

How to vaccinate health system

The Supreme Court recently heard oral arguments in a case likely to have profound effects on how vaccines are marketed, distributed and developed.

The Court's verdict could affirm the existing regulatory framework for testing and labeling vaccines. That would be good news, as vaccines are among the most effective medical advancements in history.

A ruling in the other direction, though, would enable a torrent of frivolous lawsuits, threatening future vaccine development and cutting off patient access to medicines.

The case — *Wyeth v. Levine* — involves a Vermont woman who claims that the manufacturer of the anti-nausea drug Phenergan failed to sufficiently warn her doctor of the dangers posed by one delivery method of the drug.

The drug's label was approved by the federal Food and Drug Administration (FDA). But a lower court ruled that the label wasn't amply informative and that the plaintiff was owed damages.

The question facing the court, then, is whether federal law preempts — or trumps — state law in the area of drug-labeling requirements. If it does, the FDA would have the final word on what needs to be included in a label. If it doesn't, a private citizen could sue for labeling liability even if the firm in question complied with federal law.

An anti-preemption decision would cause an uptick in litigation against drug makers, particularly vaccine manufacturers.

Vaccines have proven susceptible to unfounded medical scare stories. Witness the high-profile campaign linking the measles-mumps-rubella vaccine with autism, led by actress and ex-Playboy Playmate Jenny McCarthy.

McCarthy's gripes are unfounded. More than 20 scientific

COLUMN:
SALLY PIPES

studies have found that the vaccine does not raise a child's risk for autism. But her efforts have scared countless parents from getting their kids inoculated.

According to the Centers for Disease Control and Prevention, there were 131 reported cases of measles during the first seven months of 2008. That's the highest total in over a decade. Ninety-five of those cases were in children who were eligible for vaccination but did not receive a shot.

Determining what health risks are sufficiently probable to warrant a warning is a technical process, best conducted by experts. That's why the FDA — which has some of the world's best-trained scientists — is so well-suited for the task.

The average American isn't so suited. Without preemption, that's who would be given the responsibility — jurors and judges.

Trial lawyers know this. They'll start fishing for plaintiffs in hopes of winning big-money judgments.

The threat of frivolous litigation will lead many vaccine manufacturers to halt production. As a study by Vanderbilt economist Kip Viscusi in the *Stanford Law Review* found, "liability hazards led many firms to exit the vaccine market."

Federal preemption would ensure uniformity in warning labels and guarantee that all Americans have equal access to vaccine information. For the sake of patients, physicians, and public health, the Supreme Court should affirm preemption.

...

Sally C. Pipes is president of the Pacific Research Institute, a public policy research group based in California.

