Counsel's Advisory

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NINTH CIRCUIT BUCKS SUPREME COURT AGAIN ON MEDICAL DEVICE PREEMPTION

by
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The U.S. Supreme Court acknowledged in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), that the Food and Drug Administration (FDA), not plaintiffs' lawyers, must enforce the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act (FDCA). It provided two reasons why the MDA impliedly preempts state-law tort claims alleging that the defendant committed fraud on the FDA by failing to disclose all the information required of it under the MDA. First, private enforcement efforts undermined the freedom Congress gave FDA to enforce the MDA as it saw fit. Second, Congress intended regulated entities to meet FDA's interpretation of the MDA, not that of various state courts. Therefore, the claims in *Buckman* were preempted because they were predicated largely on the plaintiff's private attempt to enforce the MDA, and thus exerted an "extraneous pull" on the legislative scheme.

In *McClellan v. I-Flow Corp.*, --- F.3d ---, 2015 WL 294292 (9th Cir. Jan. 23, 2015), the plaintiff sought to instruct the jury on a negligence *per se* claim premised on a violation of the MDA. In other words, her claim was predicated, not just largely, but *exclusively* on a private attempt to enforce the MDA. But the Ninth Circuit nonetheless held the jury instructions were not preempted. The erroneous decision rested primarily on three misunderstandings of Supreme Court precedent.

First, *McClellan* incorrectly applied the standard presumption against preemption in areas traditionally occupied by state law, holding that *Buckman*'s obviation of that presumption was specific to fraud-on-the-FDA claims. In reality, *Buckman* held the presumption did not apply because a fraud-on-the-FDA claim, like the claim in *McClellan*, ultimately alleged violation of federal law, and thus it could not have been a subject traditionally reserved to the states.

Second, *McClellan* misread the Supreme Court's opinion in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), to hold that state-law claims alleging an MDA violation are "parallel" to federal requirements, and thus not preempted. But *Lohr* holds only that state-law parallel claims are not *expressly* preempted by the MDA, because they require nothing different from or additional to federal requirements. It does not even address implied preemption and thus cannot be construed to foreclose or limit *Buckman*.

Third, *McClellan* misinterpreted *Buckman* as preempting only state-law fraud-on-the-FDA claims. But *Buckman* did not preempt those claims because they alleged fraud on the FDA, but because they alleged the fraudulent information was submitted to the FDA *in violation of the MDA's requirements*. This is why *Buckman*'s analysis focused on impingement of the FDA's enforcement prerogative and the proliferation of interpretations of the MDA, both of which are implicated—not just by fraud-on-the-FDA claims but by *any* private attempt to enforce the MDA.

Because of the analytical shortcomings in *McClellan*, the Ninth Circuit now considers *Buckman* essentially no obstacle even to state-law claims that are solely private attempts to enforce the MDA. *McClellan* thus solidifies the Ninth Circuit's defection from the Sixth and Eighth Circuit's interpretation of *Buckman*, and it embraces the Fifth and Seventh Circuits' countervailing understanding. The circuit split regarding *Buckman* thus remains, as does the potential for the Supreme Court to clarify that *Buckman*'s logic extends beyond the fraud-on-the-FDA claims with which it dealt.

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