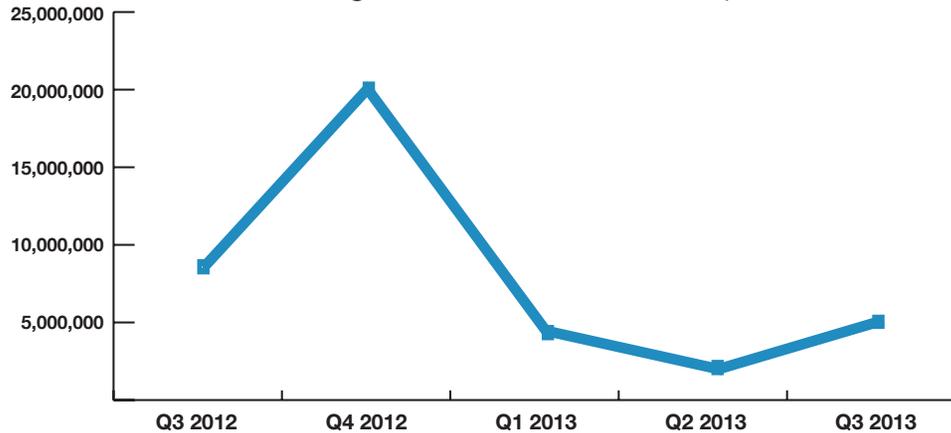
Recalls documented in the third quarter were initiated by 136 companies. Of these companies, 40 faced more than one recall. One company faced 24 recalls this quarter, followed by three other companies that faced more than 10 recalls.

Of the recalls documented by the FDA in the third quarter, 30 recalls affected customers nationwide. In this same period, 19 recalls affected customers in the U.S. and at least one other country or U.S. territory.

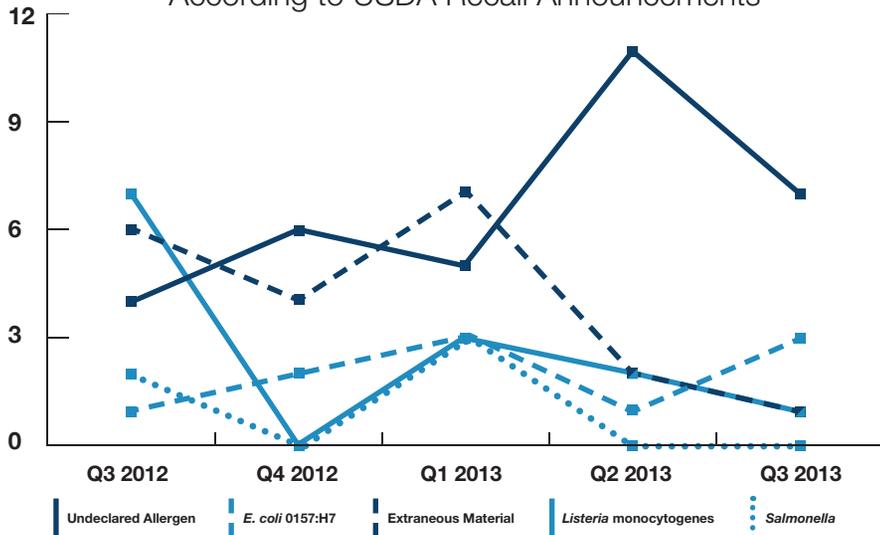
The ExpertRECALL Index also analyzed third quarter FDA recall announcements, which revealed the following:

- Allergens were the single largest cause of food recalls, representing approximately 40 percent of recalls reported in the third quarter. Note that allergen recalls can be a result of contamination or labeling issues. Allergens have been the first or second largest cause of food recalls in the past seven quarters.
- In the third quarter, more than 90 percent of recalls and recalled units were classified by the FDA as either Class I or Class II recalls. Further, the volume of Class I and II units recalled during this period increased by more than 95 percent. This increase was due in large part to two separate recalls by the same company because of Salmonella contamination.
- Foodborne illness remains a top concern, as Salmonella, Listeria and Botulism accounted for more than 40 percent of recalls reported during the third quarter.
- The number of third quarter Class I recalls increased more than eight percent from the previous quarter. Additionally, the number of companies involved in FDA food recalls increased by 17 percent from the previous quarter.
- Only four companies in the third quarter had more than ten recalls. Yet, one company's 24 recalls accounted for more than nine percent of all food recalls.
- The total number of recalled units more than doubled during the third quarter to seven million units despite a small (14 percent) drop in the total number of recalls. Companies that faced a recall event recalled a much higher volume of products – on average, an increase of almost 16,000 more units per recall. Food manufacturers must recognize the growing impact and expenses associated with a single recall and actively prepare for such situations.

Pounds of Food Recalled by Quarter
According to USDA Enforcement Reports



Leading Causes of Food Recalls
According to USDA Recall Announcements



There were 14 recalls of meat, poultry or processed egg products in the third quarter according to USDA reports. Third quarter recalls impacted 519,465 lbs. of product, which is up more than 105 percent from the previous quarter with 250,829 lbs. of product.

Twelve recalls were documented as Class I recalls, two were classified as Class II and none were designated as Class III recalls. Two companies faced multiple recalls this quarter.

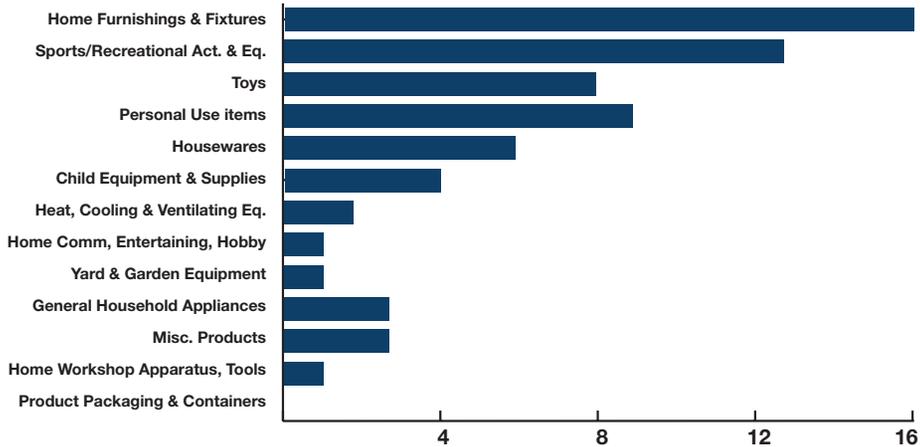
The ExpertRECALL Index analysis also revealed the following:

- The number of pounds of food recalled during the third quarter increased by more than 105 percent from the second quarter, marking the largest amount of food recalled in the last three quarters.
- More than 85 percent of USDA recalls in the third quarter were classified as Class I recalls, representing the highest proportion in seven quarters. Additionally, 83 percent of recalled food by weight was assigned a Class I designation.
- Two companies had more than one recall this quarter, compared to not a single company the previous quarter.
- Undeclared allergens continued from last quarter to be the single largest cause of recalls this quarter with seven recalls, followed by three recalls due to *E. coli*.
- The top two recalls made up more than 55 percent of the total amount of food recalled by weight.
- There were three less recalls since the previous quarter, resulting in the lowest number of recalls in the last seven quarters.

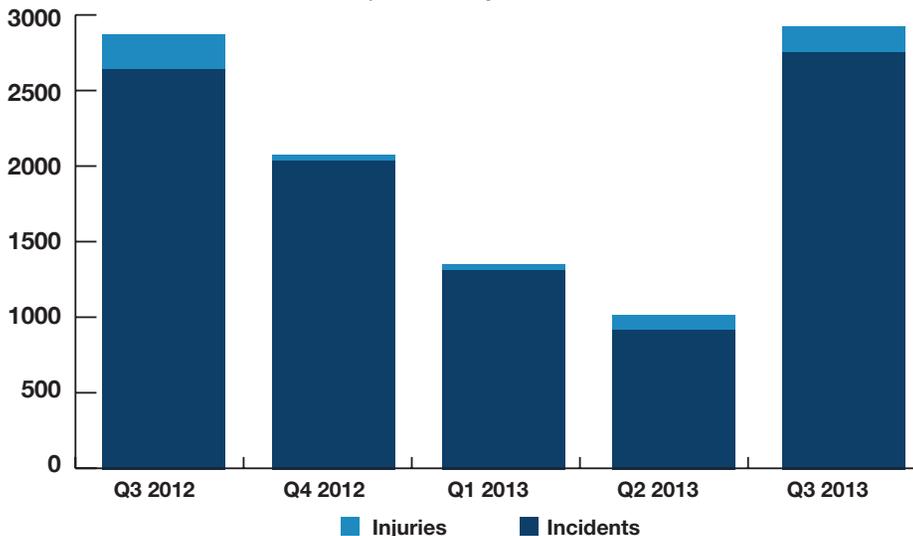
Trend Report

This quarter marked the fourth consecutive increase in the proportion of total USDA recalls categorized as Class I, the organization's most severe classification. Since the fourth quarter of 2012, the total number of USDA recalls classified as Class I has increased by between 6.5 and 15 percent each quarter.

CPSC Recalls by Product Category



Injuries and Incidents As reported by the CPSC



Recall Index – Third Quarter 2013

Consumer Product Recalls

Consumer product recalls initiated at the request of the CPSC decreased to 67 recalls during the third quarter of 2013, down from 71 recalls in the previous quarter. The number of affected units also decreased by approximately five percent compared to the second quarter.

There were more CPSC recalls than the previous quarter for home furnishings and fixtures, general household appliances, and miscellaneous products.

All other categories, including sports and recreational activity and equipment, personal use items, toys, housewares, child equipment and supplies, heat, cooling and ventilating equipment, home communication, entertainment and hobby, yard and garden equipment, home workshop apparatus, tools, and product packaging and containers were either flat or saw minor declines.

The ExpertRECALL Index analysis also revealed the following:

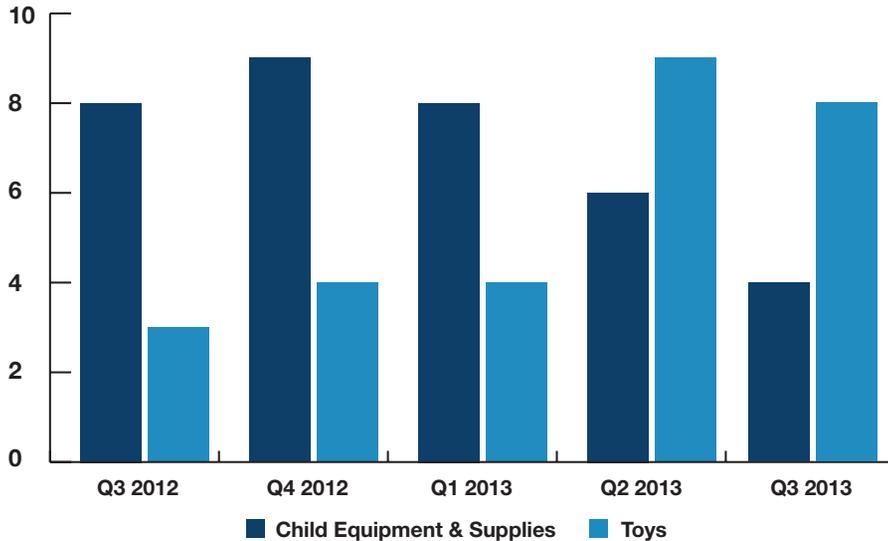
- Products recalled in the third quarter were responsible for 2,676 product safety incidents, nearly three times the 917 incidents in the second quarter of 2013. Of the reported incidents, 197 resulted in injury, an increase from 109 incidents during the previous quarter.
- The total number of recalls this quarter decreased by six percent from the previous quarter. The total number of units affected in the third quarter decreased five percent.
- Home furnishings and fixtures and sports and recreational activities and equipment, remained the top two product categories with the most recalls in the third quarter. This trend has continued through the past three quarters.
- The largest cause of recalls in this category was the presence of a fire hazard, which when combined with a laceration threat, accounted for over 35 percent of all recalls.

Best Practice

Five companies announced more than one consumer product recall, a significant increase from only one company last quarter. One improperly handled recall can be damaging to a company's brand. More than one can be disastrous. Companies that have undergone a recent recall should channel their experience into preventative strategies to preempt a recall and reactive strategies to best respond to a future recall.

Children's and Infant Product Recalls

Infant and Children's Product Recalls



There were 12 CPSC recalls of children's and infant products in the third quarter of 2013, a decrease of three recalls from the previous quarter. Recalls of child nursery equipment and supplies decreased by two from the previous quarter, compared to toy recalls, which decreased by one. Recall volume of children's and infant products decreased in the third quarter from 3,223,949 units last quarter to 615,800 units this quarter.

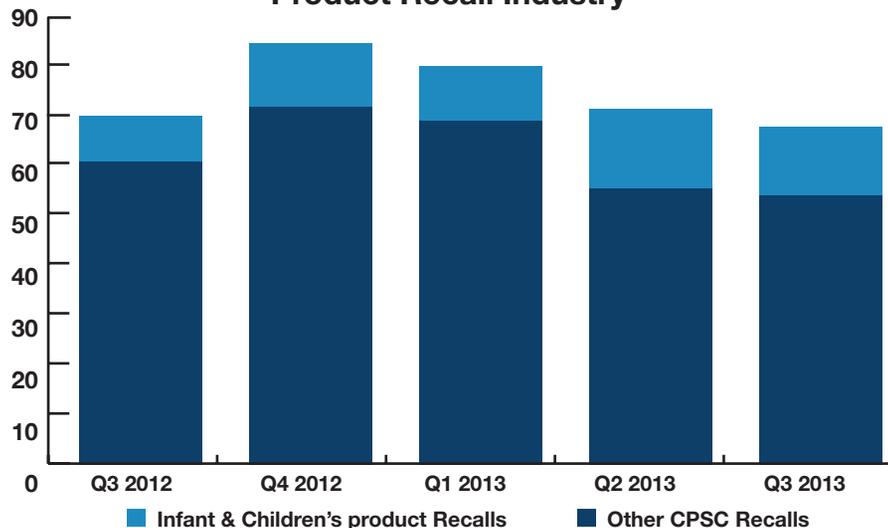
Of the 15 product categories recognized by the CSPC, child nursery equipment and toys accounted for approximately 18 percent of the total recalls and more than ten percent of the units affected.

The two primary causes of children's and infant product recalls were ingestion and choking, which each led to three recalls. The risk that a child could fall out of the product was documented as the primary hazard for two recalls. The risk of drowning, fire, impact, laceration and burns each led to one recall in the third quarter.

The ExpertRECALL Index analysis also revealed the following:

- The total retail value of all recalled units in the third quarter was over \$41 million, which is a 15 percent increase from last quarter. Further, the average price of a single unit recalled in the third quarter was approximately \$67, more than six times the average price of a unit recalled in the second quarter.
- Children's and infant recalled products were responsible for 159 product safety incidents in the third quarter, a 55 percent increase from the previous quarter.

Children's Product Recalls Within the Consumer Product Recall Industry



Best Practice

This quarter marked the highest number of reported incidents and injuries associated with the use of recalled children's and infant products in the past five quarters. During this period, recalled children's and infant products were responsible for 63 injuries, which is an increase of 18 percent from last quarter. Even more shocking, a single recalled product this quarter was responsible for over 96 percent of these reported injuries. Through mining data such as customer reviews, social media conversation, and product usage reports, companies can proactively identify a situation that may warrant a recall and potentially avoid such a significant number of injuries.

Recall Index – Third Quarter 2013

Medical Device Recalls

FDA Enforcement Reports documented 415 medical device recalls in the third quarter of 2013, an increase of one percent from the previous quarter.

There were approximately 29 million units recalled in the third quarter, a dramatic increase of 215 percent from the previous quarter, resulting in the highest level of units affected in five quarters. Two recalls affected more than three million units, 13 recalls affected between 500,000 and one million units, and 400 recalls affected less than 500,000 units.

Recalls were issued by 171 companies in the third quarter. Of these companies, 36 percent issued more than one recall. One company announced 23 recalls, and nine companies announced 10 or more recalls each.

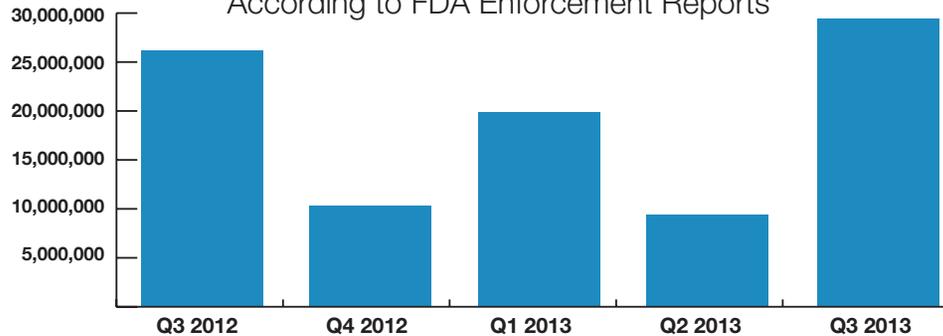
Medical device recalls documented during the third quarter of 2013 affected both domestic and international customers. The majority of recalls (300) impacted customers nationwide. There were also 236 recalls that affected customers in the United States and at least one other country or territory.

The ExpertRECALL Index analysis also revealed the following:

- The number of Class I units recalled increased by more than 485 percent during the third quarter. The number of Class II units recalled increased over 50% during the third quarter as well.
- 90 percent of recalls were classified as Class II, an eight percent increase from the previous quarter.
- Despite only a slight increase in the number of recalls this quarter, the number of total units recalled increased by 215 percent from last quarter. This figure represents the highest number of units recalled in the last five quarters.
- Approximately 36 percent of companies that engaged in a recall faced more than one, a trend that has continued from previous quarters.
- The number of international medical device recalls rose from last quarter by more than 19 percent, reaching 57 percent this quarter.
- One company faced 23 recall events in the third quarter, which marked a 35 percent increase from the highest number of recall events faced by one company last quarter.

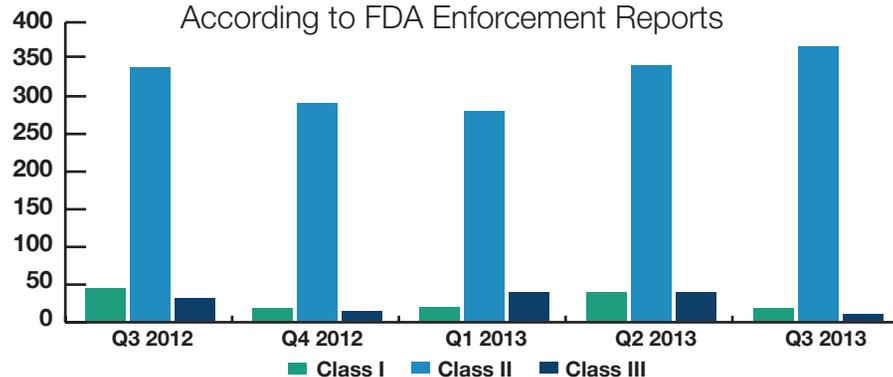
Medical Device Units Recalled

According to FDA Enforcement Reports



Medical Device Recalls by Class

According to FDA Enforcement Reports



Trend Report

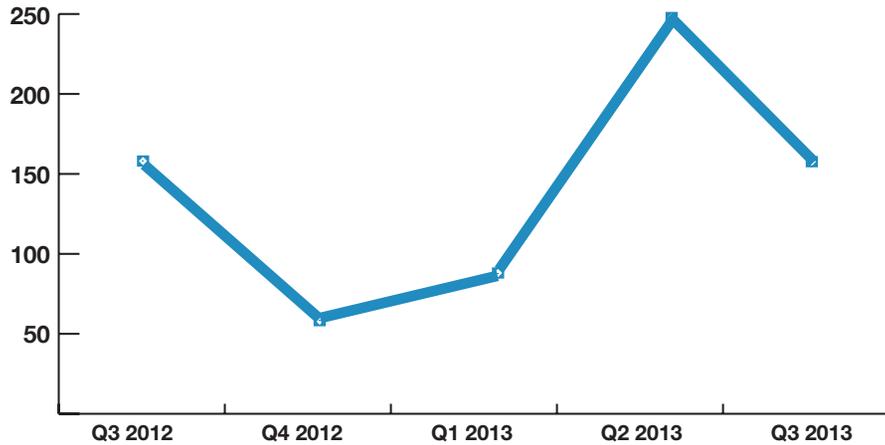
This quarter saw the highest volume of recalled units in five quarters. Two recalls combined resulted in almost half of all units recalled in the third quarter. In September, the FDA released a final rule requiring medical devices to include a unique device identifier (UDI).² According to the FDA, the UDI system is aimed at improving the quality of information in medical device adverse event reports, which in turn will result in identifying product problems more quickly, enhance recall scale and targeting, and improve patient safety. As medical device manufacturers adapt operations to comply with the UDI system, so too must they reevaluate their recall plans as more discrete data on specific usage and potential safety issues becomes available.

²<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm369276.htm>

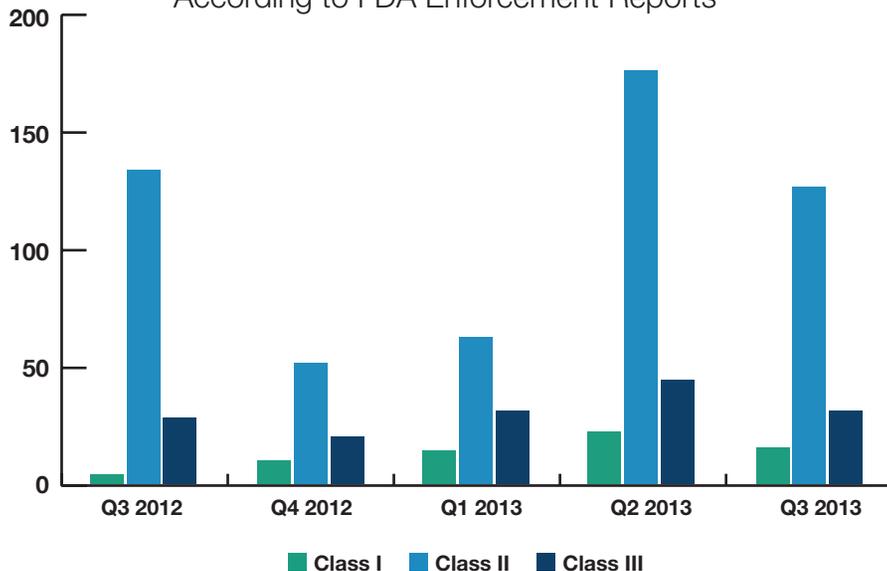
Recall Index – Third Quarter 2013

Pharmaceutical Recalls

Pharmaceutical Recalls
According to FDA Enforcement Reports



Pharmaceutical Recalls by Class
According to FDA Enforcement Reports



FDA Enforcement Reports in the third quarter of 2013 documented 171 drug and pharmaceutical recalls, a decrease of 29 percent from the previous quarter.

Units affected by recalls increased in the third quarter, affecting 27,495,299 units, compared with 17,354,390 units in the second quarter. According to FDA Enforcement Reports, five recalls affected more than one million; five recalls affected between 500,000 and one million units; and 161 recalls affected fewer than 500,000 units.

Sixteen recalls were documented as Class I recalls, 124 were documented as Class II, and 31 were Class III.

Pharmaceutical recalls in the third quarter affected domestic and international customers. Of recalls documented in the third quarter, 125 recalls affected customers nationwide, and 20 recalls affected customers in the United States and at least one other country or territory.

The ExpertRECALL Index analysis also revealed the following:

- A few recall events drove a significant volume of the total number of recalled units this quarter. In fact, one pharmaceutical manufacturer recalled more than eight million units, which represents almost 30 percent of total units recalled.
- Total recalled units increased by 58 percent, representing the highest number of recalled units in five quarters. Most notably, three companies drove more than 60 percent of all recalled units in the third quarter.
- 73 percent of all recalls this quarter were nationwide, which is a 24 percent increase from the previous quarter.
- In the third quarter, 20 recalls affected the international community, representing a significant increase from last quarter when only nine recalls affected the U.S. and one other country.
- 74 companies recalled products in the third quarter, as compared to only 62 companies last quarter.

Regulatory Update

The number of units recalled in the third quarter was the second highest volume of total units recalled in the past six quarters. As the U.S. Congress continues its discussion on the proposed **Pharmaceutical Quality, Security, and Accountability Act**, which would establish a uniform national prescription drug-tracing framework, pharmaceutical manufacturers must diligently adapt their practices and procedures to adjust to the evolving regulations.³ This includes anticipating and preparing for a recall situation.

³<http://www.usatoday.com/story/news/nation/2013/08/11/texas-compounding-pharmacy-recall/2641009>