

RECALL INDEX

Q4  
2016

# Consumer Products APPLIANCE NONCOMPLIANCE



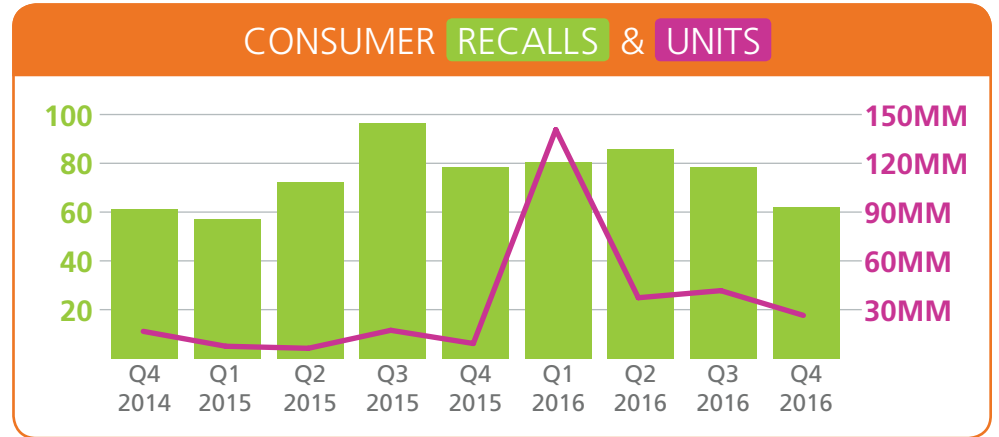
There were 62 CPSC recalls in Q4 – a 21% decrease compared to Q3. Recalled units decreased 37% to about 26 million, marking the lowest quarter of 2016, but still higher than any quarter from Q2 2012 through the end of 2015.



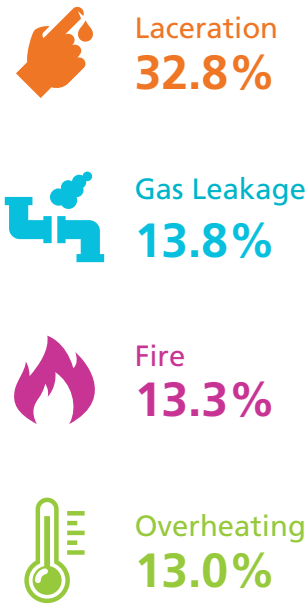
**51.1%** of recalled units were in the general household appliances category.

## CONNECTING THE DOTS

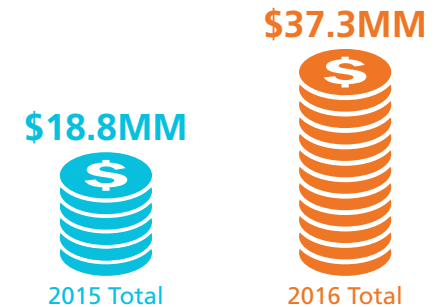
- 32.8% of recalled units were recalled due to laceration hazards. No other cause accounted for more than 15% of recalled units.
- 51.6% of CPSC recalls listed either a refund or replacement as the remedy.
- There were 3,473 reported incidents and 86 injuries. This is an 81% increase in incidents, but a decrease of 85% in injuries.



## TOP HAZARDS BASED ON UNITS



## FINES ISSUED BY CPSC



Fines in 2016 nearly doubled over 2015.

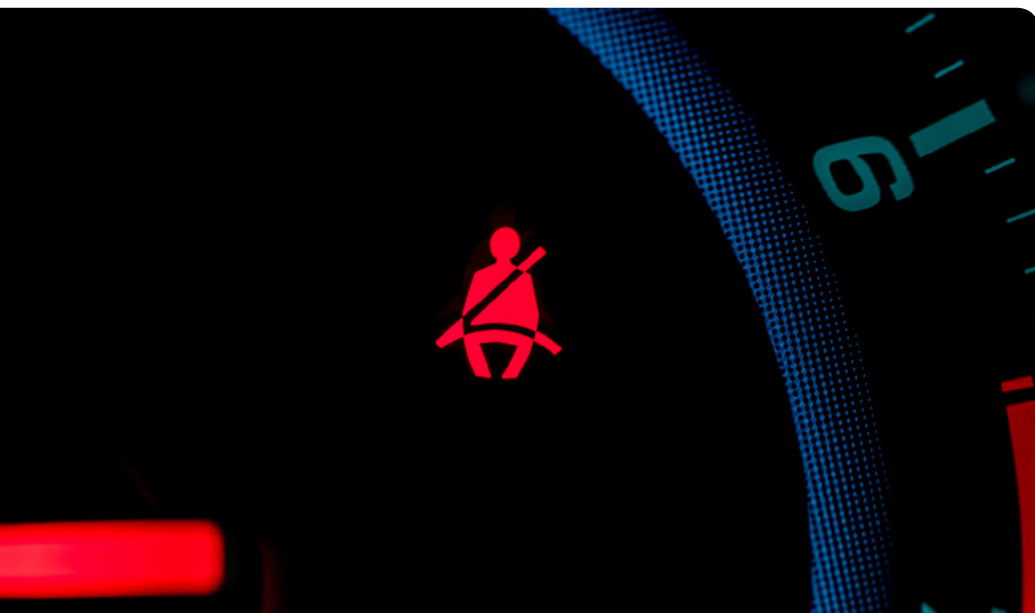
## REPORTED CONSUMER INJURIES



# Automotive SEAT BELTS EXTENDED



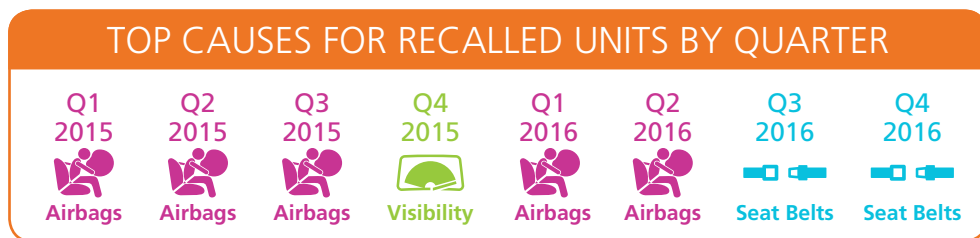
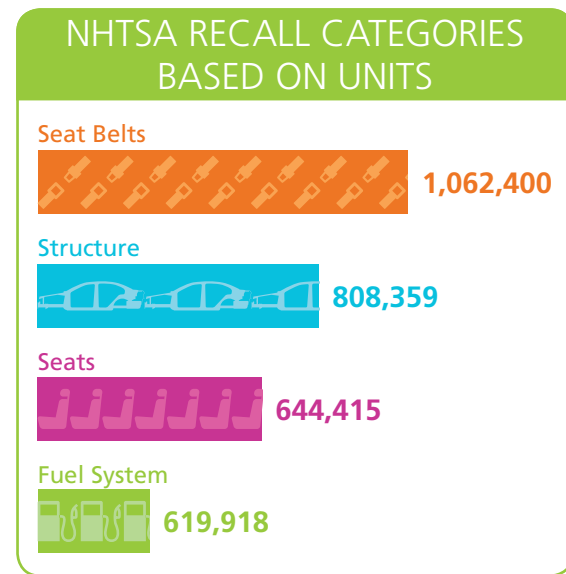
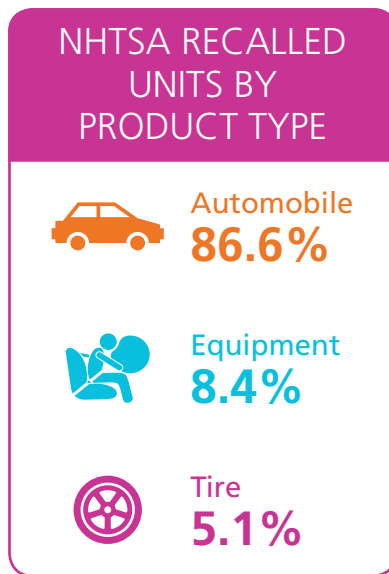
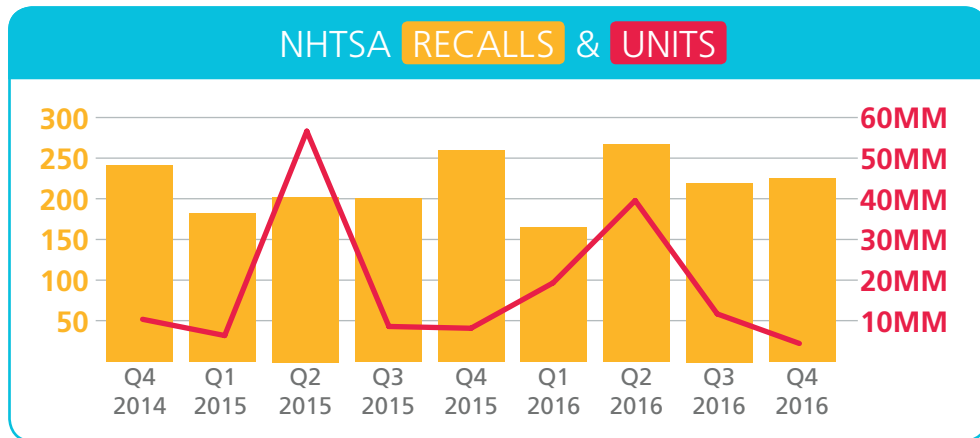
Recalls increased 3% to 225, while recalled units dropped 57% to nearly 5.3 million – the lowest quarter since Q1 2013.



**20.1%** of recalled units were seat belts, making it the top cause for the second quarter in a row.

## CONNECTING THE DOTS

1. Equipment and electrical system issues combined for 31.1% of NHTSA recalls.
2. 91.1% of NHTSA recalls were for automobiles.
3. Five companies accounted for 74.5% of automobile recalled VINs.



# Pharmaceuticals DEVIATION DIFFICULTIES



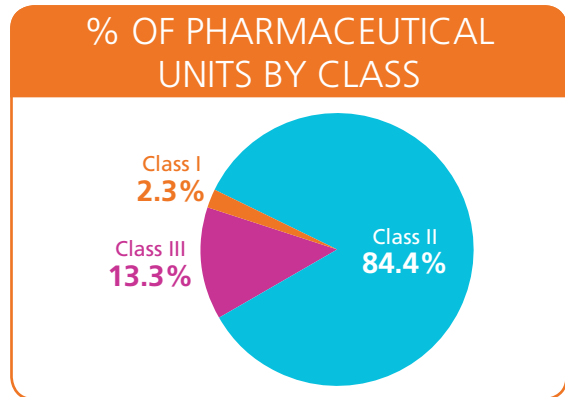
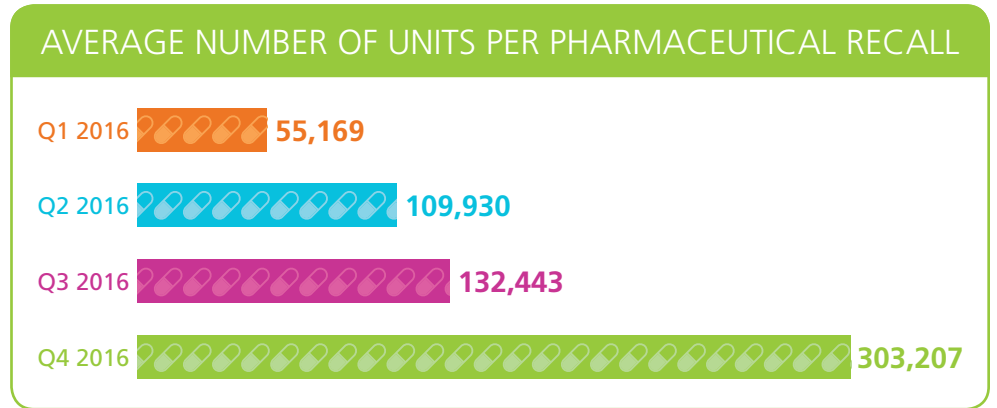
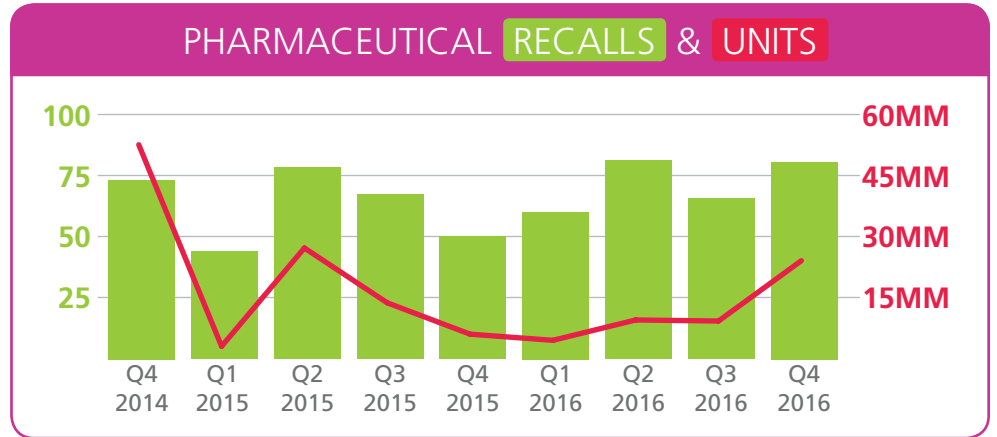
Pharmaceutical recalls increased 28% in Q4 to 83, the highest level since Q3 2014. Recalled units jumped 192% to more than 25.1 million – the highest since Q2 2015 and the third highest since Q1 2012.



**75.6%** of recalled units were due to deviations in Current Good Manufacturing Practices (CGMPs), mostly from one large recall.

## CONNECTING THE DOTS

1. For the second quarter in a row, failed specifications, sterility issues, and mislabeling were the top three causes based on recalls, accounting for a combined 63.9% of recalls in Q4.
2. Average event size continued to climb throughout the year, reaching 303,207 units in Q4 – the highest level since Q2 2015.
3. Class II situations accounted for 84.4% of recalled units, a return to the historical trend.



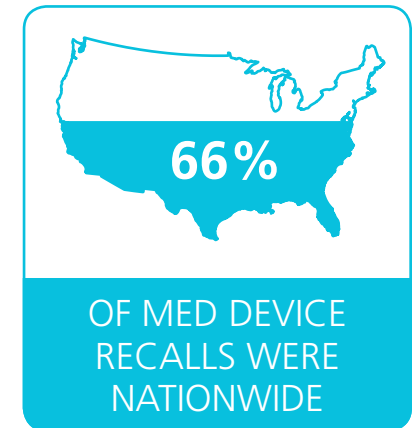
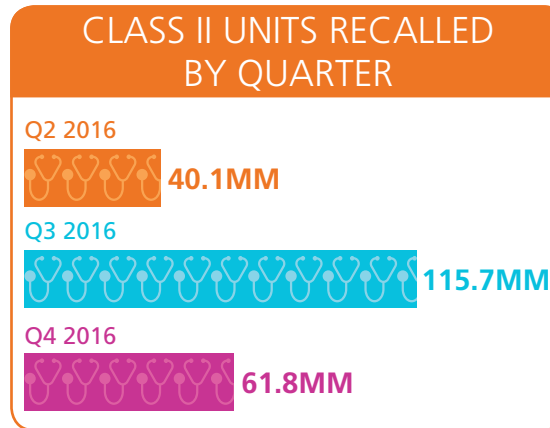
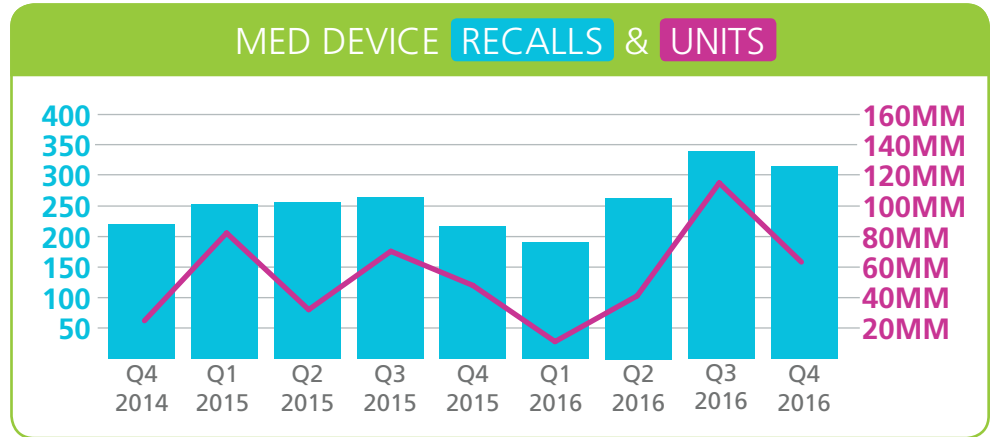
# Medical Device SOFTWARE SNAGS



After medical device recalls in Q3 reached their highest level since at least 2000, recalls dipped by only 8% in Q4 to 313. This is still the second highest quarter since Q1 2014. Recalled units decreased 46% to just over 63.1 million.

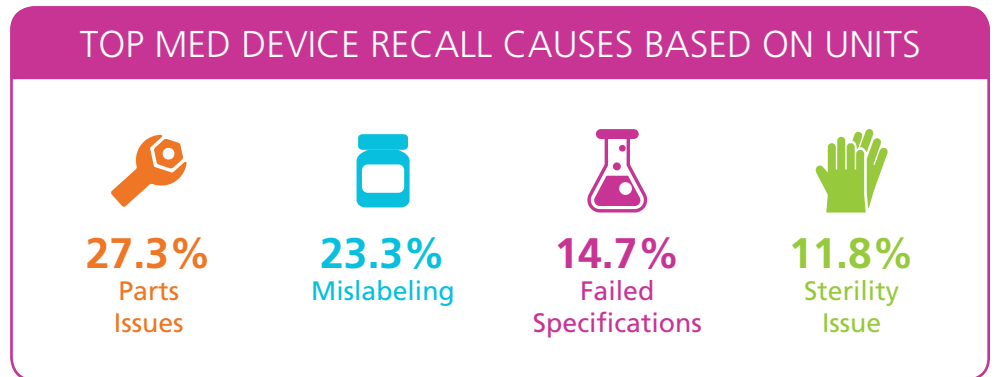


**23%** of recalls were for software issues.



## CONNECTING THE DOTS

1. Parts issues and mislabeling were the cause for 50.6% of recalled units.
2. 207 recalls were nationwide, making up 66% of medical device recalls and marking the highest number since Q1 2014.
3. 46 companies experienced more than one recall in Q4, the second highest number since Q1 2014.



# Food & Beverage FOWL PLAY



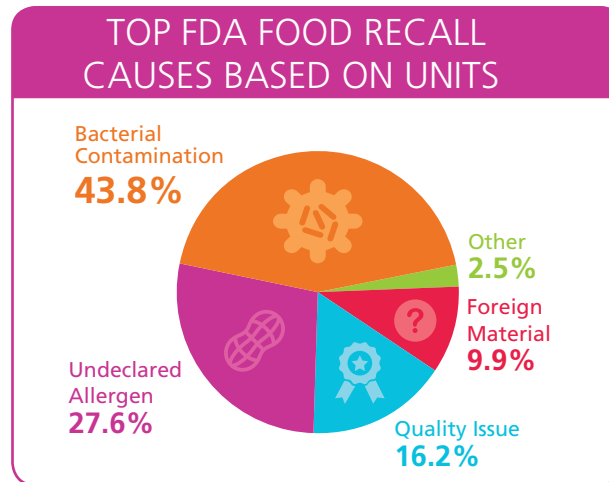
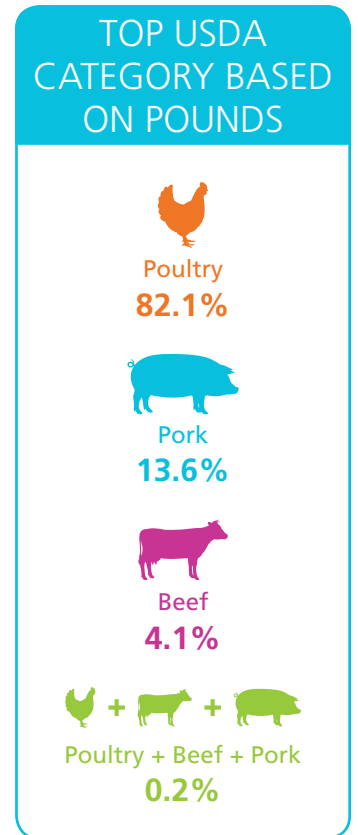
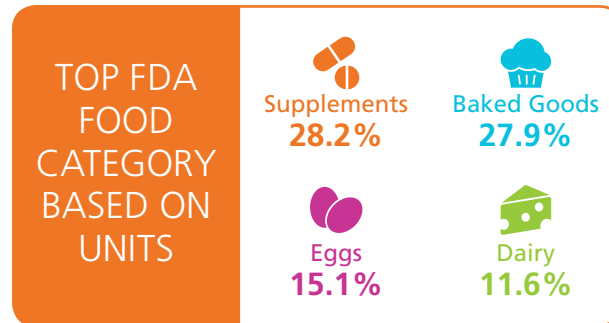
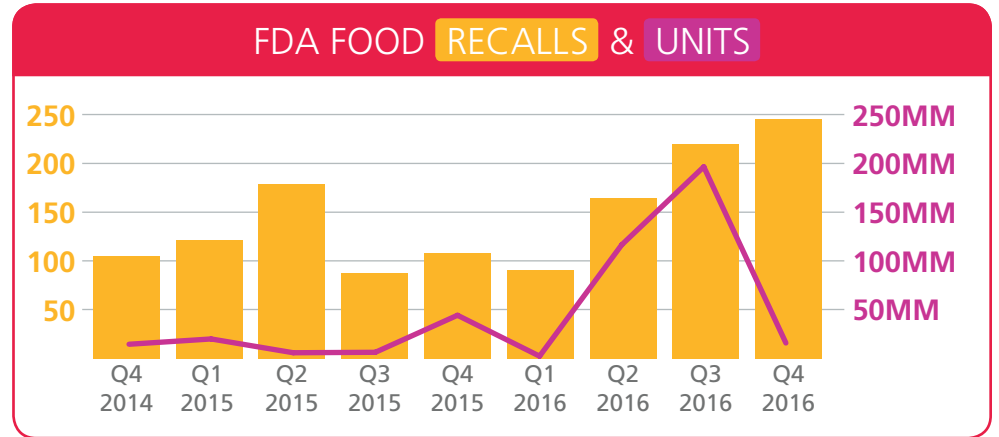
FDA recalls rose 12% in Q4 to 246 – the highest since at least Q1 2010. Recalled units were down 92% to about 15.2 million – still higher than 14 of the last 19 quarters. USDA recalls dropped 16% to 32, while recalled pounds decreased 10% to 2.8 million.



**82.1%** of USDA recalled pounds were poultry.

## CONNECTING THE DOTS

1. Supplements and baked goods combined to make up 56.1% of FDA recalled units.
2. Quality issues were the cause of 70.5% of USDA recalled pounds.
3. The top four causes of FDA recalled units remained unchanged from Q3, with bacterial contamination ranking highest at 43.8%.



# Stericycle ExpertSOLUTIONS & the Recall Index Explained

Stericycle ExpertSOLUTIONS helps 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. This helps our partners navigate the regulatory environment and identify trends.

## How the Stericycle Recall Index is Compiled

The Stericycle Recall Index gathers and tracks cumulative data from the four primary federal agencies that oversee recalls in the United States: the Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA), the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA), and the National Highway Traffic Safety Administration (NHTSA).

### FDA Data

To track trends in food, pharmaceutical, and medical device recalls, the Stericycle Recall Index uses information publicly available in news releases posted on the FDA website. For additional insight into recalls governed by the FDA, Stericycle 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 analyzes data from CPSC recall announcements. When compiling statistics and analyzing trends for consumer product recalls, the Stericycle Recall 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 Stericycle Recall 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.

### NHTSA Data

To understand trends in the automotive industry, the Stericycle Recall Index analyzes data from NHTSA reports on recalls of autos, child seats, equipment, and tires.

### 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 that are summarized based on the FDA assigned Event ID. 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.*