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The Effect of Product Liability Litigation on CPSC Regulatory Compliance

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Product liability litigation and regulatory activities in the U.S. 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.

Many times, the persons defending litigation (in-house attorneys, corporate risk management personnel, insurance company claims personnel and defense counsel) are not the people who are responsible for regulatory compliance. In fact, in many companies, the personnel who are responsible for dealing with the Consumer Product Safety Commission (CPSC), Health Canada and other agencies are not lawyers and do not work on litigation.

This division of responsibilities results in a lack of coordination where a manufacturer sometimes fails to learn about a safety issue during litigation that creates a reportable matter to a government agency. It can also result in a manufacturer undertaking some corrective action as requested by the government that can adversely affect current litigation or help to create additional litigation.

The CPSC has various regulations requiring manufacturers to consider what goes on in litigation in determining whether a report needs to be filed about a potential safety problem. The result is that companies who sell regulated products are well advised to coordinate litigation management and regulatory compliance, either by using the same law department personnel or by at least having the responsible personnel communicate more closely over strategy in both areas.

CPSC Regulations Regarding Litigation

The most important basis for reporting to the CPSC is section 15(b)(3), which requires reporting, in part, 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 this section, a product without a defect is not necessarily required to report even if injuries occur. Many products are reasonably safe and not defective and people still get hurt.

However, the regulations 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.

The regulations also 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, 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]

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 when a matter becomes 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 in certain situations specified in the statute. However, the CPSC makes it clear that a manufacturer does not need to wait for an adjudication by a jury that its product is defective before they report. Claims personnel need to be sure that those responsible for regulatory compliance know the results of litigation, especially where serious injuries or deaths have occurred. It should be the regulatory personnel who decide whether they are required to file under section 37.

What Does this Mean?

The 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 and 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 don't think so, 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. If in doubt, the manufacturer could report and deny defect or that the defect creates a substantial product hazard and explain why they disagree with the court's ruling or jury's finding.

What about a manufacturer who tries similar fact scenarios to jury verdicts and gets inconsistent results? 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. Or, they could say that the fact that one jury said the product was defective means that it is defective for their purposes.

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 make sure that the basis of the decision is adequately documented.

To do this, 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 will consider a report to be appropriate. And, the manufacturer must also manage its dealings with the CPSC with an eye towards how it will be perceived as evidence in any current or future product liability cases.

Evidence of CPSC Actions 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 question, 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 is defective and 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 to support 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 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 for information in the CPSC's file that 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.

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. Plaintiff should be required to prove that the injury was caused by that aspect of the product that caused the recall 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 it 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 you undertook has been deemed inadequate.

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 are aware of information that may arguably trigger a reportable matter. And they need to have some input into 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. These are all important decisions that will have long lasting effects on the company and its products.

Other articles by the author:

[Liability for Marketing Communications](#)

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