

Vol. 17 No. 37

September 6, 2002

IN THE EYE OF THE STORM: TIPS FOR MANAGING AN FDA RECALL

by

David M. Hoffmeister and Wayne L. Pines

Although no firm expects to have a product recall, or a crisis situation involving product tampering or risks to public health, at some point virtually every company that makes a health care product will face such a situation. The prospects of these types of events causes a visceral reaction in executive offices and boardrooms. Unless all aspects of the crisis are carefully managed, a recall can threaten a company's reputation and very existence, or cause severe damage to a product's sales.

The mantra for effective recall and crisis management is a simple one: be prepared.

Crisis preparation can save a lot of time, effort and money down the road, when an actual crisis occurs. Every company should have in place a recall and crisis response policy, as well as rehearsed procedures for what to do during a real crisis. Thinking through what kinds of crises may occur and developing procedures and systems for managing them constitutes good management. The best policies are those that have been tested, under controlled circumstances, in a hypothetical crisis simulation.

Such policies should provide a step-by-step guideline for assessing whether a product should be recalled, how the evaluation process can occur quickly, and how action, if any, can be taken promptly. The Food and Drug Administration (FDA) has three levels of recall, depending on the health risk. The criteria that FDA applies — its own standards for recalls, as published in the Code of Federal Regulations — provide the point of departure for a company's own internal assessment as to whether a product should be recalled.

Since most companies have written crisis and recall policies, the discussion below will focus on who within a corporation should make the recall decision or participate in the management of a crisis, and critical activities that must be managed, including controlling documentation and interacting with the media.

One point goes without saying: the best crisis preparation is crisis prevention. Very often crises

David M. Hoffmeister is a partner with the law firm Wilson Sonsini Goodrich & Rosati, where he leads the firm's Drug and Device Regulatory and Healthcare Law practice within the Life Sciences Group.

Wayne L. Pines is a consultant and serves as President of Regulatory Services and Healthcare at APCO Worldwide, an international consulting firm.

such as recalls can be prevented by a careful evaluation of a company's vulnerabilities, by taking steps to fix those things that can be fixed, and by not letting problems go unfixed for too long.

But if there is going to be a recall or a similar kind of crisis, here are some tips on how to do it:

THE RECALL TEAM

One person in the corporation should be designated the recall coordinator. The reason is that a recall requires focused attention. If a single person takes the responsibility, then there is a higher likelihood that everything will get done in a timely manner. The person who takes on this responsibility should be educated about recall procedures, be in a position to make decisions, and have the time to dedicate to the task. Recalls must be carefully managed.

This individual should be responsible for: chairing all recall meetings; insuring that all appropriate individuals and disciplines are present and available to participate in the decision making process; keeping and preparing meeting minutes; briefing select corporate officials; and acting as the official repository for all drafts and final copies of press releases, recall notices, media scripts, and other internal and external communications.

The recall team should consist of individuals with the expertise to evaluate whether a recall is warranted and if so the capability to carry it out. This team should include representatives from quality assurance/quality control, manufacturing, regulatory affairs, legal, medical, public affairs, and senior management. Depending on the situation, other disciplines within the company may be needed and should participate (e.g., Investor Relations, Materials Engineering, Sales and Marketing).

Each individual representative should have a designated backup. For smaller companies that do not have internal medical personnel, attorneys, or other essential professionals, bringing in outside resources is almost always prudent and necessary. These individuals should be identified, retained and be available long before a recall or another type of crisis occurs.

DOCUMENT MANAGEMENT

How documents are created and retained is extremely important during any crisis situation, and must be managed appropriately. Failure to carefully and effectively control document generation and retention has been costly to many companies that must defend lawsuits or are subject to congressional hearings after completing a recall or a crisis situation.

The recall team should create and retain only documents that are needed to accomplish the tasks at hand. This includes documents that will be needed to defend any future legal claim and those which show that procedures were in place and followed. Meeting minutes are also important to establish that the company thoroughly investigated and took prompt and effective action to remove the product from the market. All documents including press releases, meeting minutes, recall notices, and media scripts should be initially marked "draft" and reviewed by counsel before being finalized. After a document is finalized, all drafts should be destroyed. Only final documents should be retained in the file. It is best not to use e-mail, or to be discrete in using it, as it is virtually impossible to purge an e-mail system of ill-advised messages.

All internal investigations, audits, and document preparation should be managed and directed by an attorney. This will help ensure that all internal communications and documents that are generated are protected by the Attorney/Client privilege and work product doctrine. Additionally, members of the recall team and any employee involved or assisting in the investigation should be discouraged from discussing the investigation or crisis except during recall meetings where company counsel is present. The reason is that anything said without counsel present might not be afforded protection in the event of later litigation.

At the end of the recall, the file should contain, at a minimum the following documents: (1) the final copy of the recall notice sent to customers; (2) final press releases; (3) all correspondence with FDA, including status reports and recall closure letter; (4) medical evaluation or health hazard analysis; (5) product accountability (including amount of product produced, and product in inventory, distributed and returned); (6) distribution lists; (7) documentation that customers have received the recall notice and followed use or return instructions; (8) final investigational reports or audits; (9) documentation of corrective action; and (10) documentation of proper disposition of the recalled product.

ACCURATE COMMUNICATION IS KEY

During a crisis, it is imperative to ensure the truth and consistency of public statements. Generally, a regulatory crisis involves assertions that a product presents a health hazard or endangers the public health. These assertions can become public through news reports, and prompt the company to give an immediate, unfocused, response.

Carefully managing the media is critical. All public statements must be accurate, truthful, and capable of being proven, for they may be closely scrutinized in the future in many different forums (e.g., lawsuits, Congressional hearings). If an assertion cannot be substantiated or, worse yet, can later be proven wrong, the statement can haunt the company for a long time in the future.

One of the most challenging documents to construct during a recall is the press release, if one is needed. Generally a press release is needed only if the product is being recalled to the consumer level and if there is some action that the consumer needs to take, such as returning the product or destroying it. A good press release will clearly explain what the product is, which lot numbers are involved in the recall, what the problem is, what the health hazard is, and what consumers should do. For Class I and some Class II recalls, FDA will want to see the press release in advance.

A balance must be drawn between the need to reach out and respond to media and other inquiries, and the need to assure that public statements do not put the company into jeopardy. Time pressures very often are responsible for causing errors. The most effective process to achieve the needed accuracy is to include the company's spokespersons in all meetings, so that they fully understand the nuances of the situation; for company statements to be reviewed carefully before issuance; and for spokespersons to be carefully rehearsed before they conduct interviews.

COMPANY SPOKESPERSON GUIDELINES

The best way to approach the spokesperson function is to assign one person to be responsible for each specific audience. That is, there should be a single person assigned to speak with the media, a person to speak with the FDA, and so on. The reason for having a single spokesperson for each audience is to assure that responsibilities are clear and that, as communications take place, there is consistency over time.

Once a media spokesperson has been identified and properly trained, the following general

guidelines should assist that person when speaking for the company:

- ▶ Be very clear as to what the messages are. Be sure that there is a clear understanding and statement, for example, of the health risks, if any, and most particularly what the public should do with the product (i.e., how to dispose of it, or whether to return it to the store where purchased).
- ▶ Be sure that all messages are cleared with the entire team, including legal counsel and senior management. As the recall situation progresses, the messages may change.
- ▶ Assure that information provided to the public closely tracks information in existing corporate files, thus avoiding a paper trail that would contradict statements made to the media.
- ▶ Avoid escalating the importance of the issue by overreacting, speculating or volunteering information that is not part of the approved message track. It is easy for the public to overreact to a health risk situation if it is not explained properly.
- ▶ Never lie or bluff. If uncertain about a specific question, say so and indicate that it will be investigated.
- ▶ Provide mechanisms for the public to obtain further information, such as an 800 number. Train all personnel that may interact with the public; usually written Q&A documents are helpful, along with rehearsals.
- ▶ A company in the midst of a recall or another crisis must be sure that personnel not involved in the situation are, first, properly informed and, more importantly, know their roles (or lack thereof). It is especially critical that phone operators, receptionists and others who come into routine contact with the general public know how to handle the situation.

CONCLUSION

By planning ahead, and identifying and training a recall/crisis spokesperson, the company will be able to minimize inappropriate or inept responses that could complicate ongoing legal problems or, worse, encourage litigation.

The management of a recall or any crisis is tricky. The first time that managers face a crisis, if they have not prepared for it or have not been exposed to a hypothetical simulation, they tend to make mistakes. Those mistakes can have severe repercussions in terms of product reputation, corporate reputation, or a compromised litigation position.