

Executing a medical device recall at the drop of a hat

Managing an immediate recall when the regulator demands it

Along with other significant changes it spurred in countries around the world, COVID-19 accelerated the efforts of lawmakers and regulators eager to protect consumers from unsafe or unreliable products during a period of great stress and uncertainty.

The risk that a regulator would require immediate corrective action increased exponentially – especially when a product is designed to be used in life-or-death situations.

With proper advanced preparation, recall management and consumer engagement, companies can ensure that they will be ready in the event a regulator unilaterally decides a manufacturer or retailer must take immediate corrective action.

Challenge

When regulators require a recall announcement to be made immediately, companies have little choice but to comply, regardless of whether they are prepared to execute the recall.

Regulators of the medical device industry often act quickly when a defect in a product is brought to their attention due to the risks posed to consumer safety with continued use. When a large medical device manufacturer identified an issue with one of its products, the company immediately notified the Food and Drug Administration (FDA), which requested that the recall be announced immediately.

Since the company took such swift action in identifying the issue and notifying the FDA, it had not yet determined how to administer the remedy. Due to the high-profile nature of the recall and the fact that the company was unable to ramp up preparation efforts prior to the recall announcement, the company turned to Sedgwick brand protection to manage the initial response.

As the scope of the recall was being defined, a contact center of 50 agents was immediately established, but quickly overwhelmed with calls from concerned patients, parents and caregivers. At the peak, hold times exceeded one hour and agents had to take down callers' information so they could be contacted at a later time with details on how a replacement product could be obtained. This combination of factors led to early frustration and concern among consumers, many of whom took to social media to voice their complaints.

FDA ENFORCED
*immediate
recall*

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HIGH-PROFILE
medical device critical
to patient health

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400
agent contact center
live in 48 hours

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70K
notifications deployed

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BESPOKE
*voucher
processing*
solution created

Solution

Sedgwick brand protections' end-to-end recall solutions provided the client with the resources and support it needed to be responsive to consumer concerns and quickly equip customers with the replacement products they needed.

As the company established a voucher system that would allow customers to obtain a free replacement product from their local pharmacies, Sedgwick worked to scale up contact center agents, reaching approximately 400 agents in just 48 hours. To accomplish this, the Sedgwick team quickly established a dedicated application for processing vouchers, which also shortened processing training times.

In addition to engaging its first-rate contact-center service, Sedgwick assisted with the notification process. The company reached out to direct account holders, who provided lists of retailers such as pharmacies, clinics and hospitals. Sedgwick sent 70,000 notifications via direct mail to these contacts. Once retailers received these notifications, they in turn reached out directly to their customers, which caused a sudden, but expected, increase in call volumes.

Results

Sedgwick's ability to quickly scale a recall response and its full suite of recall management capabilities helped this company respond effectively and successfully to a recall on short notice.

Sedgwick's vast experience with patient-level medical device recalls allowed the recall management team to anticipate call spikes and maintain the appropriate number of agents. Once staffing levels were ramped up, agents worked to answer the continuing influx of inbound calls while simultaneously reaching out to the affected consumers who had previously called and provided their contact information. By day four, call times were reduced to mere minutes.

On the product-management side, many customers immediately discarded the affected product because they were able to quickly order and pick up replacement products from their local pharmacies. Even with this streamlined process, Sedgwick sent return kits to customers to make returns of previous devices easy. The returned units were then processed, quarantined and stored in Sedgwick's secure facility, reducing the risk that the affected products returned to market.

Key takeaways

- Regulators can be unpredictable when determining how soon a company needs to announce a recall. Establishing a substantive recall management plan that provides for a scenario where the regulator requires immediate corrective action will ensure companies aren't caught off guard.
- If a recall includes a potentially life-saving device, consumers are likely to demand immediate action and will be quick to turn against a company if their demands aren't met. Ensuring that the consumer hears directly from the company following a recall with concrete steps for receiving a new product builds consumer trust and loyalty and can help protect the company's brand.
- A strong partnership with a recall expert is critical to effective event management. The expertise and scalability offered prevents even the biggest challenges – such as fielding thousands of consumer calls and making thousands of notifications to retailers – from significantly affecting recall effectiveness.

Sedgwick brand protection

Brand and reputation are the most valuable and vulnerable assets a business has. Brands embody and encapsulate everything a business does, and its customers expect. Nothing says more about a company's commitment to its customers than its efforts to uphold promises of safety, quality, and service. That's why companies are often remembered more for how they handle an in-market challenge than for the problem itself. We know what it takes to manage recalls in a way that upholds your commitments to customers, supply chain partners, industry and regulators.

Trusted by the world's leading brands and businesses, we work in partnership to manage the risks and minimize the impacts of in-market business and product crises. Since 1995, we have managed more than 5,000 of the most sensitive and time-critical recall and remediation programs - spanning 60+ countries and 20+ languages.

To learn more about our recall, remediation and retention solutions, contact us today.

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To learn more about our integrated and customized solutions, visit [SEDGWICK.COM](https://www.sedgwick.com)
