

Proposed Rule Boosts Preemption Defense

Pharmaceutical manufacturers who use preemption as a defense in state product liability lawsuits got a boost last week from an FDA proposed rule.

The rule would require firms submitting changes being effected (CBE) supplements for labeling modifications prior to agency review only when they have new information demonstrating sufficient evidence of a causal association about a safety issue that either was unknown to the agency or has a greater severity than previously understood.

However, the FDA reiterates its position on preemption in the rule as well. According to Stephanie Scharf, a product liability attorney and partner at Schoeman Updike & Kaufman, the proposed rule enhances a preemption defense because not only does the agency reiterate its

position on the doctrine, but it does so in the context of state failure-to-warn laws.

“To the extent that state law would require a sponsor to add information to the labeling for an approved drug or biologic without advance FDA approval based on information or data as to risks that are similar in type or severity to those previously submitted to the FDA or based on information or data that [do] not provide sufficient evidence of a causal association with the product, such a state requirement would conflict with federal law,” the FDA says in the Jan. 18 *Federal Register*.

“In such a situation, it would be impossible to market a product in compliance with both federal and state law, and the state law would ‘stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,’” the FDA adds. The agency is inviting states to comment on the rule.

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Scharf emphasized that the rule stipulates that there must be sufficient evidence of a causal association to justify a CBE supplement. “A simple association is not enough,” Scharf said.

Under the proposed rule, CBE supplements can be used only to change product labeling to reflect new safety information, such as strengthening the contraindications, warnings, precautions or adverse reactions sections. The rule simply clarifies long-standing policy, the agency says.

According to former FDA Associate Commissioner for External Relations Peter Pitts, the rule sanctions pharmaceutical companies to change physician labeling in situations of emerging safety issues.

“I think [the rule] is empowering, and it will force the pharmaceutical firms to put their money where their mouth is rather than saying the FDA

didn’t let us, or that’s the FDA’s job,” Pitts said. “Whenever new safety information did not make it onto a label change with alacrity, the company would say this is something we have to do in consultation with the FDA. That was the standard kind of sound bite statement.”

Pitts explained that it was important to understand the current legislative environment that this rule is being promulgated in, as the FDA now has the authority to mandate labeling changes (*WDL*, Oct. 15, 2007).

“This rule is saying that when new information arises that is relevant from a safety perspective, the company can change the label. Even though there has always been the opportunity for a company to do that, that has not been the practice.”

More information can be accessed at www.fda.gov/OHRMS/DOCKETS/98fr/08n-0021-npr0001.pdf. Comments are due March 17.
— Christopher Hollis