The Supreme Court Should Rule for Mrs. Levine

*by Thomas N. Tiedt**

The United States Supreme Court soon may decide a blockbusting drug case: *Wyeth v Levine*, and its ruling will undoubtedly have an enormous impact on the industry. The High Court is scheduled to review the Vermont Supreme Court's ruling in favor of Diana Levine, a professional musician who suffered amputation of her arm as a result of an intravenous injection of Phenergan for nausea.

Seeking relief, Wyeth argues that FDA approval of prescription drugs preempts tort litigation regardless of the fact that Congress — unlike it did in 1976 regarding FDA-approved medical devices — has not similarly preempted such pharmaceutical litigation, even after three decades of lobbying for such preemption.

Because a Supreme Court Ruling favoring Wyeth provides potentially expansive legal precedent, diverse industries support Wyeth's petition for tort preemption, including the prescription pharmaceutical industry, Boeing, Ford Motor Company, General Electric, Microsoft and R. J. Reynolds Tobacco Company. Ironically, these industries now are showing uncharacteristic confidence in a federal agency to regulate consumer products.

In 2002 — a year into the Bush administration — FDA abruptly changed its position regarding preemption of tort litigation. Historically, FDA had held that FDA approval did not preempt tort litigation, that tort litigation benefited drug safety and that FDA approval set only minimal standards and that states were free to provide additional protections. Now, FDA is partnering with Wyeth and other industry defendants against consumer and institutional plaintiffs in favor of preemption, arguing that FDA approval provides "optimal regulation." Outside of this odd partnership with FDA, industry often disagrees with agency decisions, such as to delay or reject product approval or to curtail product use over government safety concerns.

Even after thousands of pharmaceutical lawsuits spanning at least a century, there is no evidence supporting FDA's speculations behind its policy conversion. Rather, there is compelling evidence that FDA's performance falls short of Congressional intent, public expectations and adequate drug safety review. Last fall, FDA's Science Board concluded: "The Agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities…The FDA cannot fulfill its mission because its scientific base has eroded and its scientific organizational structure is weak." Just a year ago, the FDA Commissioner said that FDA is inadequate in its regulations and will fail in consumer protection. Only with the passage of The Food and Drug Administration Amendments Act of 2007 — enacted in response to FDA's poor performance — has components of a credible drug safety system been funded, while its beneficial results remain to be determined. Accordingly, reliance on hopes for improved FDA performance and on supremacy of a single federal agency is premature if not excessive.

Historically, tort litigation has served the first responder to serious drug risks too often ignored by a well-meaning-but-over-worked and heavily-lobbied FDA until critical masses of litigation, accusatory media coverage and Congressional attention have been compiled. Furthermore, tort litigation has revealed too often that pharmaceutical marketers have manipulated safety data submissions to FDA and research reports published in the peer-reviewed literature, uncovering critical drug toxicity that otherwise would not have been made public or reasonably available to FDA and, unfortunately, grist for sensational media coverage and Congressional concern that profits outweigh safety. According to the chair of an FDA's advisory, "The basic plot of the rosiglitazone story quickly became obvious to the advisory committee: a new "wonder drug," approved prematurely and for the wrong reasons by a weakened and underfunded government agency subjected to pressure from industry, had caused undue harm to patients."

Preempting pharmaceutical litigation would remove incentive for FDA and industry to improve product safety and would largely preempt discovery of concealment and misrepresentation of drug safety risks, which when identified have served to prompt FDA enforcement and new directions in drug safety research and therapeutics. The difficulties and expenses of the drug safety system are not disproportionately caused by litigation. At least as important are federal bureaucracy impediments and the reliance of most of the decision makers in drug safety on drug sales for their income, health benefits and pensions, which may skew or pre-determine litigation strategies as well as drug safety policy and development.

Improvements in drug safety and long-term industry vitality will not result from litigation preemption but rather from pluralistic mechanisms, including the risk identification afforded by as well as government, corporate and therapeutic response to tort litigation.

The Supreme Court should dismiss the notion that a single federal agency's 'supremacy' preempts tort litigation and rule in favor of Mrs. Levine. Ruling in favor of Wyeth would presage the most significant change in product safety jurisprudence in history and dramatically alter the historical balance between federal and state power.

For more comprehensive articles on this issue by Dr. Tiedt, see 62 *Food and Law Journal* 547-558 (2007) and the upcoming issue (September/October) of *Update.*

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