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Drug Approval Is Not a Shield From Lawsuits, Justices Rule

By DAVID STOUT

WASHINGTON — In one of the most important business cases in years, the Supreme Court on Wednesday ruled that a drug company is not protected from injury claims in state court merely because the federal government had approved the productand its labeling.

The 6-to-3 ruling went in favor of a Vermont musician, Diana Levine, who was awarded more than $6 million after losing much of her arm following a botched injection of an anti-nausea drug. It was a defeat for the Wyeth pharmaceutical company, which had asked the justices to throw out the award, and by extension other companies that might have pursued Wyeth's line of argument in similar cases.

Ms. Levine, who lost her livelihood because of the injury, had settled a parallel claim against the clinic where she was treated.

The key issue before the justices was whether the Food and Drug Administration's approval of drug labels should pre-empt lawsuits in state courts contending, as Ms. Levine's did, that the labels did not contain adequate warnings.

Wyeth's lawyers, supported by the Bush administration, had argued that the company provided "ample, lavish warnings," as one attorney put it, and that Wyeth should not have been held liable, because the Food and Drug Administration had approved the label on the drug in question, Phenergan.

But the high court held, in an opinion by Justice John Paul Stevens, that Wyeth's reading of the pertinent federal regulation was "cramped" and based on a "fundamental misunderstanding."

"It is a central premise of the Food, Drug and Cosmetic Act and the F.D.A.'s regulations that

the manufacturer bears responsibility for the content of its label at all times," the majority concluded in Wyeth v. Levine, No. 06-1249.

The majority upheld the Vermont Supreme Court, which in 2006 rejected Wyeth's argument that it had been put in an untenable position: having to comply with federal law, given its requirement that the F.D.A. approve drug labels, and yet being punished by the state jury's verdict for not using a different, more inclusive label. Federal law "provides a floor, not a ceiling, for state regulation," the Vermont Supreme Court declared in the ruling that the United States Supreme Court affirmed on Wednesday.

Ms. Levine's suffering began in the spring of 2000 when, suffering from a migraine, she visited a local clinic for a treatment she had received many times: Demerol for pain and Phenergan for nausea.

If Phenergan is exposed to arterial blood, it causes swift and irreversible gangrene. Therefore, it is typically administered by intramuscular injection. Ms. Levine's lawyers said an intravenous drip is also quite safe.

But a physician's assistant used a third method, injecting the drug into what she thought was a vein, using a technique known as "IV push." The assistant apparently missed a vein and hit an artery instead, causing Ms. Levine's right hand and forearm to turn purple and black in the following weeks, leading to amputation of much of her arm.

The F.D.A.-approved label warned that "inadvertent intra-arterial injection" can cause gangrene requiring amputation, but it did not rule out administering the drug by the "IV push" method. The Vermont trial judge instructed the jury that compliance with F.D.A. requirements did not establish that the warnings on the labels were adequate.

Justice Stevens noted that the trial record contained evidence of at least 20 reports of amputations similar to Ms. Levine's since the 1960's. Phenergan was first approved in 1955.The justices who sided with Ms. Levine on Wednesday said that "Wyeth could have unilaterally added a stronger warning about IV-push administration" without running afoul of federal regulations. Justices Anthony M. Kennedy, David H. Souter, Ruth Bader Ginsburg and Stephen G. Breyer joined Justice Stevens, while Justice Clarence Thomas filed an opinion concurring in the overall judgment.

Justice Samuel A. Alito Jr. wrote a dissent declaring, "This case illustrates that tragic facts make bad law." Joining him with Chief Justice John G. Roberts Jr. and Justice Antonin Scalia.

“The unfortunate fact that respondent’s health care providers ignored Phenergan’s label may make this an ideal medical-malpractice case,” Justice Alito wrote. But the outcome in Ms. Levine’s case, he lamented, turned “a common-law tort suit into a ‘frontal assault’ on the F.D.A.’s regulatory regime for drag labeling.”

Bert Rein, an attorney for Wyeth, said the company “fully complied with federal law” in its labeling, and that the F.D.A. “is in the best position to weigh the risks and benefits of a medicine.”

Ms. Levine, now 63, was overjoyed. “Oh, my God. I’m so, so happy,” she told The Associated Press in a telephone interview. “I’m just ecstatic. I’m going to have to sit down.”