Legal Backgrounder

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WHAT'S THE IMPLICATION?
COURTS AND THE SCOPE OF IMPLIED MEDICAL DEVICE PREEMPTION

by
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Congress authorized the Food and Drug Administration ("FDA") as the exclusive enforcer of the Food, Drug and Cosmetic Act ("FDCA") and its Medical Device Amendments ("MDA"). That exclusivity implicitly preempts civil plaintiffs from seeking to impose liability on medical device manufacturers solely for violations of the FDCA. But does it preempt traditional state law claims that allege such violations? Does the FDA's prior determination of such violations allow the courts to use them as a predicate for civil liability without intruding on the FDA's authority, or does even the imposition of damages impinge on the FDA's regulatory sphere? These are just some of the questions still swirling around the doctrine of implied preemption.

Because medical device manufacturers are subject to federal regulations, state law claims involving medical devices are subject to preemption – both express and implied – by federal law. Though the parameters of express preemption are fairly well-defined,[1] the scope of implied preemption increasingly depends upon which interpretation of the United States Supreme Court's delphic opinion in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), controls. According to some federal appellate circuits, *Buckman* preempts only the specific "fraud-on-the-FDA" claims it dealt with, because they are essentially improper federal claims that invade the FDA's exclusive authority to enforce the FDCA. According to other circuits, *Buckman* also acknowledges that the FDA is entitled to determine all FDCA violations in the first instance, in order to avoid conflicting determinations by the courts. In those circuits, *Buckman* preempts even traditional state law claims alleging regulatory violations the FDA has not already determined to exist.

The Ninth Circuit Court of Appeals' recent opinion in *Stengel v. Medtronic, Inc.*, 676 F.3d 1159 (9th Cir. 2012), not only noted the circuit split regarding *Buckman* implied preemption, but widened it by holding that certain traditional state law claims alleging FDCA violations are preempted even when the FDA has already determined those violations to exist. According to *Stengel*, *Buckman* preempts such claims not because of a potential conflict with the FDA (the agency's prior determination of a violation obviates that issue), but because they would "exert an extraneous pull" on the FDA's regulatory scheme. Further complicating matters, the Ninth Circuit recently reheard *Stengel en banc*, throwing its validity in doubt, and highlighting the confusion surrounding *Buckman* and thus the potential benefit of Supreme Court review.

[1] *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008) (state law claims involving medical devices "approved" under the FDA's rigorous premarket approval process are expressly preempted by § 360k of the MDA, to the extent those claims add to or are different from the conditions of PMA approval); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 492-94 (1996) (state law claims involving medical devices that were "cleared" through the FDA's less-rigorous § 510(k) process are not expressly preempted).

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Buckman Co. v. Plaintiffs' Legal Committee

"Fraud-on-the-FDA" Claims. *Buckman* involved state tort claims alleging that a medical device manufacturer "made fraudulent representations to the FDA, as to the intended use of [its] bone screws and that, as a result, the devices were improperly given market clearance and were subsequently used to the plaintiffs' detriment." The Court labeled these as "'fraud-on-the-FDA' claims," and noted that "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied." "To the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." Because the manufacturer's "dealings with the FDA" were prompted and dictated by the MDA, the normal presumption against federal preemption of state health and safety regulation did not apply. The Court therefore found that "fraud-on-the-FDA" claims "conflict with, and are therefore impliedly preempted by, federal law." The rationales it gave for preemption, however, were also driven by concern for the FDA's exclusive authority to enforce the FDCA.

The "Exclusivity" Rationale. The core of the "exclusivity" rationale was simply that only the federal government is "authorized to file suit for noncompliance with the [MDA]." This exclusive authority – combined with executive enforcement measures such as investigations, seizures, and criminal prosecutions – gives the FDA plentiful options for enforcing the FDCA. The variety of enforcement options in turn provides the FDA flexibility, which is "a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." That framework preempted "fraud-on-the-FDA" claims because they were, as the district court below held, "an improper assertion of a private right of action under the MDA" that impinged upon the FDA's exclusive authority to pursue, or forego, civil enforcement of the FDCA.

The "Conflict" Rationale. Though the "exclusivity" rationale was sufficient to dispose of *Buckman*'s "fraud-on-the-FDA" claims, the Court also identified a potential conflict raised by *any* claim alleging regulatory violations not previously determined by the FDA: disclosures deemed appropriate by the FDA could later be judged insufficient in state court. Device manufacturers would thus face the prospect of "unpredictable civil liability" due to "complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes." *Buckman* thereby suggested that any state law claim was preempted to the extent it would require courts to determine an FDCA violation where the FDA had not. Yet *Buckman* preempted the "fraud-on-the-FDA" claims without addressing whether the FDA had previously determined the FDCA violations alleged, thereby suggesting the Court was relying on the "exclusivity" rationale, which in turn rests on the unique nature of "fraud-on-the-FDA" claims.

The Distinction of "Traditional State Law Claims". Indeed, the Court focused on two distinct aspects of "fraud-on-the-FDA" claims in its analysis of the plaintiff's citations to *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), and *Medtronic*. First, they were premised on federal regulations, not traditional state law tort theories. Second, because they were not traditional state law claims, they were essentially attempting to enforce the FDCA, which impinged the FDA's exclusive authority to do so.

The Court's focus on the peculiar nature of impliedly preempted "fraud-on-the-FDA" claims, in contrast to "traditional state law claims," suggests that the latter are not impliedly preempted. This suggestion collides with the "conflict" rationale, which logically preempts even traditional state law claims if the plaintiffs alleged FDCA violations not previously determined by the FDA. *Buckman*, however, offered no guidance on the scope of the "conflict" rationale. In fact, its failure to establish the factual predicate to the conflict rationale – *i.e.*, whether the FDA had previously determined the alleged FDCA violations – calls into question the extent to which the Court applied it at all.[2] Then again, *Buckman* clearly identified the "conflict" rationale, and

[2] *Buckman*, 531 U.S. at 354-55 (Stevens, J., concurring) (noting that, under Justice Stevens' analysis, the FDA's prior determination of fraud would allow the respondent's case to proceed "without second-guessing the FDA's decisionmaking or overburdening its personnel," whereas, under the majority's analysis, "parties injured by fraudulent representations to federal agencies would have no remedy even if recognizing such a remedy would have no adverse consequences upon the operation or integrity of the regulatory process").

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incorporated it – by reference to "the reasons stated above" – as grounds for its conclusion that "this sort of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore preempted by that scheme."

Conflicting Interpretations of Buckman

On one hand, *Buckman* specifically articulated the "conflict" rationale distinct from its "exclusivity" rationale. On the other, *Buckman* did not address the application of the "conflict" rationale beyond "fraud-on-the-FDA" claims, and did not explicitly apply that rationale in disposing of those claims. It is therefore unsurprising that federal appellate interpretations of *Buckman* have diverged regarding whether the "conflict" rationale has any currency.

Second, Fifth, and Seventh Circuits:* Buckman *Has No Application Beyond "Fraud-on-the-FDA" Claims. On one end of the spectrum, some courts have focused solely on the "exclusivity" rationale in holding that *Buckman* preempts only "fraud-on-the-FDA" claims, not traditional state law claims. For example, in *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 87-88 (2d Cir. 2007), the Second Circuit faced a Michigan statute that granted immunity from state product liability claims to prescription drug manufacturers whose products were approved by the FDA, unless the plaintiff could prove that the manufacturer withheld or misrepresented information to the FDA. The court held that *Buckman* did not preempt the plaintiffs' ability to make such proof because they "are not pressing 'fraud-on-the-FDA' claims …. They are, rather, asserting claims that sound in traditional state tort law." *Buckman*, the court noted, distinguished *Medtronic* because it involved the same traditional tort claims.[3]

Sixth, Eighth, and Ninth Circuits:* Buckman *Preempts Traditional State Law Claims Premised on a Regulatory Violation Not Previously Determined by a Federal Agency. Other courts have recognized *Buckman*'s "conflict" rationale, and held that it preempts traditional state law claims alleging regulatory violations not previously determined by the federal agency. In *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1202-03 (9th Cir. 2002), the plaintiff brought a state law claim alleging that the defendant had misled the Environmental Protection Agency ("EPA") to the plaintiff's detriment. The Ninth Circuit acknowledged *Buckman*'s exclusivity rationale, but focused on its conclusion that, "in addition to interfering with the FDA's regulatory duties, state-law fraud-on-the-FDA claims would impose significant burdens on applicants seeking FDA approval that had not been anticipated by Congress." The latter rationale compelled preemption, in part because of the prospect that "an applicant's disclosures under [federal law], although not challenged by the EPA …, may be judged illegal under state law."[4]

Similarly, the Sixth Circuit, construing the same Michigan statute as *Desiano*, *supra*, held in *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004), that *Buckman* prohibits a plaintiff from relying on *state court* findings to prove that the manufacturer withheld or misrepresented information to the FDA. However, *Buckman*'s "inter branch meddling" concerns "do not arise when the *FDA itself* determines that a fraud has been committed on the agency during the regulatory-approval process." Thus, *Buckman* did not preempt a plaintiff from proving fraud to the extent "the federal agency itself determines that fraud marred the regulatory-approval process."[5]

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[3] *Cf. Bausch v. Stryker Corp.*, 630 F.3d 546, 557 (7th Cir. 2010) (rejecting *Buckman* preemption of the plaintiff's claims because they were "tort law claims based on manufacturing defects, not fraud on a federal agency."); *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 775 (5th Cir. 2011) (rejecting *Buckman* preemption because plaintiff "is asserting a recognized state tort claim").

[4] The Ninth Circuit has also preempted federal Lanham Act claims premised on alleged FDCA violations without a prior FDA determination, though it cast the "conflict" rationale as a function of the "exclusivity" rationale. *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010) This confuses the FDA's exclusive right to bring suit to restrain FDCA violations with its right to determine the existence of violations free from a conflicting court ruling.

[5] *Cf. Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 943-44 (8th Cir. 2011) (holding prior FDA determination of drug "adulteration" meant state law claims were "grounded in the agency's explicit actions" and thus the plaintiff "would be able to establish causation without second-guessing the FDA's decisionmaking or overburdening its personnel.").

Stengel*:* Buckman *Preempts Certain Traditional State Law Claims Alleging FDCA Violations, Even When the FDA Has Already Determined the Violations to Exist*. On the other end of the spectrum is the Ninth Circuit's opinion in *Stengel*, the only federal appellate case to find *Buckman*'s exclusivity rationale preempts traditional state law claims alleging FDCA violations even when the FDA has already determined the violations to exist.[6] There, the plaintiffs sought leave to assert a failure-to-warn claim alleging Medtronic's "failure to report information to the FDA, as was required by FDA regulations." The district court denied leave because the claim was impliedly preempted.

On appeal, the plaintiffs argued *Buckman* was distinguishable because "it only requires preemption of fraud-on-the-FDA-type claims where the FDA has not previously determined that the manufacturer violated federal reporting requirements," whereas they had an FDA warning letter identifying the same violations they alleged. The court rejected this distinction because it was based on the *Buckman* concurrence's rationale. The majority rationale "was not solely based on a desire to avoid jurors second-guessing the FDA's decision making; it was also based on the idea that state fraud-on-the-FDA claims would 'exert an extraneous pull on the scheme established by Congress,' in which the FDA was supposed to enforce the FDCA's disclosure requirements."

The *Stengel* court pointed out a circuit split regarding whether *Buckman* preempts failure-to-warn claims, aligning itself with the Eighth Circuit and explaining why the Fifth Circuit's countervailing view was unpersuasive. It concluded by "recogniz[ing] that it may seem harsh to deny compensation to a person who alleges serious injury from a medical device. But such is the direction from the Supreme Court for cases like the one before us. We are required to follow the Court." The Ninth Circuit later granted rehearing *en banc*.

Observations

Stengel's specific identification of a circuit split and blame for its harsh result on Supreme Court jurisprudence seems a calculated attempt by the three-judge panel to draw the high court's attention. If so, its odd interpretation of *Buckman* was counterproductive because it instead attracted the attention of its own *en banc* panel. To be sure, *Stengel* was within Ninth Circuit precedent such as *Kimmel* in noting that *Buckman* was animated by more than a "conflict" rationale. But to the extent *Stengel*'s appropriation of *Buckman*'s "extraneous pull" language is meant to invoke its "exclusivity" rationale in preempting a traditional state law claim, *Stengel* seems to misapply *Buckman*. The "exclusivity" rationale is rooted in the FDCA's ban on private lawsuits filed to enforce the MDA. It therefore preempts "fraud-on-the-FDA" claims because they are essentially "proceedings for the enforcement, or to restrain violations, of [the FDCA]." This, combined with *Buckman*'s distinction of "fraud-on-the-FDA" claims from traditional state law claims, suggests that its "exclusivity" rationale does not apply to *Stengel*'s state-law failure-to-warn claim. As a result, *Stengel*'s appropriation of *Buckman*'s "extraneous pull" language cannot invoke its "exclusivity" rationale, and thus appears a make-weight attempt to justify *Stengel*'s refusal to recognize the limits of the "conflict" rationale.

Moreover, *Stengel*'s disregard for the FDA's prior determination of the alleged regulatory violation makes it an outlier in its own circuit. The Ninth Circuit has long acknowledged, in cases like *Kimmel* and *PhotoMedex*, that state law claims alleging regulatory violations are only preempted under *Buckman* if the federal regulatory agency has not previously determined the violation alleged. This disjunction with prior authority may well have been the reason for rehearing, in which case any resulting *en banc* opinion will likely pull *Stengel* back in line with Ninth Circuit precedent. Even so, however, some form of circuit split regarding the proper application of *Buckman*'s "conflict" rationale will continue. There thus remains room for the Supreme Court to intervene and provide the clarity that the *Buckman* implied preemption doctrine sorely needs.

[6] The Eighth Circuit applied the same rationale, but without specifically discounting a prior FDA determination. *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205-06 (8th Cir. 2010) (finding state law claims alleging failure to provide FDA with sufficient information were "simply an attempt by private parties to enforce the MDA").