Product Liability Litigation

By Kenneth Ross

The Effect of Product Safety Regulatory Compliance

Product liability litigation and product safety regulatory activities in the U.S. and elsewhere often become intertwined.

Product liability claims and lawsuits can generate reports to the government and recalls. And, on the flip side, recalls can generate product liability and other lawsuits and contribute to findings of liability.

Despite that, the people defending litigation (in-house attorneys and corporate risk management personnel, insurance company personnel and defense counsel) are usually different from the people who are responsible for regulatory compliance. In fact, in many companies, those responsible for dealing with the Consumer Product Safety Commission ("CPSC"), Health Canada, and other safety agencies are not lawyers and do not work on litigation.

The effect of this division of responsibilities can be a lack of coordination, resulting in a manufacturer sometimes failing to learn about a safety issue from the litigation that creates a reportable matter to a government agency and also in a manufacturer taking regulatory action that can adversely affect current litigation or help to create additional litigation.

Reporting a safety issue to the government and undertaking a recall can certainly make defending a product liability case much harder. And, while it doesn't amount to absolute liability, reporting and recalling certainly increases the interest of

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plaintiff's attorneys and can serve as the basis for a plaintiff's verdict and possible award of punitive damages.

The CPSC has various regulations requiring manufacturers to consider what goes on in litigation in determining whether a report needs to be made about a potential safety problem. The increased risk of being sued in product liability and increased need to report to U.S. and foreign government agencies has made product safety regulatory compliance a very complex and risky global task.

The result of this increased complexity is that companies that sell regulated products are well advised to coordinate litigation management and regulatory compliance, either by using the same law department personnel or law firm or by at least having the responsible personnel communicate 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 or rule (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), a product without a defect is not necessarily subject to the reporting requirements, even if injuries occur. Many products are reasonably safe and are not defective and 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. The regulations say:

> Defect, as discussed in this section and as used by the Commission and staff, pertains only to interpreting and enforcing the Consumer Product Safety Act. The criteria and discussion in this section are not intended to apply to any other area of the law.

16 CFR §1115.4.

> The CPSC makes it clear that a manufacturer does not need to wait for adjudication by a jury that its product is defective before they report.

But, the CPSC regulations require product liability in general to be considered in connection with a determination of whether a product is defective. They 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 utility of the product involved; the nature of the risk of injury which the product presents; the necessity for the product; the population exposed to the product and its risk of injury; the Commission's own experience and expertise; the case law interpreting Federal and State public health and safety statutes; *the case law in the area of products liability*; and other factors relevant to the determination. [Emphasis added]

16 CFR §1115.4.

The factors contained in these regulations track pretty closely the factors that a jury 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.
> (5) Complaints from a consumer or consumer group.

16 CFR §1115.12(f)

The regulations make it clear that the reporting company may deny that its product is defective when it reports. The regulations say:

> A subject firm in its report to the Commission need not admit, or may specifically deny, that the information it submits reasonably supports the conclusion that its consumer product is noncomplying, contains a defect which could create a substantial product hazard within the meaning of section 15(b) of the CPSA, or creates an unreasonable risk of serious injury or death.

16 CFR §1115.12(a).

Therefore, while the manufacturer can submit a report and deny that the product is defective and creates a substantial product hazard, or deny that it 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. And, at a minimum, the manufacturer would have to explain why it reported and recalled the product if it wasn't defective or had a substantial risk of injury. That may be hard to do.

Another ground for reporting is if the product presents an unreasonable risk of serious injury or death (section 15(b)(4)). This regulation does not require that a product be defective before a reporting responsibility arises. 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 it 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 CPSC will 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

15 U.S.C. 2084.

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

…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 adjudication by a jury that its product is defective before they report.

Incidents occurring outside the United States must be considered and could create a reporting responsibility to the CPSC, even if no incidents occurred in the U.S.

And lastly, the regulations state that information outside the United States must also be considered when it says that:

Such information may include information that a firm has obtained, or reasonably should have obtained in accordance with §1115.11, about product use, experience, performance, design, or manufacture outside the United States that is relevant to products sold or distributed in the United States.

16 CFR §1115.12(f).

Therefore, incidents occurring outside the United States must be considered and could create a reporting responsibility to the CPSC, even if no incidents occurred in the U.S.

International Reporting Requirements

Given the paucity of product liability litigation in the EU, Canada, and Australia, it is no surprise that the reporting requirements enacted by these jurisdictions do not contain similar requirements as those promulgated by the CPSC. Canada and Australia's requirements are based, in part, on the occurrence of an incident anywhere in the world involving serious injury or death after a use or foreseeable misuse of the product.

Therefore, a duty to report to these agencies could be triggered well before litigation in that country or in the United States is commenced. However, if litigation occurs outside the United States, the manufacturer would have to consider the facts of the occurrence and any judge's or expert's opinions (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 Does This Mean?

These CPSC regulations can create substantial confusion as they relate to the effect of litigation on the duty to report.

Let's say that there are incidents and the company investigates and determines that there is no defect in the product and really has no reason to conclude that the incident was caused by the product. In that case, there should be no duty to report.

Then, a lawsuit is filed and an allegation is made that the product is defective and caused the injury. Does that create a duty to report? I don't think so. 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; there are going to be several opinions and a dispute over whether the product is defective and caused harm. I still think there is a good argument that there is no duty to report.

But the CPSC may disagree with this conclusion. They might believe that a report is triggered merely by the issuance of the plaintiff's expert report opining that the product caused the incident. 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 and that it was merely unsupported speculation.

Now let's 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 don't think it should always result in a report. Certainly, after any verdict by a jury or a judge finding liability, the manufacturer should document the file as to why it believes the jury verdict does not create a reportable matter. But, if in doubt, the manufacturer could report and deny defect and explain why they disagree with the court's ruling or jury's finding.

What about a manufacturer that tries similar incidents to a jury verdict and gets inconsistent verdicts? In one case, the jury says that the product is defective and caused harm. And, in the other case, they rule 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 they don't get any further adverse results. Is that some proof that the product is defective? Does that make it reportable under section 15 or section 37?

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 evidence available to it that is required by the regulations, make a decision that is supported by technical analysis and the law, and make sure that the basis of the decision is adequately documented.

The manufacturer must manage its litigation and any response to litigation (*i.e.*, safety improvements in new products) in a way that will help them identify when a duty to report might arise or whether it is possible that the CPSC or foreign government agency will consider a report to be appropriate. And, the manufacturer must also manage its dealings with the CPSC and other agencies with an eye towards how it will be perceived if admitted into evidence in any current or future product liability cases.

> 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.

Evidence of CPSC Actions or Inaction in Litigation

If there has been a report to the CPSC and a subsequent corrective action or the CPSC has taken some regulatory action concerning the product in litigation, the plaintiff will 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. And the plaintiff will be very happy if the CPSC has sent a letter to the manufacturer, stating that they have made a preliminary determination that the product contains 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 the position that the product is not defective, does not create a substantial product hazard, and is not unreasonably dangerous. And, if a corrective action was 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 as the plaintiff's attorney is evaluating the case for settlement or trial.

Clearly, 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. This is true even if much of this information in the CPSC's file cannot be disclosed by the CPSC under FOIA because it contains business confidential information. The information that is produced in litigation, depending on the court, 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 CPSC's employees are 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.

And, 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 their contention that the product did not violate the CPSC's rules or regulations. However, the evidence of inaction might not be admissible in that the CPSA says:

> The failure of the [Consumer Product Safety] Commission to take any action or commence a proceeding with respect to the safety of a consumer product shall not be admissible in evidence in litigation at common law or under state statutory law relating to such consumer product.

15 U.S.C. §2074(b).

And the Sixth Circuit Court of Appeals recently opined in *Cummins v. BIC USA, Inc.*, 727 F.3d 506, 2013 WL 4082013 (decided August 14, 2013) about the proper use of this limiting rule in a defective cigarette lighter case. Despite the above regulation, the court held that the trial court properly admitted evidence of CPSC inaction provided by a former CPSC employee on a safety feature as proof that the lighter did not violate any safety rule.

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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, although not impossible. Plaintiffs should be required to prove that the aspect of the product that caused the recall also caused the injury before they could get testimony admitted 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.

And, the manufacturer can retain an expert to defend the adequacy of the recall so, in the event the recall gets into evidence, they have something to say. 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, they then need to prove that if the manufacturer did a better job, that the plaintiff's product would have been recalled, and the accident would not have happened. That may be hard to do.

It is very easy to argue that more could be done in a recall. And virtually all recalls are only modestly effective. Therefore, manufacturers rightly 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 an additional report to the CPSC because the corrective action the manufacturer undertook has been deemed inadequate by a jury. As a result, in my experience, where inadequate recall is alleged, many of these cases are settled before trial.

For more on recall adequacy, see Ross, *Adequate and Reasonable Product Recalls,* For the Defense, Defense Research Institute, Inc., October 2003 and Ross, *Recall Effectiveness: An Update,* Strictly Speaking, Defense Research Institute, Inc., March 28, 2013.

Conclusion

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

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 arguably trigger a reportable matter. 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.

Of course, a manufacturer cannot let litigation cloud its judgment in deciding what to do concerning future safety. So, a company may decide to report to the government and implement a recall, even though the product can be successfully defended in product liability litigation. IDQ