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Preemption At Forefront Of Product Liability In 2009

By **Shannon Henson**

Law360, New York (December 19, 2008) -- In 2009, the attention of product liability attorneys will be on a case that was already argued before the U.S. Supreme Court yet has the potential to greatly alter the landscape of the field — Wyeth v. Levine.

Described by one attorney as the 800-pound preemption gorilla, the case was heard by the high court in November and centers on whether the U.S. Food and Drug Administration's approval of a drug preempts state-law product liability claims.

"A lot of eyes will be on the U.S. Supreme Court's decision in Wyeth v. Levine," said John Boudet, a partner with Roetzel & Andress. "The case deals with preemption, and that remains the hot issue for the pharmaceutical area. In turn, the pharmaceutical area continues and will continue to be the most active area in traditional product liability law."

Aside from pending cases such as the Wyeth litigation, attorneys said other hot litigation issues in 2009 will involve the importation of goods from other parts of the world and the Consumer Product Safety Improvement Act.

Wyeth v. Levine And Preemption

The case was brought by Diana Levine, a musician, who went to the hospital for a headache and received an intravenous push injection — rather than the preferred, yet slower to work, intravenous drip — of Wyeth's anti-nausea medication Phenergan. Levine consequently developed gangrene and had to have her right arm amputated.

Levine's suit claimed that the drug's labeling should have foreclosed such an injection because of the risk of injury. Wyeth countered that the FDA's approval of the drug preempted any state law

claims over the product.

The Vermont Supreme Court upheld a $7 million judgment for Levine in October 2006 and ordered Wyeth to modify the drug's label to reflect the alleged risk. Wyeth appealed to the U.S. Supreme Court.

Most attorneys didn't want to predict how the Supreme Court would rule in the case, especially given the number of recent narrow rulings and split decisions.

Kurt Stitcher, a partner with Levenfeld Pearlstein LLC, said the “consequences would be swift and dramatic” if the Supreme Court rejected implied preemption and allowed state tort law to impose a duty for drugmakers to change their warning labels even without the FDA’s approval.

“Companies would probably inundate the FDA with [labeling change] requests, even on scant evidence, for fear of facing 'failure to warn' liability if they didn't do so. The FDA would quickly be overwhelmed by the filings. And if the FDA denied a request, the manufacturer would then have to decide whether to make the change anyway, thus, perhaps, avoiding tort liability, but buying a whole lot of trouble from the FDA,” Stitcher said.

A ruling for Wyeth, however, could “prove a devastating blow to plaintiffs' personal injury lawyers, who rely on nebulous 'failure to warn' claims in their suits against a number of popular prescription drugs,” Stitcher said. “Given that warnings claims drive the entire field of pharmaceutical product liability, a broad implied preemption ruling from the Supreme Court could eviscerate such claims.”

However, if there is a ruling for Wyeth in the case, attorneys predict that a Democratically-controlled Congress and Obama administration would work quickly to wipe it out. The recent election could also have an impact on the court's finding.

John Thomas, of counsel with Bryan Cave LLP, noted that the Supreme Court recently ruled against federal preemption — contrary to the general trend — in a case that pitted smokers against Philip Morris.

The high court split 5-4 in Altria Group Inc. v. Good, ruling that smokers may use state deceptive-practices laws to sue cigarette manufacturers for the way they marketed light or low tar brands. Thomas thought the court was influenced by the federal government's opposition of Altria in the case.

“With Obama about to take control, it will be interesting what the federal government's take will be on preemption. It could have an impact,” he said.

Thomas, who was counsel for more than 25 years for Ford Motor Co., said preemption has spilled into the auto industry, where lawsuits have been brought alleging that car makers use unreasonably dangerous glass in windows.

Preemption has also seeped into the vaccine industry, with a Pennsylvania state court ruling in August that the Vaccine Act preempted design defect and failure-to-warn claims.

Philadelphia Common Pleas Judge Arnold L. New said the Vaccine Act explicitly preempted the design defect claim and that plaintiffs had not sufficiently distinguished their failure-to-warn claim to warrant any different analysis or result. He noted in his decision that only one court had ruled differently in such cases.

Stitcher said it was “hard to say if [vaccines] will become a burning issue, but thimerosal, which is a mercury preservative that plaintiffs have tried to tie to autism, has been bouncing around the courts for a few years now, so it's possible that we could see some appellate cases that try to tamp down these types of theories.”

Branded drugmakers aren't the only ones affected by the war over preemption. Stitcher noted that a judge in the U.S. District Court for the Western District of Kentucky recently held that if the FDA approved a branded label, it had also approved a generic label of that product, preempting failure-to-warn claims against the generics.

However, a Washington federal judge reached the opposite conclusion, in Laisure-Radke v. Par Pharma. Inc., as had a California appellate court.

“We may have the makings of a conflict among the circuits that could, eventually, lead to Supreme Court review of preemption principles in the context of generic-drug manufacturers,” Stitcher said.

Conte v. Wyeth

A case on appeal to the California Supreme Court concerns whether makers of brand-name drugs can be held responsible for failing to warn of side effects suffered by those taking the generic equivalents of their medications.

In November, the First District Court of Appeals in San Francisco reinstated a case Elizabeth Conte brought against Wyeth alleging the generic version of the anti-heartburn medication Reglan caused her to contract a neurological disorder.

Conte had allegedly been taking a generic version of Reglan for four years when she developed tardive dyskinesia, a debilitating neurological disorder.

She alleged that the drug companies knew or should have known of a tendency among doctors to misprescribe Reglan and its generic equivalents for periods longer than the approved 12 weeks because the labeling understates the risks of extended use.

The appellate court said the risk of harm to patients whose doctors rely on Wyeth's product information when prescribing Reglan or its generic equivalents is foreseeable to the company.

Post-R.J. Reynolds Tobacco Co. v. Engle

Product liability attorneys are also watching Florida courts as the so-called Engle progeny cases make their way through the court.

The case was a large class action accusing the tobacco companies of conspiring to cover up the side effects of smoking. The suit alleged that the behavior of the tobacco companies ultimately caused the plaintiffs to become addicted to nicotine and develop health problems such as cancer.

In 2006, the Florida Supreme Court refused to reinstate a $145 billion punitive damage award handed down by a jury. It also declined to revive the class action status of the lawsuit.

But the state's high court did allow the up to 700,000 individuals who could have won judgments under the original verdict to use findings from the jury trial to bring new cases against the tobacco companies.

Now, “many thousands of cases are winding their way through the courts. There are a lot of unanswered questions,” Boudet said. “No one is quite sure what these cases are going to consist of — if they will be full-blown tobacco trials, a hybrid no one has seen before ... It's all very much up in the air.”

Globalization

Ali A. Beydoun, an associate with Carr Maloney PC, said he was watching cases in which the courts have to decide whether a manufacturer can be held liable for failing to warn of the hazards of another manufacturer's product.

As manufacturing goes global, a slew of companies make product-utilizing components that could end up containing melamine or lead, which can lead to lawsuits and big dollar settlements. For example, RC2 Corp. reached a $30 million settlement in litigation related to its recall of China-made toys tainted with lead.

Beydoun pointed to two cases recently decided by the Washington Supreme Court that found that manufacturers couldn't be held liable for failing to warn about the dangers of asbestos used to insulate their products but not sold or supplied by the manufacturers.

Michael Pope, a partner with McDermott Will & Emery LLP, also said foreign-made products will continue to be a problem. “How in the world do you defend against the claims over the products, and then how do you get money back from the manufacturer? That remains a big issue.”

Consumer Product Safety Improvement Act

President Bush signed the legislation in August, giving the Consumer Product Safety Commission the resources and authority to more effectively police product safety — especially products used by children.

In its efforts to re-energize the CPSC, which came under heavy fire in 2007 and 2008 as a slew of contaminated children's products were recalled, the law will pump more money into the commission from 2010 to 2015, starting at $118 million and ending with $136 million per year.

The law also calls for importers and U.S. manufacturers to certify that their products conform with laws governing all consumer hazards regulated by the agency.

Sarah L. “Sally” Olson, a partner with Wildman Harrold Allen & Dixon LLP, said the law may generate more litigation. Plaintiffs lawyers, she said, closely watch the CPSC's movements for trends and product recalls, so a regulatory shift could be a harbinger of things to come.

Pope said the CPSC had been restricted by its budget but will become a more important agency. Recalls, which are under the commission's provenance, are an important part of litigation.

"How a recall is done is also about how a company is posturing itself when it's in litigation three years later," Pope said. "You want to be in a position where you can said you acted reasonably."
