



## PAST PREEMPTION OPINIONS MAY INDICATE NEWEST JUSTICE'S PULL ON COURT'S STATUTORY-CONSTRUCTION TUG-OF-WAR

by Frank Cruz-Alvarez and Talia Zucker

Over the last decade, the US Supreme Court justices have engaged in an intellectual tug-of-war in the area of statutory construction. The textualist underpinning of Justice Thomas's approach to statutory construction has become increasingly influential. In the context of preemption, Justice Thomas appears to have successfully persuaded The Chief Justice, Justice Alito, and the late Justice Scalia. With the latter's passing, textualism lost a powerful anchor, threatening the intellectual ground won over the course of many years.

It appears, however, that the appointment and confirmation of Neil Gorsuch represents a positive step toward solidifying the Court's commitment to textualism. Moreover, in the tug-of-war on statutory construction, Justice Gorsuch appears to be a strong addition to the side favoring textualism, in particular in preemption jurisprudence. Although one can never predict for certain, a review of Justice Gorsuch's two preemption opinions from his time on the US Court of Appeals for the Tenth Circuit should give solace to adherents of textualism and to those wanting consistency in the Court's preemption jurisprudence.

Judge Gorsuch's majority opinion in *Caplinger v. Medtronic*, 784 F.3d 1335 (10th Cir. 2015), provides the best insight into his approach to preemption. In *Caplinger*, the Tenth Circuit affirmed a district court's decision to preempt a plaintiff's claim based on off-label use of Medtronic Inc.'s Infuse, a bone-graft device. Patricia Caplinger alleged that Medtronic representatives promoted Infuse to her and her doctor for an off-label use. Caplinger elected to use the device in this off-label manner and suffered complications. She then brought a lawsuit against Medtronic under a variety of state-law theories. The district court granted Medtronic's motion to dismiss on the ground that Caplinger's state-law claims were expressly preempted by federal law. The Tenth Circuit affirmed.

Judge Gorsuch began his analysis by criticizing the Supreme Court's numerous decisions that offer different views about the appropriate role of the Medical Device Amendments' (MDA) preemption provisions, which he argued caused considerable "uncertainty." *Id.* at 1338. Despite the law's express preemption language, the Court has rejected the notion that state-law tort suits are always preempted. *See Medtronic Inc. v. Lohr*, 518 U.S. 470 (1996). Instead, the court held that state tort suits are not preempted "so long as the duties they seek to impose 'parallel' duties found in the [MDA]." *Caplinger*, 784 F.3d at 1338.

Caplinger failed to identify a viable parallel federal statute or regulation for her design-defect and breach-of-warranty state-law claims. Although she identified candidates for a parallel federal duty for her claims of failure to warn, negligence, and negligent misrepresentation, a close inspection revealed there was no actual parallel. In the end, Caplinger's state-law claims "substantially exceed[ed] the potential scope of any federal regulation she's identified" making dismissal of her claims appropriate. *Id.* at 1341.

Caplinger further argued that even if no federal parallel existed, it was irrelevant because preempting a claim concerning off-label uses, for which the Food and Drug Administration does not conduct studies and safety

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assessments, was improper. *Id.* at 1343. The Tenth Circuit did not embrace this argument. Judge Gorsuch found that the plain language of the MDA states that a plaintiff may not invoke state law to impose “any requirement that ‘relates to the safety or effectiveness of [a] device’ that is ‘different from, or in addition to, any requirement applicable ... to the device.’” *Id.* at 1344. There is no distinction between whether a plaintiff seeks to use state law to impose requirements for off-label uses or on-label uses. The statute preempts “any effort to use state law to impose a new requirement on a federally approved medical device.” *Ibid.* Moreover, Congress “spoke directly to off-label uses” when it said that healthcare practitioners can “prescribe or administer any legally marketed device” without interference. *Ibid.* “Knowing about (even encouraging) off-label uses,” Congress still preempted any state tort suit that challenged the safety of a federally approved device. *Ibid.*

Finally, Caplinger argued that preemption should only occur when a state requirement “differs from or adds to” a federal regulation covering the “same subject.” *Ibid.* Since there is no federal regulation covering off-label use, she argued off-label claims should not be preempted. The court considered this another “textual dead-end” in that the statute requires preemption when state law is used to impose “any” requirement which relates to the safety and effectiveness of the device. *Id.* at 1344-45. The plain text of the statute would have to be revamped to accommodate Caplinger’s argument, a judicial power the court did not possess. *Id.* at 1345.

The other noteworthy preemption opinion written by Judge Gorsuch is *Cook v. Rockwell International Corporation*, 790 F.3d 1088 (10th Cir. 2015), which dealt with field preemption. This case involved a government contractor’s mishandling of radioactive waste at a nuclear weapons production facility. Property owners filed a civil lawsuit under the Price-Anderson Act (PAA) and state nuisance law for harm allegedly caused by improper disposal of waste. Notably, under the PAA, if plaintiffs are able to prove that a nuclear incident occurred and harmed them, certain special rules apply that limit defendants’ liability by requiring the government to pay any damages not covered by insurance. At trial, the jury awarded \$177 million in compensatory damages and \$200 million in punitive damages. Defendants appealed, arguing that the district court’s jury instruction regarding plaintiffs’ burden of proof as to a nuclear incident was too permissive (in other words, plaintiffs’ harm was not a “nuclear incident” under the PAA). The Tenth Circuit agreed and vacated the judgment.

On remand, plaintiffs wisely discarded their PAA claim (recognizing that they could not meet their burden of proof that a nuclear incident caused damages to real property) and proceeded solely on their state nuisance claim, maintaining the validity of their judgment as to that claim. Defendants argued that the PAA preempts any state-law recovery where a nuclear incident is asserted but unproven. The district court sided with defendants, finding that the PAA preempted plaintiffs’ state-law nuisance claim. This time, plaintiffs appealed.

On appeal, the Tenth Circuit found that defendants’ preemption arguments failed for two reasons. *Id.* at 1093. First, and as a matter of procedure, defendants forfeited any preemption argument in the first appeal. Second, even if the court were to excuse this procedural problem and consider a field preemption defense, a substantive issue arises as the PAA is not preemptive without the occurrence of a nuclear incident. *Id.* at 1094.

Judge Gorsuch began by applying the presumption against preemption. Then, he conducted a simple review of the PAA’s text, which revealed that Congress did not intend to expressly preempt all state-law tort recovery for plaintiffs who plead but do not prove a nuclear incident. *Id.* at 1094-95. Further inquiry revealed that “[s]urrounding textual features” and the PAA’s history confirm that Congress made a deliberate decision not to bar state tort recovery when a nuclear incident is alleged but unproven. *Id.* at 1095-96. The court ultimately remanded the case for reinstatement of the jury’s verdict as to the nuisance claim.

Review of Justice Gorsuch’s Tenth Circuit record suggests that his appointment should help maintain the status quo as it relates to preemption jurisprudence. More significantly, the addition of Justice Gorsuch should weigh in favor of the side pulling for textualism in the ongoing tug-of-war over statutory construction in the Supreme Court. Only time will tell whether the ground gained on this issue will be permanent.