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THE U.S. SUPREME COURT CLEARS THE PATH FOR PLAINTIFFS TO SUE DRUG COMPANIES

In a long-awaited legal decision, last Wednesday the U.S. Supreme Court ruled 6-3 that patients who are injured by a drug can sue the drug's manufacturer for damages, even if the drug has been granted FDA approval. In *Wyeth v. Levine*, 555 U.S. ---, No. 06-1249 (2009), the Court upheld a \$6.7 million verdict in favor of Diane Levine, a Vermont musician whose arm had to be amputated after Wyeth's Phenergan anti-nausea drug hit an artery and caused gangrene. This potential complication is rare, but it is acknowledged on the drug's labeling or "package insert." Wyeth argued it was shielded from lawsuits alleging inadequate label warnings because the FDA had found the warning to be sufficient and that preempted the state law action.

Justice John Paul Stevens wrote Wyeth's argument that Congress impliedly pre-empted state law claims "relies on an untenable interpretation of congressional intent and an overbroad view of an agency's power to pre-empt state law." "In short, Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling," Stevens said. "Congress has repeatedly declined to pre-empt state law, and the FDA's recently adopted position that state tort suits interfere with its statutory mandate is entitled to no weight."

"This case illustrates that tragic facts make bad law," according to the dissent, written by Justice Samuel A. Alito, Jr. "The court holds that a state tort jury, rather than the Food and Drug Administration, is ultimately responsible for regulating warning labels for prescription drugs."

The U.S. Supreme Court is more sympathetic to express pre-emption arguments, as illustrated by the decision last year in *Riegel v. Medtronic*, 552 U.S. ---, No. 06-179 (2008). In *Riegel*, the Court found express language in a federal law protected medical device makers from many injury suits over certain products approved by the federal government, including heart stents and artificial limbs. Democratic lawmakers indicated they will soon reintroduce legislation known as the Medical Device Safety Act, which would supersede the decision in *Riegel*.

Editor's Note: Physicians and other medical professionals should brace themselves for what is widely predicted to be a flood of new lawsuits against drug companies. The fallout from the decision in *Levine* could be far-reaching. Plaintiff's tort lawyers are expected to begin aggressively soliciting clients to bring state law tort claims against drug companies. Although the drug companies are the primary targets in these types of lawsuits, the prescribing physicians and other medical professionals administering drugs are also typically named as defendants. Doing so not only provides what plaintiff's lawyers often

perceive to be additional “deep pockets,” it also provides plaintiff’s lawyers with what they perceive to be a more favorable forum because the inclusion of in-state defendants generally means the cases cannot be removed from state court to federal court.

ANESTHESIOLOGY GROUP’S EXCLUSIVE PAIN MANAGEMENT ARRANGEMENT WITH HOSPITAL FAILS PERSONAL SERVICES EXCEPTION UNDER STARK AND ANTI-KICKBACK STATUTES

Recently, the Third Circuit Court of Appeals reversed a summary judgment granted in favor of a hospital in a *qui tam* action brought under the False Claims Act, finding the “personal services” exceptions under the Stark and Anti-Kickback statutes inapplicable to an exclusive service arrangement between an anesthesiology group and a hospital. In *Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88 (3rd Cir. 2009), Blue Mountain Anesthesia Associates, P.C. (“BMAA”), located in Pennsylvania, entered into a written agreement in 1992 to provide all anesthesia services required by the patients at a hospital owned and operated by Carlisle HMA, Inc. (“HMA”) and its parent company, Health Management Associates, Inc. In the written agreement, the parties contemplated that BMAA may also provide pain management services for HMA in the future.

In 1998, HMA built a new, stand-alone facility, containing a pain clinic, where BMAA provided pain management services to patients. However, the parties did not amend the 1992 Agreement or enter into a new agreement. HMA did not charge BMAA rent for the space and equipment, or a fee for the support personnel it provided to BMAA at the Pain Clinic. BMAA provided a physician to see patients in the pain clinic, and this physician when serving there had no other anesthesiology duties at the hospital. As with the anesthesia services, BMAA physicians submitted claims to Medicare for the professional services performed during these visits, and the Hospital submitted claims for the facility and technical component of the visits. No one other than BMAA provided pain management services at the Pain Clinic.

Both the district court and the court of appeals concluded the arrangement between BMAA and HMA implicated the Stark and Anti-Kickback statutes. BMAA received numerous benefits as a result of its relationship with HMA, including the exclusive right to provide all anesthesia and pain management services, and the receipt of office space, medical equipment and personnel, all of which constitute remuneration in-kind from HMA to BMAA. The court of appeals disagreed with district court that the arrangement between BMAA and HMA at the pain clinic qualified for the personal service exception because there was no express agreement reduced to writing and signed by the parties specifying all of the services to be provided by the physicians and all of the remuneration to be received for those services. The only written contract in existence between the parties was the 1992 agreement, which did not apply to services at the then non-existent facility. Further, with respect to the value to be received by BMAA for its services, the 1992 agreement said nothing whatsoever about free office space, equipment and staff necessary to the practice of pain management. Finally, the court found no arm’s length negotiations that could vouch for the fair match of service and compensation.

Editor’s Note: We expect to see more cases like *Kosenske* with the explosive growth of ambulatory centers in recent years. The lesson from *Kosenske* is that even seemingly insignificant changes in circumstances or arrangements by or between physicians, practice groups, and hospitals require analysis for the potential of Stark and Anti-Kickback violations.

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