

Opinion • Lawrence J. McQuillan

Warning: Tort lawyers may be dangerous to the nation's health

The U.S. Supreme Court recently heard *Wyeth v. Levine*, a case that could send shock waves through the health care industry.

Central to the case is the concept of "pre-emption." Article VI of the Constitution says that federal laws and regulations outweigh, or "pre-empt," any conflicting state laws or regulations. In other words, federal law trumps state law. But *Wyeth v. Levine* challenges this principle.

The case involves a Vermont woman who was improperly administered the anti-nausea drug Phenergan at her local health center and suffered a significant injury as a result. She successfully sued the health center and several staff members. Seemingly, justice was done.

But she went on to sue the drug's manufacturer, Wyeth Pharmaceuticals, claiming that the warning labels were insufficient and that the U.S. Food and Drug Administration (FDA) shouldn't have approved the way in which the drug was administered.

Phenergan had been in use safely since 1955, and FDA scientists had approved the contents of its warning labels. The label specifically warned of the exact injury the woman suffered.

A jury second-guessed the FDA scientists and found in favor of Levine. Wyeth lost on appeal. Apparently, the Vermont Supreme Court believes that FDA regulations do not preempt state laws. But that is wrong.

The FDA consists of more than 8,000 experts charged with keeping us safe and healthy by evaluating drugs and their labels. The Vermont jury was made up of registered voters, not experts. Should 12 randomly selected laypeople determine health policy instead of highly trained expert scientists?

If the judgment against Wyeth stands, it will open the floodgates for lawsuits challenging the authority of the FDA.

In an attempt to head off costly litigation, warning labels will expand to cover every imaginable use or misuse of a given drug. This will lead to "over-warning," where relevant warnings are buried in a sea of outlandish ones, diminishing the impact of real safety information. Faced with 50 different state standards and an avalanche of lawsuits, drug manufacturers will stay away from developing new, life-saving drugs because they deem them too costly to pursue. Or they might pull existing drugs off the

market. The cost of defending and insuring against these lawsuits drives healthcare prices up. If the FDA doesn't get the last word in drug approval, we will see a chaotic patchwork of state- and jury-written warning labels. Imagine the confusion if the same drug bore vastly different warnings in every state.

The goal of tort law is to deter wrongdoers and compensate unjustly injured victims. When implemented fairly, the system works. When corrupted, frivolous lawsuits and mind-boggling monetary awards can drastically slow the economy and damage our quality of life.

If the U.S. Supreme Court allows a jury to supplant FDA scientists, we will be taking a major step backwards in the struggle for better health care. Here's a warning label for the justices: "An unwise decision may cause medical confusion, enrich personal injury lawyers, and increase health care costs."

Lawrence J. McQuillan, Ph.D., is Director of Business and Economic Studies at the Pacific Research Institute and coauthor of the 2008 U.S. Tort Liability Index. Contact him at LMcQuillan@pacificresearch.org.

