

## **Recall Effectiveness: A Hot Topic**

### **By Kenneth Ross\***

#### **Introduction**

Most manufacturers, at some point, will have to undertake a post-sale remedial program in connection with one of its products. The program could include a consumer warning, recall, retrofit, or safety upgrade. Such a program may be instituted as a result of a series of accidents or consumer complaints, lawsuits, an adverse jury verdict, a safety improvement, a change in standards, or a request or order of a governmental entity in the United States or foreign country.

Recalls occur somewhere in the world every day. Unless they are 100% effective, these recalls can have a huge impact on the manufacturer, product seller, consumer and even the manufacturer's shareholders. These negative impacts result from, among other things, the cost and disruption of the recall itself, lost goodwill for the recalled product, penalties levied by government agencies, and injuries and lawsuits that result from the product problem.

Any manufacturer selling in the United States needs to assume it has, at a minimum, a post-sale duty to warn, since significantly more than half of the states have adopted some version of this duty, either through the courts or the legislatures. On the regulatory side, U.S. governmental agencies have revised their regulations to require reporting of more safety issues which has and will result in more recalls. In addition, governments in the European Union, Canada, Japan and Australia have passed or are considering new laws increasing a manufacturer's responsibility to recall its products from the marketplace. And lastly, Congress recently passed legislation and is considering new legislation which enhances recall responsibilities for manufacturers and product sellers.

This author has previously published many articles on a manufacturer's post-sale duties as enunciated by the common law and legislative law in the U.S. and elsewhere and how to comply with those duties (see <http://www.productliabilityprevention.com/plparticles.html>). The intent of this article is to summarize the law and then to discuss recent and future efforts around the world which will further define and improve efforts to recall products. These new benchmarks will have a big impact on manufacturers and product sellers. If these entities do not complete an effective recall, these benchmarks will be used to argue that the recall was inadequate. These enhanced requirements may make it even harder to perform an "adequate" recall and defend a lawsuit involving a recalled product.

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## The Common Law of Post-sale Duties

The common law basis for post-sale duty to warn is negligence. So, the higher the risk, the more the manufacturer needs to do to minimize the risk to consumers and other product users. This formulation was confirmed in the *Restatement of Torts: Third (Products Liability)* (“Restatement”), published in 1998.

As with all questions of reasonableness under negligence principles, the common law provides no further guidance to a manufacturer to understand how effective its remedial program must be in order for it to be considered non-negligent. As long as the product injured someone, the jury could find that the manufacturer or product seller could have done more to recall the product and therefore was negligent.

In addition, a post-sale duty to warn is a separate cause of action from pre-sale defect. So, even if a manufacturer successfully defends the post-sale negligence cause of action, it may still be liable. If the manufacturer’s product was deemed defective at the time of sale, the manufacturer could still be held liable for selling a defective product.

All of this makes it important for manufacturers to be prepared to institute a post-sale remedial program quickly, and for the program to be as effective as it can be under the circumstances. This effectiveness will reduce the number of products in the field that could harm people, and will hopefully allow the jury and any affected government agency to conclude that the manufacturer’s conduct was reasonable and not negligent. And, even if the manufacturer is held liable under strict liability or negligence for selling a defective product, its actions and due diligence should be helpful in defending against any claim of punitive damages.

The Restatement states that there is no common law duty to recall a product. However, it also says that if there is a mandatory or voluntary recall and a manufacturer fails to act reasonably, it can be held liable. Again, there is no further guidance on what is reasonable. It is up to the jury. Also, the Reporter’s Notes to comment “d” of section 11 say that there is “a paucity of authority discussing the legal effect of the efforts of a manufacturer to recall its products when such efforts are not successful in avoiding injury due to the fact that either dealers or purchasers do not take advantage of the recall.”

The ability of the plaintiff to argue that more could have been done will be boundless. And, plaintiffs may not even need an expert to support this theory. In such cases, the defendant will need to prove that their conduct was “state of the art,” complied with all applicable governmental statutes and regulations, and was as comprehensive as necessary considering the level of risk.

However, Section 4 of the Restatement clearly says that compliance with applicable governmental regulations or statutes is a minimum requirement and “does not prevent a finding of negligence where a reasonable man would take additional precautions.”

Based on this law, it is apparent that a manufacturer may not be able to successfully defend itself by claiming that a government agency “approved” its post-sale program. While this “approval” by a government agency may not get into evidence, it should be able to be used by an expert witness who can cite it as one of the bases for opining that the manufacturer’s conduct was reasonable and the post-sale program adequate.

Given the paucity of judicial authority describing an adequate post-sale remedial program, it is necessary to consider United States and foreign regulatory law, guidelines and regulations as well as suggestions provided by those in the recall industry to help establish an outline of an “adequate” program. There has been a huge amount of recent activity in this area as government agencies try to improve recall effectiveness.

## **U.S. Consumer Product Safety Commission**

Many U.S. regulatory agencies provide helpful guidelines to manufacturers on how to undertake a recall and how to make it more effective. One of the most useful documents is the CPSC Recall Handbook. See <http://www.cpsc.gov/businfo/8002.html>.

The CPSC handbook states that the core element of a recall is as follows:

A company that undertakes a recall should develop a comprehensive plan that reaches throughout the entire distribution chain to consumers who have the product. The company must design each communication to motivate people to respond to the recall and take the action requested by the company.

The handbook goes on to say that the objective of any recall is:

- to locate all defective products as quickly as possible;
- to remove defective products from the distribution chain and from the possession of consumers; and
- to communicate accurate and understandable information in a timely manner to the public about the product defect, the hazard, and the corrective action.

A large part of the handbook discusses the many ways in which the manufacturer or other entities in the chain of production or distribution can communicate with consumers. However, it leaves it up to the party doing the recall to determine what is appropriate. The CPSC says that in determining what forms of notice to use, the paramount consideration should be the level of hazard that the recalled product presents.

Nowhere does the CPSC say how effective the recall must be to be considered successful. Recalls or retrofit programs with an effective rate of less than 10% have been deemed acceptable by the CPSC. And, the CPSC has said that the average response rate for most recalls is between 4% and 18%.

Because of concern that effectiveness rates are too low and can be improved, in 2003 the CPSC commissioned a study of recall effectiveness that included public meetings to discuss successful techniques for recalls, a literature search, an evaluation of consumers’ behavior as it relates to recalls, and an evaluation of the CPSC recall database to assess the effectiveness of previous recalls.

As part of this effort, in August 2003, the CPSC released a new study that organized and summarized the literature found on recall effectiveness and effective safety communications, including warnings. For a copy of the full report, go to <http://www.cpsc.gov/LIBRARY/FOIA/FOIA03/os/RecallEffectiveness.pdf>.

The report concluded by saying:

The research collected and reviewed for this project details the large number of steps required for a recall message to achieve an active response from an affected product user. Users must receive the message, internalize and comprehend its instructions, determine that a response is necessary, and be willing to perform that response even if there are costs associated with doing so. In the case of product recalls, they must follow through on that willingness to check if they have an affected product, then take additional actions to eliminate or reduce the hazard.

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We believe that the materials identified and reviewed for this report provide a more than adequate foundation for an assessment of ways in which recall programs—and particularly recall communications—might be modified to improve potential response rates.

The author of this 2003 report, Dr. Ed Heiden, recently published an article that discussed what the CPSC has done since 2003 in this area and some of his ideas on how best to assess and measure recall effectiveness (see <http://www.productsafetyletter.com/news/5649-1.html/>). It shows that the CPSC did not follow-up on their 2003 efforts. However, with three new commissioners and a significantly larger budget, it is likely that the CPSC will try to provide ways that the CPSC and product sellers can improve recall effectiveness.

The CPSC recently launched “CPSC 2.0,” a comprehensive networking initiative that will make safety information more accessible to consumers. This initiative will use blogging, widgets, and social networking sites to transmit safety information consumer and engage in a dialogue on safety issues. See <http://cpsc.gov/cpscpub/prerel/prhtml09/09346.html>.

## **U.S. Congress**

Congress has also gotten into the act. In 2008, the Congress passed the Consumer Product Safety Improvement Act. A number of the sections are meant to enhance recall effectiveness. These sections are described as follows:

- Enhanced recall authority and corrective action plans (Section 214) – Congress adopted a number of provisions increasing the CPSC’s authority (1) to order manufacturers to include Spanish on recall notices; (2) to revoke acceptance of a corrective action preventing the manufacturer from selling its products or require the manufacturer to amend its remedial plan; (3) to require recall notices to include certain additional information; and (4) to require manufacturers to offer a replacement, refund or repair of recalled products.
- Tracking labels for children’s products (Section 103) – The CPSIA requires manufacturers of children’s products to add permanent markings to help identify recalled products. The markings must include the product’s source, production date, and batch. Markings must be in place by August of 2009.
- Prohibited sale, manufacture, or import of recalled products (Section 216) – The CPSIA prohibits everyone in the chain of distribution from selling, manufacturing or importing products that have been recalled. This section also prohibits the sale

of a product without required certificates (see toy and children's product certification requirements) or with false certifications.

- Increased use of registration cards for durable infant and toddler products (Section 104) – To increase recall response rates, the law requires that manufacturers provide registration forms to consumers and better track registered consumers.

Congress is also considering additional legislation that is meant to “establish a simple, centralized, and comprehensive public information process to notify American consumers about product recalls.” It is called the “Consumer Product and Food Safety Information Act of 2009” and it has been assigned to a House Committee for consideration. Lastly, several Senators said that they will likely have hearings on the subject of recall effectiveness in the near future.

## **European Union**

In January 2004, the EU increased the responsibilities of manufacturers to report safety problems to a governmental agency and the responsibility of agencies to be more proactive in dealing with post-sale problems. The 2004 General Product Safety Directive (“GPSD”) substantially expanded a manufacturers’ and government’s post-sale responsibilities. It attempts to strengthen each member state’s powers to monitor and to improve collaboration on market surveillance and enforcement. The mechanism for this effort is a Product Safety Network and Rapid Alert System (RAPEX) procedures. RAPEX requires member states to inform the European Commission of serious risks so that it can alert other members.

The 2004 GPSD also increases responsibilities for manufacturers and distributors. Distributors now have to monitor the safety of products placed on the market, especially by passing on information on product risks, keeping and providing documentation necessary for tracing the origin of products, and cooperating in actions taken by manufacturers and governmental agencies to avoid the risks. Both manufacturers and distributors have a duty to immediately notify agencies when they know or ought to know that a product they have placed on the market poses risks to the consumer that are incompatible with the general safety requirement of the GPSD.

One of the most useful guides on recalls is an excellent pamphlet published in 2004 by the EU and other safety organizations. It provides comprehensive guidance on evaluating risk and communicating to product users about safety issues involving consumer products. (See [http://ec.europa.eu/consumers/cons\\_safe/action\\_guide\\_en.pdf](http://ec.europa.eu/consumers/cons_safe/action_guide_en.pdf)).

Failing to take these post-sale responsibilities in Europe seriously because of the lack of product liability litigation in Europe can be a big mistake. In addition to causing legal problems in the EU, the failure to take appropriate remedial actions in the EU might even creep into your U.S. litigation. In two cases where the author was retained as an expert witness, one involved an allegedly inadequate recall in Europe and the other involved, in part, a failure to recall a product in Europe after recalling the product in the United States. Plaintiffs will most likely inquire into whether the manufacturer undertook any post-sale remedial program in any country outside the U.S., and try to get that fact into evidence to support negligence or punitive damages.

The Freshfields law firm published a report in 2008 on industry attitudes concerning product safety and recalls in the EU. To see this report, go to <http://www.freshfields.com/publications/pdfs/2008/mar10/21238.pdf>.

## Other Recall Effectiveness Activities

There has been a flurry of recent activity from other countries and organizations on recall requirements and guidance on how to perform effective recalls. These all stem from the perception that recalls are not effective and that the goals of improving product safety are not being met.

- On September 30, 2009, the FDA issued a new Strategic Plan for Risk Communication. The plan is meant to help improve the FDA's communication about the risks and benefits of regulated products. Risk communications concerning recalls are part of the communications that the FDA believes needs to be improved. These communications should not overwarn or underwarn about risks and the benefits of continued use of certain products such as drugs and medical devices. And communications after the recall is over need to clearly transmit the message that certain products can now be purchased and used. See <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM183683.pdf> to obtain the report.
- The Australian Competition and Consumer Commission is undertaking a worldwide survey so it can draft recommendations to improve the handling of recalls in Australia. The ACCC is soliciting suggestions from various safety agencies and companies around the world in the hopes of coming up with "best practices." Of course, these recommendations could assist with improving recalls in all countries. See <http://www.accc.gov.au/content/index.phtml/itemId/349534> for ACCC's information page on recalls in Australia. See [http://www.icpsc.org/Recall\\_Effectiveness.html](http://www.icpsc.org/Recall_Effectiveness.html) for more information on this survey and future analysis.
- Canada is considering adoption of a product safety law. The law, referred to as C-6, is moving through the legislative process. It would have a significant effect on a manufacturer's and product seller's post-sale responsibilities. If enacted, it will result in more recalls and give more power to the government to establish regulations that will make recalls more effective. See [http://www.hc-sc.gc.ca/cps-spc/legislation/acts-lois/bill\\_c6-loi-eng.php](http://www.hc-sc.gc.ca/cps-spc/legislation/acts-lois/bill_c6-loi-eng.php).
- The International Consumer Product Safety Caucus ("ICPSC") (<http://icpsc.org/>) is facilitating the exchange of information on consumer product safety issues in the area of governmental policy, legislation and market surveillance with a view to strengthening collaboration and cooperation among governments and regulatory agencies around the world. Current active members of the ICPSC are representatives from several countries in Asia, Australasia, North and South America and Europe.

In addition, delegates from twenty countries gathered in Stockholm, Sweden on September 10th for the ICPSC International Conference on Product Traceability and Tracking Labels. And, the ICPSC will hold a workshop on recall effectiveness in Washington DC on February 15<sup>th</sup> in conjunction with the annual meeting of the International Consumer Product Health and Safety Organization ([www.icphso.org](http://www.icphso.org)). It is expected that regulators from many countries will participate.

See [http://www.icpsc.org/Recall\\_Effectiveness.html](http://www.icpsc.org/Recall_Effectiveness.html) for links to a variety of documents concerning recall effectiveness.

- Japan has adopted new legislation forming a Consumer Affairs Agency which commenced operation on September 1, 2009. This agency has expanded recall responsibilities and powers and is working on a revision to a manual concerning recalls in Japan. See <http://www.caa.go.jp/en/index.html> for information on this new agency.
- An international recall standard is being worked on by a committee of the International Organization for Standardization. The committee held its first meeting in May of 2009 in Malaysia. The target date for completion of this standard is 2012. The new standard will provide a guide for organizations “to plan and execute timely and cost effective product recalls...” See <http://www.iso.org/iso/pressrelease.htm?refid=Ref1227> for more information.
- Recall service providers are providing more useful information to manufacturers on how to prepare for recalls, how to implement recalls, and how to locate appropriate third party resources to assist in these areas.

For an article by Stericycle on the five biggest mistakes companies make during recalls, see <http://www.productsafetyletter.com/news/5607-1.html>. And, see <http://www.adksafetyinfo.com/Overview.html> to obtain a Product Safety and Recall Directory from ADK Project Resource Group which will be published this fall.

## **Conclusion**

Manufacturers need to be prepared to recall their products even if they have never had a recall in the past. Once a product safety issue arises, it is too late to develop a plan. Preparing for a recall before it occurs can significantly increase its effectiveness and lessen the costs and disruption. Of course, the manufacturer also needs to employ pro-active pre-sale product liability prevention techniques so that a recall is not necessary in the first place.

It is clear that governments around the world will focus more on identifying product safety problems and forcing or encouraging manufacturers to do something about them. Keeping up with the state of the art will require paying attention to what other companies, government agencies and standards groups are doing. This vigilance will pay large dividends.

Manufacturers should not assume that their effectiveness rates are static and can't be improved. Technology is available today that could increase their ability to quickly communicate with the distribution chain and even consumers about the recall. They should continually look for ways to significantly improve the success of their recalls and other post-sale remedial programs. And they should continually strive to properly and accurately document their efforts. Hopefully, this will minimize risks and the potential for accidents and provide some type of defense if an accident occurs.