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PROFESSIONAL ISSUES

Court to rule on drug labels as liability shield

The Supreme Court will decide whether federal law preempts product liability suits at the state level if the warning labels are FDA-approved.

By Amy Lynn Sorrel, *AMNews* staff. Dec. 1, 2008.

Washington -- The U.S. Supreme Court, during oral arguments Nov. 3, appeared just as divided as physicians over whether federal law shields pharmaceutical manufacturers from state liability claims if their drug labels received Food and Drug Administration approval.

The court's answer to that question could threaten medical care, say physicians on different sides of the debate. The decision is expected to have a far-reaching impact on prescription drugs as well as other federally regulated products.

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Some doctors say the courts have provided an important check on the FDA, which -- plagued by a lack of funding and resources -- cannot adequately supervise the drug industry.

Other physicians fear that drug availability could be stifled if juries are allowed to second-guess the FDA's scientific determinations.

Those concerns played out before the U.S. justices. They were asked to overturn a 2006 Vermont Supreme Court decision awarding Diana Levine $7 million after complications from an IV injection of Wyeth's anti-nausea drug Phenergan led to gangrene and the amputation of Levine's right arm. Wyeth had requested stronger warnings for IV-related use of Phenergan, which the FDA rejected. Yet a Vermont jury determined the label failed to include adequate cautions about the medication's risks.

In 2008, the Supreme Court ruled that FDA approval of certain medical devices

Such a conflict puts pharmaceutical companies in a tough spot, making it difficult to comply with both federal and state standards, Wyeth's attorney Seth P. Waxman argued to the nation's high court. The company provided ample information to allow the FDA to balance drug risks and benefits and allow "medical professionals to make their judgments," he said. "Taking options away from physicians is not always better."

preempted liability lawsuits against manufacturers.

Levine's lawyer, David C. Frederick, countered that manufacturers have a duty to promptly and completely share new risk information with the FDA -- which he argued Wyeth failed to do -- and be held accountable when they don't. "The idea that a label is set in stone for all time misunderstands the way the process works," he said.

An FDA attorney in court maintained state claims that clash with the agency's labeling decisions would be preempted by federal regulations, disputing a purported policy change. Discussion over what constitutes new risk information suggested the court could preempt state lawsuits under narrow circumstances, unless drug companies misled the FDA or hid known dangers about a drug.

Justice Ruth Bader Ginsburg questioned the FDA's evaluation of Phenergan based on Wyeth's disclosures. "The risk of gangrene and amputation is there. No matter what benefit there was, how could the benefit outweigh that substantial risk?" she asked Waxman.

Justice Antonin Scalia, however, said the label spelled out the risks involved with the drug and probed Levine's lawyer on the effect liability threats could have in forcing unnecessary changes or restrictions on medication labels.

"If you're telling me the FDA acted irresponsibly, sue the FDA," he told Frederick. "If you are simply eliminating certain drugs ... you're not benefiting the public."

Justices also noted similarities and differences in their February decision in *Riegel v. Medtronic,* in which they favored preemption of lawsuits involving certain FDA-approved medical devices. A decision in *Wyeth v. Levine* is expected by June.

Doctors debate patient care impact

Physicians remain split over the implications the court's decision could have for patient care. The threat of liability has encouraged transparency by drug manufacturers and prodded them to report new findings to the FDA and the medical community, said Gregory D. Curfman, MD, who attended the oral arguments.

"If that second layer of regulation [through the courts] is removed, it's going to have negative ramifications for the safety of the drug supply," said Dr. Curfman, who is executive editor of the *New England Journal of Medicine,* which filed a friend-of-the-court brief in the case. "It's also going to put heightened pressure on the FDA when it's already stretched to the limit and might result in fewer drugs being approved."

If patients have no recourse against drug manufacturers, liability could shift to physicians, added Jay H. Henderson, who filed a joint friend-of-the-court brief on behalf of the Texas Medical Assn. and North Carolina Medical Society. The California Medical Assn. also submitted a brief expressing similar concerns.

"If doctors are left with this dilemma of not having a legitimate understanding of drug risks, a realistic route is to stop using the drug," Henderson said.

Excessive warnings, however, can be just as harmful, some doctors say. The FDA process weighs the need to inform physicians of drug safety with the danger of over-warning and discouraging beneficial drug use, the American College of Emergency Physicians argued in an opposing brief it filed along with the Washington Legal Foundation.

"If the courts start determining what is considered to be the standard of care versus what science determines is the standard of care, and drugs which we commonly use are banned from our use, it's going to make our job [as physicians] harder," said Linda L. Lawrence, MD, ACEP immediate past president. "If physicians use an FDA-approved drug by FDA guidelines, that should carry some protection, and a lay jury should not be able to say the FDA was wrong."

The American Medical Association's House of Delegates in November voted to support state and federal legislative efforts to grant physicians who appropriately use FDA-approved drugs and medical devices the same level of liability protections as manufacturers for adverse events. The AMA was not involved in either Supreme Court case.

ADDITIONAL INFORMATION:

Case at a glance

Does federal law preempt state liability claims against drug manufacturers if their product labels are FDA-approved?
The U.S. Supreme Court will decide. The high court in a similar case ruled that FDA regulations shield medical device makers from claims challenging the labeling or design of certain products.

Impact: Some physicians say the courts have helped drug safety by forcing manufacturers to remain transparent about drugs' risks and benefits. Other doctors fear treatment options could be limited if lay juries are permitted to question the FDA's scientific determinations.

Wyeth v. Diana Levine, Decision pending; oral arguments heard Nov. 3; *Donna S. Riegel v. Medtronic Inc.*, Feb. 20

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