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RECALL INDEX

Q1
2018

Consumer Products

Consumer product recalls decreased by just 3% to 72 – marking two consecutive quarters with more than 70 recalls for the first time since Q3 2016. Recalled units decreased 92% to about 8.4 million, still only slightly lower than the quarterly average from 2013 through 2015.
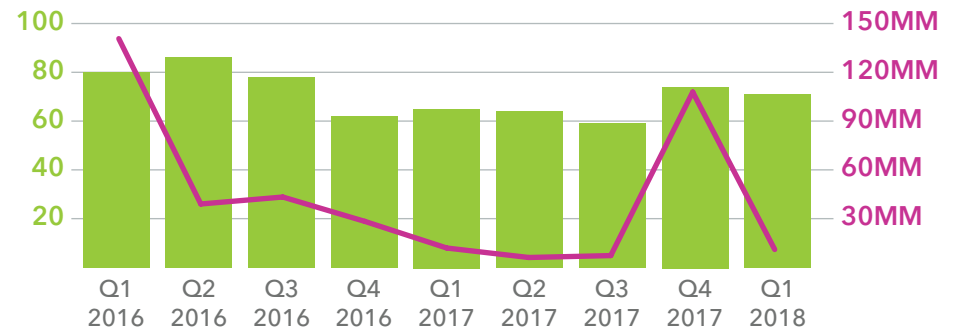
FURNISHING A RECALL RISE

The top product category based on recalls was home furnishings & décor, with **29.2%** of the total. This breaks a four-quarter streak for sports and recreation.
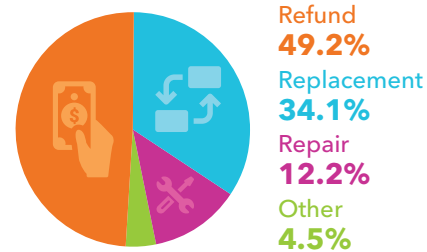
CONNECTING THE DOTS

1. There were no fines issued in Q1 2018. This is only the third two-quarter stretch without fines in the last 20 years, and the first since Q3 and Q4 2013.

2. For the first time since Q4 2016, the top hazard based on recalls was fire, at 33.3%. Fire was also the top hazard based on units.

3. Incidents increased for the second quarter in a row, by 11.4%. Injuries decreased 57.5%, making it the lowest quarter since Q1 2015 and the third consecutive quarter with a decrease.
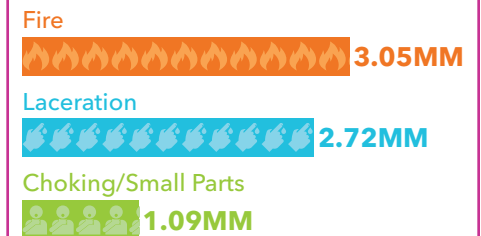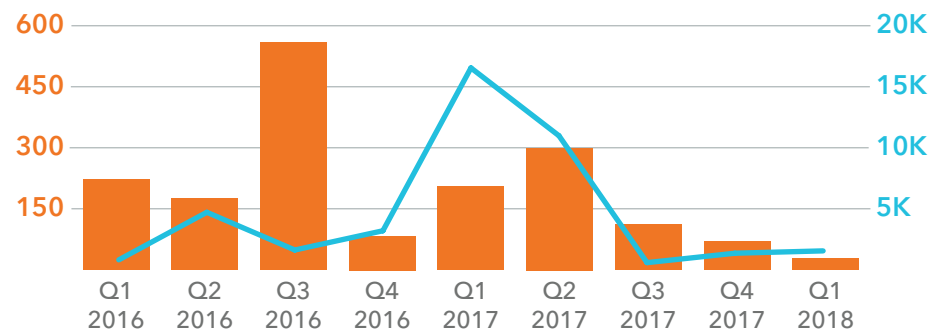
CONSUMER RECALLS & UNITS

(Bar/line chart — quarters Q1 2016 through Q1 2018; left axis 20–100, right axis 30MM–150MM)

TOP REMEDIES BASED ON UNITS

- Refund **49.2%**
- Replacement **34.1%**
- Repair **12.2%**
- Other **4.5%**

TOP HAZARDS BASED ON UNITS

- Fire **3.05MM**
- Laceration **2.72MM**
- Choking/Small Parts **1.09MM**

CONSUMER INCIDENTS & INJURIES

(Bar/line chart — quarters Q1 2016 through Q1 2018; left axis 150–600, right axis 5K–20K)

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Automotive

NHTSA recalls increased 1% to 215 – the highest quarter since Q4 2016 and in line with the average over the last 19 quarters. Recalled units declined 31% to 10.2 million, lower than 5 of the last 8 quarters.
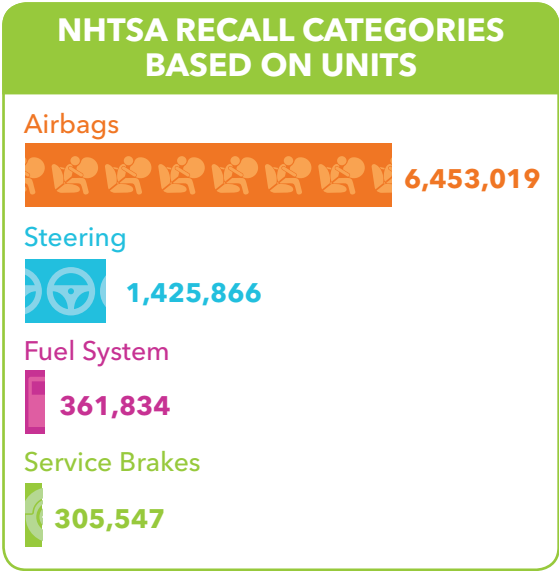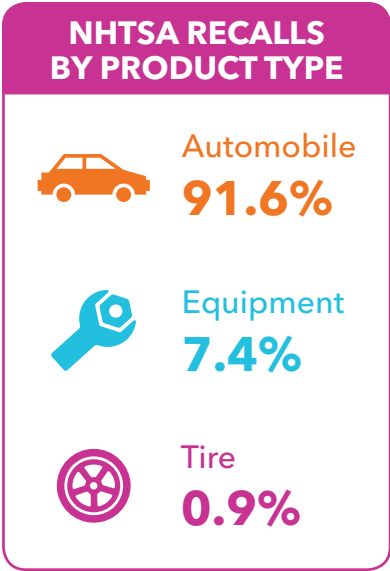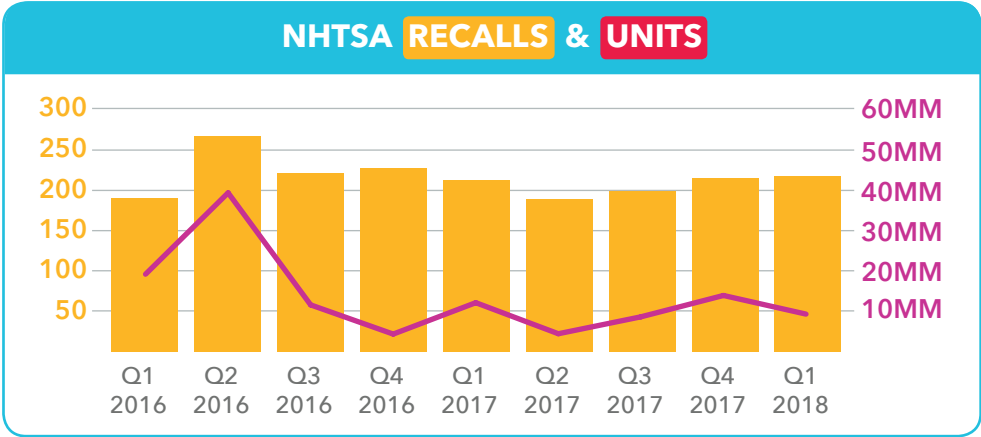
NHTSA RECALLS & UNITS

AIRBAGS ASCEND

63.6% of recalled NHTSA units were due to airbags, the highest percentage since Q1 2017 and a **3.5** times increase from last quarter.
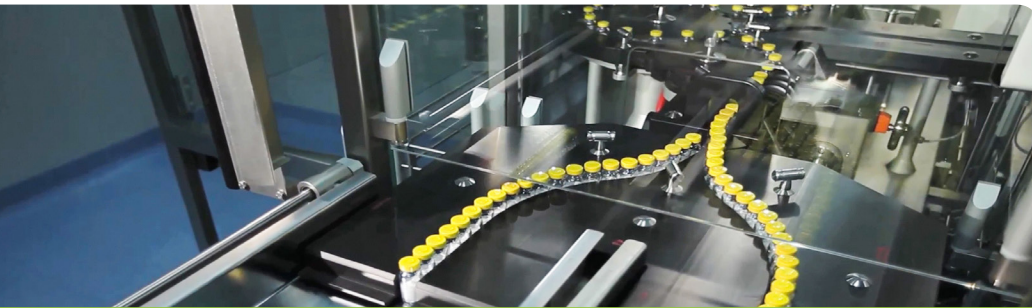
CONNECTING THE DOTS

1. Equipment was the top cause for NHTSA recalls for the fourth quarter in a row.
2. Automobiles accounted for 66.9% of recalled units, down from 81% in Q4 2017.
3. 49.9% of recalled automobile VINs were issued by 5 companies.

NHTSA RECALLS BY PRODUCT TYPE

Automobile
91.6%

Equipment
7.4%

Tire
0.9%

NHTSA RECALL CATEGORIES BASED ON UNITS

Airbags
6,453,019

Steering
1,425,866

Fuel System
361,834

Service Brakes
305,547

TOP CAUSES OF RECALLED UNITS BY QUARTER

Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018
Airbags	Seat Belts	Seat Belts	Airbags	Airbags	Airbags	Equipment	Airbags

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Pharmaceuticals

Pharmaceutical recalls increased 52% to 105 – the highest since Q3 2013 and the third highest since at least 2005. Recalled units jumped more than 100 times to nearly 332.5 million units – the highest quarter by far since Q2 2007 and second highest since 2005. This is mostly due to one large recall.

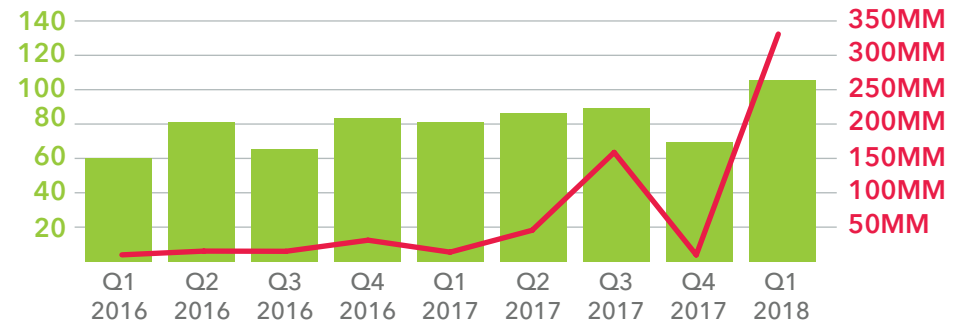## PHARMACEUTICAL RECALLS & UNITS

OUT OF PRACTICE

Largely due to one large recall, the top cause based on units was Current Good Manufacturing Practice (CGMP) deviations, at **94.7%** of recalled units.

TOP PHARMACEUTICAL CAUSES BASED ON RECALLS

Failed Specs	Sterility	Mislabeling	Foreign Materials	Subpotency
21.9%	15.2%	14.3%	11.4%	9.5%

CONNECTING THE DOTS

1. Failed specifications made up the top cause of recalls for the seventh consecutive quarter.

2. 84 companies reported at least one recall in Q1 2018 – the highest number since at least 2012.

3. Class I recalled units increased for the second quarter in a row – this time by 192.8%. There were more than 1 million Class I recalled units in Q1 2018 – higher than any quarter from 2016 and three of the quarters in 2017.

% OF PHARMACEUTICAL UNITS BY CLASS

Class I 0.3%
Class III 1.3%
Class II 97.8%
Unclassified 0.6%

79%
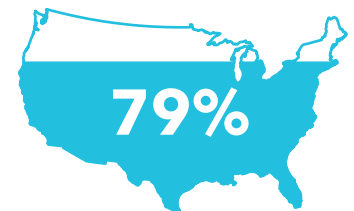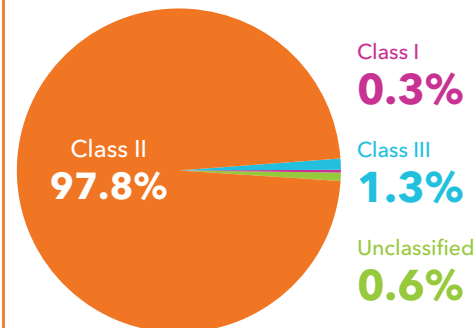
OF PHARMACEUTICAL RECALLS WERE NATIONWIDE

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Medical Device
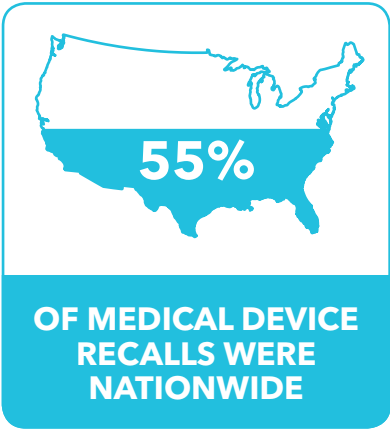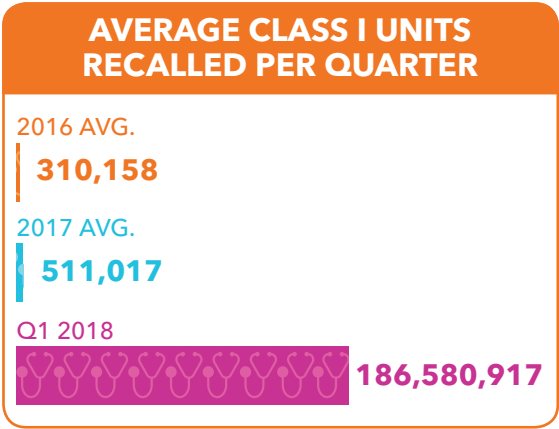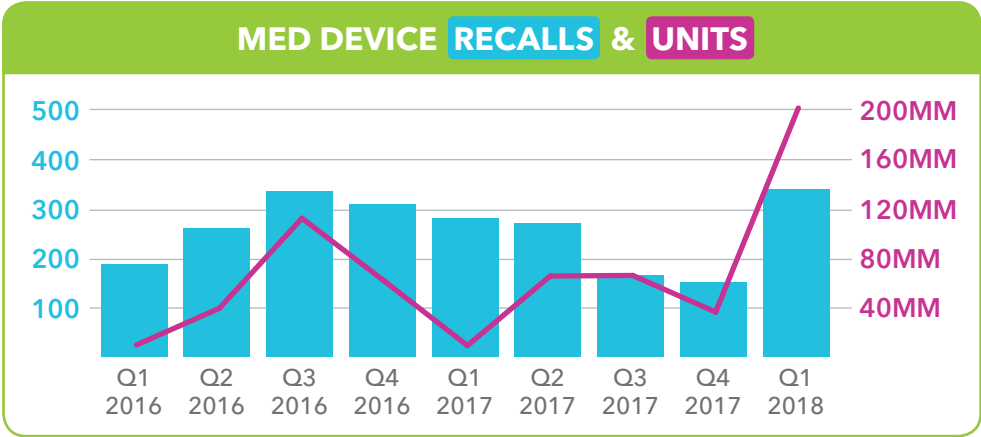
Medical device recalls increased 126% to 343 – more than double last quarter and the largest quarter since at least 2005. Recalled units increased to about 208.4 million – 4.5 times higher than the previous quarter, 45 million larger than any quarter since at least 2005, and higher than all of 2017 combined.

MED DEVICE RECALLS & UNITS

THE DEFECT EFFECT

93.7% of recalled units were due to manufacturing defects making it the top cause for the second quarter in a row, largely due to one recall.

AVERAGE CLASS I UNITS RECALLED PER QUARTER

2016 AVG.
310,158

2017 AVG.
511,017

Q1 2018
186,580,917

55%

OF MEDICAL DEVICE RECALLS WERE NATIONWIDE

CONNECTING THE DOTS

1. The average recall size was 607,512, up considerably from last quarter's 245,862 and higher than any quarter since Q3 2007.

2. 22.7% of recalls were for software, making it the top cause for the eighth consecutive quarter.

3. Recalls of products distributed both domestically and globally dropped to 36%, lower than any quarter since at least 2012.

TOP MEDICAL DEVICE CAUSES BASED ON RECALLS

Software Issue	Mislabeling Issue	Quality Issue	Outside of Specifications
78	**73**	**46**	**33**

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Food & Beverage

FDA food recalls declined 8% to 138 – the lowest quarter since Q1 2016. Recalled units increased 6% to nearly 7.5 million, still below 7 of the last 9 quarters. USDA recalls stayed equal at 28 –lower than 4 of the last 6 quarters. Recalled pounds increased 69% to just over 1 million – still lower than 13 of the last 16 quarters.
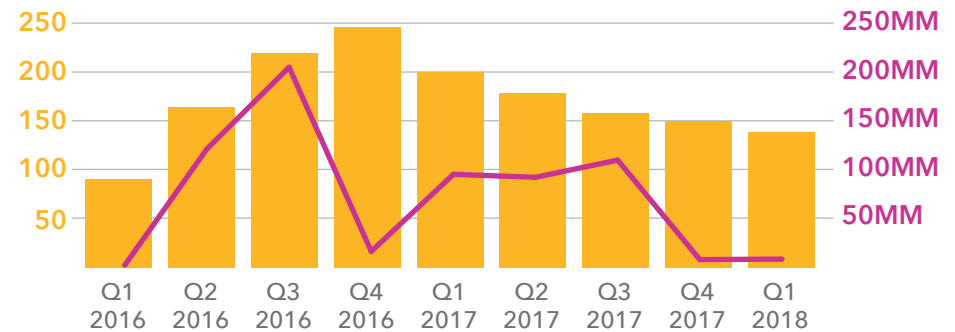
HEAVY METAL

At **53.5%**, foreign material was the top cause of recalled FDA units for the first time since Q1 2016. Most (**78%**) were caused by metal.

CONNECTING THE DOTS

1. Beef was the top category for USDA recalled pounds for the first time since Q1 2016, breaking up a two-quarter streak for multiple proteins.

2. Flavoring was the top category for recalled FDA units at 43.3%, up from just 0.6% in Q4 2017.

3. For the fifth quarter in a row, the top FDA product category in terms of recalls was prepared foods, this time with 18.8%.
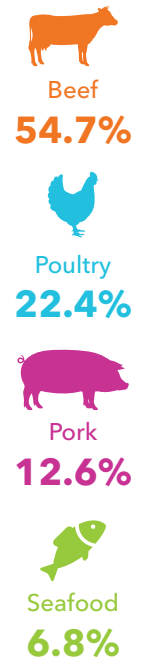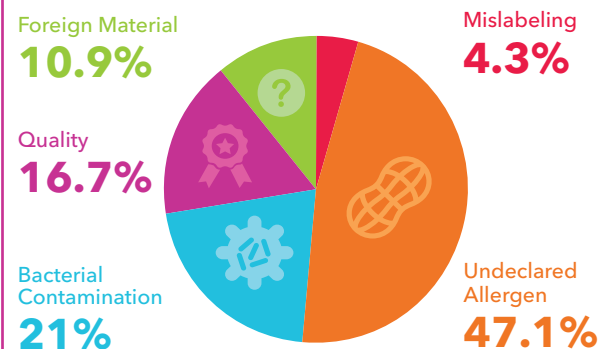
FDA FOOD RECALLS & UNITS

	Q1 2016	Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018

TOP USDA REASON BASED ON RECALLS

Undeclared Allergen	Bacterial Contamination	Foreign Material
28.6%	25%	14.3%

TOP USDA CATEGORY BASED ON POUNDS

Beef
54.7%

Poultry
22.4%

Pork
12.6%

Seafood
6.8%

TOP FDA FOOD RECALL CAUSES BASED ON RECALLS

Foreign Material
10.9%

Mislabeling
4.3%

Quality
16.7%

Bacterial Contamination
21%

Undeclared Allergen
47.1%

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Stericycle Expert Solutions & the Recall Index Explained

Stericycle Expert Solutions 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.

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