

FIRST QUARTER 2013

# ExpertRECALL

QUARTERLY RECALL INDEX



## Recall Index – First Quarter 2013

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, who 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.

### What's New

**For the first time, this report adds a new dimension to our Food Recalls reporting by including data from the U.S. Department of Agriculture (USDA).**



## Overview

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

**75**  
percent

Nearly 75 percent of FDA-reported food recalls in the first quarter were issued by companies facing more than one recall

**28**  
percent

28 percent of recalls requested by the USDA were the result of potential extraneous materials, a trend that continues to rise

**26**  
recalls

26 recalls of sports/recreational activity & equipment products occurred in the first quarter, reaching an 11-quarter high

**50**  
percent

50 percent of children's and infant recalls involved product safety incidents in the first quarter

**40**  
percent

40 percent of medical device companies named in FDA Enforcement Reports faced more than one recall in the first quarter.

**107**  
recalls

107 recalls of drug and pharmaceutical products were documented in the first quarter, an increase from both the previous quarter and year-over-year

## Recall Index – First 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, Stericycle 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, Stericycle ExpertRECALL analyzes information 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

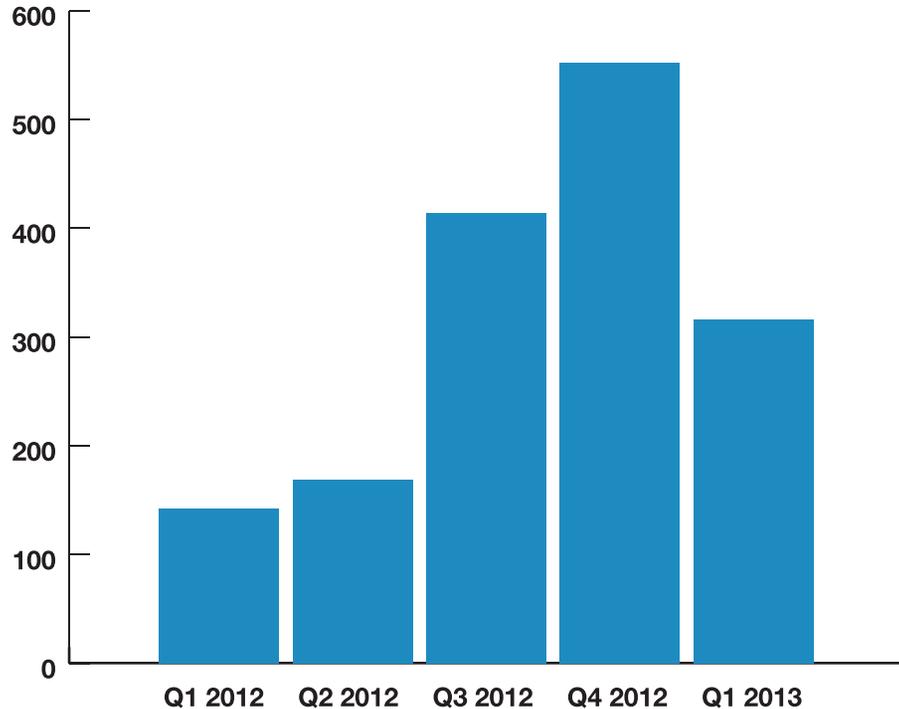
For additional insight into food recall trends involving meat, poultry, and egg products, the ExpertRECALL Index collects and analyzes data from recall announcements posted on the USDA's FSIS website. Statistics and trends are compiled using standard product categories, classifications and reasons for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

#### Terminology

Announced recalls represent events documented in news releases published on agency websites. Enforced recalls refer to events 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.

**Food Recalls by Quarter**  
According to FDA Enforcement Reports



### Brand Alert

Although recalls due to allergens are relatively consistent quarter-over-quarter, studies showing increased allergies in children mean ever increasing scrutiny on brands.

# Recall Index – First Quarter 2013

## Food Recalls

FDA Enforcement Reports documented 316 food recalls in the first quarter of 2013, representing a 43 percent decline over the previous quarter and returning to the average of the previous four quarters. First quarter recalls affected about 9.7 million units, nearly half of the about 18.4 million units affected in the previous quarter. According to FDA documentation, one recall affected between 1 million and 5 million units and two recalls affected between 500,000 and one million units. The remaining recalls affected less than 500,000 units, with 289 affecting less than 100,000 units.

Of recalls documented in FDA Enforcement Reports during the first quarter, 36 percent were classified as Class I events, 55 percent were categorized as Class II recalls, and 9 percent as Class III. For the first time in a year, there were fewer Class I events, which present the most risk to consumers, than Class II events. Class II recalls were also responsible for 85 percent of all units recalled in the first quarter.

Recalls documented in the first quarter were initiated by 133 companies. Of these companies, 49 faced more than one recall. One company faced 51 events this quarter, followed by another company with 12 recalls, another with nine recalls and two companies that each issued eight recalls.

Of the recalls documented by the FDA in the first quarter, the majority (208) affected customers in specific U.S. states. There were 38 recalls that affected customers nationwide, as well as 61 that affected customers in the U.S. and at least one other country or U.S. territory. There was also one recall which was limited to international customers and eight which impacted Puerto Rico customers alone.

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

- Allergens were the single largest cause of food recalls, composing approximately 34 percent of recalls initiated in the first quarter. Note that allergen recalls can be a result of contamination or labeling issues. On average, allergens have been the first or second largest cause of food recalls in the past five quarters.
- Foodborne illness remains a top concern, as Salmonella, Listeria and E. coli accounted for nearly one in every four recalls initiated during the first quarter. However this is down from 65 percent in the fourth quarter of 2012.
- Foreign material in food products caused 13 recalls, which is significantly higher than the average of two recalls per quarter (due to foreign materials) from the previous ten quarters.
- Three out of every four recalls in the first quarter were issued by companies facing more than one recall.

# Recall Index – First Quarter 2013

## USDA

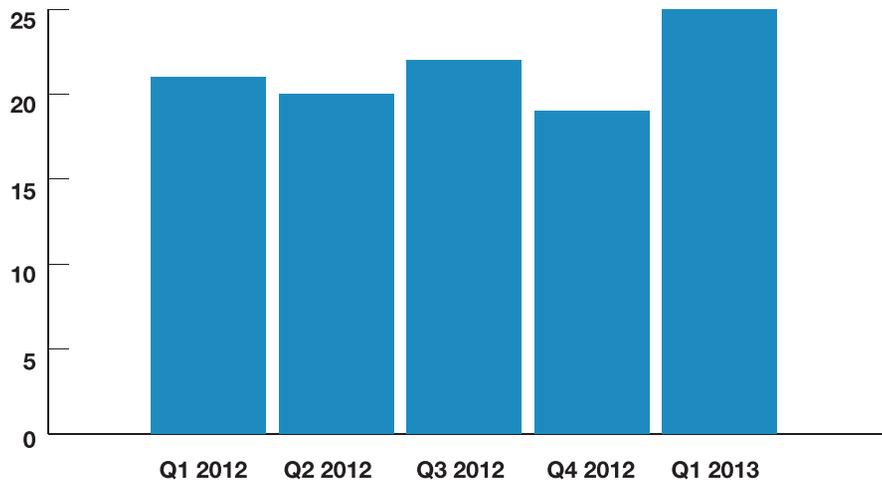
There were 25 recalls of meat, poultry, or processed egg products in the first quarter according to USDA reports. For comparison, this is slightly above the average number of events per quarter in 2012. First quarter recalls impacted 450,415 lbs. of product, which is up year-over-year compared to the first quarter of 2012 but down slightly from last quarter, when one Class III event impacted 1,768,600 lbs. of product.

Sixteen recalls were documented as Class I recalls, 7 were classified as Class II and two were designated as Class III events. A single Class I recall affected nearly 200,000 lbs. of product, which was significantly higher than 43,000 lbs., the average amount of product per recall in 2012.

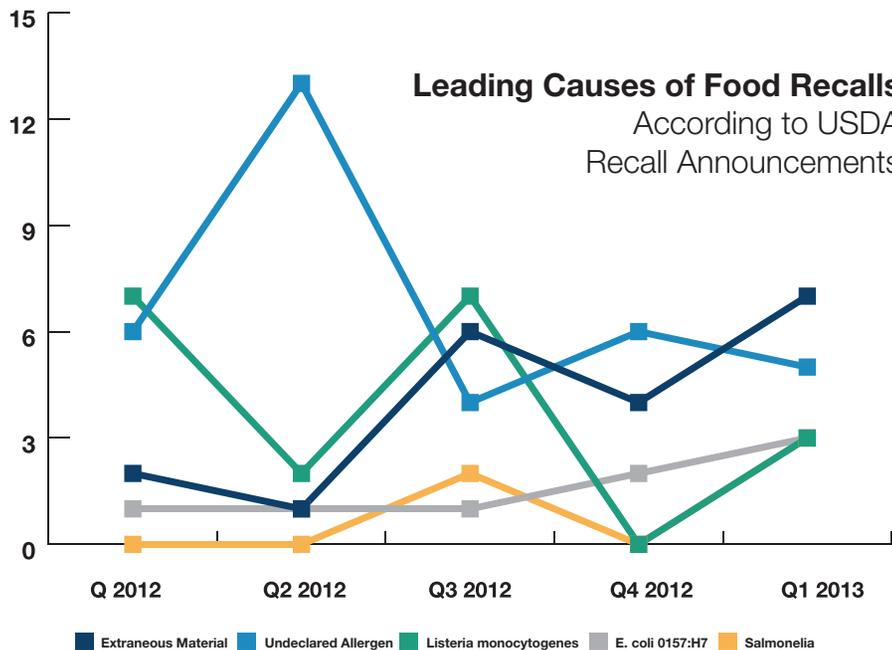
The ExpertRECALL Index analysis also revealed the following:

- Number of recalls over the past four quarters has been relatively steady, averaging 21 events per quarter over the past five quarters.
- Extraneous material was the single largest cause of recalls this quarter with seven events. Allergens were the second largest reason behind recalls with five events.
- Foodborne pathogens continue to present a threat to supply chains. When combined, Salmonella, E. coli and Listeria were the primary cause of nine recalls this quarter, up from five last quarter.

**USDA Food Recalls by Quarter**  
According to USDA Recall Announcements



**Leading Causes of Food Recalls**  
According to USDA Recall Announcements



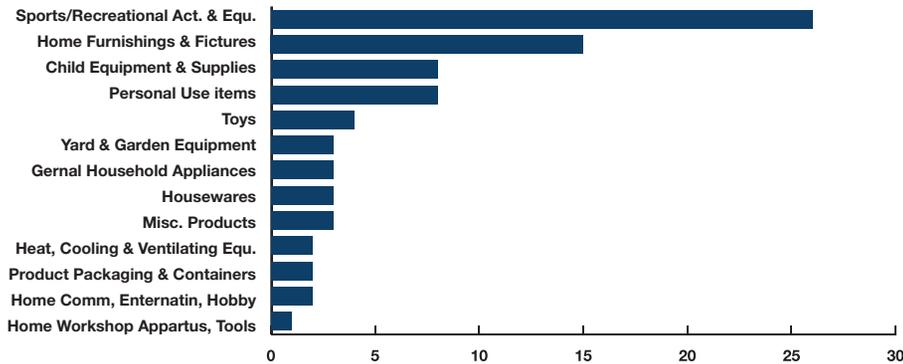
### Trend

**More than half of recalls due to extraneous material were due to traces of plastic found in products. Despite best efforts at prevention, the threat of a foodborne recall still exists throughout companies' supply chains. With increased media and government scrutiny, companies should prepare now in order to meet this threat head on. It's the only way a company can effectively protect its consumers and its brand.**

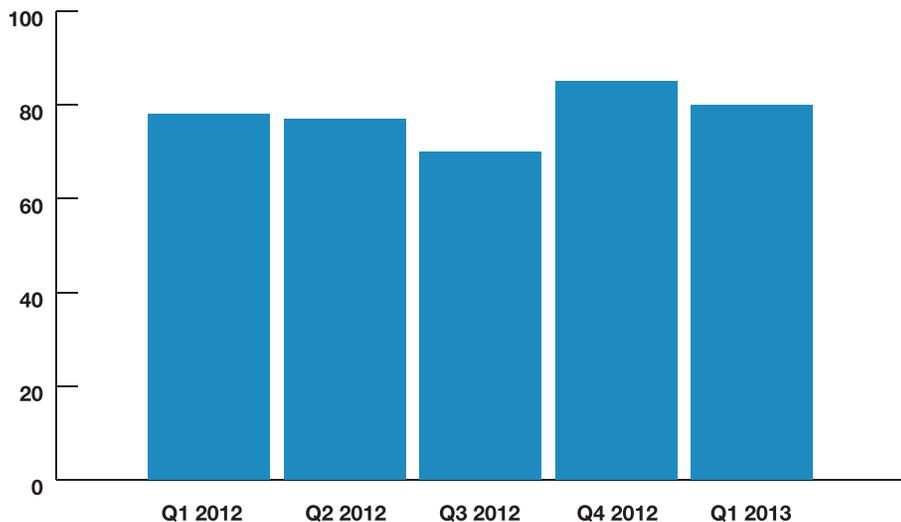
# Recall Index – First Quarter 2013

## Consumer Product Recalls

CPSC Recalls by Product Category



Consumer Product Recalls by Quarter



Consumer product recalls initiated at the request of the CPSC decreased to 80 events during the first quarter of 2013, down from 85 recalls in the previous quarter. Although the number of recalls decreased in the first quarter, the number of affected units increased significantly from 3 million units to more than 6 million units.

Products recalled in the first quarter were responsible for 1,333 product safety incidents, down from 2,015 in the fourth quarter of 2012. Of the reported incidents, 46 resulted in injury and three resulted in death. All three deaths were attributed to home furnishing products.

The CPSC initiated more recalls than the previous quarter for sports/recreational activity & equipment products and personal use items, with 26 and eight total events, respectively. All other categories, including child nursery equipment, toys, housewares, yard & garden, and general household appliances were either flat or saw declines.

The ExpertRECALL Index analysis also revealed the following:

- The total number of units affected in the first quarter was up nearly 100 percent from the previous quarter, driven by one recall that produced 2.3 million affected units, or nearly half of the total units recalled this quarter.
- Recalls of products with a potential for overheating or laceration each increased by close to 100 percent from the previous quarter and were the top reasons for consumer product recalls in this quarter.
- The number of companies issuing recalls (72) and the number of companies that initiated more than one recall (6) remained stable versus the previous quarter.

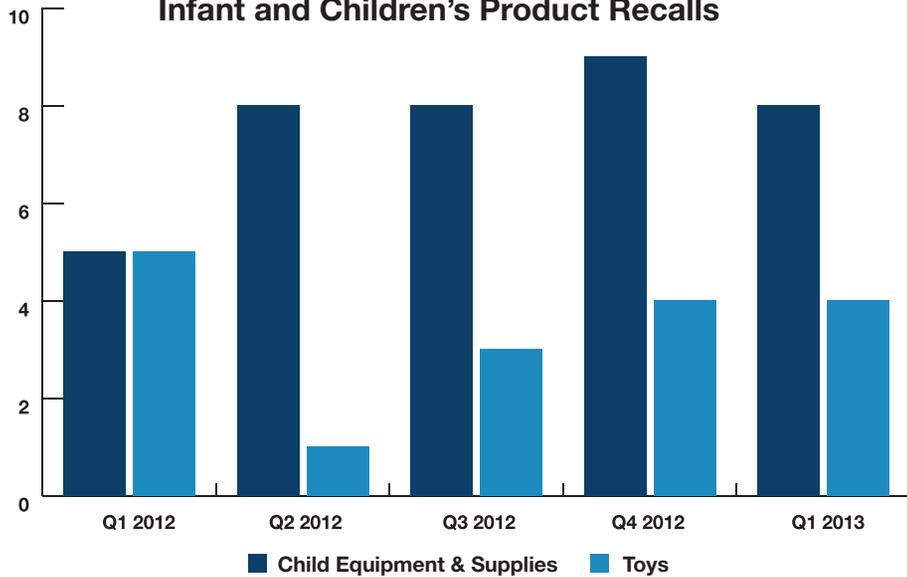
### New High

**Sports and recreational activity equipment product recalls reached an 11-quarter high. There were 26 recalls in the first quarter alone. As summer approaches and more children are playing outside, it's important for companies to identify problems quickly and communicate with stakeholders – particularly parents – in order to prevent any potential injuries.**

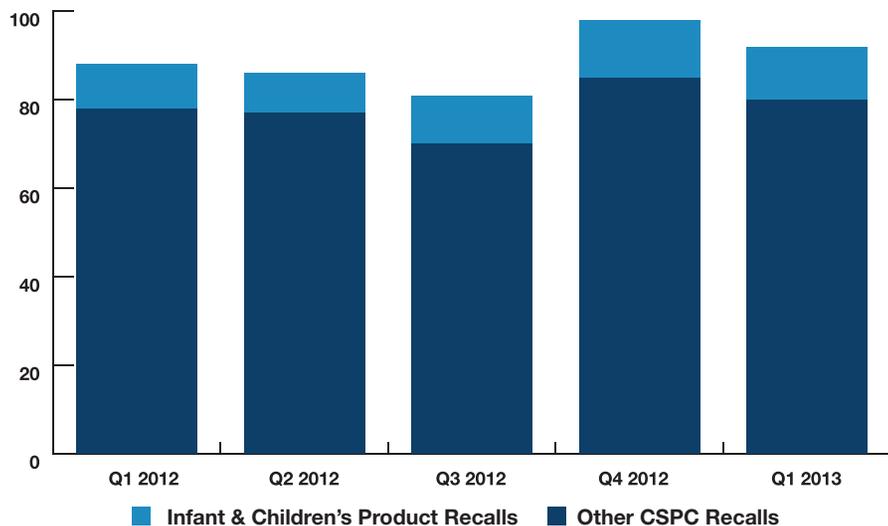
# Recall Index – First Quarter 2013

## Children’s and Infant Product Recalls

**Infant and Children’s Product Recalls**



**Infant and Children’s Product Recalls**  
Within the Consumer Product Recall Industry



The CPSC initiated 12 recalls of children’s and infant products in the first quarter of 2013, a decrease of one event compared with 13 in the previous quarter. Recalls of child nursery equipment & supplies decreased by one compared to the previous quarter, while the toys category remained consistent from the previous quarter with four recalls. Recall volume of children’s and infant products was down in the first quarter, from 455,725 units in the fourth quarter of 2012 to 199,410 units this quarter.

Of the children and infant product recall categories, child nursery equipment and toys accounted for less than 15 percent of total recall events and less than 4 percent of units affected.

The primary cause of children’s and infant product recalls was the risk of entrapment and strangulation, which led to five recalls, compared with two in the previous quarter. Hazardous material concerns and choking and small parts risks were each documented as the primary hazard for two recalls. The risk of structural collapse, laceration concerns, and the risk that a child could fall out of the product each led to one recall.

The ExpertRECALL Index analysis also revealed the following:

- Eleven companies faced recalls in the first quarter, resulting in no change from the previous quarter. Only one company faced more than one recall.
- Children’s and infant recalled products were responsible for 86 product safety incidents in the first quarter, down from 201 in the previous quarter. There were no injuries or deaths as a result of these incidents.

### Trend

**For only the second time in at least 11 quarters, no children’s and infant product recall affected more than 500,000 units, a trend that carried over from the fourth quarter. While this could be for a number of reasons, including smaller lot sizes during production or enhanced analysis, companies should not be complacent in recall preparation.**

# Recall Index – First Quarter 2013

## Medical Device Recalls

FDA Enforcement Reports documented 315 medical device recalls in the first quarter of 2013, remaining consistent with the number of events in the previous quarter. However, first quarter recalls increased 14 percent compared to the 277 recalls documented in the first quarter of 2012.

There were 19.4 million units affected by recalls in the first quarter, a dramatic increase of nearly 100 percent from previous quarter which saw a six-quarter low of 10 million units. One recall involved more than 5 million units and three recalls affected more than 1 million units, compared to the last quarter, when no recalls affected more than 5 million units.

Recalls were issued by 143 companies in the first quarter. Of these companies, 52 issued more than one recall. One company announced 24 recalls, and two companies announced 15 recalls each.

Medical device recalls documented during the first quarter of 2013 affected both domestic and international customers. The majority of recalls (198) impacted customers in the United States and at least one other country or territory. There were 90 nationwide recalls, 25 recalls that affected U.S. customers in certain states only, and two recalls that affected only customers outside the United States.

The ExpertRECALL Index analysis also revealed the following:

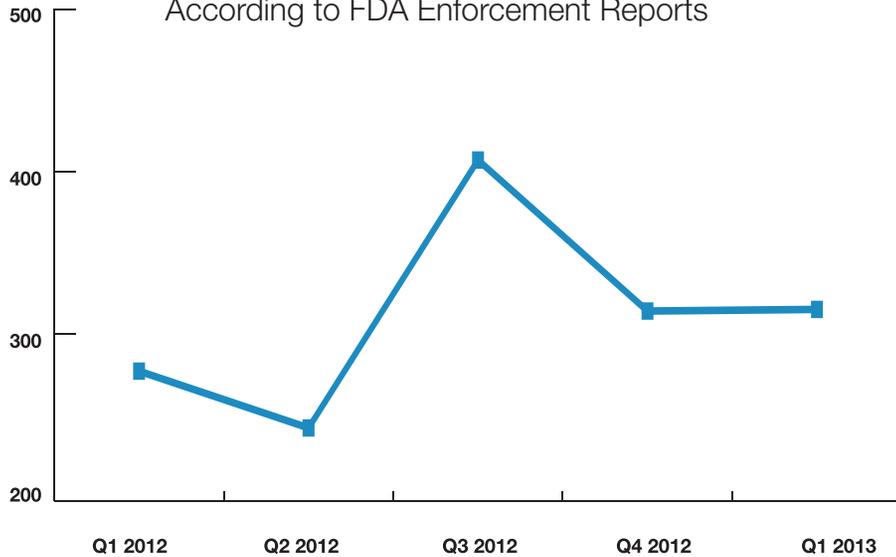
- Recalled units were up nearly 100 percent this quarter compared with the previous quarter, driven by a number of high-volume Class II recalls. In fact, four high-volume recalls were responsible for 63 percent of the total units affected.
- Once again, close to 40 percent of companies named in FDA Enforcement Reports in the first quarter were named in more than one recall.
- Class II recalls made up 82 percent of total recalls. Class I recalls were the least frequent classification, comprising five percent of total recalls.

### Trend

**For the third straight quarter, nearly forty percent of medical device companies named in FDA Enforcement Reports were involved in two or more recalls. Those within the industry should take this time to make sure that they have procedures in place to properly assess the scope of any recall event. By ensuring that all potentially affected products are accounted for and collected in an efficient manner, customers and patients will be much more likely to remain loyal to a brand.**

### Medical Device Recalls

According to FDA Enforcement Reports



### Medical Device Recalls by Class

According to FDA Enforcement Reports



# Recall Index – First Quarter 2013

## Pharmaceutical Recalls

FDA Enforcement Reports in the first quarter of 2013 documented 107 drug and pharmaceutical recalls, an increase of 32 percent from the previous quarter and higher than the average number of events last year.

Units affected by recalls were also up in the first quarter, affecting 13,102,606 units, compared with 11,687,326 in the fourth quarter of 2012. According to FDA Enforcement Reports, three recalls affected more than 1 million units but less than 5 million units; five recalls affected between 500,000 and 1 million units; and 98 recalls affected fewer than 500,000 units.

Fourteen recalls were documented as Class I recalls, 62 were documented as Class II and 31 were Class III – all increases over the previous quarter. Six recalls of the 107 affected over-the-counter (OTC) products. The remaining 101 recalls affected prescription medications, of which 14 were Class I, 61 were Class II and 26 were Class III events.

Pharmaceutical recalls in the first quarter affected domestic and international customers. Of recalls documented in the first quarter, 67 recalls affected customers nationwide, while 31 recalls affected customers in the United States and at least one other country or territory. Eight recalls affected U.S. customers in only certain states and one recall affected customers only outside of the United States.

The ExpertRECALL Index analysis also revealed the following:

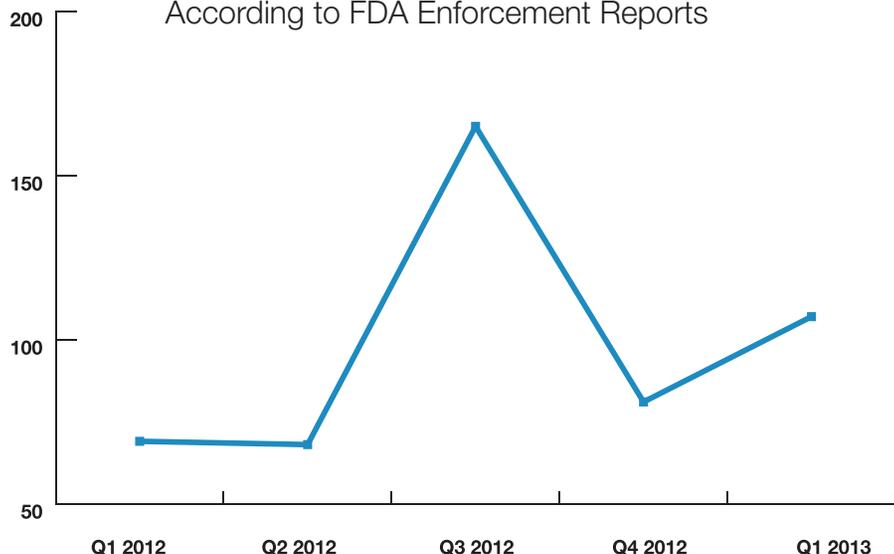
- While events were up slightly, we saw a dramatic increase of Class I recalls of prescription drugs, which increased by 100 percent compared to the fourth quarter.
- Three high-volume OTC recalls made up 85 percent of the OTC affected units.
- Compounding pharmacies continue to show frequent recall activity. This quarter, a compounding pharmacy faced the most recalls of any other company with 13 events.

### Global Perspective

**31 recalls affected the U.S. and at least one other country last quarter. Being prepared means knowing the various regulations and requirements in all countries where a product is sold.**

### Pharmaceutical Recalls

According to FDA Enforcement Reports



### Pharmaceutical Recalls by Class

According to FDA Enforcement Reports

