"Adequate and Reasonable" Product Recalls

by Kenneth Ross

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 abroad.

Any manufacturer selling in the United States needs to assume it has at 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. Governments in the European Union will be required next year to issue new regulations increasing a manufacturer's responsibility to withdraw its products from the marketplace. In addition, the U.S. Consumer Product Safety Commission has recently sponsored meetings and studies on recall effectiveness to try to help manufacturers develop better ways to recall their products.

If the manufacturer's product was defective at the time of sale, the common law provides generally that a highly effective recall will not cut off liability for the manufacturer. A post-sale duty to warn is a separate cause of action, based on negligence. So, while a manufacturer may successfully defend this cause of action, the existence of the recall or other remedial program may be considered an admission that the product is defective. And, as long as the product injured someone, 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 that the program be as effective as it can 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, 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 a claim of punitive damages.

This article will describe various guidelines, regulations, and best practices for implementing a post-sale remedial program and will discuss how to defend the adequacy of a post-sale program. This article will not discuss when a manufacturer should or is legally required to report a post-sale problem to the government or how to set up a product safety management program, including a post-sale planning protocol. I have already discussed these issues in "Establishing an Effective Product Safety Management Program," in the January 2003 issue of *For The Defense*, and "The Increased Duty to Take Post-Sale Remedial Action," in the April 2002 issue.

Common Law and the Restatement

The common law basis for post-sale duty to warn is negligence. So, using Judge Learned Hand's formula for negligence, the basis for determining whether this duty has been met is the reasonableness of the manufacturer's conduct after balancing the risk of harm against the burden on the manufacturer to reduce the harm. The higher the risk, the more the manufacturer needs to do to minimize the risk to consumers and other product users.

However, as with all questions of reasonableness under negligence, the common law provides no further basis for a manufacturer to understand how effective its remedial program must be in order for it to be considered non-negligent.

The 1997 *Restatement (Third) of Torts: Products Liability* has three sections that are pertinent to this examination. They discuss the post-sale duty to warn, the duty to recall a product, and the effect of compliance or non-compliance with product safety statutes or regulations. (For a comprehensive discussion of the common law in all 50 states and of U.S. and foreign regulatory law on this subject, see *Post-Sale Duty to Warn*, a monograph published in September 2003 by the American Bar Association's Section of Litigation.)

Section 10 establishes four criteria to consider when deciding whether a manufacturer has a post-sale duty to warn. Failure to issue such a warning would be unreasonable and a basis for liability. The criteria are similar to the Learned Hand formula—the higher the risk, the more responsibility to warn, unless the burden is too high. This section provides nothing more than a reasonableness test for determining if the duty has been met. And the trier of fact, of course, decides this issue.

Section 11 of 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 are no further criteria to provide guidance on what is reasonable. Also, the Reporter's Notes to comment d of this section says 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."

However, the few cases cited in Section 11 and other relevant cases basically show that the plaintiff can always argue that the manufacturer should have done more. The recall letter or other notice could have been sent out earlier and could have contained more explicit language. Or, it could have been sent certified mail or sent out more than once. Or, the advertisement could have been on page 2 instead of page 40 of the magazine.

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 the conduct by the manufacturer was "state of the art," complied with all applicable governmental statutes and regulations, and was as comprehensive as necessary considering the level of risk.

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That leads to the third relevant section of the Restatement. Section 4 clearly says that compliance with applicable governmental regulations or statutes is a minimum requirement. The Reporter's Notes to Section 4 cite Section 288C of the Second Restatement, which says, "Compliance with a legislative enactment or an administrative regulation 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. However, while this "approval" by a government agency may not get into evidence directly, 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.

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.

If there is a mandatory or voluntary recall and a manufacturer fails to act reasonably, it can be held liable.

The CPSC will classify the hazard as A, B, or C. Class A is defined as a risk of death or grievous injury or illness that is likely or very likely, or serious injury or illness is very likely. This hazard requires the recalling entity to "take immediate, comprehensive, and imaginative corrective action measures to identify and notify consumers, retailers and distributors…"

The CPSC also provides a recall checklist that is helpful for manufacturers and retailers in implementing a consumer product recall. This checklist can be found at http://www.cpsc.gov/businfo/recallcheck.pdf.

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 percent have been deemed acceptable by the CPSC. And, the CPSC has said that the average response rate for most recalls is between four percent and 18 percent.

Because of concern that effectiveness rates are too low and can be improved, the CPSC has instituted a recall effectiveness project that includes public meetings to discuss successful techniques for recalls, a literature search and evaluation of consumers' behavior as it relates to recalls, and an evaluation of the CPSC recall database to assess the effectiveness of previous recalls. This was prompted in part by the urging of consumer advocates and some in Congress.

Several meetings discussing recall effectiveness have taken place. The first meeting took place on May 15, 2003; the subject was "Motivating Consumers to Respond to Recalls." (See http://www.cpsc.gov/businfo/rem_sum1.pdf for a summary of this meeting). Eighteen social marketing and public relations experts discussed the following four questions: How can we motivate consumers to act? Which campaigns/programs have motivated consumers to act? Which specific ideas from these programs could increase consumers' response to product safety recalls? How do we measure whether we have motivated consumers?

The experts at the May 15 meeting identified creative techniques that are not part of the standard recall procedures that have been used for years. While most of these techniques would not be considered "state of the art" today, they may in the future. Therefore, manufacturers should consider such suggestions and test some of them in a future remedial program.

A second meeting took place on July 25, 2003. It focused on "tools" that manufacturers, retailers, and others who distribute safety information use to notify consumers of recalls. Panelists included retailers, manufacturers, credit card companies, and various public interest entities. A third meeting took place on September 9; the attendees discussed new methods to be considered to provide a more complete account of recalled products.

In another significant effort in this area, on August 5 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.

In addition, the authors reviewed empirical data developed by the CPSC and others on recall effectiveness. This report also contains information on the effectiveness of NHTSA and FDA recalls. It should be re-

viewed by manufacturers of any product since it identifies studies that have analyzed how to motivate consumers on safety matters. 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 August 5 report and research summarized therein will also be useful to cite in defending the adequacy of a recall since it confirms how difficult it is to motivate consumers to respond to what would clearly be an adequate notice.

The report also pointed out that the CPSC last evaluated recall effectiveness rates from its database in the early 1980s. The CPSC staff said in February of this year that it would be undertaking such an evaluation of recent effectiveness data, including indications of which techniques have worked in the past to increase effectiveness.

The result of all of this activity is that the CPSC will most likely eventually come out with updated and improved regulations and guidelines on how to undertake a recall. Hopefully, these new requirements and suggestions will help improve recall effectiveness rates and, if they comply, will help manufacturers present evidence that they were reasonable and did the best they could under the circumstances.

Food and Drug Administration

The FDA has jurisdiction over most foods and all cosmetics, drugs, and medical devices. The FDA, like the CPSC, will classify the level of hazard when it receives a report; the hazard levels are I, II, and III. Class I recalls are the highest level and are for dangerous or defective products that predictably could cause serious health problems or death.

After classifying the hazard, the FDA, unlike the CPSC, develops a strategy for each individual recall that sets forth how extensively it will check on a company's performance in recalling the product in question. For a Class I recall, for example, FDA would check to make sure that 100 percent of the defective products have been recalled or reconditioned. Effectiveness rates for Class II or III would be much less.

The regulations describing recall strategy and recall communications are set forth in 21 C.F.R. Subpart C, §7.42 *et seq.* These regulations make clear that the recalling entity must conduct the recall in accordance with an approved strategy. The strategy will need to address the depth of the recall (to whom the communications are directed), whether the public as well as health care professionals are alerted, and which effectiveness checks will be used. The regulations identify five effectiveness levels—Levels A thru E, with A requiring 100 percent effectiveness and B through E much less.

The regulations describe the types of recall communications that should be considered by the recalling entity. 21 C.F.R. Subpart C, §7.49. These communication techniques are similar to those described in the CPSC Recall Handbook. They also provide that a recall will be terminated when the FDA "determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy…" 21 C.F.R. Subpart C, §7.55.

The FDA's recall procedures are set forth in Chapter 7 of its Regulatory Procedures Manual (http://www.fda.gov/ora/compliance_ref/rpm_new2/ch7.html). This manual describes the recall strategy that FDA develops with each manufacturer as follows:

> Each circumstance necessitating a recall is unique and requires its own recall strategy. FDA will review and/or recommend the firm's recall strategy, and will develop a strategy for its own audit program based on the agency's hazard evaluation and other significant factors such as type or use of the product, distribution pattern, market availability, etc. The need for publicity, the depth of the recall, the level of effectiveness and audit checks, and other recall implementing factors will be a part of the recall strategy. The strategy is separate from, and not tied to, the class of recall selected.

The procedures manual also describes the FDA's approach to analyzing effectiveness:

> It is FDA policy that after a firm decides to recall its products and so notifies the agency and recipients of the products, the recalling firm has the responsibility to determine whether the recall is progressing satisfactorily. Because effectiveness checks aid in verifying that all known, affected consignees have received notification about a recall and have taken appropriate action, it is the obligation of all recalling firms to conduct effectiveness checks as part of their recall strategy. Only in this way can the firm fulfill its responsibility to FDA and consumers.

The manual contains a number of helpful sample recall documents and guidances in various areas. For example, there is a guidance on how to evaluate hazards in order to make the initial decision on whether a recall is necessary, and then how to create an acceptable recall strategy. The factors to consider are the usual ones that any manufacturer uses to evaluate future risk—what is the hazard, when does it occur, what type of people will be exposed to it, what is the probability of the hazard occurring, and what are the consequences if it occurs.

U.S.D.A. and N.H.T.S.A.

The United States Department of Agriculture's Food Safety and Inspection Service is responsible for meat and poultry that is in interstate commerce. Intrastate food safety is the responsibility of state and local food inspectors. Like the FDA, the FSIS classifies hazards as Class I, II, and III, with I being the most hazardous.

The FSIS's primary role is to closely monitor the effectiveness of the firm's recall procedures and to provide scientific and technical advice. FSIS has a standing Recall Committee that works with the company to coordinate

the recall. It is chaired by the Recall Management Division and consists of scientists, technical experts, field inspection managers, enforcement personnel, and communications specialists. More guidance is provided on FSIS procedures at http://www.fsis.usda.gov/OA/background/bkrecalls.htm.

The National Highway Traffic Safety Administration provides a comprehensive compendium of information concerning recalls, dated June 2001, on its Web site. See http://www.nhtsa.gov/cars/rules/standards/recompendium.pdf. It summarizes all of the regulations and procedures for undertaking a recall.

NHTSA recalls are a bit different than consumer product recalls and many FDA recalls. Since on-road motor vehicles must be registered with some governmental entity, it is generally easier to find the current owner and communicate with him or her. However, certain important motor vehicle equipment, such as baby car seats, are not registered, and owners can change a number of times over the seat's lifetime.

The kinds of information to be provided to the purchaser are described in this compendium. It is similar to the information that the FDA and CPSC require to be provided. Other content of the compendium includes press releases to the public, notice to the dealers, forms for reporting to the NHTSA, sample letters to consumers and dealers, and the possible need to renotify all of the affected parties if NHTSA deems the recall not totally effective. The recalling entity must report quarterly to NHTSA on the progress of the recall.

The compendium does not discuss recall effectiveness or the criteria used by NHTSA to determine if a recall has been successful. Again, because motor vehicles are registered and the products expensive, it would be expected that response rates on recalls would be high where the risk is perceived to be significant by the consumer.

Other Governmental Agencies

A few other agencies require certain manufacturers to report and to undertake recalls. These include Bureau of Alcohol, Tobacco and Firearms (alcoholic beverages), Coast Guard (recreational boats and equipment), Environmental Protection Agency (pesticide products and vehicle emission control system) and the Department of Housing and Urban Development (manufactured housing).

European Union

The EU has recently 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. See Ross, "The Increased Duty to Take Post-Sale Remedial Action," April 2002 *For The Defense* 37.

The revisions to the EU's General Product Safety Directive will become effective in January 2004. Then, each EU member state must enact legislation incorporating the requirements of the new GPSD. It could be expected at that time that governments in the EU will provide more guidance on how manufacturers should undertake a recall.

The 2004 GPSD substantially expands 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 will be a Product Safety Network that will develop 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 objective of the new Product Safety Network will be to facilitate the exchange of information on risk assessment, dangerous products, test methods and results, and recent scientific developments. In addition, joint surveillance and testing projects, the exchange of expertise and best practices, and cooperation in training activities will be established and executed. Presumably, there will be close cooperation within the European Union and also with foreign agencies responsible for product safety, in the tracing, withdrawal, and recall of dangerous products.

The 2004 GPSD also increases responsibilities for manufacturers and distributors. Distributors will 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 will 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.

The GPSD applies only to consumer products. However, the EU is proposing that the law be changed so that the market surveillance and product withdrawal responsibilities also apply to industrial products and other products governed by the New Approach Directives (such as machinery, toys, low voltage equipment, medical devices, etc.).

In some recent reports, the EU has focused on providing guidance to member states about how to improve and make consistent throughout the EU market surveillance techniques used to identify unsafe products that need to be withdrawn from the marketplace. See, "Guide to the Implementation of Directives based on the New Approach and the Global Approach" (September 1999), http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/legislation.htm, and "Enhancing the Implementation of the New Approach Directives COM (2003) 240" (July 5, 2003), http://europa.eu.int/comm/enterprise/newapproach/index.htm.

For example, the July 2003 report describes market surveillance techniques in the EU as follows:

> Some Member States have a "proactive" approach to market surveillance, while others adopt a "reactive" strategy. A reactive strategy covers activities such as response to complaints, safeguard clause notifications of other Member States and basic customs checks. A proactive approach suggests targeted campaigns, use of risk assessment tools, co-operation with other authorities.

The report also says "Member States need to ensure effective communication and coordination at national level between their market surveillance authorities and their other authorities which work in the field of product safety such as occupational health and safety authorities and customs."

On the issue of encouraging companies to

report and voluntarily withdraw their products from the market, the July 2003 report states "Deterrent measures like strong sanctions against persons or companies repeatedly misusing the freedoms offered by the New Approach system, product recall actions or information campaigns are appropriate actions to help reduce the number of deficient products on the Internal Market."

The EU also envisions much greater cooperation between member states in transmitting information about unsafe products. The July 2003 report states: "Information about non-complying products, especially those that are subject to frequent complaints, need to be passed from one national authority to all other national market surveillance authorities faster than the products can be moved from one national market to the other."

However, one organization avers that there is no way for market surveillance bodies to exchange information among themselves within a short space of time, thereby making it possible for an unsafe product taken off the market in one country to be on sale for a long time in another country. The solution, according to the Information and Communication System for Market Surveillance (http://www.icsms.org), is an Internet-based system made up of manufacturers, trade associations, and governments that will then be able to more quickly transmit safety information concerning market surveillance and product safety issues.

Despite all of this new legislation and guidance, few manufacturers selling in the EU know how to withdraw products from the marketplace and how effective the recall must be. The focus seems to be much more on governments mandating recalls and product withdrawals and then placing public notices in various locations concerning the recall.

However, a failure to take your European responsibilities 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.

Other Nations

One of the most useful guides on recalls is an excellent pamphlet published in 1999 by the United Kingdom's Department of Trade and Industry. *Consumer Product Recall: A Good Practice Guide* (see http://www.dti.gov.uk/CACP/ca/advice/productrecall/pdf/consumer.pdf). It provides excellent guidance on communicating to product users about safety issues involving consumer products; it also lists other guides in the U.K. on recalling cars, food, medicine, aerosol products, and appliances. This guide also includes: planning for a recall, deciding whether to recall, what the recall message needs to say, how to deliver the recall message, and innovative ways to improve your recall. The guide also provides case studies of actual recalls and the lessons learned from the recall.

Given the variables of determining the adequacy and effectiveness of a recall program, it is difficult to come up with definite strategies for defending the recall.

In addition, the U.K.'s DTI has issued a useful report called *Product Recall Research* (http://www.consumer.gov.uk/homesafetynetwork/gh_recal.htm), which surveyed recalls in the U.K. from 1990 to 1996 and, in part, identified the key reasons and factors as to why certain recalls were particularly successful or not successful. The response rates averaged 37 percent with the largest number of recalls coming in at less than 10 percent.

The highest levels of response were attributable to a high-perceived risk, comprehensive mailing lists, a high expenditure of money on published notices, and a high level of free publicity. The low levels of recall effectiveness were attributable to the age of the product (they'll continue using a product that has been used safely for years), the low cost of the product (they'll just throw the product away), and a low perceived risk (they'll just continue using the product). And, unfortunately, it will be difficult to consider products that are just discarded or not used anymore as a result of the recall notice in tracking response rates.

The Consumer Safety Unit of the Australian Treasury published a recall guide in July 2002. It can be found at http://www.recalls.gov.au/recalls_guide1.cfm. Its content is similar to the U.K. and CPSC manuals described above. However, a manufacturer recalling any consumer product in Australia should consult this guide for any requirements that are particular to Australia, especially those involving reporting the recall to the Australian government.

In Canada, the Consumer Products Division of the Health Ministry has powers to enforce the Hazardous Products Act, but does not have recall powers. In addition, manufacturers and importers do not have a specific duty to recall their products. However, their products can be seized if they violate the Act. As a practical matter, the Ministry does not have a public list of recall procedures. Instead, it works with each manufacturer or importer to develop a recall strategy for the specific product. The Canadians probably rely on procedures and guidelines similar to those of the CPSC and other safety agencies.

The Canadian Motor Vehicle Safety Act does give Transport Canada the right to order recalls, although there do not appear to be any recall guidelines for manufacturers. Basic instructions on how to implement a recall and how to report the recall's progress are in the Act, but there is no mention of required recall effectiveness.

The Canadian Health Products and Food Branch Inspectorate of Health Canada has published product recall procedures for food, drugs, cosmetics, medical devices, and radiation emitting devices. These procedures

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can be found at http://www.hc-sc.gc.ca/hpfb/inspectorate/recall_procedure_entire_e.html. They are similar to the recall procedures issued by the United States FDA. HPFB helps companies develop a recall strategy, communication effort, and effectiveness checks. And the government classifies hazards with the designation Class I, II and III and with similar recall effectiveness checks.

How to Perform an Effective Recall

The first question is: what is an effective recall? Since this is dependent on so many variables and there are no set numbers or even ranges of numbers that would allow one to conclude that a recall has been reasonable and effective, there is no good answer. It is very specific to the types of products, cost of the product, risks in using the product, perceived risks by the consumer, distribution techniques, difficulty in reducing or eliminating risk, and other factors.

Another question to ask is how effective does the recall have to be? This goes to the question of the level of risk that exists if people continue to use the product. In many recalls, the goal is at least to get the message out about a hazard and not necessarily to get the product back. The consumer could destroy the product, not use it, or change his or her behavior when using it. In these types of remedial programs, it is impossible to track a "response" since the consumer doesn't have to respond to the public notice or recall letter or safety bulletin. Also, many products may have been already taken out of service or are not being used anymore. So, tracking the number of products sold versus the number of products recalled or fixed is not an accurate measure of the effectiveness of the recall.

The guides published by the various governmental agencies should, of course, be reviewed. However, except for medical devices recalled in the United States, there are no effectiveness levels established in the regulations. So the manufacturer has flexibility to develop a rationale to convince the agency and possibly a jury that the effectiveness rate was adequate.

Some of the conclusions from the CPSC recall effectiveness study issued in August 2003 confirm ways in which a recall can be more effective. Consumers are less likely to comply where compliance is inconvenient, takes time, or costs money. For example, where consumers must return the recalled product before they receive a replacement, response rates have been low.

One of the principal authors of the CPSC recall effectiveness study is Ed Heiden, the former chief statistician for the CPSC. He has written extensively on how to perform a recall, how to measure recall effectiveness, and how to defend the adequacy of recalls. Several years ago, Ed analyzed the potential to increase recall response rates by increasing the receipt of product registration cards. He thinks that the chances of increasing the receipt of such cards will not be significantly improved with more effort and that the value of the cards diminishes with time. People move frequently (16 percent per year) and products are sold or discarded. Instead, Heiden believes that using modern communication media such as the Internet might increase effectiveness.

Many observers have written over the years on the subject of how to perform a recall. Typically, they focus on pre-recall planning, management techniques to establish for obtaining and analyzing post-sale information and performing the recall, logistics and communication planning, post-recall tracking, and follow-up. Most of their suggestions are similar to those contained in the various government documents.

An entire coterie of consultants has emerged to help with recalls—crisis management experts, legal experts in recalls, financial and logistics experts, and experts in what is called "reverse marketing." A manufacturer should at least consider these resources in determining how best to perform a remedial program.

Defending the Adequacy of the Recall

Given the variables of determining the adequacy and effectiveness of a recall program, it is difficult to come up with definite strategies for defending the recall. As stated earlier, the best recall most likely will not automatically cut off liability for the manufacturer for selling a defective product. And, given the fact that most recall letters admit that the product is defective, defense counsel needs to look elsewhere for a good defense.

Of course, the best approach would be to keep the recall from being introduced into evidence. You can argue that the recall is a subsequent remedial measure and should not be allowed into evidence. See Carter, "Defending Against Product Recall Evidence at Trial," April 2002 *For The Defense* 43. However, often a good plaintiff's attorney can somehow get the recall into evidence or find an expert to argue that the product should have been recalled. In fact, it may be beneficial to the manufacturer to affirmatively place the recall in evidence as proof of the manufacturer's commitment to safety and the well being of its consumers.

Having the recall in evidence would be necessary to use some of the other possible defenses. The best one is that the recalled product or part of the recalled product that was defective did not cause the injury or damage. Of course, the existence of the recall, if it gets into evidence, will muddy the facts and may result in liability even without causation.

The next good defense would be that the consumer saw the message or received the letter and ignored the recall. While it may be hard to prove an assumption of the risk, this argument should at least help establish some contributory fault on the injured party. When using this defense, it is imperative to be able to prove that the "warning" in the letter or notice was adequate, using general warning principles. That is why some type of comprehension testing of recall letters may be helpful before they are sent out. However, these kinds of surveys can also be performed during the defense of the case to support the adequacy of the notice.

If the recall is to be performed by an intermediary such as a dealer or retailer, and they did not do it adequately, the manufacturer might be able to pass along some or all of the liability to that entity. For example, in one case, a propane gas dealer was held liable and the manufacturer was absolved because the dealer did not send out the manufacturer's recall letters to their customers after promising to do so. His failure to send out the letters constituted a superseding, intervening cause. Similarly, a retailer's failure to remove recalled products from the shelves and warehouse, or failure to place the recall notice in a conspicuous place, may also constitute some contributory fault or intervening cause.

If you can't break the causal link, then you must defend the adequacy of the specific recall or post-sale program. Since the recall was presumably not effective to the injured party, the plaintiff will argue that the manufacturer could have and should have done more. The manufacturer will have to evaluate the techniques it employed, the effectiveness rates as compared to others for similar products, try to explain the effectiveness rate in the context of limitations to increasing the rate, and discuss why doing more would not have necessarily increased the rate.

An analysis of past punitive damages awards clearly shows that the basis for most such awards

is that the jury believed that the manufacturer failed to undertake adequate post-sale remedial measures. At a minimum, hopefully the manufacturer can minimize or prevent the chance that punitive damages will be imposed by establishing lack of causation, intervening cause, or other contributory fault, or defend the effectiveness of the response and limitations on improving it.

Conclusion

Manufacturers need to be prepared to recall their products even if they have never had to do so 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 are doing and what government agencies are requiring. 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. Hopefully, this will minimize risks and the potential for accidents and provide some type of defense if an accident happens. FD