Lawyer Insights

Considering Disclosure Risks In Sensitive Product Recalls

By Syed S. Ahmad and Geoffrey B. Fehling
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A New York trial judge recently denied a pharmaceutical company's motion to seal status reports between the company and the U.S. Food and Drug Administration concerning recalls of contaminated vitamin products. The New York Supreme Court rejected the company's argument that the status reports contained proprietary business information about customers and the recall that could be used by customers in future litigation.

The decision highlights the balancing act between comprehensive disclosures during recall efforts and the use of those communications in subsequent insurance or personal injury lawsuits arising out of the recall.

Background

In *Otsuka America Inc. v. Crum & Forster Specialty Insurance Co*.[1] the parent company of vitamin maker Pharmavite filed a lawsuit alleging that its insurer, Crum & Forster, improperly denied benefits under a product recall insurance policy. Pharmavite alleged that it had incurred covered losses in the withdrawal, destruction and disposal of tainted products in a recall. In June 2016, Pharmavite was forced to recall a number of dietary supplement products produced at its Opelika, Alabama, facility following testing protocol issues discovered during an FDA audit.

Pharmavite provided notice of the recall to Crum & Forster, who disclaimed coverage. Pharmavite later filed suit seeking a declaratory judgment that its policy provides coverage for losses sustained as a result of the recall and asserting a breach of contract claim against Crum & Forster for failing to reimburse covered losses under the policy. Pharmavite claims that it suffered $9 million in uninsured losses, including costs associated with the withdrawal, destruction and disposal of adulterated products, lost profits, increased operating costs and other expenses associated with the recall and third-party liabilities.

The Pharmavite Communications

Pharmavite corresponded frequently with the FDA during the recall process, including by providing numerous status reports updating the FDA on the progress of the recall efforts. Pharmavite argued, however, that four such status reports contained "proprietary business information" about the practices and procedures utilized in the recall.

Pharmavite asserted that other documents disclosed specific communications with its customers, including one letter from Pharmavite to its customer forwarding correspondence it had received from the FDA outlining its recommendations to Pharmavite in light of the specific products and contamination discovered during the audit. That information, Pharmavite argued, could "impact current or contemplated

litigation against Pharmavite by individuals alleging bodily harm from ingesting Pharmavite's products."

Pharmavite filed a motion to seal the confidential and potentially damaging documents, which Crum & Forster did not oppose. The court denied the motion with respect to all documents. Despite recognizing its court authority under New York law to seal documents upon a finding of good cause, the trial court outlined numerous competing interests supporting public proceedings and disclosure of documents utilized in litigation. As the court explained, "[t]he public needs to know that all who seek the court's protection will be treated evenhandedly," and "[t]here is an important societal interest in conducting any court proceeding in an open forum."[2]

To establish good cause, Pharmavite carried the burden to demonstrate "compelling circumstances to justify restricting public access" that is sufficiently supported by affidavits from persons with knowledge of the alleged sensitive materials explaining why they should be sealed[3] With respect to alleged trade secrets or proprietary information, documents may only be sealed where the movant shows that disclosure "could threaten a business's competitive advantage."[4]

Applying these standards, the court denied the motion. The court found that good cause existed to redact some of the FDA status reports, but only to the extent the reports identify Pharmavite's customers. The court disagreed with Pharmavite's blanket categorization of these documents as containing "proprietary business information," however, and found that Pharmavite had failed to articulate how the alleged proprietary information in the FDA communications could threaten its competitive advantage. "Without more," the court stated, it was being asked "to make conjectures concerning a sound basis or legitimate need to take judicial action."[5]

The court took Pharmavite to task for failing to cite any specific cases addressing the context of the sealed records at issue and seeking to conceal from the public the fact of the recall or that efforts were made to assess and execute the recall, noting "neither the potential for embarrassment or damage to reputation, nor the general desire to privacy, constitutes good cause to seal court records."[6]

The court found it was quite the opposite, ruling that where the communications at issue concern product recalls, "the potential impact on current or contemplated litigation by individuals who allegedly ingested the products is precisely why such information should not be concealed especially by aid of the court."[7]

Takeaways

As the New York authorities relied upon by the Otsuka court explained, given the strong interest in public judicial proceedings, confidentiality of records "is clearly the exception, not the rule."[8] The court's ruling in the Pharmavite sealing dispute raises several takeaways for businesses to consider when dealing with sensitive product recalls, clashes over insurance coverage and similar disputes.

First, the Otsuka ruling highlights the inherent risk of sensitive disclosures in product recall matters, which place a company's desire to fully cooperate with powerful state and federal authorities by providing frequent, comprehensive updates about the scope, status and conclusions in any recall efforts against the potential use of that information against the company in future disputes arising from the recall. This balancing act plays out frequently in courts, where parties move to seal communications with federal or state agencies.[9]

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In fact, the recent opinion was not the first time that Pharmavite's FDA correspondence had caused problems during the litigation. Only months earlier, Crum & Forster had filed a motion to dismiss the lawsuit due to alleged spoliation of the contaminated dietary supplements, which it alleged were destroyed without notice or opportunity to perform independent testing.

Pharmavite had indeed destroyed the products in January 2017, but only after being instructed by the FDA to "[p]lease proceed with the destruction" and after responding to all of the insurer's outstanding requests for information. Crum & Forster denied coverage two weeks later on the ground that there was no "insured event" triggering coverage, which was based in part on its belief that there had been no testing of the products to confirm that they were, in fact, "contaminated."

Insurance imposes another layer of cooperation and disclosure, requiring policyholders to reveal nearly all aspects of the underlying recall event to insurers to receive the benefit of recall insurance and maximize recoveries. Enlisting experienced coverage counsel early on in the recall process can help mitigate the risk of unnecessary disclosures and protection of particularly sensitive records in the event coverage litigation is required.

Second, if sensitive recall communications or information is subject to disclosure in litigation, parties should carefully review all applicable state and federal sealing requirements and then request specific, narrowly tailored relief supported by sufficient factual evidence. The Federal Rules of Civil Procedure or their state equivalent are oftentimes further supplemented by local rules that require particularized showings.

Blanket or conclusory statements about protecting a party's desire for confidentiality or business interests may not suffice, even where the opposing party does not oppose the request to seal. Sealing requirements are particularly stringent in federal courts. As the U.S. Court of Appeals for the First Circuit explained, "[s]ealing orders are not like party favors, available upon request or as a mere accommodation."[10]

The success of those motions are mixed, although courts do grant relief based on well-supported motions that make particularized showings as to why disclosure would harm the business, particularly where there is proof of harm other than risk of adverse consequences in current or future litigation.[11]

Resolving product recalls quickly and efficiently, including by making detailed and complete reports to regulators, is of paramount concern to businesses for obvious reasons. In addition, given the typically large losses and exposures associated with recalls, companies should cooperate with insurers by sharing information to maximize recall insurance recoveries. In the event those disputes proceed to litigation, however, companies can take steps to minimize unnecessary disclosures and, if needed, protect their legitimate business interests by sealing court records.

Notes

[1] No. 650463/2018, 2019 WL 2931902 (N.Y. Sup. Ct. July 03, 2019).

[2] Id. at *2 (quoting *Arkun v. Farman-Farma*, No. 1073352006, 2006 WL 8088157, at *2 (N.Y. Sup. Ct. Sep. 28, 2006)).

[3] Id. (quoting *Mosallem v. Berenson*, 76 A.D.3d 345, 349 (N.Y. App. Div. 2010)).

[4] Id. (quoting *Mosallem*, 76 A.D.3d at 350-51).

[5] Id.

[6] Id. (quoting *Mosallem*, 76 A.D.3d at 351).

[7] Id.

[8] *Mosallem*, 76 A.D.3d at 349 (quoting In re Will of Hofmann, 284 A.D.2d 92, 93, 727 N.Y.S.2d 84, 85 (N.Y. App. Div. 2001)).

[9] See, e.g., *Forst v. Smithkline Beecham Corp*., 639 F. Supp. 2d 948, 956 (E.D. Wis. 2009) (denying motion to seal company's communications with FDA and deposition testimony regarding those communications); *Phillips v. C.R. Bard, Inc.*, No. 3:12-CV-00344-RCJ, 2015 WL 3485039, at *1 (D. Nev. June 1, 2015) (denying motion to seal product design and testing, including communications with FDA, and other materials due to lack of a "compelling reason" to seal and the "only harm that could come to [the movants] from the release of [the] information is the precipitation of further lawsuits against it").

[10] *R & G Mortg. Corp. v. Fed. Home Loan Mortg. Corp*., 584 F.3d 1, 12 (1st Cir. 2009).

[11] Compare *Supernus Pharm., Inc. v. TWi Pharm., Inc.*, No. CV 15-0369 (RMB/JS), 2017 WL 3671522, at *2 (D.N.J. Aug. 24, 2017) (granting motion to seal materials, including "confidential communications with the FDA," where defendants submitted two declarations sufficiently describing the nature of the materials at issue, sought only a partial redaction, and established that they "possess a legitimate private interest in keeping the subject materials confidential" because "if the subject materials are made public, defendants could be harmed by way of competitive disadvantage in the pharmaceutical marketplace"), with *United States v. Dish Network, L.L.C*., 943 F. Supp. 2d 891, 895 (C.D. Ill. 2013) (granting motion to unseal settlement communications between a company and the FTC where the company had "not adequately explained how [the sealed] information... is confidential business information, the disclosure of which would put [it] at a competitive disadvantage").

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