

Ariz. High Court Rejects 9th Circ. Preemption Ruling

By Emily Field

Law360 (December 18, 2018, 11:18 PM EST) -- The Arizona Supreme Court on Tuesday contested a Ninth Circuit panel's 2013 decision on whether state failure-to-warn claims are preempted by federal law while hearing a case about an Arizona man who says a defective pain pump caused him permanent injuries.

The state high court tackled the issue of whether federal law preempts an Arizona common law failure-to-warn claim based on a medical device maker's alleged failure to send adverse event reports to the U.S. Food and Drug Administration. In doing so, the Arizona Supreme Court addressed the Ninth Circuit's 2013 decision in *Stengel et al. v. Medtronic Inc.*

The instant suit brought by Raymond R. Conklin, like the 2013 decision, alleges that Medtronic failed to report adverse events about an infusion pump. Unlike the Ninth Circuit's 2013 decision, the state supreme court reversed an appellate court's decision and found Conklin's state law failure-to-warn claim was preempted by federal law.

In the 2013 ruling, the Ninth Circuit held that Arizona resident Richard Stengel's state law failure-to-warn claim paralleled a federal-law duty under the Medical Device Amendments to the Food, Drug and Cosmetic Act and therefore cannot be preempted.

The Arizona high court said the Ninth Circuit's decision was based on the unsupported premises that "Arizona law contemplates a warning to a third party such as the FDA" and that under the state's law, a manufacturer can satisfy their duty if it warns a third party and there's reasonable assurance that the information in the warning would be spread to patients, the state high court said.

"Neither premise comports with Arizona law," the Arizona Supreme Court said in addressing both the Ninth Circuit decision and the lower court decision in Conklin's case. "Arizona law would recognize a claim for a failure to provide an adequate warning to the patient directly or through certain third parties [including health care providers], but established law does not recognize a claim merely for failing to provide something like adverse event reports [which may not qualify as "warnings" under Arizona law] to a government agency that has no obligation to relay the information to the patient."

The plaintiff in the instant case, Conklin, had hip surgery in 2013 and claimed that he was permanently injured when his Medtronic SynchroMed II pain pump released too much medication, according to the opinion.

Conklin alleged that, before he was injured, the FDA sent warning letters to Medtronic telling it that the pump was adulterated and misbranded and stating that Medtronic had failed to report adverse events to the FDA after the pump went on the market.

Conklin also alleged that before his 2013 injury, the FDA issued two recalls of the pump over the device unintentionally injecting or stopping drugs, and that after his injury, another recall was issued over the pump unintentionally delivering drugs that could cause an overdose.

"This decision serves to condone the type of bad conduct that prompted the FDA to discipline Medtronic and two of its officers. It closes the courthouse doors to thousands of Arizonans harmed by defective medical devices and shifts the economic burden to the victims," Jonathan O'Steen of O'Steen & Harrison PLC, counsel for Conklin, told Law360 on Tuesday. "While device manufacturers will escape liability for concealing critical safety information, Arizona physicians will bear full legal and financial responsibility when their negligent actions compound a device manufacturer's wrongful conduct."

Representatives for Medtronic didn't immediately respond to requests for comment on Tuesday.

Conklin is represented by Jonathan V. O'Steen and Paul D. Friedman of O'Steen & Harrison PLC.

Medtronic is represented by Andrew E. Tauber and Kenneth S. Geller of Mayer Brown LLP and E. Jeffrey Walsh, Michael T. Liburdi, and Nicole M. Goodwin of Greenberg Traurig LLP.

The case is Conklin v. Medtronic, case number CV-17-0322-PR, in the Supreme Court of the State of Arizona.

--Editing by Michael Watanabe.