YAHOO! NEWS

August, 15, 2008

Lawsuits help guarantee drug safety, doctors say

By Ricardo Alonso-Zaldivar, Associated Press Writer

Top doctors at the helm of one of the nation's most influential medical journals are giving the Supreme Court some unsolicited legal advice about a major case.

The Food and Drug Administration "is in no position" to guarantee drug safety, the editors of the New England Journal of Medicine said in a friend-of-the-court brief. Lawsuits can serve as "a vital deterrent" and protect consumers if drug companies don't disclose risks.

At issue is Wyeth v. Levine, a case expected to be heard this fall that could have far-reaching implications for litigation over allegedly harmful drugs, such as the painkiller Vioxx.

Diana Levine, a Vermont guitarist, lost her right arm below the elbow after she was injected with Phenergan, a medicine for nausea, and developed gangrene. She sued the manufacturer, Wyeth, arguing that the company had a duty to warn consumers that such injections could have devastating consequences. The courts in her state agreed, awarding her nearly $7 million.

But Wyeth appealed, countering that it was protected from such lawsuits. It argued that the FDA's judgment could not, in effect, be overruled by a state court. FDA scientists had weighed the risks and benefits of Phenergan in approving the drug's prescribing literature, or label, as a guide for doctors. The FDA was aware of risks associated with injecting some forms of Phenergan, but the label did not specifically warn about the technique used with Levine.

Although the FDA is often called "the gold standard" in drug evaluation, the journal editors urged the justices to be skeptical.

"The FDA alone simply lacks the ability to serve as the sole guarantor of drug safety," the doctors said in a brief filed Thursday. Without the discoveries dredged up by plaintiffs' lawyers through liability litigation, "the FDA would be stripped of an essential source of information that the agency has consistently relied on when making its regulatory decisions, and the American public would be deprived of a vital deterrent against pharmaceutical company misconduct."

The medical editors joined 47 state attorneys general and two former FDA commissioners — David Kessler and Donald Kennedy — in supporting Levine's position. Kessler served in the Clinton administration and that of George H.W. Bush. Kennedy served in the Carter administration.

The case is being closely watched because earlier this year the Supreme Court ruled that manufacturers of FDA-approved medical devices were shielded from litigation in state courts.

However, David Vladeck, a lawyer representing Kessler and Kennedy, said the statute that applies to medical devices is different from the law that governs medications.

"The law in the (devices) case had a pre-emption provision," said Vladeck. "Congress has never put a pre-emption provision in the Food and Drug Act."

Nonetheless, the Bush administration is supporting Wyeth's position.

"FDA considers and approves specific labeling for a drug, and the drug manufacturer is generally barred from making unilateral changes to the FDA-approved labeling," Solicitor General Paul D. Clement wrote in the administration's brief.

But journal editor Dr. Jeffrey M. Drazen said in an interview that he hoped arguments over legal distinctions would not obscure the reality that the FDA is overwhelmed trying to keep up with drug safety problems, which can range from rare but serious side effects, to shortcomings in manufacturing plants as far away as China.

"Even if the FDA is doing the best it can, it simply can't see the future clearly enough to pre-empt manufacturers from litigation," he said. "The (court) system represents one of the key defense mechanisms that individuals have if a manufacturer has not made the risks of a product clear to the public."