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Safely recalling an essential medical device

Managing a recall when the health and well-being of patients is at stake

With medical device recalls come unique challenges, especially when those devices are used in hospitals, health clinics, doctors' offices, and in patients' homes around the world.

Effective communication, reverse logistics, repairs and software fixes and customer management are essential elements of any successful recall. They become even more critical when the recalled device is used for monitoring and protecting patient health.

Challenge

What started as a straightforward consumer notification about a medical device malfunction risk quickly snowballed into a full-scale recall and discontinuation of a blood monitoring device.

In-home medical devices are among the most complicated products to recall because abruptly pulling a product off the market without careful transition and adequate replacement can do more harm than good to patients. A world-leading developer of point-of-care diagnostic devices faced this challenge when it initiated a voluntary recall of its in-home blood monitoring systems, which are used to monitor patients taking a common blood-thinning medicine.

When the company started receiving reports of malfunctions, it proactively reported these device concerns to the Food and Drug Administration (FDA) and began conducting a thorough investigation. As part of its commitment to patient safety, the company initiated a voluntary correction action to inform certain users that they should not use the blood monitoring system while the company worked on a software fix.

Over the course of two years, the company invested in the research and development of software enhancements to fix the device's accuracy, but the FDA ultimately decided the software updates were not a sufficient remedy. The company worked with the FDA to determine the most appropriate timing for a product discontinuation while providing guidance on transitioning patients to an alternate solution in the least disruptive manner possible.

WORLD-LEADING

medical device

manufacturer

MULTILINGUAL

call center network established

INBOUND AND OUTBOUND

capability

40+

country toll-free numbers set-up

Solution

Our end-to-end recall management offerings allowed the manufacturer to satisfy complex FDA regulatory requirements and compliance specifications, while seamlessly coordinating notification and response, data management, product retrieval and destruction of the devices.

Due to the scope of the outreach, the company turned to Sedgwick brand protection to spearhead the notification effort. One of the biggest challenges was that the company had limited information about its customers since it sells the device via distributors. Having faced this challenge before, Sedgwick knew the path to success. Under the direction of the client, Sedgwick contacted every distributor to compile a master patient database and commence the notification process.

In further support of this effort, Sedgwick quickly launched and staffed numerous call centers to handle all outbound and inbound recall communication. More than 40 toll-free numbers for different countries and languages were established to ensure that every potential patient, healthcare provider and distributor could reach an expert fluent in their language.

Sedgwick also managed the assembly, shipping and retrieval of device return kits, allowing the manufacturer to focus on other critical tasks. Since the device was blood-related, Sedgwick advised the company to include an alcohol wipe and instructions on decontamination prior to shipping. This helped the company avoid the biohazard label, ensuring compliance while reducing transportation and disposal costs.

Results

An unwavering commitment to protecting the safety of patients, while removing a potentially malfunctioning product from the marketplace, protected the company's reputation during a product crisis.

The call center operation exceeded the client's expectations in terms of notification and continued communication with patients, providers and distributors across all geographies.

Effective data management was also critical to the recall's success. Sedgwick's proprietary data management system tied all recall data into one system, providing full visibility into event progress and fulfilling all regulatory documentation requests.

So, while medical device manufacturers typically face reticent in-home medical device users, the effective call center and data management enabled the manufacturer to achieve a return rate far above the industry norm for a patient-level recall.

Key takeaways

- When dealing with a possible malfunction in a medical device, it is important to remain in contact with those who may be distributing or using the device, as well as any relevant regulatory bodies. Keeping these parties in the know will increase consumer trust in the company and prevent any surprise activity from regulators.
- Even after taking all the necessary steps to remedy an issue, regulators may still call for the product to be recalled or withdrawn from the market. Establishing a recall management or product withdrawal plan before this happens will help facilitate a fast, compliant response to the regulator's demand.
- When working with patients during a recall of an in-home medical device, it is important to communicate with them clearly and effectively, as well as provide them with all the information they need to secure an alternative device. By following these steps, you will be more likely to successfully recall more affected devices.

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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.

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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**