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RULING REMOVES FDA SAFETY NET

The US Supreme Court has just removed one of the pharmaceutical industry's main defences to product liability claims, write **Angus Rodger**, **Gavin Coull** and **Gary Farmer**.

Drug warning labels in the US are regulated by the Food and Drug Administration (FDA). Its job is to ensure that drugs are safe for public distribution by approving the warning labels before any drug is put on the market, and by overseeing any proposed changes to the labels over the drug's lifetime.

In recent years, pharmaceutical companies have been trying to use the FDA's role as a shield to product liability lawsuits brought against them in state courts. Their argument was: "Drug safety questions are a matter for the federal government (in the form of the FDA) to decide – it is nothing to do with state courts and state tort laws." The companies have used this defence, known as "federal pre-emption", with some success. In the past, several cases were thrown out of state courts long before trial, so saving considerable defence costs. But some state courts rejected the defence and allowed claims against the manufacturers to proceed.

The validity of the defence was brought before the US Supreme Court recently in *Wyeth v Levine* 129 S.Ct. 1187 (2009). In a blow to the industry, the court roundly rejected the pharmaceutical companies' defence.

WYETH DECISION

The Wyeth case began when the claimant, Diana Levine, went to her local clinic for treatment for a migraine. She was given an injection of the anti-nausea drug Phenergan, manufactured by Wyeth. The drug caused gangrene and she had to have her forearm amputated, resulting in the loss of her career as a professional musician.

Ms Levine sued Wyeth in state court in common law negligence and strict liability, claiming that Wyeth's warnings for Phenergan were inadequate. The warning label stated that the drug could cause gangrene, but it did not warn that the method by

which Ms Levine was given the drug (IV-push administration) increased the risk.

Wyeth argued that Ms Levine's state law claims were pre-empted by federal law. According to Wyeth, it could not be sued under state law because the FDA had approved Phenergan's warning label, and Wyeth could not unilaterally change the label. Changing its warning labels to satisfy state law would, in Wyeth's view, have frustrated Congress's purpose in establishing the FDA as the authority on drug regulation across the US.

The court disagreed, holding that it was not Congress' intent to pre-empt state law tort claims when it established the FDA. The court noted that, on the contrary, "the FDA traditionally regarded state law as a complementary form of drug regulation." The court concluded that Wyeth could have strengthened its label while complying with both state and federal law, and that Ms Levine's claims did not obstruct Congress's intent for the FDA. Wyeth could not simply hide behind the FDA's regulatory approval of its existing labels to absolve it from state-level products liability claims for failure to warn.

The Wyeth case is important for all insurers and reinsurers who provide product liability coverage for pharmaceutical companies. Federal pre-emption has, in recent years, been one of the main ways in which pharmaceutical companies have been able to knock out claims without trials: it has helped to keep defence costs down and has probably acted as a strong deterrent to other claimants. The removal of this defence will increase the prospect of cases reaching trial. As a result, it is sure to increase substantially insurers' exposure to defence costs, settlements and indemnities.

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