



## Off-Label Promotion, State-Level Injury Lawsuits, and Preemption

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The issue of preemption in product liability cases involving medical device products continues to evolve. Recently, the U.S. Court of Appeals for the 10th Circuit found that federal law preempts injury and negligence claims, brought under state law, even if the claims arise out of potential off-label promotion by the device manufacturer. The decision seemingly reaffirms a trend toward preemption although, with all cases, tort claims are fact- and pleading-specific.

### Background

The case, Caplinger v. Medtronic, Inc., 784 F.3d 1335 (10th Cir., 2015), involved a party who sued a medical device manufacturer under state law claims of injury and negligence. The party alleged that her surgeon used the company's bone growth stimulator product for off-label, *i.e.*, unapproved, uses during surgery, and the off-label use was due to the device company's off-label promotion.

Medtronic's device, approved pursuant to a Premarket Approval Application (PMA), includes a Food and Drug Administration-required label warning that it should only be used for anterior, not posterior, surgical procedures. The approved label for the device noted there is potential risk of possible posterior bone formation and, according to the plaintiff, the company promoted the device for off-label posterior uses, despite these recognized risks. The plaintiff required follow-up surgery due to complications, which she alleged were due to the off-label promotion, and brought a state-level complaint with claims relating to product liability, defective product design, inadequate use of warnings, breach of warranty, negligent misrepresentation, and negligence.

### Appellate Court Decision

The 10th Circuit agreed with Medtronic that the Federal Food, Drug, and Cosmetic Act (FDC Act) and, specifically 21 U.S.C. § 360k(a), preempts the state law claims. The statutory provision notes that, with limited exception:

No State or political subdivision of a State may establish or constitute in effect with respect to a device intended for human use any requirement

1. which is different from, or in addition to, any requirement applicable under this Act to the device, and
2. which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

The appellate court noted that the FDC Act includes a practice of medicine provision to protect doctors' ability to prescribe a medical device for "any condition or disease within a legitimate health care practitioner-patient relationship," citing 21 U.S.C. § 396. The court wrote:

Knowing about (even encouraging) off-label uses in § 396, Congress proceeded in § 360k(a) to preempt any state tort suit challenging the safety of a federally approved device without qualification about the manner of its use. Given that Congress well understood the difference between on-and off-label uses and exhibited its facility with those terms in § 396, the absence of any mention of this in § 360k(a) becomes all the harder to ignore.

The 10th Circuit also expressed concern that, if it allowed the state-law claims relating to off-label promotion to proceed, there could be negative effects on innovation and delayed access to life-saving devices. By permitting potentially 50 different state standards for warning requirements concerning off-label uses to arise, the court said that this would “introduce sufficient uncertainty and cost that manufacturers would delay or abandon at least some number of life-saving innovations.”

It is noteworthy that, while the 10th Circuit preempted the state-law claims, one judge issued a concurring opinion, where he rejected a blanket preemption or complete immunity when the injury resulted due to an adulterated or misbranded medical device. This concurrence suggested some of the plaintiff’s claims should have survived a motion to dismiss at the lower level, and the judge concluded he would have remanded “for the district court to revisit its analysis with a proper understanding of this regulatory regime.”

## Observations

1. The case is limited in precedential value to those jurisdictions covered by the 10th Circuit. However, it does favor the device manufacturer and preemption, even where the injury might result from off-label promotion.
2. The appellate court cited two statutory provisions that are specific to medical devices. The particularity of the FDC Act’s medical device provisions relating to preemption and the practice of medicine seems to have made the case easier for the 10th Circuit to decide in favor of the device manufacturer.
3. The issue of preemption in the area of medical device liability continues to evolve, particularly since the U.S. Court’s decision in Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996). In that case, the plurality found no express preemption for devices cleared through the FDA’s 510(k) premarket clearance process. Subsequently, in Buckman v. Plaintiffs’ Legal Committee, 531 U.S. 341 (2001), the Supreme Court held that state laws based on an allegation that the device company made misrepresentations to, or concealed relevant information from, FDA as part of the federal approval process were preempted. Three years later, in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), the Court found that, for PMA products, where safety and efficacy data are specifically reviewed and required by FDA, the FDC Act expressly preempts state-law negligence, strict liability, and implied warranty claims.
4. There have been many cases involving preemption and the FDC Act over the years, particularly at the district court level. While the multitude of decisions is beyond the scope of this article, it is important to note that results vary.
5. Distinct from the case law involving preemption and product liability, FDA enforcement of off-label promotion continues to evolve. The agency has issued enforcement letters to life science companies for unlawfully marketing products for unapproved uses or broadening the approved or cleared indications while such FDA enforcement has been primarily against pharmaceutical companies, device companies have found themselves recipients of Untitled Letters or Warning Letters.

However, FDA is also cognizant that off-label dissemination, rather than promotion, of information may provide legitimate, scientific benefit to medical professionals and consumers. The agency does not want companies to circumvent the marketing authorization process by promoting proactively affirmatively unapproved uses; yet, it allows companies to respond to requests for off-label information or even permit proactive dissemination of certain types of objective, independently-produced medical information, within specific parameters. The agency has issued written guidances to industry in an attempt to find an appropriate balance of scientific exchange of information, even if off-label, and unlawful promotion. Furthermore, FDA (and Congress) respects the practice of medicine, where physicians may exercise independent medical judgment and prescribe or use medical products outside the products’ approved or cleared indications.

Nevertheless, despite FDA's efforts to walk this fine regulatory tightrope, it faces legal challenges. As of this writing, it finds itself defendant in a First Amendment challenge, sued by Amarin Corporation, for allegedly restricting commercial speech. The outcome of that litigation is eagerly watched by industry.

6. One cannot ignore prosecution of off-label promotion by the United States Justice Department or State Attorneys General. Even where FDA might not take enforcement action against off-label promotional activities, other government agencies may proceed to bring False Claims Act allegations, unlawful advertising challenges, or consumer deception claims against product manufacturers, which are often resolved by multi-million dollar settlements.
7. The issue of off-label promotion brings a wrinkle to the preemption discussion, because of First Amendment free speech issues, practice of medicine, and FDA enforcement. However, at least in the Caplinger case, the majority of the 10th Circuit did not find this wrinkle sufficient to permit the state law claims to proceed. The FDC Act's provisions, and the presumed Congressional intent, favors preemption for devices that have undergone premarket review. Whether the trend in favor of preemption will continue is difficult to predict, with each case and claim fact-specific but, in this case, the device companies scored another win.

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