A PUZZLING PRESCRIPTION:
THE INCREASING COMPLEXITY OF PHARMACEUTICAL RECALLS
A Puzzling Prescription: The Increasing Complexity of Pharmaceutical Recalls

Pharmaceutical recalls have always been rife with complexity, given the various types of drugs on the market and the myriad of regulations they face. Emerging trends, including a rise in mergers and an increase in drug approvals, are making the industry even more complex.

MULTIPLE PATHS CREATE MULTIPLE ISSUES
Over-the-counter, prescription, and compounded medications take different paths to the consumer, making effective recalls a challenge for each – but in their own unique way.

MERGERS & ACQUISITIONS: CONSOLIDATION CAUSES COMPLEXITY
2015 saw a record number of pharmaceutical mergers and acquisitions, which means the remaining companies must absorb new markets, existing systems, and additional regulations.

A HIGH DOSE OF CHANGE
More drugs are entering the market – in both good and bad ways. Drugs are being approved by the Food and Drug Administration (FDA) faster than ever, but counterfeits are also booming.
Multiple Paths Create Multiple Issues

Three categories of drugs dominate the pharmaceutical market. Each introduces unique challenges to the recall process.

**Over-the-counter (OTC)** medications are inexpensive, widely distributed, and often leave the company with no direct link to the consumer should a recall occur. Although packaging is labeled by lot number, making it easier for consumers to identify whether their product is affected, they are typically only notified of OTC recalls online or through the media. This places effectiveness at the mercy of consumers' awareness.

**Prescription** drug recalls typically follow the supply chain. The manufacturer or distributor contacts the pharmacy or healthcare professional who issued the drug, who then contacts the patient. But without an easily identifiable batch number printed on each label, companies are forced to rely on date ranges, which can widen the scope of the affected product and increase the cost of the recall.

Recalls of **compounded** medications tailored for specific patients present their own unique challenges. The direct link to the patient facilitates the notification process, but there are other issues at play. Once the offending ingredient is found, it often expands the recall across multiple drug classifications, each with its own set of regulations regarding transportation and, ultimately, disposal.
Mergers & Acquisitions: Consolidation Causes Complexity

Mergers and acquisitions (M&A) activity reduced the number of pharmaceutical companies initiating recalls in 2015. But as companies combine, they become more complicated – leading to new and bigger challenges moving forward.

M&A in the pharmaceutical, medical device, and health insurance space set a record in 2015, with deals totaling $687 billion in the United States (U.S.) alone¹. In fact, the marquee merger of 2015 saw the creation of the world’s largest pharmaceutical company to date.

Pharmaceutical recalls were down in 2015, as were the number of companies experiencing a recall. In fact, affected companies decreased from 60 to 44 – down a quarterly average of 30 percent. With heightened M&A activity, we expect this trend to continue.

Increased M&A activity will also introduce new layers of complexity into pharmaceutical recall execution. Disparate tracking systems and quality control mechanisms must be merged. In addition, new geographic markets with new sets of regulations – and new language barriers – must be navigated.

¹www.chicagotribune.gov

Average Number of Companies Experiencing a Recall Per Quarter

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Companies</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>58</td>
</tr>
<tr>
<td>2014</td>
<td>60</td>
</tr>
<tr>
<td>2015</td>
<td>44</td>
</tr>
</tbody>
</table>

$687B
Total of pharmaceutical, medical device, and health insurance merger and acquisition deals in 2015
A High Dose of Change

2015 saw significant changes in the industry. Counterfeit drugs and newly approved FDA medications flooded the market. Adding to the complexity, the FDA is working with manufacturers to provide new guidance on technology.

Climbing prescription drug prices, new manufacturing advancements, and the simplicity and privacy of purchasing drugs via the internet have all led to massive increases in counterfeit drug production – which reached $200 billion in 2015. Pharmaceutical companies facing a recall must ask themselves an increasingly common question: Is it even our drug that needs to be pulled from the market?

The FDA approved 45 new medications in 2015 – more than double the number approved just ten years ago. Never before has the FDA’s stamp of approval been granted so many times in one calendar year. The 21st Century Cures Act moving through Congress could make the high number of FDA approvals in 2015 the beginning of a trend, not a statistical outlier.

As the FDA works to improve quality control via technological advancements, it is seeking pharmaceutical industry partners to both write and test the regulations that will soon govern their manufacturing processes. Companies that participate will have the opportunity to shape new rules and preemptively implement systems that may reduce the number of recalls in the future.

Click here to learn how to partner with the FDA or visit www.fda.gov
The Prescription for Adapting to Changes

2015 saw significant changes in the pharmaceutical marketplace.

With each evolution comes new challenges in recall execution. Navigating the changing pharmaceutical landscape became even more difficult last year; but with careful planning and smart strategies, companies can steer a clear path that circumvents new complexities, protects their brand, and keeps customers safe.
FDA

**FDA TOTAL RECALLS**
- **374**
- **10%** from Q3 2015

**FDA MED DEVICE RECALLS**
- **216**
- **18%** from Q3 2015

**FDA FOOD RECALLS**
- **108**
- **24%** from Q3 2015

**FDA PHARMA RECALLS**
- **50**
- **25%** from Q3 2015

**FDA FOOD RECALLS TOP PRODUCT CATEGORIES**
- **Vegetables** 19%
- **Baked Goods** 10%
- **Supplements** 9%
- **Candies** 9%

**PHARMACEUTICAL UNITS RECALLED BY QUARTER**
- **Q1 2015**: 1.7 in Millions
- **Q2 2015**: 28.7 in Millions
- **Q3 2015**: 13.6 in Millions
- **Q4 2015**: 5.0 in Millions

**MED DEVICE UNITS RECALLED BY QUARTER**
- **Q1 2015**: 82.5MM
- **Q2 2015**: 70.2MM
- **Q3 2015**: 47.4MM

**COMPANIES WERE INVOLVED IN A FDA FOOD RECALL**
- **105**

**82% OF PHARMACEUTICAL RECALLS WERE NATIONWIDE**

**89% OF RECALLED FDA FOOD UNITS WAS CUMIN**
Recall Index, Q4 2015 The Recall Scorecard

**USDA**

- **24** USDA FOOD RECALLS
  - Down 25% from Q3 2015

**TOP CAUSE OF USDA RECALLS**

- **42%** Misbranding

**NHTSA**

- **760K+** POUNDS OF FOOD WERE RECALLED BY THE USDA

**NHTSA RECALLS**

- **259** NHTSA RECALLS
  - Up 30% from Q3 2015

**TOP CAUSES FOR AUTOMOTIVE RECALLS**

- **15%** Equipment
- **10%** Powertrain
- **10%** Electrical System
- **10%** Equipment Adaptive

**TOP HAZARDS BEHIND CPSC EVENTS**

- **15%** Liquid Leakage
- **15%** Fire
- **13%** Structural Collapse
- **9%** Laceration
- **8%** Overheating
- **8%** Entrapment / Strangulation

**CPSC**

- **78** CPSC RECALLS
  - Down 19% from Q3 2015

**156** REPORTED INJURIES AS A RESULT OF CPSC RECALLS

- Up 15% from Q3 2015

- **8.9MM** TOTAL UNITS RECALLED
  - Down 5% from Q3 2015

**TOP CAUSE OF USDA RECALLS**

- **Misbranding** 42%

**CPSC TOP CAUSES**

- **Video Tape** 15%
- **Lung Cancer** 15%
- **Bladder Cancer** 13%
- **Prostate Cancer** 9%
- **Heart Disease** 8%
- **Stroke** 8%

**TOP HAZARDS BEHIND CPSC EVENTS**

- **Liquid Leakage** 15%
- **Fire** 15%
- **Liquid Leakage** 10%
- **Powertrain** 10%
- **Equipment** 10%
- **Equipment Adaptive** 10%

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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 six 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.