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PRODUCT RECALLS: ANTICIPATING THE PRODUCT LIABILITY LAWSUITS

It is an unfortunate fact of life that some products cause unforeseen dangers, and must be recalled. From the manufacturers' perspective, it is also unfortunate that product recall announcements can quickly lead to class action lawsuits. Recalls generate copious adverse publicity, and plaintiffs' lawyers can learn of many recalls almost immediately, even before most of the affected consumers.[1]

There are, of course, more immediate legal concerns that demand focused attention. The manufacturer may need to contact regulators, such as the Consumer Product Safety Commission ("CPSC") or the Food and Drug Administration ("FDA"). A major recall could be material to the company's financial position, requiring the attention of securities counsel. And companies facing recalls should immediately determine if they have insurance coverage, whether they need to provide notice to the insurer, and how to best preserve and maximize coverage.

But despite the need to attend to these pressing concerns, it is not too soon to begin planning for litigation. The manner in which a recall is conducted could have a significant impact on whether the recall will strengthen litigation defenses or merely fan the flames. This *Commentary* surveys recent recall-related cases and draws lessons on how to position oneself to minimize liability.

LESSON #1: WATCH WHAT YOU SAY

Even before announcing a recall, it is imperative for a manufacturer to gain control over its internal and external communications. Inconsistencies can prove lethal before a jury. All communications should be centrally controlled, vetted for accuracy, and processed through counsel to preserve attorney-client and work product protections. But even in the best of circumstances, manufacturers face a daunting task in walking the fine line between saying too much and saying too little.

Government regulators often demand fulsome disclosures. The FDA, for example, wants recall notices to explain "the reason for the recall and the hazard involved."[2] But the perils of saying too much are clear; any statement could wind up in front of a jury.

Manufacturers will often have grounds for seeking to exclude recall announcements from evidence. Recall notices are often a "subsequent remedial measure," and hence inadmissible to prove negligence, culpability, or the existence of a defect.[3] But there is certainly no guarantee that a motion to exclude recall communications will be successful. Although recall notices are likely inadmissible for certain purposes, the same document may be admissible for others, and the immunity may not apply at all if the alleged injury occurred after issuance of the recall notice.[4] The subsequent remedial measures rule may also be inapplicable if the recall is compelled by government regulators. Furthermore, in some states the rules of evidence expressly make recall notices admissible.[5] Other states, either by rule[6] or by caselaw,[7] do not exclude evidence of subsequent remedial measures in product liability cases. And one state rejects the subsequent remedial measures rule entirely.[8]

Even where government regulators are heavily involved, manufacturers usually maintain significant control over their communications. The CPSC will at times agree to refrain from using the word "recall" on its web site. The CPSC recently agreed to call a remediation program a "voluntary repair program," and did not require the manufacturer to deem the program a "recall." And under FDA terminology, oftentimes a recovery of products is not a "recall," but is instead classified as a "market withdrawal" or "stock recovery."[9] Furthermore, when submitting reports or other information to the FDA, a manufacturer "need not admit, and may deny, that the report or information … constitutes an admission" of fault, defect, or resulting injury.[10] Thus, where the existence of a defect is in doubt, a manufacturer should be able to avoid making admissions that would preclude valid defenses.

But it is also important to avoid saying too little. Without a sufficiently detailed description of a safety issue, the recall might not be effective in preventing further harm to consumers. From the manufacturer's point of view, an ineffective recall can create the worst possible scenario: widespread adverse publicity combined with potential liability for subsequent injuries. Furthermore, in states that follow the approach of the recent Restatement,[11] one can face liability for a negligent recall or a negligent failure to warn.

And, of course, whatever a manufacturer does say should be accurate. Manufacturers are increasingly being hit with securities class actions alleging that the manufacturers inflated their stock prices by "downplaying" the seriousness of recall problems. A recent Eighth Circuit case[12] threw cold water on one such set of allegations, holding that the statements in question were not materially misleading. In August 2011, the First Circuit similarly threw out a securities case alleging that a series of public statements relating to a product recall misled the public regarding the risk—which was quickly realized—of further recalls. The plaintiffs failed to prove that the manufacturer acted with scienter (an intent to deceive). But the First Circuit cautioned that "it is unusual to grant summary judgment on scienter," and the court's holding depended upon a very fact-intensive inquiry into when exactly management became aware of the scope of the potential product defects.[13] In other words, a manufacturer is far better off making unambiguously correct statements than having to rely upon proof of its good intentions.

Plaintiffs continue to bring suits alleging recall-related securities fraud. For example, in November 2011 consumers initiated a class action claiming that the manufacturer of contact lenses "artificially inflated stock values by hiding known problems with the contact lenses." For recalls involving a major product, a manufacturer should consider consulting with a securities lawyer for advice regarding the contents and manner of disclosures, and regarding whether it should prohibit trades by insiders.

LESSON #2: FIGURE THINGS OUT FAST

When problems with a product first arise, it can be hard to know whether a recall is needed. Investigation is required to determine whether a product malfunction is due to the product, or due to misuse or other factors. If the fault lies in the product, the manufacturer needs to know how widespread the problem is. Is the defect confined to a single unit or batch? Does the problem taint an entire production run,

the output of a whole facility, or an entire product line? And if there is a defect, how dangerous is it? An imminent health hazard calls for a very different response than a technical violation of an obscure regulation.

But although the process begins with considerable uncertainty, safety, regulatory, and litigation concerns place a premium upon a speedy and focused investigation. Companies regulated by the CPSC must report a "substantial product hazard" within 24 hours of obtaining reportable information.[14] Without solid information, one cannot know which products to recall. Nor can one effectively communicate unknown risks, and one risks being inaccurate by attempting to provide substantive information without a solid foundation. While a manufacturer can always state that it is recalling products "in an abundance of caution," the vaguer the recall statement, the less likely it is to provide an adequate warning, and the more the manufacturer opens itself up to accusations of hiding the full scope of the problems.

Worse, waiting too long before initiating a recall could itself create a cause of action, at least under the most liberal authority. Last April, a Florida court held that a class action plaintiff stated a violation of Florida's unfair trade practices statute by alleging that the defendant waited "nearly a week" before beginning a recall.[15]

Once the lawsuits begin, the manufacturer's conduct will be attacked with the benefit of hindsight. It therefore pays to ensure that all decisions are as informed as the circumstances permit.

LESSON #3: A ROBUST RECALL CAN MOOT OR PROVIDE DEFENSES AGAINST MANY LAWSUITS

Many plaintiffs who bring post-recall suits—particularly class actions—do not claim physical injuries. Increasingly, class actions are brought for so-called "economic injuries" by plaintiffs who merely purchased the recalled product.

These cases can at times be mooted through voluntary recalls. The 2011 Florida case noted above held that a manufacturer's offer to provide a refund precluded the plaintiff from alleging economic injury, even if the plaintiff would not have purchased the product had he been aware of the alleged defect.[16] However, the ability to moot class actions is limited, and courts have refused to dismiss cases where the plaintiff alleges that some defective products were not recalled, or where the plaintiff seeks a more generous remedy.[17]

But even if a recall does not moot the entire case, a recall can defeat class certification. This was the holding in an important appellate decision from last September, *In the Matter of Aqua Dots Products Liability Litigation*, 654 F.3d 748 (7th Cir. 2011).

In *Aqua Dots*, a distributor of toy beads recalled them after learning that they could injure small children who ate the beads. Chief Judge Easterbrook held that consumers had standing even without suffering physical injury, notwithstanding the distributor's recall and the availability of a refund. "The plaintiffs' loss is financial: they paid more for the toys than they would have, had they known of the risks the beads posed to children."[18] But because of the recall, and because the remedies sought in the lawsuit largely duplicated the refund offer, it was proper for the district court to deny class certification. "A representative who proposes that high transaction costs (notice and attorneys' fees) be incurred at the class members' expense to obtain a refund that already is on offer is not adequately protecting the class members' interests."[19]

Other courts have cited to Rule 26(b)(3) in denying class certification where a lawsuit is not found to be superior to a recall as a method for redressing the class members' grievances.[20] The Seventh Circuit rejected this theory. While reaching the same result by applying Rule 26(a)(4), the *Aqua Dots* court held that reliance on Rule 26(b)(3) was improper, since that rule allows a court only to determine "whether a single suit would handle the dispute better than multiple suits."[21]

An effective recall can also provide defenses even where a plaintiff alleges significant personal injury. A plaintiff may be found to have assumed the risk if he or she received a warning (in a recall notice or otherwise), and continued to use the product anyway. A defendant could also interpose the defenses of contributory negligence and superseding causes if the owner of the product ignored a recall warning, particularly if the owner was not the person injured by the product.

LESSON #4: SECURE THE EVIDENCE–AND RETURNED PRODUCTS COULD BE EVIDENCE

Too often, a party with insufficient evidence will seek to make up the shortfall through accusations of spoliation. The duty to avoid destruction of evidence does not arise the moment a manufacturer first contemplates recalling a product, but the manufacturer should begin thinking about how it will respond to accusations of spoliation.

The duty to preserve evidence, according to an major 2011 decision, attaches "when litigation is pending or reasonably foreseeable."[22] Before that time, it is not improper to discard documents or other materials that would have constituted evidence in later-filed lawsuit. Be mindful, however, that some judges have conflated the timing of the duty to preserve evidence with the Federal Rules' standard for when work product becomes protected from discovery.[23] Parties defending a prelitigation destruction of documents may wish to avoid claiming that other documents, dating from before the document purge, were "prepared in anticipation of litigation."

In addition to preserving documents, a party may also need to preserve physical evidence. This can run counter to ordinary instincts regarding the disposition of products. Tainted food, for example, is generally destroyed as quickly as possible. Doing so avoids the risk of contaminating other food or accidentally selling the tainted products. But destroying recalled food products may lead to charges that the manufacturer has destroyed important physical evidence.

An October 2011 decision in a food-recall case is instructive. The manufacturer defeated accusations of spoliations and demands for court orders regarding the handling of returned products because the manufacturer had preserved 100,000 specimens, had segregated these materials from products it would be selling, and had secured from the court, early in the litigation, an order governing the retention of returned products.[24]

CONCLUSION

When manufacturers contemplate a recall, they should expect that litigation and the second-guessing of their conduct will swiftly follow. A recall necessarily publicizes the possibility of a product defect, and the publicity can generate lawsuits. The lawsuits will scrutinize the accuracy and timeliness of recall-related statements, and will seek to maximize the remedies available to consumers. While lawsuits cannot be prevented, the outlines of such suits can be anticipated, and defense planning should be an integral part of the recall process.

LAWYER CONTACTS

Jones Day's multidisciplinary Product Recall & Accident Response team assists clients who have questions, concerns, or problems related to product recalls, as well as government civil and criminal investigations into product safety, both in the United States and around the globe.

For more information, *see* http://www.jonesday.com/product__recall__accident__response, or contact Dana Baiocco at dbaiocco@jonesday.com. Alternatively, please contact your principal Firm representative or the lawyer listed below. General email messages may be sent using our "Contact Us" form, which can be found at www.jonesday.com.

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ENDNOTES

1 The Food and Drug Administration posts announcements to its web site regarding almost every recall that the FDA oversees. The FDA also sends, to everyone who signed up for the service, daily emails summarizing the day's recall announcements.

2 21 C.F.R. § 7.49(c)(1)(iii). See generally 21 C.F.R. §§ 7.42(b)(2), 7.49 regarding recall communications for an FDA-regulated product.

3 *See* Federal Rule of Evidence 407.

4 *See id.*

5 *See, e.g.*, Texas Rule of Evidence 407(b) ("A written notification by a manufacturer of any defect in a product produced by such manufacturer to purchasers thereof is admissible against the manufacturer on the issue of existence of the defect to the extent that it is relevant"); Maine Rule of Evidence 407(b) (same).

6 Alaska Rule of Evidence 407 ("This rule does not require the exclusion of evidence of subsequent measures when offered … [to prove] defective condition in a products liability case …."); Connecticut Code of Evidence, §4-7(b) ("Where a theory of liability relied on by a party is strict product liability, evidence of such measures taken after an event is admissible …."); Hawaii Rule of Evidence 407 ("This rule does not require the exclusion of evidence of subsequent measures when offered … [to prove] dangerous defect in products liability cases …."); Iowa Rule of Evidence 407 ("This rule does not require the exclusion of evidence of subsequent measures when offered in connection with a claim based on strict liability in tort or breach of warranty ….").

7 The leading case for this proposition is *Ault v. International Harvester Co.*, 13 Cal.3d 113, 528 P.2d 1148 (Cal. 1974). The rule announced in *Ault*, although adopted by a number of courts in other states, is directly contrary to the current Federal Rule of Evidence 407, and even among state jurisdictions remains a minority rule.

8 Rhode Island Rule of Evidence 407 ("evidence of the subsequent measures is admissible).

9 21 C.F.R. § 7.3(j), (k). A "stock recovery" involves products that have not yet been marketed. A "market withdrawal" corrects a regulatory violation too minor to warrant enforcement action, or a reflects a situation where there has been no violation.

10 Food, Drug, and Cosmetic Act § 756. This same section also states that the report or information should not be construed as an admission. The robustness of Section 756's protections remains untested; no published case cites that provision.

11 *See* Restatement of the Law Third, Torts, Product Liability (1997), §§ 10 (liability for harm caused by post-sale failure to warn), 11 (liability for harm caused by post-sale failure to recall product).

12 *Detroit General Retirement System v. Medtronic, Inc.*, 621 F.3d. 800 (8th Cir. 2010).

13 *Mississippi Public Employers' Retirement System v. Boston Scientific Corp.*, 649 F.3d 5, 19-21 & n. 14 (1st Cir. 2011) (affirming grant of summary judgment).

14 Consumer Product Safety Act, § 15(b). The CPSC encourages companies to report potential substantial product hazards even while investigations are continuing. However, if a company is uncertain as to whether information is reportable, the company may spend a reasonable time investigating the matter. That investigation should not exceed 10 working days unless the company can demonstrate that a longer time is reasonable in the circumstances. 16 C.F.R. § 1115.12.

15 *See Jovine v. Abbott Labs., Inc.*, 795 F.Supp.2d 1331, 1343-44 (S.D. Fla. 2011). The court held that the complaint properly alleged a violation of FDUPTA, but ultimately dismissed that claim due to a lack of injury.

16 *Jovine v. Abbott Labs., Inc.*, 759 F.Supp.2d 1331, 1343-44 (S.D. Fla. 2011).

17 *See Martin v. Ford Motor Co.*, 765 F.Supp.2d 673, 681-82 (E.D. Pa. 2011).

18 *Aqua Dots*, 654 F.3d at 750-51; accord *Askin v. The Quaker Oats Co.*, No. 11 CV 111, -- F.Supp.2d --, 2011 WL 4840704 (N.D. Ill. Oct. 12, 2011).

19 *Aqua Dots*, 654 F.3d at 751, 752, *citing* Federal Rule of Civil Procedure 26(a)(4).

20 *Webb v. Carter's Inc.*, 272 F.R.D. 489, 504-05 (C.D. Cal. 2011) (denying class certification because, although product was not recalled, availability of refund meant that a class action was not superior); *In re Conagra Peanut Butter Products Liab. Litig.*, 251 F.R.D. 689, 699-700 (N.D. Ga. 2008) (collecting cases).

21 *Aqua Dots*, 654 F.3d at 751-52.

22 *Micron Technology, Inc. v. Rambus Inc.*, 645 F.3d. 1311 (Fed. Cir. 2011).

23 *See* Federal Rule of Civil Procedure 26(b)(3)(A).

24 *Brandner v. Abbott Laboratories, Inc.*, CA No. 10-3242, 2011 WL 4853384 (E.D. La., Oct. 13, 2011).