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By Mike Gentine,
Nico Zimmerman, and
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Clear communication between design teams and counsel can help ensure that innovative product changes aren't mistaken for modifications stemming from product safety issues.

Tort Law Versus the CPSC Treatment of Design Changes

Two of the most prominent bodies of law governing American manufacturers' (and importers') potential liability for alleged injuries associated with their products are the common-law tort litigation system and the statutes

and rules administered by the U.S. Consumer Product Safety Commission (CPSC).

In many respects, these bodies of law overlap. For instance, Congress expressly built the Consumer Product Safety Act of 1972 (CPSA)—the CPSC's seminal organic statute—on the foundations laid down by tort common law. "Your committee has not included a definition of 'unreasonable hazards' within this bill [because] the courts have had broad experience in interpret-

ing the term's meaning and application," wrote the House Committee on Interstate and Foreign Commerce in its report on the House version of the bill that became the CPSA.

The tort-CPSC overlap is not entire, however, and there are important distinctions. The most obvious is that tort litigation is intended to compensate an injured plaintiff and thus operates only if and after an injury occurs, whereas, in principle,

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the CPSC—whose principal functions are to set and enforce standards and disseminate product-safety information to consumers—plays its role in advance of at least some injuries, ideally preventing any from occurring at all. In this sense, the CPSC’s creation was not a re-invention of the product-safety wheel, but an opportunity for that wheel to spin earlier in a potential product hazard’s lifecycle and reduce or eliminate the number of injuries associated with an alleged hazard.

Some of the differences that have emerged between the CPSC’s regulatory reality and the familiar tort law principles upon which it was founded are subtler and perhaps less intentional. Among these are disparate views between the two bodies of law on how changes in a product’s design or manufacture relate to alleged safety concerns in that product.

Tort Law: Subsequent Remedial Measures

In general, the common law does not allow an allegedly injured plaintiff to introduce evidence of actions taken after an alleged injury—collectively “subsequent remedial measures” (SRMs)—as proof that a defendant was negligent. At the federal level, this longstanding principle has been codified in Federal Rule of Evidence (FRE) 407.

When measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove:

- negligence;
- culpable conduct;
- a defect in a product or its design; or
- a need for a warning or instruction.

But the court may admit this evidence for another purpose, such as impeachment or—if disputed—proving ownership, control, or the feasibility of precautionary measures.

The FRE advisory committee noted two bases for this principle. First, the relevance of SRM evidence is questionable, since, even where an injury has been alleged, people may take actions that post-date the alleged injury for reasons unrelated to the facts alleged. Second, as a matter of policy, the courts do not wish to discourage potential or actual defendants from addressing potential safety concerns by allowing any

actions they take toward that end to be later used as evidence against them.

The state-level Uniform Rules of Evidence (URE), adopted by more than thirty states in some form, contain the same exclusion, resting it on the same foundations of relevance and policy. Even states that have not adopted the URE may nonetheless retain some vestige of this longstanding principle.

Notably, the application of this exclusion in product liability actions—particularly those premised on strict liability, rather than negligence—is inconsistent. The 1997 amendments to the FRE and the 1999 update to the URE expressly applied the exclusion to product liability actions, the latter doing so even while its editors noted that “the states are almost evenly divided on the issue.” In state court or diversity actions, practitioners must, as always, ascertain the applicable rule for the jurisdiction. For present purposes, however, we treat the FRE and URE provisions as the default rule: tort law does not permit the introduction of evidence of SRMs to prove negligence or defect.

CPSC: Design Changes

At its core, the CPSC would seem to be wholly supportive of design changes to address potential safety concerns. As products become iteratively safer, the CPSC’s mission of reducing unreasonable risks of injury to consumers becomes easier and more complete. In one noteworthy aspect, however, the CPSC has impliedly taken a position on design changes, the effects of which may be contrary to the FRE drafters’ policy view.

Under the CPSA, a company must report to the CPSC when it obtains “information which reasonably supports the conclusion” that a product contains a defect or noncompliance that could present a substantial product hazard (SPH) or presents an unreasonable risk. 15 U.S.C. §2064(b) (“Section 15”). Companies that fail to do so violate the CPSA and are exposed to substantial civil and even criminal penalties. 15 U.S.C. §§2068-70. In pursuing penalties, the CPSC frequently suggests that a company implemented changes in a product’s design or its manufacturing process in order to address reportable safety concerns, thus demonstrating that the company was aware of a reporting obligation.

In individual enforcement actions, the CPSC has employed this rationale for decades, but, in the rulemaking context, the Commission has never expressly articulated its views on the policy issues on both sides of this rationale. When, as directed by Congress in the Consumer Product Safety Improvement Act of 2008, the CPSC issued an interpretive rule reflecting the factors the agency uses in determining the amount of a civil penalty, that rule (including its Federal Register preamble) was silent on design changes. At no point has the CPSC formally asserted that a company’s changing a product in light of allegations of safety concerns could either trigger or aggravate a penalty, but the penalty record suggests that the agency sees changes as useful evidence.

This record also suggests that the CPSC does not believe that using design changes as evidence of potential defects will necessarily threaten to stifle innovation. This is not to suggest that the CPSC is cavalier or heavy-handed in its determination of the kinds of changes that can prove knowledge, and it may be that the agency has internal sensitivities to the risk of discouraging companies from seeking to make their products safer, balancing that risk against the merits of the penalty case at issue. However, the CPSC does not keep with the FRE principle as a blanket rule.

The CPSC might correctly point out that it is using design changes not as evidence of defect (or knowledge thereof) but as evidence of knowledge of *reportability*, and, by design, those are distinct issues. A product’s manufacturer (or distributor or retailer) must report to the CPSC under Section 15 when it knows a defect and SPH are *possible*, even if the company and the CPSC ultimately agree that there is no defect or no hazard. In principle, the CPSC could penalize a failure to report even in the absence of an actual defect, though we are not aware of any instance of a penalty that was not preceded by a recall. However, where the concern is the effect of the use of such evidence upon companies’ willingness to innovate, this is largely a distinction without a difference. Whether as proof of liability for defect or proof of liability for reportability, any apprehension attaching to SRM or design-change evidence would likely function similarly.

The CPSC would likely also correctly assert that the statutes it administers pursue different policy goals than the tort system does. Litigation is intended solely to compensate those who allege they have been injured by products. If an injury goes unlitigated and thus unremedied, the resulting harm falls only on the injured consumer, who may have consciously elected to forego any pursuit of compensation. By contrast, where a company allegedly fails to report safety-related information to the CPSC, the agency's opportunity to intervene in the market before some (or, ideally, any) injuries have occurred is diminished. Thus, while the risks to innovation that inhere in using design change evidence may be the same, the benefits are broader and, arguably, more compelling.

Protecting Innovation

To avoid situations in which well-meaning, responsible changes to a product are rightly or wrongly construed as responses to reportable information, counsel should ensure they build robust relationships and encourage open communication with development teams. The goal is not to stifle or inhibit the innovation that drives continued product improvement and business success, but simply to understand what innovations are happening and provide well-informed advice to the company about any legal or regulatory consequences. With the right level of integrated teamwork, counsel can improve both the flow of legally valuable information and the reception of legal advice.

If a contemplated change has been preceded by consumer complaints, counsel should assume that the CPSC will be inclined to believe the change to have been a response to those complaints. Similarly, if those complaints have fairly or unfairly alleged safety concerns, counsel should assume any resulting changes at least have the potential to appear to suggest knowledge of a potential safety issue that could rise to the level of reportable information.

Of course, the facts of any product's marketplace experience will necessarily control the application of broad regulatory principles to that specific product. To the extent the CPSC presumes, based on some of those facts, that the product was changed because of a known safety concern, the manufacturer will have the opportunity, in its engagement with the agency, to draw on other facts to demonstrate that no such concern exists, that any concern did not rise to the level of reportable information, or that any change was made for other reasons and thus should not be used as evidence of reportability.

Aside from factual complexity, another difficulty facing counsel in rendering opinions about reportability in light of design changes is that the speed of the modern consumer market and the breadth and complexity of products increase the odds of changes occurring without counsel's having real-time visibility. To guard against negative outcomes stemming from any such changes, companies should encourage product teams to document their rationales.

The CPSC is most likely to conclude that a design change is evidence of knowledge of reportable information if the agency does not see a documented, contemporaneous rationale for the change. To the extent that consumer complaints do provide the impetus for a change, the complaints and the change should be reviewed with counsel to determine whether a reporting obligation may exist. Where other factors, such as changes in supplier relationships or cost considerations, drive product changes, those reasons should be recorded. As other legal considerations, such as discoverability, may attach to documents pertaining to design changes and their rationales, counsel should be involved in creating templates and protocols for these documents.

Conclusion

At a policy level, it is an open question—and perhaps an unanswerable one—as to the extent to which the CPSC's divergence from FRE 407 in its treatment of design changes has an effect on innovation. At a legal practice level, in-house and outside counsel should be aware of that divergence and best position their clients to reduce the risk of the agency imputing an awareness of a reporting obligation where a product has evolved for reasons unrelated to safety. Without such counsel, if the agency later has safety questions, a company's good-faith product improvement may take on a different character.

