Pre-Emption Issue Weighed in Label Cases

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In two appeals that could have a huge impact on the litigation of drug product liability cases, the 3rd U.S. Circuit Court of Appeals heard arguments this week on the issue of whether plaintiffs should be pre-empted from suing over allegedly inadequate warnings on prescription drugs because the warning labels were approved by the Food & Drug Administration.

Lower court judges have reached opposite conclusions, with U.S. District Judge Michael M. Baylson in the Eastern District of Pennsylvania holding that such claims are pre-empted, and U.S. District Judge Jerome B. Simandle in the District of New Jersey holding that they are not.

Both cases stem from suicides in which the plaintiffs claim that manufacturers of anti-depressant drugs failed to warn of the increased risk of suicidality.

In Colacicco v. Apotex Inc., Baylson found that the plaintiffs' state law tort claims are pre-empted because Congress granted control to the FDA to regulate the prescription drug industry, including the authority to regulate "the specifics of drug labeling."

But in McNellis v. Pfizer Inc., Simandle concluded that a state tort claim was not pre-empted because the FDA's regulations "empower drug manufacturers to enhance the labeling warnings beyond the approved text when new risks emerge."

In nearly two hours of oral argument on Monday, the three-judge panel appeared inclined to rule in favor of the drug manufacturers on the grounds that the FDA has explicitly rejected the plaintiffs' proposed warnings for Paxil, Zoloft and Prozac - anti-depressant drugs known as "selective serotonin reuptake inhibitors" or SSRIs.

Six lawyers presented arguments, including a Justice Department lawyer arguing for the FDA who urged the court to side with Baylson and hold that such claims are pre-empted.

Arguing for the plaintiff in the Colacicco case, attorney Derek T. Braslow of Pogust & Braslow in Conshohocken told the court that Baylson should be reversed because the FDA's regulatory process does not conflict with a state tort claim that accuses a manufacturer of failing to add to its warnings when it gets new information that shows an increased risk.

But Braslow was soon peppered with questions from all three judges - 3rd Circuit Judges Dolores K. Sloviter and Thomas L. Ambro and visiting Judge Jane A. Restani of the U.S. Court of International Trade.

Restani asked if there were an "actual conflict" because the FDA has specifically rejected proposals to add suicide warnings to SSRIs.

Braslow insisted there was not because the manufacturers control the process of negotiating with the FDA on labels and never told the agency of the suicide risks it had discovered.

Under the FDA's own rules, Braslow said, a manufacturer is required to enhance its warnings whenever it discovers a risk that is not yet on the label.

In the case of Paxil, Braslow said, the FDA never told GlaxoSmithKline or the generic manufacturer, Apotex, that it was not required to strengthen the warnings.

Sloviter disagreed, saying "the FDA said more than that" by telling the manufacturers that it did not want the approved SSRI labels changed "because it will confuse people. . . . People who might get help from the drugs won't take them if you put too many warnings on them."

"Why isn't that a conflict?" Sloviter asked.

But Braslow insisted that the information in the hands of the manufacturers was never passed on to the FDA and that the agency's decision about the warnings on the labels therefore did not conflict with a state tort claim that accused the manufacturers of ignoring that risk.

Attorney Sol H. Weiss of Anapol Schwartz Weiss Cohan Feldman & Smalley, arguing for the plaintiff in the McNellis case, said that the FDA's decision is not entitled to deference because the agency conducts no clinical trials of its own and instead relies on the manufacturers to supply all of the evidence that supports its decisions.

Attorney Charles Becker, arguing for the Pennsylvania Association for Justice, formerly known as the Pennsylvania Trial Lawyers Association, said that the tort system is an "important and necessary adjunct to the regulatory process" and that, until recently, the FDA has always agreed with that premise and taken the position that drug products liability suits are not pre-empted.

Ambro asked Becker if the FDA should be accorded significant deference because of its "unique expertise."

But Becker said the FDA should not be allowed to dictate to the courts on an issue of constitutional law, and that the agency's current position should be rejected because it directly conflicts with the regulations - which allow manufacturers to enhance warnings - and because the FDA has been inconsistent on the issue of whether such suits are pre-empted.

GlaxoSmithKline's lawyer, Chilton D. Varner of King & Spalding, urged the court to uphold Baylson's ruling on the grounds that the FDA "has watched this issue . . . over 16 years" and has specifically ruled that suicide warnings should not be added to SSRIs.

"When a federal agency - the expert scientific federal agency to whom Congress has delegated authority to make certain that prescription drug labeling renders that drug safe and effective - says you can't do it, and the plaintiff wants a state jury to say you can be liable because you didn't do it, that is just an irrevocable conflict," Varner argued.

When pressed by Ambro to articulate the specific conflict that should result in pre-emption, Varner said "a warning that has been declared adequate under federal law cannot be declared inadequate under state law."

Justice Department attorney Sharon Swingle told the judges that, in the case of SSRIs, the FDA's decisions about warning labels should be read as establishing both a "floor" and a "ceiling" and that the plaintiffs' claims were effectively demanding that the manufacturers violate that rule.

If the manufacturers had done what the plaintiffs asked, Swingle said, their drugs would have been deemed "mislabeled."

Swingle also said the Colacicco claim was flawed because the plaintiff in that case took a generic version of the drug and was demanding that a generic manufacturer alter the label that was taken from the brand-name drug - something FDA regulations do not allow.

But Braslow argued that Swingle's description of the regulations was flawed and that both generic and brand-name manufacturers have an affirmative duty to enhance their warning labels when evidence exists of a risk that is not included on the FDA-approved version of the label.