Products Liability Law Daily Wrap Up, PREEMPTION—MEDICAL DEVICES—Ariz. App.: Pain pump failure to warn claims survive preemption, (Oct. 23, 2017)

Products Liability Law Daily Wrap Up

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By Susan Lasser, J.D.

A patient's product liability, negligence, and breach of express warranty claims against the manufacturer of a pain pump device that had been implanted in the patient and injured him were preempted by federal law, an Arizona appellate court ruled, affirming the trial court overseeing the matter. However, the court of appeals vacated the lower court's dismissal of the patient's failure to warn and punitive damages claims, as well as his wife's loss of consortium claim, finding that the claims were not expressly or impliedly preempted by federal law. The case was remanded for further proceedings consistent with the court's opinion (*Conklin v. Medtronic, Inc.*, October 19, 2017, Howe, R.).

In March 2008, to manage the patient's chronic pain, a physician surgically implanted in him a Medtronic SynchroMed II 40 ml infusion pump and catheter, Model 8637-40 (Medtronic Pain Pump), which was designed, manufactured, and marketed by Medtronic, Inc. The product is a Class III medical device regulated by the Food and Drug Administration (FDA) under the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act (FDC Act). Class III medical devices are subject to the FDA's pre-market approval (PMA) process. Five years later, the patient had hip surgery and later suffered permanent injury by drug over-infusion, allegedly caused by the pain pump. The patient subsequently filed suit against the manufacturer, alleging several Arizona common law tort claims, including product liability (design and manufacturing defect), failure to warn, negligence, breach of express warranty, and loss of consortium. The patient and his wife also sought punitive damages. The patient alleged that before he was injured, the FDA had sent warning letters to the manufacturer, advising that the Medtronic Pain Pump was adulterated and misbranded and stating that Medtronic had failed to report adverse events to the FDA after PMA. He also alleged that before the injury occurred, the FDA had issued two Class I recalls of the Medtronic Pain Pump. Moreover, the patient claimed that after he was injured, the FDA issued another Class I recall of the device relating to the unintended delivery of drugs that could result in a drug overdose. The patient asserted that the maker's failure to report post-PMA adverse events to the FDA in violation of federal law gave rise to liability under Arizona common law.

Medtronic moved to dismiss, arguing that the patient's claims were preempted by federal law, and the trial court granted the manufacturer's motion, dismissing the action with prejudice. The lower court denied the patient's motion for reconsideration and the patient appealed.

Preemption. The MDA expressly preempts certain state-law requirements concerning medical devices. It was Medtronic's burden to prove preemption. For express preemption to apply, the manufacturer had to meet two conditions: (1) the federal government must have established requirements applicable to the device at issue, and (2) the patient's common-law claims relating to the device had to include requirements that were "different from, or in addition to" those federal requirements. If those conditions were met, then the patient's common-law claims challenging the safety or effectiveness of the medical device which had received PMA from the FDA would be expressly preempted. Moreover, the MDA also impliedly preempts actions for the enforcement or restriction of violations of the FDC Act because those actions only can be brought by or in the name of the United States. However, a state-law claim can be viable if it is a "parallel claim"—one that is based on state requirements that are "equal to or substantially identical to, requirements imposed by or under the act," or premised on a violation of FDA regulations.

Because the Medtronic Pain Pump is a Class III medical device, the appellate court said, the PMA process imposed federal requirements contemplated by §360k(a) of the MDA for express preemption purposes, satisfying part one of the express preemption test.

Imposition of requirements different from or in addition to federal law. The court found that the patient's design and manufacturing defect claims were expressly preempted. The patient alleged that the pain pump was defective when manufactured in design and formulation and when it dispensed an excess of narcotic drugs to him. Medtronic contended that absent an allegation that the pump was designed or manufactured in any manner other than what was required by the FDA, it was expressly preempted. The court agreed, noting that these claims would require a jury to find that the design and manufacturing process that had been approved by the FDA through the PMA process was defective as a matter of state law, which would add requirements to the process that the FDA established.

Similarly, the appellate court found the patient's breach of express warranty claim was preempted because to succeed on that claim, the patient would have to persuade a jury that the pain pump was not safe and effective. Such a finding would be "contrary to the FDA's approval of the PMA" and, thus, expressly preempted.

Failure to warn. However, the court of appeals found that the patient's failure to warn claim was not preempted. The patient asserted that the manufacturer violated federal law by failing to report post-PMA adverse events concerning the Medtronic Pain Pump to the FDA and others, which in turn violated its duty under Arizona law to use reasonable care to warn the patient of the dangers inherent in using the defective device. The patient alleged that Medtronic violated specific federal regulations and a specific provision under the FDC Act. He based his Arizona failure to warn claim on Medtronic's violation of the federal duty to report post-PMA adverse events to the FDA. According to the Arizona appellate court, this requirement is not "different from, or in addition to" requirements imposed by federal law. FDA regulations required the pain pump maker to file an adverse event report with the FDA if it learned of information that reasonably suggested that one of its devices could have caused or contributed to a death or serious injury, which is what was alleged by the patient. Therefore, the claim was not expressly preempted.

Further, the court found that the cause of action for failure to warn also was not impliedly preempted because the patient's action was not seeking to enforce the FDC Act, but rather to recover under Arizona state law for the manufacturer's alleged failure to warn of dangers discovered after sale. However, to the extent that the patient alleged a violation of any state-law duty to directly warn him or his physicians, such a claim would be expressly preempted because that duty would be in addition to requirements imposed by federal law.

The court disagreed with Medtronic's contention that the patient did not adequately allege a causal connection between the failure to report adverse events and his injuries. A sufficient causal connection was alleged under Arizona's notice pleading standard. Thus, the court of appeals held that because the patient's failure to warn claim was not expressly or impliedly preempted, the trial court erred by dismissing the claim.

Negligence. The patient alleged several negligence causes of action. As explained above, while the patient could bring his failure to warn claim against the manufacturer because it was not expressly or impliedly preempted, his claims of negligent manufacture and design were preempted. The patient also argued that the manufacturer had a "continuing duty to monitor the product after premarket approval and to alert the FDA" about complaints relating to the product's performance, and to "submit medical device reports" to the FDA, pursuant to FDA regulations and the FDC Act. The patient contended that Medtronic's failure to adhere to these regulations was negligence per se. The court agreed with the patient that a federal statute or regulation could be adopted as a standard of conduct to support a negligence per se claim. The court noted that the patient could request that the trial court apply the negligence per se doctrine to assist him in proving his failure to warn claim.

Loss of consortium and punitive damages. Finally, the appellate court ruled that because the patient's failure to warn claim was not preempted, the patient and his wife could proceed with the derivative claim for loss of consortium. Also, punitive damages claims carried no special pleading requirement. Therefore, the trial court erred in its dismissal of these claims.

The case is No. 1 CA-CV 16-0252.

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Companies: Medtronic, Inc.

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