Products Liability Law Daily Wrap Up, PREEMPTION—MEDICAL DEVICES—S.D. Fla.: MDA preempts wearable defibrillator case, (Jan. 19, 2017)

Products Liability Law Daily Wrap Up

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By Miriam A. Friedman, J.D.

Products liability, misrepresentation and fraud claims based on the failure of a wearable defibrillator to administer a required shock were preempted by the Medical Device Amendment (MDA) of the Food, Drug, and Cosmetic Act (FDCA), a federal court in Florida ruled. The court also dismissed a patient's other claims against the manufacturer of the device, including breach of warranty and negligent infliction of emotional distress, on the ground that they failed to state a claim (*Godelia v. Zoll Services, LLC*, January 18, 2017, Gayles, D.).

The patient acquired a LifeVest, a wearable defibrillator for patients at risk for sudden cardiac arrest, manufactured and marketed by Zoll. The LifeVest was a Class III medical device that had been approved for sale by the FDA and required a physician's prescription. When the patient experienced a defibrillation event, her LifeVest sounded an alarm, but failed to deliver the required shock. The patient died two days later. The patient's husband and minor child filed suit, asserting state law claims for (1) strict liability manufacturing defect; (2) negligent manufacturing defect; (3) fraudulent misrepresentation; (4) fraudulent omission/concealment; (5) fraudulent marketing/promotion; (6) breach of express warranty; (7) negligent misrepresentation; and (8) negligent infliction of emotional distress. The manufacturer moved to dismiss on the grounds that the MDA preempted all state-law claims.

Express preemption. Medical devices, such as the LifeVest, are regulated by the FDCA, as amended by the MDA, which expressly provides for the preemption of claims for strict products liability and negligent manufacturing. Permitting these claims to go forward could have resulted in conflicting results had a jury found the LifeVest to be defective in spite of FDA pre-market approval.

The patient's husband's and minor child's reliance on an FDA warning letter to demonstrate a parallel claim was misplaced, as that letter, which had been issued subsequent to the patient's death, related to LifeVest's inappropriately delivering unwarranted shocks in some instances, while the patient's LifeVest had failed to deliver a shock when necessary. Accordingly, there was no nexus between the warning letter, patient's LifeVest, and her death.

Remaining claims expressly preempted. The claims for fraudulent misrepresentation, fraudulent marketing/promotion, breach of express warranty, negligent misrepresentation, and negligent infliction of emotional distress were based on representations regarding the efficacy of the LifeVest. Although couched in terms of misrepresentations and inaccurate statements, these claims could have survived only if a factfinder had determined that the patient's LifeVest was defective. Therefore, the court found that these claims were likely to conflict with the FDA's findings regarding the LifeVest. And, thus, were expressly preempted as well.

Breach of warranty. The court further found that the breach of express warranty claim failed to state a claim. Under Florida law, "warranty-based claims, including breach of express warranty, require privity of contract." Because the patient required a prescription to obtain the LifeVest, she could not have purchased the device directly from the manufacturer, and, as such, no privity existed.

Negligent infliction of emotional distress. Finally, the court found that the claims for negligent infliction of emotional distress, even if not preempted, also failed to state a claim, as they did not indicate any "discernable physical injury." The patient's husband complained of "insomnia, depression, short-term memory loss, inability to stop reliving the death, muscle and stomach pain," while her minor son experienced "inability to stop reliving the event, depression, short-term memory loss, muscle and other pain." The court found that these did not compare

to "death, paralysis, muscular impairment, or similar objectively discernable physical impairment[s]" that would have been required for such a claim to proceed.

Implied preemption. The court found that even had the claims not been expressly preempted, they would likely have been impliedly preempted because Florida courts have consistently refused to recognize private causes of action for violations of FDA regulations.

The case is No. 16-cv-.60471-DPG.

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Companies:Zoll Services, LLC

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