RECALL: PREVENT, MANAGE, MITIGATE, AND SURVIVE

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Surviving a medical device recall is no easy feat. It takes a toll on a company whose product is recalled — financial costs, human resource and moral impact, and market reputation fallout. On February 2, 2011, Hodgson Russ attorneys participated in a half-day educational event organized by MedTech, an upstate bioscience and medical technologies industry group where the real life stories of surviving a product recall were discussed by manufacturers, contractors, and service providers. We share here some of those discussions.

Financial cost and risk stemming from product recalls were primary topics addressed.

The direct financial costs include:

- Cost of product removal, services, or correction
- Administration of the recall (including legal fees, contractor fees, and perhaps overtime for employees)
- Shipping and product replacement costs

The indirect costs include:

- Competitive disadvantage in the marketplace
- Potential decrease in the stock price
- Warranty claims and other customer issues (perhaps even including product liability claims)
- Workplace stress

Unfortunately for the FDA-regulated industry, a product recall has become a harsh reality. It is no more a question of if it will happen, but when it will happen. The number of recalls has significantly increased in the past few years, and in 2010 there were nearly 500 Class I FDA-regulated recalls — nearly a 160 percent increase over 2009. According to industry experts who have survived one or more recalls, a company can survive a recall or multiple recalls only if it is proactive and has a solid recall team comprised of qualified technical, managerial, and legal professionals. Defective planning and an improperly handled recall can result in significant economic loss and loss of goodwill.

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Before a Recall

Prevention is the best medicine, so first and foremost a recall strategy must be sketched out by the recall prevention and management team and controls must be implemented to prevent design or manufacturing defects. The product warnings and directions of use must be evaluated and amended, if required. The recall strategy and loss prevention plan should be incorporated in every relationship of the company — ensuring that legal relationships with contractors, suppliers, and distributors clearly spell out the anticipated recall responsibilities and set forth appropriate product warranties, disclaimers of warranties, and limitations of liability (including the exclusion of consequential damages). This is also the time to thoroughly evaluate insurance options and understand your notice and reporting responsibilities. Finally, in the pre-recall stage, manufacturers should prepare a policy for evaluating product complaints and defects and assessing potential health hazards in the event of a problem. Ideally, the health hazard analysis will match with the FDA hazard analysis procedures so that a company can proactively anticipate the FDA's classification of a recall.

These may seem like inconsequential actions, but they have been proven invaluable in a company's ability to survive a recall.

During a Recall

If the recall cannot be prevented by better-quality management in supplier and manufacturing processes, then a company moves into the growing class of manufacturers who have recalled an FDA-regulated product. Learning from your peers' mistakes and victories can be very useful to surviving your own recall. FDA has several resources and published guidance on its website dealing with the subject of recall, but a well-drafted recall strategy and support of a fully equipped recall team will be critical in managing a recall and mitigating your losses.

First of all, it is important to understand whether the recall is actually a recall — a corrective action for a medical device may also be a "market withdrawal" or a "stock recovery," which technically are different from a recall. A market withdrawal is a firm's removal or correction of a distributed product involving a minor violation that would not be subject to legal action by the Food and Drug Administration or involving no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc. A stock recovery means a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm; i.e., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use. Understanding these distinctions is important because they determine the firm's reporting obligations to the FDA.

While evaluating whether the corrective action is reportable or simply must be documented internally, manufacturers should immediately be scientifically assessing the root cause of the recall. Recall survivors suggest conducting a product risk assessment within 24 to 48 hours of the issue identification and recommend classifying (Class I, II, or III) the recall internally before even contacting the FDA. Even though a reportable recall is ultimately classified by the FDA, an internal classification will be very helpful in determining the extent of the recall, products included and excluded, determining which countries must be notified, what kind of public notices must be issued, and in drafting a Corrective and Preventive Action (CAPA) Plan for the FDA.

The importance of approaching the FDA with a thorough and comprehensive recall package can never be overestimated. The FDA will review the adequacy of a proposed recall strategy developed by a recalling firm and recommend changes as appropriate. A recalling firm should conduct the recall in accordance with the FDA-approved recall strategy but need not delay the initiation of recall pending FDA review of its recall strategy. Recall survivors from the New York area note that FDA feedback on a proposed recall strategy can often take weeks. To avoid unnecessary delay, a recalling firm should be familiar with FDA expectations and have the confidence to implement the recall even before receiving formal FDA feedback.

At this time it is also critical that the plethora of often mandatory and time-pressed communications with the different domestic and foreign agencies, customers, contractors, suppliers, etc. have an oversight of an appropriately skilled and knowledgeable attorney. Any miscommunication can be potentially damaging in dealing with the FDA, future customer litigation and settlement, and recovering losses from your contract and component part manufacturers and insurance carriers.

It is also at this time that all the contracts and agreements and their provisions relating to warranties, disclaimers, remedies, etc. will be put to test and those agreements drafted by skilled legal counsel in anticipation of a recall will now be extremely handy.

After a Recall

Obtaining a closure letter from FDA "terminating" a recall can be a very lengthy process. Regardless of the formal FDA closure, after surviving a recall it is extremely important for the recalling firm to evaluate its implementation of the recall strategy, discuss shortfalls that occurred, and then amend the recall strategy to be better prepared in the future. Some self-evaluation in this area will be invaluable to future recalls. It has also been suggested by recall survivors that conducting mock recalls internally to periodically evaluate and improve the recall strategy and test the effectiveness of a recall team can be very useful.

Anticipating a recall before it happens, understanding the process, and having an expert recall team will go a long way in easing some of the anxiety and confusion of what is likely to be an inevitable recall.