Defending Against Label-Based Lawsuits

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Commentary *Article*

Best practices for defending against lawsuits based on pharmaceutical labeling, including avenues for early resolution of the case and, as necessary, strategies for developing the best evidence for defense.

Could you be sued based on what the label of a product sold at a pharmacy does—or does not—say? If you make it, distribute it, or sell it, the answer may be "yes."

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In many product liability lawsuits, the plaintiff alleges injuries based on the product label's failure to adequately warn consumers of some material information or risk of using the product.In class-action lawsuits, for instance, the plaintiff alleges the labeling was false and that they would not have bought the product had the truth been known. In pharmaceutical litigation, the plaintiff often alleges that she would not have taken the

medication had she known of a particular adverse effect or risk of the medication.

Below are several best practices for seeking early resolution of these cases, such as using the discovery process—including taking depositions—to obtain helpful admissions that may allow the case to be dismissed earlier than trial.

A Powerful Shield: Preemption

Federal preemption is a legal doctrine that can be an exceptional bulwark against labeling claims. Preemption is a defense that stops lawsuits from proceeding where the result would conflict with federal law.

There are different types of preemption. One is "express preemption," which is when federal law expressly states that statutes or regulations that conflict with federal law are preempted. Another is "implied preemption," where compliance with state law would conflict with federal law. Because preemption is based on the specifics of federal law, its application varies depending on the specific federal law at issue and often, product-by-product (and thus case-by-case).

Express Preemption

For some OTC products, Congress expressly preempted non-product liability claims premised on labeling. For example, acetaminophen, cold medicine, and even deodorant are such OTC products. This preemption allows you to winnow label-based claims not sounding in product liability and then focus on any remaining claims, which may still be void due to implied preemption.

For dietary supplements, Congress has expressly forbidden states from requiring any changes to the label of a dietary supplement that otherwise conforms with the FDCA. For example, a claim alleging that a dietary supplement's label stating it supported "healthy hair and skin" was deceptive to consumers was dismissed as impliedly preempted.

Implied Preemption

Implied preemption may be available in cases involving prescription, OTC, and dietary supplement products, where the lawsuit alleges a failure to comply with state-law requirements that conflict with federal law. For example, courts have found the following claims to be barred by implied preemption:

- Claiming a label needs additional or different warnings when FDA dictates the precise content of the warnings on the label.
- Alleging nonconformance with labeling requirements under the Food Drug & Cosmetics Act (FDCA) when the FDCA makes it the exclusive responsibility of the federal government to prosecute claims for FDCA violations.
- Alleging that a defendant should stop selling an FDA-approved product.

Thus, when confronted with a lawsuit that challenges a statement on a label, an important step is assessing preemption as a defense. Preemption arguments can be successful on an early motion to dismiss, but sometimes cannot be made successfully until summary judgment if they require consideration of documents outside the pleadings.

Don't Defend Against the Undefined

The crux of a labeling-based claim is that the label was improper and a proper label would have prevented the claimed injury. The plaintiff should be able to identify what allegedly was improper about the label and what a proper version would say. If the pleadings do not make this clear, one strategy is to force clarity through briefing on a motion to dismiss or motion for more definite statement, depending on applicable law.

Once you (or the Court) force the plaintiff to commit to identifying a specific labeling defect or what a proper label should look like, the scope of the litigation will be better defined, such as the scope of discovery, potential defenses, and potential exposure.

For example, vaguely alleging that a prescription's label needed additional warnings, without stating what those warnings should have stated, may allow for depositions of myriad employees and corporate representatives related to all aspects of the drug's development, approval, marketing, and sale. If the allegation must be refined to a more detailed warning, the scope of discovery should likewise be limited.

Requiring an up-front definition of the labeling error may lead the plaintiff to commit to invalid theories of liability. For example, a lawsuit was recently dismissed on the pleadings where the plaintiff claimed hand sanitizers with labels that said, "Kills More than 99.99% of Germs" and "Kills More than 99.99% of Most Illness Causing Germs" were misleading consumers into believing they killed 99.99% of all germs in existence.

Because the back of the label clarified that the sanitizers killed 99.99% of "most common germs that may cause illness," the

consumer could not explain how it was reasonable to believe the product killed 99.99% of all germs or all known germs.

Further, the court held that no reasonable consumer would expect a low-cost hand sanitizer to kill all known germs—let alone all germs in existence. As such, the plaintiff could not meet the relevant legal standard (i.e., show the front label claims were literally false or that the front labels as clarified by the back label were false and misleading), the theory of liability was invalid, and the case was dismissed.

No Reliance? No Causation

Another strategy is to hold off until the written discovery or deposition phase to seek important clarifications about a label. For instance, if a consumer did not rely on a product's label when deciding whether to use the product, then any additional warning could not have prevented that consumer's injury.

This breaks the causal link between the contents of the label and any claimed injury, which is fatal to most label-based claims. As such, discovery aimed at unearthing the plaintiff's true knowledge about and reliance, if any, on the product label is essential to testing this defense.

Depositions are a great place to test reliance on the label. As opposed to written discovery responses or responses to motions to dismiss, depositions can provide relatively candid responses from the plaintiffs. For example, in a recent lawsuit, a plaintiff claimed that the label of cooking spray misled consumers into believing it contained butter and argued that the label should have been clearer that it did not contain butter and was merely butter flavored.

After the lawsuit was filed, the product's label was changed to state it was "Butter Flavor"-ed, making it clearer that the spray did not contain butter. The defendant's theory was that the plaintiff did not care what the label said and would have bought the product regardless of what it said about butter.

At the plaintiff's deposition, the defense attorney showed the plaintiff the updated label indicating it was "Butter Flavor" cooking spray. The plaintiff made concessions helpful to the defense, namely that he believed the updated label was on the product he purchased. In other words, he would have bought the product even with the improved label requested in his complaint.

Afterwards, the plaintiff argued this was an attempt to trick him into giving false testimony, and initially the court seemed inclined to agree. The court questioned why defense counsel had shown the plaintiff a label that did not exist until after the plaintiff had purchased the product and filed suit.

The defendant explained that the testimony went directly to reliance, namely that the plaintiff did not rely on the label when purchasing the spray, as evidenced by his testimony that he would have bought the product even if the label said it was butter flavored. This line of inquiry revealed that the plaintiff likely had never seen—let alone relied upon—various statements he and/or his attorney alleged to be misleading in the complaint.

This strategic use of depositions can be particularly effective in defeating labeling-based lawsuits. Potential topics and related goals for securing helpful admissions about labels at depositions include:

- The plaintiff's history with the product, including first awareness, first use, and any continued or even ongoing use of the product, which may show the plaintiff used the product prior to the allegedly deficient label or continued to use the product while the allegedly deficient label was in use.
- The reasons for and expectations when the plaintiff was buying the product, which can expose that the plaintiff's reasons for buying and/or expectations for the product had nothing to do with the labeling or that the reliance was unreasonable.
- The label itself, including its overall appearance, substantive content, deficiencies, and how to remedy any such deficiencies, which if done without showing the label itself can reveal that the plaintiff is not familiar with a label that was allegedly so impactful it formed the foundation of a lawsuit.
- For prescription products, what events led to the prescription and any interactions the plaintiff had with healthcare providers along the way, which may uncover other potential sources of information besides the label that the plaintiff relied upon and, in some jurisdictions, may give rise to defenses related to the learned intermediary doctrine.

Defeating Class Certification

In a class action challenging label claims, the plaintiff attempts to prove that the class is similarly situated while the defense attempts to show that individual issues predominate in order to defeat class certification. Often defendants have the upper hand here because no two people are the same in terms of how they review, understand, interpret, or care about claims

made on labels. Potential topics to emphasize and develop through class certification discovery and argument include:

- The individual analyses needed to determine whether each class member can establish causation, which involves showing that they relied upon the manufacturer's label and/or they would have relied on any proposed alternative label and, due to such reliance, would not have used the product at issue.
- The proposed class representatives' ability to represent the class, including whether their claims arise from products/labels that are not the same or substantially similar to those underlying the claims of other class members.
- Whether the class seeks (or could seek) damages such as pain, suffering, or emotional distress that would require an individual analysis.
- Whether the available defenses turn on the particular facts of a plaintiff's claim, including the application of the learned intermediary doctrine, the individual knowledge of any healthcare provider prescribing or otherwise recommending the product, the risk-benefit analysis applied to a particular plaintiff's use of the product, and each individual plaintiff's knowledge of a product's potential risks.

Awareness of these options and related case trends can assist defendants in efficient resolution of lawsuits based on label claims. Faced with novel theories and vague allegations, those defending against label-based claims should consider whether any of these strategies may increase their chances of favorably resolving such claims.

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