PREEMPTION AND THE LEARNED INTERMEDIARY DOCTRINE

Harvey L Kaplan and Jon A Strongman of Shook Hardy & Bacon LLP examine the latest developments in US pharmaceutical litigation

Pharmaceutical litigation in the United States is constantly evolving as plaintiffs' lawyers seek to create new avenues of recovery, state and federal governments adopt legislation that affects the legal playing field, and new court decisions usher in changes in the law. Currently, there are debates concerning two issues that lie at the heart of pharmaceutical litigation: preemption and the learned intermediary doctrine.

Preemption is simply a doctrine of federal law that trumps conflicting state law. In the pharmaceutical litigation context, that means approval of prescription drug warnings by the US Food and Drug Administration (FDA) preempts any state-law claim that a different warning was necessary to render the product safe. Those opposed to preemption argue that FDA approval is simply a safety 'floor', not a 'ceiling'. On 3 November 2008, the US Supreme Court heard arguments on this issue in *Wyeth v Levine*. Specifically, in *Levine* the Supreme Court will decide "whether the prescription drug labeling judgments imposed on manufacturers by the [FDA]...preempt state-law product liability claims..." The *Levine* ruling will have a significant impact on the landscape of pharmaceutical litigation.

Another recent development concerns an attack on the learned intermediary defence. Recognising the physician's role in prescribing medications, courts have widely held that a prescription drug manufacturer's duty to warn runs to the physician (the 'learned intermediary'), not directly to the patient. Before 2007, more than 40 jurisdictions had adopted the learned intermediary doctrine; and no court had rejected the doctrine outright. However, in *State ex rel Johnson & Johnson Corp v Karl*, the West Virginia Supreme Court declined to adopt the learned intermediary doctrine, holding that the justification for the doctrine was "outdated" and "unpersuasive."

This article focuses on current developments relevant to preemption and the learned intermediary doctrine, and thoughts about what the future may hold on these issues.

DEVELOPMENTS IN PREEMPTION

The roots of preemption

The doctrine of preemption is rooted in the Supremacy Clause of the US Constitution, which states that the laws of the United States "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Law of any State to the Contrary notwithstanding." Simply put, preemption mandates that a "state law that conflicts with federal law is 'without effect'" (see *Cipollone v Liggett Group Inc*).

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There may be either express preemption or implied preemption. Express preemption comes about when there is specific language in a Congressional enactment stating an intent to preempt any other law dealing with the subject matter of the federal statute. In such situations, a court must only decide if the state law is one that Congress intended to preempt. Implied preemption, on the other hand, occurs when either federal law exclusively occupies an entire field of regulation (field preemption), or an implicit conflict exists between a Congressional enactment and a state law (conflict preemption).

Although there is an express preemption provision in the statutes governing the FDA approval of so-called 360k medical devices (see 21 USC section 360k(a)), there is no such provision in the statutes for the FDA's approval of prescription drugs. Accordingly, in *Wyeth v Levine*, Wyeth argued that FDA approval impliedly preempts state tort-law claims due to inherently conflicting requirements.

Wyeth v Levine: *how we got here*

In April of 2000, Diana Levine was treated for migraines and nausea with the prescription medication Phenergan. She first received Phenergan by intramuscular injection. Ms Levine returned to the doctor as her symptoms continued. She was then given 50mg of Phenergan intravenously by the 'IV Push' method – twice the recommended dosage. Ms Levine received all 50mg of Phenergan continuously despite complaining of pain during the injection. Ms Levine later developed symptoms of arterial exposure. As a result of this error, Ms Levine developed gangrene, ultimately requiring the amputation of her forearm.

At the time Ms Levine received Phenergan, the product labelling included several warnings about improper administration, the risk of arterial exposure, and the resulting risk of gangrene. The label, however, did not explicitly contraindicate the 'IV push' method. The Phenergan label had been reviewed a number of times by the FDA as well as by an expert advisory committee. Plaintiff argued that Wyeth should have specifically contraindicated the

'IV push' method. Wyeth argued that it could not change the FDA-approved labelling without violating federal law.

Plaintiff sued Wyeth in a Vermont trial court claiming that the Phenergan labelling and warnings were inadequate. In dispositive motions, Wyeth argued that plaintiff's claims were preempted, but they were denied by the trial court. The jury returned a verdict for plaintiff in the amount of US$6.7 million. On appeal, the Vermont Supreme Court affirmed the trial court's decision. The US Supreme Court granted Certiorari in January of 2008, and oral argument was held on 3 November 2008.

Predicting the outcome of Levine

Recent preemption decisions in *Riegel* and *Kent* involved much different circumstances; however, these opinions, the FDA's position in *Levine*, and the exchange between counsel and the court at oral argument provide some clues as to the Supreme Court's ruling in *Levine*.

Riegel v Medtronic

In *Riegel v Medtronic*, plaintiff alleged injuries due to a defective heart catheter. The heart catheter at issue was a Class III medical device that had been approved by the FDA through the rigorous pre-market approval (PMA) process. Medtronic argued that plaintiff's claims were preempted by the express preemption clause (section 360k(a)) of the medical device statute. On 20 February 2008, in an 8-1 decision with Justice Ginsberg as the lone dissenter, the US Supreme Court held that state-law tort claims against medical device manufacturers were preempted so long as the device was approved by the FDA through the PMA process. *Riegel* gave the pharmaceutical industry reason for optimism, although the decision only applies to a narrow set of circumstances.

Warner-Lambert v Kent

In *Warner-Lambert v Kent*, Michigan plaintiffs alleged injuries as a result of Rezulin® – a prescription drug approved to treat diabetes. A Michigan statute barred personal injury suits against prescription drug manufacturers, but included an exception if the plaintiff could prove that the manufacturer deliberately withheld information from the FDA that would have prevented the FDA from granting approval. The defendants argued the Michigan statutory exception was preempted under *Buckman Co v Plaintiff's Legal Committee*, holding that 'fraud on the FDA' claims were impliedly preempted. The Second Circuit reversed, concluding that the Michigan statute did not create a new cause of action for defrauding the FDA.

On 3 March 2008, just seven days after the oral argument, the Supreme Court handed down a per curiam opinion, noting that the court was deadlocked at 4-4. Chief Justice John Roberts recused himself. Further complicating the matter, in the case of a deadlocked vote, the Supreme Court does not disclose how the justices voted. It is important to note, however, that the missing justice in *Kent* was Chief Justice Roberts, who is typically viewed as pro-business.

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The FDA's position

In *Levine*, the US solicitor general filed an amicus brief in support of Wyeth. Since 1992, the Supreme Court has decided seven preemption cases where the federal government has filed amicus briefs setting forth its position. In all but one of those cases, the court's ruling was consistent with the federal agency's position. Wyeth is hoping that trend continues.

The potential legislative response

Depending upon the scope of the Supreme Court's ruling, a legislative response could follow. Shortly after the Supreme Court handed down its ruling in *Riegel*, the Democratic-led Congress introduced legislation that would essentially reverse that decision. In fact, several prominent Congressional Democrats filed an amicus brief on behalf of plaintiff Diana Levine. Their brief states:

> *For more than 70 years, Congress has operated against the background understanding that FDA approval of a drug label does not bar state-law failure-to-warn claims. If that rule of law is to be altered, it should be changed directly by Congress.*

The questioning by the justices at the 3 November oral argument in *Levine* suggests that the Supreme Court is divided in *Levine*, as they were in *Kent*; and that an 8-1 decision, as in *Riegel*, is highly unlikely. Indeed, trying to predict which way the *Levine* court will decide is a bit like reading tea leaves. If the court decides in Wyeth's favour, the scope of the ruling is most important to the future of pharmaceutical products litigation. Regardless of the outcome in *Levine*, however, the preemption battle is probably not over.

KARL AND THE LEARNED INTERMEDIARY DOCTRINE

The origins of the learned intermediary doctrine

The learned intermediary doctrine was first adopted in 1948 in *Marcus v Specific Pharmaceuticals*, where plaintiff sued a drug manufacturer claiming that his child died as a result of an overdose of suppositories prescribed by the child's physician. The court held that the manufacturer could not be liable to the plaintiff: "[I]t is difficult to see on what basis this [manufacturer] defendant can be liable to plaintiff. It made no representation to plaintiff, nor did it hold out its product to plaintiff as having any properties whatsoever. To physicians it did make representations. . . . It may be safely conceded that these allegations would be sufficient if the product were sold to the

public generally as a drug for which no physician's prescription was necessary. The situation alleged is materially different." This marked the beginning of a difference in the legal duty to warn between products sold directly to the public and pharmaceutical products for which a physician's prescription is required.

The phrase "learned intermediary" came about years later in an Eighth Circuit case, *Sterling Drug Inc v Cornish*. The court stated: "we are dealing with a prescription drug rather than a normal consumer item. In such a case the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer." The doctrine is now recognised in virtually every state (see *In re Norplant Contraceptive Prods Liab Litig*).

Rationale behind the doctrine

The rationale supporting the learned intermediary doctrine is based on the following: physicians are in the best position to evaluate risks and benefits and make an appropriate treatment decision; manufacturers are unable to effectively communicate with patients directly; and requiring manufacturers to warn patients directly would unduly interfere with the physician-patient relationship (see *Larkin v Pfizer Inc*).

Perez and the DTC exception

The New Jersey Supreme Court in *Perez v Wyeth Labs Inc* adopted an exception to the learned intermediary doctrine for products that were advertised directly to consumers (DTC). The court held that the justifications behind the doctrine simply did not exist when manufacturers reached out directly to consumers through DTC advertising. The *Perez* court, however, also stated that if a manufacturer complied with the FDA regulations for such DTC advertisements, there would be a presumption that the manufacturer satisfied its duty to warn. No other court has adopted the *Perez* DTC exception, but as explained below, the *Perez* decision played a significant role in the *Karl* opinion.

The Karl *decision*

In 2007, the West Virginia Supreme Court in *State ex rel Johnson & Johnson Corp v Karl* became the first court in the country to reject the learned intermediary doctrine all together.

The facts

The *Karl* case involved Propulsid®, a prescription medication indicated for heartburn. The patient, Nancy Gellner, was prescribed Propulsid® and, on the third day after starting the medication, she died suddenly. Her estate filed suit against both the manufacturer, Janssen, and the prescribing physician. The trial court denied both a summary judgment motion and a motion in limine seeking application of the learned intermediary doctrine. Janssen then filed a petition in the Supreme Court of Appeals for a writ of prohibition.

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The holding

The court in *Karl* held: "[U]nder West Virginia products liability law, manufacturers of prescription drugs are subject to the same duty to warn consumers about the risks of their products as other manufacturers. We decline to adopt the learned intermediary exception to this general rule."

In explaining its decision, the court attacked the rationale for the doctrine as "largely outdated and unpersuasive." The court focused on the recent emergence of DTC advertising, and noted that: "Significant changes in the drug industry have post-dated the adoption of the learned intermediary doctrine in the majority of states in which it is followed. We refer specifically to the initiation and intense proliferation of direct-to-consumer advertising, along with its impact on the physician/patient relationship, and the development of the internet as a common method of dispensing and obtaining prescription drug information."

The impact of Karl

While the *Karl* decision remains an 'outlier,' it has invigorated plaintiffs' lawyers in their efforts to undermine the learned intermediary doctrine. For example, in 2008, plaintiffs' lawyers sponsored legislation in California that would have codified a "*Perez*-like" DTC exception to the learned intermediary doctrine that was at the heart of the *Karl* decision (see California Assembly Bill 2690).

If other courts follow *Karl*, manufacturers will have to reassess the methods by which they disseminate prescribing information. Ironically, if the learned intermediary doctrine should be further eroded, the public can expect an increase in DTC advertising and a flood of safety information – precisely what the Karl court criticised.

Moving forward, it is critical for defence counsel to be aware of the *Karl* decision and to adopt strategies to avoid any further deterioration of the learned intermediary doctrine.

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The path of pharmaceutical litigation in the US is uncertain. The preemptive effect of FDA approval on product-liability litigation may be redefined by the US Supreme Court in *Levine* – and perhaps by the US Congress. Additionally, the unique role of the prescribing physician in weighing the benefits and risks of medication is in a state of flux. If the learned intermediary doctrine is discarded by other jurisdictions (as West Virginia did in *Karl*), manufacturers will find themselves injected into the practice of medicine. The future interpretation of these two important issues – preemption and the learned intermediary doctrine – remains unclear. But, regardless of how these issues evolve, plaintiffs' lawyers will undoubtedly continue to seek creative ways to maintain product liability litigation against the pharmaceutical industry.