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INSIGHT: Supreme Court Unlikely to Rob Drug Companies of a Preemption Defense, Undermine FDA

By Michelle M. Bufano

Last month, the U.S. Supreme Court heard oral argument in *Merck v. Albrecht (In re Fosamax)* where the Court again considered the issue of whether a state-law failure-to-warn claim was preempted when the Food and Drug Administration rejected a drug maker's proposed warning or whether such a case must go to a jury for speculation as to why the proposed warning was rejected.

While it is impossible to predict the ultimate outcome, a majority of the court appeared to agree with Merck's position that such a claim should be preempted. A ruling for Merck would be a victory for pharmaceutical companies as it would maintain one of the most effective defenses against state-law product liability claims: preemption.

That said, none of the justices indicated a desire to overturn the 2009 holding of *Wyeth v. Levine*, in which the court refused to apply preemption in the absence of clear evidence that the FDA would have rejected a label change.

While it seems likely that the Supreme Court will issue a decision applying *Levine* to the particular facts of this case, it probably will be disinclined to interpret *Levine* in the same manner as the Third Circuit in the underlying appeal. Namely, the Third Circuit, in considering the appeal in the *Fosamax* case, interpreted the *Levine* ''clear evidence'' standard to require a '' 'smoking gun' rejection letter.''

If the questions at oral argument are any indication, we expect a close vote, and the ramifications will be significant if the court rules against Merck.

Potential to Undermine FDA Review First, a finding against Merck likely will undermine the FDA's review process. The need for a ''smoking gun'' rejection letter may serve as incentive for manufacturers to submit multiple versions of proposed warnings—with the goal of trying to ensure that some future jury (more later on the peril invited by requiring a jury to make this determination) will find the FDA's rejection to satisfy the ''smoking gun'' standard.

Manufacturers may feel compelled to overwhelm the FDA with information for the purpose of protecting against potential liability.

The inevitable result will be the creation of a system that incentivizes manufacturers to deluge the FDA with multiple iterations of proposed labeling. The by-product of this sort of regime will materially impair the FDA's ability to carry out its mission of protecting public health.

Under this scenario, the agency would need to devote and divert countless resources to review these submissions—at the expense of the public that has committed to protect and serve.

Potential to Chill Innovation Second, finding against Merck also has the potential to chill innovation. The research and development process required to bring a new drug to market is very long and costly.

According to the Pharmaceutical Research and Manufacturers' Association of America, ''[f]rom drug discovery through FDA approval, developing a new medicine on average takes 10 to 15 years and costs $2.6 billion (citation omitted). Less than 12% of the candidate medicines that make it into phase I clinical trials are approved by the FDA.''

Because of the immense costs associated with researching and developing new medicines, the scope of litigation risk necessarily will have an impact on a pharmaceutical company's decision to devote money, time and other resources to innovation.

The likely result is that less investment will be made in innovation resulting in less medications brought to market. And the availability of fewer medications certainly will have a direct impact on public health.

Use of Jury Defies Legal Precedent Finally, a word on the notion that a jury should and could speculate regarding hypothetical FDA action. As Justice Gorsuch noted during oral argument and Respondent's counsel conceded, preemption is a ''matter of law.''

Allowing a jury to guess what a federal agency might have done in a different factual situation if presented with a hypothetical drug labeling proposal defies legal precedent.

It is the FDA that possesses the expertise to evaluate scientific data and opine on whether such data supports a label change. The Agency considers and approves new drugs based on this very expertise it is known to possess.

Moreover, in *Daubert v. Merrell Dow Pharmaceuticals*, the Court expressly bestowed upon judges the role of ''gatekeeper'' of science and the law to prevent junk science from reaching and confusing juries. If a jury is not equipped to distinguish legitimate science from junk science, it is hard to understand how it could or should supplant the scientific expertise of the FDA.

Ultimately, this case presents a chance for the Court to clarify *Levine* by articulating what is meant by ''clear evidence.'' It remains to be seen whether that clarification will require ''smoking gun'' evidence and jury speculation. It seems unlikely.

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