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Articles

- Ask an Expert
- Risk Management 101
- The Hartford Loss Control
- Webinars
- Announcements & Events
- Regulatory 360
- Products Liability 360
- Medmarc Business Network

Publications: Articles

News/Resources » Articles » Improving Recall Effectiveness for Medical Devices « Previous | Next »

Tools

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Improving Recall Effectiveness for Medical Devices

By Kenneth Ross, Esq.

As we all know, recalls can be one of the most costly and damaging events in any manufacturer's corporate experience. Not only do recalls bear tremendous reputation implications, but they also cost a great deal to implement and resolve. Recalls can generate many new products liability cases and make any such existing cases harder to defend. In addition, they might even generate class-action lawsuits which can cost many millions of dollars to resolve.

Since recall adequacy is based on a negligence theory, it is left to a jury to decide whether the manufacturer could have done more. Adopting the best practices that have been issued by government agencies and standards groups and utilized by other manufacturers can be very difficult to do. There are many different ways to undertake recalls and it is difficult to know exactly which approach would work best for a particular company and its products.

As a result, a manufacturer must try to be aware of the various ways in which recalls have been undertaken, and are suggested to be undertaken, so that it can adopt and be prepared to utilize techniques that are effective, not too costly, and defensible. In addition, when defending the adequacy of a recall, considering the "best practices" employed or suggested by others can be helpful in arguing that a company did conduct an adequate, or non-negligent, recall.

While relying on the government's regulations, guidelines, and its approval of the company's recall plan will not provide an absolute legal defense to a claim of negligent recall, it can be helpful in bolstering an argument that the company did all that was necessary. As a result, it is useful to learn about new developments and new research on what is considered an effective recall plan.

The GAO issued three reports in 2011 and 2012 making recommendations about how recalls could be improved for medical devices, food, and motor vehicles. The GAO analyzed recalls implemented by the Food and Drug Administration (FDA) and the National Highway Traffic Safety Administration (NHTSA) and made recommendations for improvements.

The first report was issued by the FDA in June of 2011, entitled "*Medical Devices: FDA should enhance its oversight of recalls*." The GAO interviewed FDA officials and examined information on medical device recalls from 2005 to 2009. Based on these interviews and a review of FDA documentation, the GAO made recommendations for developing enhanced procedures and criteria for assessing the effectiveness of recalls, as well as for documentation of the agency's basis for terminating individual recalls.

This report was undertaken at the request of Congress, which was concerned with the effectiveness of the medical device recall process, as there had been reported incidents where individuals were seriously injured or died due to defective devices that had been recalled.

The GAO evaluated 3,510 recalls conducted from 2005 to 2009, which revealed some interesting statistics on the time required to complete individual recalls, as well as which kinds of products were most frequently subject to recalls. (Among general hospital and personal use devices, cardiac devices required the longest amount of time to complete a recall, and infusion pumps were the most commonly recalled.) In addition, the GAO classified the root causes of these recalls and concluded that deficiencies in process controls, device design, and component design and selection resulted in the greatest number of recalls.

The FDA found gaps in the medical device recall process which limited effectiveness and timeliness of recalls. In particular, the GAO felt that the FDA's procedures for overseeing recalls were unclear, and that the FDA had not established criteria, based on the nature or type of devices, for assessing whether firms corrected or removed a sufficient number of recalled devices. Also, the FDA did not document its justification for terminating recalls and sometimes took too long to officially terminate recalls.

There were some anomalies noted by the GAO report. The majority of recalls are deemed Class II, yet Class I recalls more than doubled between 2008 and 2009. Further, many recalls have been ongoing for 5 years – a fact that could not be explained by the FDA. In addition, there were concerns expressed by manufacturers about the length of time it can take the FDA to classify recalls as well as the confusion that can be created, especially when a recall starts off as Class II and is then re-classified by the FDA as Class I.

The GAO identified a variety of inconsistencies in how recall audit checks were implemented and documented, especially how it is determined by an investigator whether an audit was effective or ineffective. The FDA admitted that there are no detailed instructions or requirements for conducting audit checks. This gap is fairly significant in that no criteria or guidance is provided by the FDA on the desired percentage of recalled products that must be corrected or removed. Medical device firms reported that the percentage of products returned was not the key factor for the FDA in determining effectiveness, as long as the company made three attempts at communicating with customers and device users about the recall.

Generally, the FDA agreed with the GAO's recommendations and has convened a working group to analyze each of the recommendations and develop improvements in its processes for analyzing, implementing, and terminating recalls.

Conclusion

Manufacturers should be aware of all good ideas in operation in order to come up with the best recall program possible for the risk that is presented. Going outside of FDA-regulated industry might yield useful results. Government agencies in the U.S. and elsewhere do discuss issues of common interest. Hopefully, improving recall procedures and effectiveness rates is or will be one of those subjects.

Manufacturers need to keep track of these developments and utilize those services that make sense for their products. When manufacturers who sell globally recall products, it is important that the recall be successful in all countries, not just the U.S. Continuing accidents and injuries, and inadequate recall completion rates in other countries, can have an adverse effect on U.S. products liability litigation. It could even trigger follow-up recall efforts by the FDA. Therefore, manufacturers should consider proactively adopting best practices being developed around the world.

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Kenneth Ross is Of Counsel to the Minneapolis office of Bowman and Brooke LLP where he practices in the areas of product safety and liability prevention and advises manufacturers, product sellers and insurers on ways to identify, evaluate and minimize the risk of products liability and contractual liability. These guides do not constitute legal advice and are very general. You should consult competent legal counsel or Medmarc Loss Control before acting on any of the information in these guides.