An Unhappy Relationship

By Kenneth Ross

Product Safety Regulatory Compliance and Product Liability Litigation

Product liability litigation and regulatory activities in the U.S. and elsewhere are increasingly becoming intertwined. Product liability incidents, claims, and lawsuits can generate investigations by the government, possibly resulting in recalls and civil penalties. And, investigations, recalls, and civil penalties can generate product liability and other lawsuits, such as shareholder derivative actions, and contribute to findings of liability.

Reporting a safety issue to the government and undertaking a recall can certainly make defending a product liability case much harder. And, while it does not amount to absolute liability, reporting and recalling a product, at a minimum, increases the interest of plaintiffs' attorneys and can serve as the basis for a plaintiff's verdict and possible award of punitive damages.

As a result, plaintiffs' lawyers and their retained experts have used and will try to use government actions as leverage to force a recall, retrofit, or refund, or argue

■ Kenneth Ross is a former partner and now of counsel to Bowman and Brooke LLP, where he provides legal and practical advice to manufacturers and other product sellers in the areas of design, warnings, instructions, safety communications, recalls, reports to the government, and all areas of product safety, regulatory compliance, and product liability prevention. An earlier version of this article appeared in the Winter 2014 edition of *In-House Defense Quarterly.* Other articles by Mr. Ross can be seen at www.productliabilityprevention.com.

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that the incident involved in a product liability case was notice that the product was defective and should have resulted in a report to the government and a subsequent recall. And, on the other side, the government can argue that a product liability lawsuit, settlement, verdict, or even just an expert's opinion triggered a duty to report, and that the company's failure to report in a timely fashion should result in a civil penalty.

The U.S. Consumer Product Safety Commission (CPSC) has various regulations requiring manufacturers to consider what goes on in litigation in determining whether a report needs to be filed with them about a potential safety problem. The increased risk of being sued in product liability in the U.S. and elsewhere, and the increased need to report to U.S. and foreign government agencies, has made product safety regulatory compliance a very complex and risky global effort.

The result of this increased complexity is that companies who sell regulated products are well advised to coordinate claims and litigation management with regulatory compliance, either by using the same law department personnel or by at least having the responsible in-house and/or outside personnel coordinate closely over strategy in both areas.

CPSC Regulations Regarding Litigation

The Consumer Product Safety Act (CPSA), section 15(b), requires manufacturers, importers, distributors, and retailers to notify the CPSC immediately if they obtain information that reasonably supports the conclusion that a product distributed in commerce: 1) fails to comply with a consumer product safety standard, rule, regulation, or banning regulation; 2) fails to comply with any other rule, regulation, standard, or ban under this chapter or any other act enforced by the Commission; 3) contains a defect that could create a substantial product hazard to consumers; or 4) creates an unreasonable risk of serious injury or death.

The most important basis for reporting to the CPSC is section 15(b)(3), which requires reporting if there exist both a defect *and* the possibility of a substantial product hazard. The first question is whether a product has a defect. Under section 15(b)(3), the manufacturer of a product without a defect does not necessarily need to report to the CPSC, even if injuries occur. Many products are reasonably safe and not defective, but people still get hurt.

The CPSC regulations say that the term "defect" used in this section is not necessarily the same as the term "defect" as interpreted in product liability law. But the CPSC regulations require product liability *caselaw* in general to be considered in connection with a determination of whether a product is defective. These regulations say:

> In determining whether the risk of injury associated with a product is the type of risk which will render the product defective, the Commission and staff will consider, as appropriate: … *the case law in the area of products liability;* and other factors relevant to the determination. (Emphasis added)

16 CFR §1115.4.

As a result, plaintiffs' lawyers and their retained experts have and will try to use government actions as leverage to force a recall, retrofit, or refund, or argue that the incident involved in a product liability case was notice that the product was defective and should have resulted in a report to the government and a subsequent recall.

I interpret caselaw to be legal opinions by trial judges or appellate judges and not decisions by juries. So, this regulation means to me that the staff can consider what judges consider as defective when making this determination. But, of course, this rationale is extremely open-ended and does not provide guidance when there are conflicting opinions or opinions in only one or two jurisdictions.

Also, the regulations that describe the factors that should be used to determine whether there is a defect closely track the factors that many juries must consider when performing a risk-utility analysis to determine if a product is defectively designed.

The regulations also require that the firm consider the following to determine whether there is a substantial product hazard:

1. Information about engineering, quality control, or production data;
2. Information about safety-related production or design change(s);
3. Product liability suits and/or claims for personal injury or damage;
4. Information from an independent testing laboratory; and
5. Complaints from a consumer or consumer group.

16 CFR §1115.12(f).

Therefore, based on this language, a plaintiff's expert's opinions, articles in consumer magazines, or reports by testing laboratories indicating that your product is defective or creates a substantial hazard could serve as a possible basis for reporting to the government and recalling your product.

The regulations make it clear that the reporting company may deny that its product is defective when it reports. Therefore, while the manufacturer can submit a report and deny that the product is defective and creates a substantial product hazard, or deny that the defect creates an unreasonable risk of serious injury or death, the fact that a report was made might be admissible in a trial to support an expert's opinion that the product was defective and hazardous. And, at a minimum, the manufacturer would have to explain why it reported and recalled the product if it was not defective nor created any substantial risk of injury.

Another ground for reporting is if the product presents an unreasonable risk of serious injury or death. CPSC section 15(b)(4). This regulation does not require that a product be defective before a reporting responsibility arises. But, for such reports, the regulations require firms to consider "reports from experts, test reports, product liability lawsuits or claims, consumer or customer complaints, quality control data, scientific or epidemiological studies, reports of injury, information from other firms or governmental entities…." The regulations then go on to say:

> While such information shall not trigger a per se reporting requirement, in its evaluation of whether a subject firm is required to file a report under the provisions of section 15 of the CPSA, the Commission *shall attach considerable significance if such firm learns that a court or jury has determined that one of its products has caused a serious injury or death* and a reasonable person could conclude based on the lawsuit and other information obtained by the firm that the product creates an unreasonable risk of serious injury or death. (Emphasis added)

16 CFR §1115.6(a)

It is interesting that this regulation makes it clear that the CPSC will attach "considerable significance" to a plaintiff's verdict in a product liability case, although it specifically says that it is not a per se reporting requirement. The manufacturer and ultimately the CPSC may need to decide what that language means in the context of making a matter reportable. And it is interesting that this language only applies to the "unreasonable risk" reporting requirement and not the one based on defect and substantial product hazard.

The last section of the CPSA dealing with litigation is section 37. This section requires manufacturers of consumer products to report information about settled or adjudicated lawsuits if:

- A particular model of the product is the subject of at least three civil actions filed in federal or state court;
- Each suit alleges the involvement of that particular model in death or grievous bodily injury—mutilation or disfigurement, dismemberment or amputation, the loss of important bodily functions or debilitating internal disorder, injuries likely to require extended hospitalization, severe burns, severe electric shock, or other injuries of similar severity; and
- During a two-year period specified in the law, each of the three actions results in either a final settlement involving the manufacturer or in a court judgment in favor of the plaintiff.

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And in these foreign countries where incidents have occurred, their laws concerning reporting requirements are different. Therefore, a duty to report to these foreign governments and undertake a recall could be triggered well before litigation in that country or in the U.S. commences.

The CPSC's regulations discuss the Commission's view on the timing of section 15(b) and 37 reports when it says:

> …in many cases the Commission would expect to receive reports under section 15(b) long before the obligation to report under section 37 arises since firms have frequently obtained reportable information before settlements or judgments in their product liability lawsuits.

16 CFR §1115.7

So, the CPSC makes it clear that a manufacturer does not need to wait for a settlement or an adjudication by a jury saying that its product is defective before it should report. Since the adoption of section 37, there has never been a civil penalty assessed for failure to file only under this section. And very few manufacturers bother to file under this section unless they are also filing under section 15(b). As a result, this section has been ignored by most manufacturers, although it still remains on the books, and it could become more important with the change in administrations.

And lastly, the regulations state that information from outside the U.S. must also be considered. Therefore, foreign incidents, claims, and lawsuits must be considered and could create a reporting responsibility to the CPSC, even if no incidents occurred in the U.S.

And in these foreign countries where incidents have occurred, their laws concerning reporting requirements are different. Therefore, a duty to report to these foreign governments and undertake a recall could be triggered well before litigation in that country or in the U.S. commences. In addition, if litigation occurs outside the U.S., the manufacturer would have to consider the facts of the occurrence and any judge's or expert's opinion (there are generally no jury trials outside the U.S.) concerning the reason for the incident in determining whether there is a duty to report to the CPSC.

What Is the Effect of These Regulations?

These CPSC regulations can create substantial confusion in trying to determine the effect of incidents, claims, and litigation on the duty to report. Considering some possible scenarios will illustrate the confusion.

Let's say that there are incidents, and the company investigates and determines that there is no defect in the product, thus not creating any basis to conclude that something in the product caused the incident. In that case, there should be no duty to report.

Then, a lawsuit is filed, and an allegation is made in the complaint that the product is defective and caused the injury. Does that create a duty to report? I do not think so. If it did, then every lawsuit could trigger a report. While some at the CPSC have

reportedly held that belief in the past, I have not heard of anyone at the CPSC officially announcing that recently.

Next, a plaintiff's expert issues an opinion saying that the product is defective and that this defect caused the incident. Now is there a duty to report? If the manufacturer hires a defense expert who reviews the report, sees the product, and then issues an opinion disagreeing with the plaintiff's expert, I would say no. Many things are going on during discovery, and there are going to be several competing opinions including a dispute over whether the product is defective and whether it caused harm. Still, I think there is a good argument that there is no duty to report.

But the plaintiff's expert could send his or her report to the CPSC and argue that the product is defective and should be recalled. And, as a result, the CPSC could initiate an investigation and ask the manufacturer to justify why the product should not be recalled. The CPSC might conclude that a report was triggered, and a recall is appropriate merely based on its interpretation and evaluation of the plaintiff's expert report. This seems inappropriate, especially if a defense expert reviews the report and concludes that there was no substantive basis for the plaintiff's expert's conclusions—it was merely unsupported speculation or outright fabrication.

If insurance companies are handling a manufacturer's insured litigation, company personnel need to be involved to the extent that they can be made aware of information that may trigger a report to some government agency. And they need to have some input in the resolution or trial of the matter so that it is consistent with the position the company is taking or would take in connection with a possible report to the CPSC and subsequent corrective actions.

From a defense litigator's standpoint, there is not much that can be done to prevent a plaintiffs' attorney or expert from contacting the CPSC. The expert's report is not privileged or confidential unless there is a protective order, and the report attaches the defendant's confidential business records. Even if such records are attached, these records in the CPSC's possession most likely would not get disseminated outside of the CPSC because of the Freedom of Information Act (FOIA) and procedures in the CPSC's regulations that allow the defendant to object to them being given to a FOIA document requester (called Section 6(b) protection).

However, having such documents could result in the CPSC staff asking lots of questions and demanding that products be sent to them as part of a preliminary investigation. The CPSC staff could write opinions concerning the safety of these products, and it is possible that someone could obtain those opinions through a FOIA request.

There can be great uncertainty as to the effect of litigation on the duty to report. While the CPSC makes it clear that information developed during litigation must be considered, there is no guidance on how to analyze the evidence and the results, especially when there are a series of cases that have inconsistent results.

In the next scenario, let us say that a manufacturer goes to trial, and the result is a plaintiff's verdict. Is this per se reportable? The regulations say no, and I agree—especially if this is the first case of its kind, and there is no indication that an incident of this type would ever happen again. However, what if the jury renders a verdict specifically saying that the product was defective, was unreasonably dangerous, and caused the accident? Again, there are many reasons why a jury rules in a certain way, and the verdict should be evaluated by the manufacturer, but I do not think it should necessarily result in a report.

Certainly, after any verdict by a jury or any ruling by a judge finding liability, the manufacturer should document the file as to why it believes the jury verdict or judge's opinion does not create a reportable matter, and a recall is not necessary. If in doubt, the manufacturer could report to the government, deny a defect, explain why it disagrees with the court's ruling or jury's finding, and say that no recall is necessary. Of course, the risk is that the government might disagree with the manufacturer's opinion and try to pressure the manufacturer into recalling the product.

What about a manufacturer who tries multiple cases involving similar incidents to a jury verdict and gets inconsistent results? In one case, the jury says that the product is defective and caused harm. And in the other case, the jury rules in favor of the manufacturer. Does the manufacturer have a duty to report? The manufacturer could report and argue that the product is not defective and that a recall or other corrective action is unnecessary. The problem is that the CPSC may disagree and argue that even though there is no defect, there is an unreasonable risk of serious injury or death and require a recall.

What if the manufacturer loses the first case and then chooses to settle other similar cases so it does not get any further published, adverse results? Or just settles all of its cases? Is that proof that the product is defective and hazardous? Does that make it reportable under section 15 or section 37? Should the product be recalled? Manufacturers should document the basis of any significant settlement (i.e., anything higher than a nuisance settlement) and, if necessary, be prepared to tell the CPSC why they believe that no report to the CPSC or recall or retrofit program is necessary.

There can be great uncertainty as to the effect of litigation on the duty to report. While the CPSC makes it clear that information developed during litigation must be considered, there is no guidance on how to analyze the evidence and the results, especially when there are a series of cases that

have inconsistent results. The manufacturer must consider all of the available evidence that is required by the regulations, make a decision that is supported by adequate technical and legal analysis, and adequately document the basis for the decision. This documentation should show that the manufacturer is quickly investigating incidents and other safety issues and making well-reasoned decisions. While the CPSC or a jury might disagree with the manufacturer's decision about whether the issue should result in a recall or other corrective action, hopefully the manufacturer will at least look like it is diligent in dealing with safety issues. This should reduce any possibility of a civil penalty from the CPSC or an award of punitive damages.

Evidence of CPSC Action or Inaction in Litigation

If there has been a report to the CPSC and a subsequent recall, retrofit, or refund, or the CPSC has taken some regulatory action concerning the product in litigation, the plaintiff will most likely try to discover all of this information and use it during litigation. Certainly, evidence of any civil penalty investigation and an award of civil penalties will be sought in discovery. And the plaintiff will be very happy if the CPSC has sent a letter to the manufacturer stating that it has made a preliminary determination that the product contains a defect that could create a substantial product hazard.

On the other hand, if a manufacturer reports to the CPSC, and the CPSC agrees that no recall is necessary, the manufacturer could try to use that evidence to support its position that the product is not defective, does not create a substantial product hazard, and is not unreasonably dangerous. And, if a corrective action were undertaken, the manufacturer could try to use the CPSC's approval of its efforts as evidence supporting the position that it was not negligent in performing the recall.

It is possible that some or all evidence of this type will not be admissible or will not be persuasive or determinative to a jury. However, it might be helpful to the manufacturer as the plaintiffs' attorney is evaluating the case for settlement or trial.

All correspondence in the manufacturer's files between the CPSC and the manufacturer concerning section 15 and 37 reports and any subsequent corrective actions is discoverable, although disclosure by the plaintiff outside litigation might be prevented under a protective order because the documents contain confidential business information. Depending on the court, the information that is produced in litigation could be admissible in a trial or at least be used by the plaintiff's expert to opine about defect and causation and other aspects of the plaintiff's case.

> The question of recall adequacy is based on negligence, and, therefore, the plaintiff must first show that the manufacturer could have done a better job.

CPSC employees are generally not permitted by the CPSC to testify in litigation about anything done or not done by them in connection with a report and any subsequent corrective action. However, former CPSC employees are free to testify.

Despite that, plaintiffs can try to use the CPSC's actions to support their case, and manufacturers can try to use the CPSC's inaction to support the defendant's contention that the product did not violate the CPSC's rules or regulations.

Evidence of Recalls

Of course, undertaking a recall can generate more litigation. Deserving and undeserving plaintiffs who may have been injured by a particular product are much more likely to sue if there has been a recall of that product. And defending such cases can be difficult. Plaintiffs should be required to prove that the injury was caused by that aspect of the product that caused the recall before they are allowed to use testimony or documents on the recall. Also, it is possible that the judge will rule that the recall is a "subsequent remedial measure" and therefore not admissible to prove a defect.

Further, the manufacturer can retain an expert to defend the adequacy of the recall. The question of recall adequacy is based on negligence, and, therefore, the plaintiff must first show that the manufacturer could have done a better job. However, the plaintiff then needs to prove that if the manufacturer had done a better job, the plaintiff's product would have been recalled, and the accident would not have happened. That might be difficult to do.

It is easy to argue that more could be done in a recall. And virtually all recalls are only modestly effective. A plaintiff can argue that the manufacturer did a poor job of implementing a recall or that it should have reissued its recall notice after instituting the recall and getting a low percentage of the products back. Manufacturers rightly should worry about a jury ruling that their recall was inadequate. Not only could that result in creating challenging evidence in future litigation, but it might also trigger a request from the CPSC to file an additional report because the corrective action the manufacturer undertook was deemed inadequate. As a result, in my experience, where inadequate recall is alleged, even though proving proximate cause is a tough bar to clear, most of these cases are settled before trial.

Conclusion

The interrelationship between litigation and regulatory activities is very complex and important. To minimize the risk in all post-sale activities, it is a good idea to seek assistance from lawyers who have expertise in both product liability litigation and regulatory compliance.

Of course, a manufacturer cannot let litigation cloud its judgment in deciding what to do concerning future safety. It must first do what is right for product users and the company. This may result in a company deciding to report to the government and implementing a recall, even though the product can be successfully defended in product liability litigation. It is imperative that a company simultaneously coordinate its actions in both litigation and regulatory compliance. Doing so will help to achieve the best possible result in both areas.