CASE STUDY
Recalled Blood Monitoring Medical Device
In-home medical devices are among the most complicated products to recall because – unlike, say, food or consumer products – abruptly pulling a product off the market without a 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.
The drug is for people at risk of developing harmful blood clots, such as those with mechanical heart valves, irregular heart rhythms, or certain surgeries.

The anticoagulation monitoring devices and test strips are used to make sure patients are getting the right doses of the drug. Too much can cause spontaneous bleeding, while too little can cause deadly blood clots to form.

In 2014 reports began surfacing that readings from the devices were between 3.1 to 12.2 units lower than clinical lab results. The misreadings meant that some patients could be at risk for uncontrolled bleeding. The company initially received nine reports of adverse events, prompting it to take action. The company ultimately received thousands of reports of malfunctions over the past two years. As part of its commitment to ensure the safety of patients, it proactively reported these device concerns to the FDA and began conducting a thorough investigation.

Since the cause of the misreadings was unknown at first, the company initiated a voluntary correction to inform users of the blood monitoring systems that patients with certain medical conditions should not be tested with the system while it worked on a software fix. The plan was to notify users experiencing inaccurate readings that they should immediately stop using the device and use an alternative testing method, such as a plasma-based laboratory international normalized ratio (INR) test, or an alternative monitoring system.

The first challenge was the sheer scope of the outreach: How do you quickly find and inform nearly 200,000 patients, health care professionals, retailers, and distributors across multiple countries and continents?
The company turned to Stericycle Expert Solutions to spearhead the notification effort because of its recall reflexes, developed over thousands of large scale recalls, which allow the company to move with the speed, efficiency, and knowledge that it needed. Stericycle Expert Solutions’ experience in being able to marshal a massive call center operation, as well as manage all the consignee responses, field corrections, regulatory reporting, and other response needs, were also critical to the company’s success and brand reputation.

One of the biggest challenges was that the company had limited information about its customers; it sells the device via distributors. Having faced this challenge before, Stericycle Expert Solutions was tasked with contacting every distributor to compile a master patient database and commence the notification process.

“Our first focus is always on the safety of patients using the company’s products. We needed speed and reach to deliver accurate and actionable information to everyone at risk,” said Stericycle Expert Solutions vice president Mike Good. “The company recognized it lacked the expertise and infrastructure to execute the notification and response effort in a timely manner, so we were enlisted because of our experience successfully executing large scale recalls efficiently and compliantly.”
PHASE 2: FULL-SCALE GLOBAL RECALL

Over the course of two years the company invested in the research and development of software enhancements to fix the device’s accuracy.

The FDA ultimately decided the software updates were not a sufficient enough remedy, so it worked with the agency to determine the most appropriate timing for product discontinuation while providing guidance on transitioning patients to an alternate solution in the least disruptive manner possible.

Since Stericycle Expert Solutions had proven itself as a trusted partner by guiding the company through a challenging patient notification phase, and because Stericycle already had vast experience managing recalls on an international scale, it re-engaged the company in 2016 to help it navigate the more complex global product recall effort. As with the 2014 notification effort, the key objective was to ensure the recall was handled with speed, safety, and compliance to best protect the patients.

Stericycle Expert Solutions was able to provide a full range of recall services, including satisfying complex FDA regulatory requirements and compliance specifications, coordinating seamless notification and response, data management, product retrieval, and destruction of the devices. The company deployed proprietary technologies and a seasoned international field force to make it happen.

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Mike Good, Stericycle vice president
Stericycle Expert Solutions’ ability to quickly staff and open call centers in under two weeks was the first step in handling the outreach and incoming calls. More than 40 toll-free numbers for different countries and languages were set up to ensure that every potential patient, healthcare provider, and distributor could reach an expert fluent in their language. All Stericycle Expert Solutions’ call center employees underwent sensitivity training to develop the “soft skills” necessary to talk to frightened, confused, or culturally-sensitive respondents.

The call center operation was particularly successful in its notification efforts, reaching patients, providers, and distributors across all geographies. A big challenge with users of in-home medical devices is their reticence to respond or take action once notified of a recall. Yet Stericycle Expert Solutions was able to achieve a return rate far above the industry norm for a patient-level recall.

Stericycle Expert Solutions also managed the assembly, shipping, and retrieval of kits in which patients returned their devices. Because it was a blood-related medical device, it was considered a potential biohazardous waste. Stericycle Expert Solutions advised the company to include an alcohol wipe and instructions on decontamination prior to shipping, using its regulatory expertise to help the company avoid the biohazard label and reduce costs.

Data was the final component to the recall’s success. Stericycle Expert Solutions was able to tie all data relating to the recall into one system to give the company full visibility into the progress, as well as provide all regulatory bodies the reports they needed for compliance.

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CRITICAL RECALL REFLEXES

- Updated consignee contact information
- Global experience and capabilities
- Speed and scalability
- Data collection for regulatory reporting