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Okla. Device Ruling Puts Other Products In Crosshairs

By **Greg Ryan**

Law360, New York (March 25, 2013, 7:59 PM ET) -- The Oklahoma Supreme Court recently held that a medical device maker can be found negligent for a plaintiff's injury under state law simply for violating federal regulations, a groundbreaking decision that attorneys said Monday could be interpreted to apply to any federally regulated product, including food and cars.

A majority of the court ruled March 19 that the Federal Food, Drug and Cosmetic Act does not bar Oklahoma plaintiffs from bringing a negligence per se claim based on a violation of regulations under the FDCA's Medical Device Amendments.

The ruling came in response to a question certified to the high court by the Tenth Circuit, in a suit brought against Zimmer Holdings Inc. by the recipient of a knee implant. Plaintiff Brian Howard alleged he was injured by the manufacturer's failure to remove oily residue from the device, a purported violation of federal regulations.

Though the majority focused on negligence per se allegations under the FDCA, the logic it used to determine the availability of the claim can be read to extend to any federal product safety regulation, attorneys say.

"The notion that federal regulations can give rise to negligence per se claims, straight up, without some sort of intervening enforcement action by federal authorities ... that could open a big can of worms," said Snell & Wilmer LLP partner Lee Mickus.

The two judges who dissented from the ruling pointed to the same possibility, saying "today's holding is so broadly worded that it allows a plaintiff to allege negligence per se based on a violation of any federal regulation."

"With the thousands of federal regulations from the various federal agencies, an overly broad holding will inevitably lead to unanticipated results," the dissenters said.

Zimmer had argued to the court that Howard's negligence per se claim failed because FDCA regulations specify that only the federal government can enforce the law. But Howard is not looking to bring a private action under the FDCA, according to the majority. He is looking to bring a claim that parallels federal regulatory requirements, as the U.S. Supreme Court allowed in Riegel v. Medtronic Inc. in 2008, it said.

Other courts have used Riegel to allow state-law claims that parallel U.S. Food and Drug Administration standards. The Oklahoma high court went a step further by holding that the allegations that avoid preemption include negligence per se claims, attorneys said.

Negligence per se claims are troublesome for defendants because they are generally easier to prove than traditional negligence claims, according to attorneys. Once plaintiffs show that a company violated a public safety law or regulation and that they meet minimal thresholds regarding the law's applicability — that they belong to the group of people intended to fall under the law's protection, for instance — they need only show that the violation caused their injuries and that they deserve damages.

The ruling "might be applied more narrowly if Oklahoma courts find, on a regulation-by-regulation basis, that a plaintiff was not the intended beneficiary of a regulation," Dechert LLP partner Hope Freiwald said. "But on its face ... the court seems to open the door for negligence per se claims based on federal regulations in a whole range of situations."

The decision is not likely to lead to an onslaught of product liability litigation in Oklahoma, given the usual barriers to establishing the state's law applies in a case, but "it raises a real question about whether other courts would be willing to follow the same reasoning," Freiwald said.

Randall Christian of Bowman and Brooke LLP said the ruling could even create new causes of action for plaintiffs. For instance, federal regulations prohibit drugmakers from promoting a drug for uses not approved by the FDA, even if they offer truthful information. Plaintiffs in Oklahoma could base a negligence per se claim on the allegation that a company's truthful, off-label promotion of a drug led to their injury, he said.

Attorneys said Zimmer could push the U.S. Supreme Court to review the ruling, though a lawyer for Howard, Matthew Free of Best & Sharp, said he did not believe it could consider the case, since the decision was based on state law grounds only.

"It's a good outcome for the plaintiff in the case," Free said. "It's been a long time coming."

The case was first launched in Oklahoma federal court in 2002 and transferred to Ohio as part of multidistrict litigation. While the suit was in Ohio, the Sixth Circuit found that Howard's negligence per se claim was not preempted by federal law. Once back in Oklahoma, a federal court ruled that state law did not recognize the claim, even if it was not preempted, and Howard appealed that decision to the Tenth Circuit.

An attorney for Zimmer could not immediately be reached for comment Monday.

Howard is represented by Timothy Best and Matthew Free of Best & Sharp.

Zimmer is represented by David Brooks and William Northrip of Shook Hardy & Bacon LLP and Michael Smith and Thomas Steichen of McAfee & Taft PC.

The case is Howard et al. v. Zimmer Inc. et al., case number CQ-110857, in the Oklahoma Supreme Court.

--Editing by Elizabeth Bowen and Lindsay Naylor.