THE U.S. SUPREME COURT EXPANDS THE SCOPE OF FEDERAL PREEMPTION OF PRODUCTS LIABILITY CLAIMS INVOLVING FDA-REGULATED PRODUCTS

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The Food and Drug Administration[1] enjoys broad authority under the Food, Drug and Cosmetic Act.[2] The FDA has used that authority to promulgate detailed regulations governing the approval, availability, and marketing of a wide variety of consumer products, such as drugs, medical devices, and radiation-emitting devices. These regulations often impose strict mandates at every stage of product development. For example, the FDA will frequently regulate experimental testing and safety and efficacy protocols. It may also regulate postmarketing product supervision and the content of warnings, labels, and advertisements. Congress has directed the FDA to enforce this regulatory scheme with a "balanced mission" of ensuring: (1) "that unsafe or ineffective products are not marketed"; (2) "the timely availability of safe and effective products that will benefit the public"; and (3) "that our Nation continues to lead the world in new product innovation and development."[3]

Over the years, the courts have struggled with how to resolve potential conflicts between the FDA's federal regulatory scheme and state law governing products liability tort claims. Consequently, these courts have reached decidedly mixed results on the issue. For example, courts have dismissed numerous claims involving medical devices under an express federal preemption provision in the FDCA. But the U.S. Supreme Court's

1. Hereinafter FDA.
2. 21 U.S.C. §§ 301, 392 (2000) [hereinafter FDCA].
3. Food and Drug Administration Modernization Act of 1997, S. Rep. No. 105–43, 106th Cong. (enacted), *reprinted in* 1997 WL 394244, at *2–*6 (1997).

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sharply divided 1996 decision in *Medtronic, Inc. v. Lohr*.[4] has led to confusion over the FDCA's reach. Furthermore, courts have offered only limited analysis of whether and when federal law impliedly preempts FDA products liability claims asserted under state law. Such preemption can be based either on the FDA's extensive product-regulation powers or on the conflict between state tort law determinations and the FDA's regulatory objectives.[5] The courts' failure to provide any clear guidance on implied preemption has been particularly significant with respect to prescription drugs, in large part because the FDCA prescription drug provisions, which predate those governing many other FDA-regulated products, do not contain an express preemption provision.

On February 21, 2001, the U.S. Supreme Court issued a landmark opinion in which it applied, for the first time, the implied preemption doctrine to a products liability claim involving an FDA-regulated product.[6] The Court held that state tort law claims alleging that a manufacturer had made misrepresentations to, or concealed information from, the FDA conflicted with the FDA's regulatory scheme, and were impliedly preempted.[7] At a minimum, *Buckman* should signal the death knell of an increasingly popular plaintiffs' tactic of asserting fraud to avoid the implications of the FDA approving an alleged defective product or label. The Court's reasoning, however, suggests that the opinion will have broader implications. By emphasizing the conflict between state tort law and the FDA's ability to carry out its delicate balance of regulatory objectives, *Buckman* may significantly expand federal preemption over any number of state tort law claims that would have a jury second-guessing FDA regulatory determinations.[8]

This article discusses the future of preemption of FDA-related products liability actions following *Buckman*. Section I reviews Supreme Court preemption law in products liability/personal injury litigation during the past twenty years and traces the Court's evolving consensus toward a guiding principle of conflict analysis. Section II focuses on the *Buckman* decision itself and the Court's recognition of and deference to the FDA's balanced

4. 518 U.S. 470 (1996).

5. *See* Hurley v. Lederle Labs., *as amended on denial of reh'g*, 863 F.2d 1173, 1179 (5th Cir. 1989) (inadequate-warning claim with respect to DPT vaccine would be impliedly preempted if it required a warning different from that approved and required by FDA); R.F. v. Abbott Lab., 745 A.2d 1174 (N.J. 2000) (holding that failure-to-warn claim against manufacturer of HIV blood screening test was impliedly preempted); Schiffner v. Motorola, Inc., 697 N.E.2d 868 (Ill. Ct. App. 1998) (state tort law claims against manufacturer of cellular telephone impliedly preempted due to FDA's authority to set standards for such products under the Electronic Product Radiation Control Act), *appeal denied*, 705 N.E.2d 449 (Ill. 1998), *cert. denied*, 526 U.S. 1017 (1999).

6. Buckman Co. v. Plaintiffs' Legal Comm., 121 S. Ct. 1012 (2001).

7. *Id.* at 1014.

8. *Id.*

regulatory objectives. Section III analyzes the impact of various state common law tort claims on the FDA's ability to pursue its regulatory objectives and the expanded scope of preemption that should now apply to such claims.

I. U.S. SUPREME COURT PREEMPTION OF COMMON LAW TORT CLAIMS PRIOR TO *BUCKMAN*

Over the past twenty years, the U.S. Supreme Court has issued a number of sharply divided opinions in which it sought to provide guidance as to when state common law products liability/personal injury claims should be preempted by federal law. While the opinions involved claims of both express and implied preemption arising under a variety of different federal regulatory regimes, the Court's analyses suggested an emerging rule that such claims should be preempted if they would interfere with federal regulatory objectives or determinations.

The Court first addressed the question of implied conflict preemption of a common law personal injury claim in *Silkwood v. Kerr-McGee Corp.*[9] In *Silkwood*, the owner of a nuclear energy plant argued that a punitive damages claim brought by a former worker exposed to plutonium was impliedly preempted based on the Nuclear Regulatory Commission's[10] exclusive regulatory authority over the safety aspects of nuclear development under the Atomic Energy Act. The U.S. Supreme Court recognized that a common law tort claim could be preempted "to the extent it actually conflicts with federal law . . . or where [it] stands as an obstacle to the accomplishment of the full purposes and objectives of Congress."[11] The Court also recognized that there was "a tension between the conclusion that safety regulation is the exclusive concern of the federal government and the conclusion that a state may nonetheless award damages based on its own law of liability."[12] Nonetheless, in a five-to-four decision, the Court held that the punitive damages claim at issue was not preempted.

The five-Justice majority based their holding on legislative history that indicated that Congress had affirmatively intended for state tort law remedies to exist in tandem with the NRC's federal regulatory authority "and to tolerate whatever tension there was between them."[13] The Court's hold-

9. 464 U.S. 238 (1984).
10. Hereinafter NRC.
11. *Silkwood*, 464 U.S. at 248.
12. *Id.* at 256.
13. *Id.*; *see* English v. Gen. Elec. Co., 496 U.S. 72, 86 (1990) (noting that decision in *Silkwood* was based in "substantial part" on affirmative evidence in the legislative history suggesting that Congress did not intend to include common law damages remedies within the preempted field).

ing is accordingly limited to "the circumstances of th[at] case."[14] However, the majority's recognition that state tort law personal injury claims could be impliedly preempted due to conflicts with a federal regulatory scheme, and the four dissenting Justices' more thorough analysis of the potential conflicts,[15] provided some indication that the Court would be receptive to such arguments in other cases.

The Court returned to the question of federal preemption of a personal injury tort claim eight years later in *Cipollone v. Liggett Group, Inc.*[16] *Cipollone* involved a variety of personal injury tort claims brought against tobacco companies by the son of a smoker who died of lung cancer. The tobacco companies argued that the plaintiffs' claims were expressly preempted by two successive federal statutes that dictated warnings that were to appear on cigarette packages and advertisements. As it had in *Silkwood*, the Court found that state common law claims could be preempted by federal law, noting that "state regulation can be as effectively exerted through an award of damages as through some form of preventive relief" and that "[t]he obligation to pay compensation can be, and is designed to be, a potent method of governing conduct and controlling policy."[17]

The Court divided sharply, however, on how preemption should be applied in that case. The four-Justice plurality focused their analysis on the language of the express preemption provisions in the statutes at issue, finding that "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not preempted."[18] The plurality held that express preemption provisions should be read "narrow[ly] . . . in light of the presumption against the pre-emption of state police powers," and proceeded with a claim-by-claim analysis in which they held preempted only those claims that were "inextricably intertwined" with claims of inadequate warnings or advertisements specifically covered by the second statute's express preemption provision.[19] The plurality's claim-by-claim analysis was rejected by the remaining five Justices, three of whom argued against preemption of any of plaintiffs' claims, and two of whom argued for preemption of all of plaintiffs' claims.

14. *Silkwood*, 464 U.S. at 256 ("We do not suggest that there could never be an instance in which the federal law would preempt the recovery of damages based on state law.").

15. *See id.* at 265 (Blackmun, J., dissenting) ("It is incredible to suggest that Congress intended the Federal Government to have the sole authority to set safety regulations, but left intact the authority of States to require adherence to a different state standard through the imposition of jury fines."); *id.* at 282 ("It is not reasonable to infer that Congress intended to allow juries of lay persons, selected essentially at random, to impose unfocused penalties solely for the purpose of punishment and some undefined deterrence. These purposes wisely have been left within the regulatory authority of the NRC.").

16. 505 U.S. 504 (1992)

17. *Cipollone*, 505 U.S. at 521.

18. *Id.* at 517.

19. *See id.* at 527.

Although disagreeing on the end result, the five dissenting Justices agreed that the plurality's attempt to narrowly construe the express preemption provisions had resulted in a patchwork analysis devoid of any consistent underlying principle.[20]

The U.S. Supreme Court next addressed this preemption issue in *Lohr*.[21] In *Lohr*, the manufacturer of a pacemaker argued that the plaintiff's personal injury claims were expressly preempted under the Medical Device Amendments of 1976[22] based on the FDA's regulatory review of the pacemaker. As in *Silkwood* and *Cipollone*, the Court issued a sharply divided opinion, with four Justices arguing against preemption, four Justices arguing for preemption, and one Justice arguing against preemption based on the specific facts at issue. Unlike in *Cipollone*, however, the Justices appeared to be in agreement on an underlying principle that should guide the preemption analysis. Returning to the doctrine of implied conflict preemption discussed in *Silkwood*, all nine of the Justices sought to explain their preemption decision by focusing on whether the state tort law claims at issue would conflict with the FDA's exercise of regulatory authority over the medical device at issue.

In finding no express preemption, the four-Justice plurality reiterated the argument made by the plurality in *Cipollone* that "express preemption provisions in federal statutes should be construed narrowly and in light of a presumption against preemption."[23] The plurality then focused, however, not on the specific words of the MDA's preemption provision,[24] but on the fact that the FDA's § 510(k) review of the medical device at issue did not involve any specific regulatory determinations of safety and efficacy that would conflict with state tort law claims:[25]

> The generality of those requirements makes this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or

20. *See id.* at 542–43 (Blackmun, J., concurring in part, dissenting in part) ("the plurality proceeds to create a crazy quilt of pre-emption from among the common-law claims implicated in this case, and in so doing reaches a result that Congress surely could not have intended"); *id.* at 553 (Scalia, J., concurring in part and dissenting in part) ("Once one is forced to select a *consistent* methodology for evaluating [issues of preemption] . . . it becomes obvious that the methodology must focus not upon the ultimate source of the duty (*e.g.*, the common law) but on its proximate application") (emphasis in original).

21. 518 U.S. 470 (1996).

22. 21 U.S.C. § 360 (2001) [hereinafter MDA].

23. *Lohr*, 518 U.S. at 485.

24. *See id.* at 486 (express preemption analysis should consider "the structure and purpose of the statute as a whole, as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law") (citation omitted).

25. *See id.* at 491–92.

> set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.[26]

Justice Breyer, who cast the deciding vote against preemption in a separate concurrence, likewise focused on the lack of conflict between the state tort law claims and the FDA's limited § 510(k) review of the allegedly defective pacemaker. Justice Breyer made clear, however, that state common law claims should be preempted if they frustrate or stand in conflict with specific FDA regulatory determinations regarding a product.[27] Justice Breyer explained his reasoning by way of the following example:

> Imagine that, in respect to a particular hearing aid component, a federal MDA regulation requires a 2-inch wire, but a state agency regulation requires a 1-inch wire. If the federal law, embodied in the "2-inch" agency regulation, pre-empts that state "1-inch" agency regulation, why would it not similarly pre-empt a state-law tort action that premises liability on the defendant manufacturer's failure to use a 1-inch wire (say, an award by a jury persuaded by expert testimony that the use of a more than 1-inch wire is negligent)?[28]

The four dissenting Justices, while arguing that the preemption analysis should be limited to a strict interpretation of the language of the MDA's preemption provision, likewise rely in their claim-by-claim analysis on their assessment whether the claim at issue conflicts with the federal regulatory scheme.[29]

The U.S. Supreme Court's endorsement of conflict analysis as the guiding principle of preemption was strengthened in *Geier v. American Honda Motor Co.*[30] In *Geier*, an injured motorist sued an automobile manufacturer for failing to equip its automobile with airbags. The automobile manufacturer argued that the plaintiff's claims were both expressly and impliedly preempted. In a five-to-four opinion, the Court held that plaintiff's claims were not expressly preempted, holding that a savings clause limited the scope of the express preemption provision in the National Traffic and Motor Vehicle Act.[31] However, in a clear departure from *Cipollone*, the Court held that the existence of an express preemption provision does not preclude preemption under ordinary principles of implied conflict preemption.[32]

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26. *Id.* at 501.
27. *See id.* at 507–08 (arguing that express preemption provision should be read in light of basic principle of implied conflict preemption).
28. *Id.* at 504–05 (Breyer, J., concurring in part and concurring in the judgment).
29. *See id.* at 513–14.
30. 529 U.S. 861 (2000).
31. *Geier*, 529 U.S. at 867.
32. *Id.* at 871 ("Why, in any event, would Congress not have wanted ordinary pre-emption principles to apply where an actual conflict with a federal objective is at stake? Some such principle is needed.").

The Court's implied conflict preemption analysis built upon many of the arguments that had been identified sixteen years earlier in *Silkwood*. The Court rejected the arguments pressed by plaintiff and the dissent[33] that the Department of Transportation[34] regulation requiring passive restraint systems in automobiles set only a minimum standard and that state common law claims alleging a higher safety standard were consistent with the DOT's goals.[35] Instead, the Court determined that plaintiff's allegation that the automobile manufacturer should be held liable in failing to go beyond the requirements of the DOT regulation claims would impermissibly interfere with the DOT's balanced regulatory scheme that sought "a gradual phase-in of passive restraints" and "a mix of several different passive restraint systems."[36] The Court held plaintiff's claims preempted despite the fact that the only piece of legislative history discussing the potential of tort liability based on an automobile manufacturer's selection of a passive restraint system appeared to assume that such claims would not be preempted.[37]

Thus, by 2001, when the Court confronted *Buckman*, the Court had begun to coalesce around a guiding principle of federal preemption that focused not on express preemption language or legislative history but on an analysis of the federal regulatory goals and the degree to which state common law claims would stand as an obstacle to those goals. With the Court's unanimous ruling in *Buckman*, this principle is now firmly established.

II. THE *BUCKMAN* DECISION

In *Buckman*, the U.S. Supreme Court addressed a split among the federal circuit courts[38] regarding whether the MDA preempted "fraud on the FDA" claims involving medical devices, under the MDA's express preemption provision. The split reflected a general confusion in the courts over the scope of the MDA's express preemption clause in the wake of the U.S. Supreme Court's 1996 *Lohr* decision.[39]

In *Buckman*, the solicitor general appeared as amicus curiae to represent the FDA's views and convinced the U.S. Supreme Court not to address

33. *See id.* at 902.
34. Hereinafter DOT.
35. *Geier*, 529 U.S. at 874.
36. *Id.* at 878.
37. *See id.* 892 n.5, 910.
38. *Compare*, *e.g.*, Kemp v. Medtronic, Inc., 231 F.3d 216 (6th Cir. 2000) ("fraud on the FDA" claim expressly preempted) *with In re* Orthopedic Bone Screw Prod. Liab. Litig., 159 F.3d 817, 821–22 (3d Cir. 1998) ("fraud on the FDA" claim not expressly preempted), *rev'd sub nom.* Buckman Co. v. Plaintiffs' Legal Comm., 121 S. Ct. 1012 (2001).
39. *See Kemp*, 231 F.3d at 224 ("[t]he various courts of appeals that have confronted issues of preemption arising under the MDA have struggled mightily with *Lohr*'s language in the effort to discern its holding").

the narrow issue of express preemption under the MDA but instead to consider whether federal law should impliedly preempt "fraud on the FDA" claims because they conflict with FDA regulatory authority and flexibility. The U.S. Supreme Court's analysis thus turned on whether the state tort law claim would contravene specific federal regulatory determinations or stand as an obstacle to the FDA's ability to carry out its regulatory responsibilities. Under the implied preemption doctrine, the Court previously held that state law can be preempted, even where Congress has not evidenced an intent to entirely occupy a given field: "state law is still preempted to the extent it actually conflicts with federal law, that is, when it is impossible to comply with both state and federal law, or where the state law stands as an obstacle of the full purposes and objectives of Congress."[40] The Court had further held that where a private plaintiff's arguments "would permit common-law actions that 'actually conflict' with federal regulations, it would take from those who would enforce a federal law the very ability to achieve the law's congressionally mandated objectives that the Constitution, through the operation of ordinary pre-emption principles, seeks to protect."[41]

The Court held in *Buckman* that federal law impliedly preempted the plaintiffs' "fraud on the FDA" claims because the defendant's "dealings with the FDA were prompted by the MDA, and the very subject matter of [defendant's] statements [was] dictated by that statute's provisions."[42] In such circumstances, the Court explained, "no presumption against preemption obtains."[43] The Court's deference to the FDA regulatory process was particularly noteworthy because the FDA had approved the medical device at issue in *Buckman* under the FDA's § 510(k) process,[44] which allows companies to market medical devices upon a relatively simple showing of substantial equivalence to "grandfathered" products on the market prior to the MDA enactment. As the Court recognized, the § 510(k) process "lacks the . . . rigor" of other FDA regulatory schemes, which require safety and efficacy determinations.[45] For example, although the § 510(k) FDA review process takes only twenty hours, an FDA safety and efficacy review of a medical device under the "premarket approval process"[46] takes up to 1,200 hours.[47] Likewise, new drug applications "typically run to hundreds of thousands of pages," and the process of securing FDA approval for a

40. Silkwood v. Kerr McGee Corp., 464 U.S. 238, 248 (1984) (citations omitted).
41. Geier v. Am. Honda Motor Co., 529 U.S. 861, 872 (2000).
42. *Buckman*, 121 S. Ct. at 1017.
43. *Id.*
44. *Id.*
45. *Id.*
46. Hereinafter PMA.
47. Medtronic, Inc. v. Lohr, 518 U.S. 470, 478–79 (1996).

prescription drug "takes an average of 15 years and costs in the range of $500 million."[48]

Notwithstanding the more limited scope of FDA regulatory oversight of § 510(k) devices, the Court held in *Buckman* that plaintiffs' allegations conflicted with federal law in two ways.[49] First, the allegations intruded upon the FDA's authority to determine what information is relevant and appropriate in deciding whether FDA-regulated products should be made available to the public.[50] As the Court explained, allowing private litigants to seek damages based on "fraud on the FDA" arguments would cause manufacturers "to fear that their disclosures to the FDA, although deemed appropriate by the Agency, would later be judged insufficient in state court."[51] Such state tort law claims would deprive the FDA of control over its regulatory responsibilities, both by "dramatically increasing the burdens" facing regulated entities that would be forced to "comply[] with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes" and by imposing "additional burdens" on the FDA, because regulated entities would "have an incentive to submit a deluge of information that the Agency neither wants nor needs."[52] Second, the "fraud on the FDA" claims deprived the FDA of the "flexibility" to respond to such alleged misconduct as it deems appropriate, which the Court held to be "a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives."[53] This conflict "stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Agency and that this authority is used by the Agency to achieve a somewhat delicate balance of statutory objectives."[54] The Court cautioned that the FDA's delicate balance "can be skewed by allowing fraud on the FDA claims under state tort law."[55]

The *Buckman* analysis underscores the fundamental difference between the goals of state tort law and the federal regulatory scheme.[56] Although state tort law focuses on safety issues with respect to a particular adverse effect and on an individual plaintiff, the FDA is charged with protecting

48. Food and Drug Administration Modernization Act of 1997, S. Rep. No. 105–43, 106th Cong. (enacted), *reprinted in* 1997 WL 394244, at *6 (1997).
49. Buckman Co. v. Plaintiffs' Legal Comm., 121 S. Ct. 1012, 1018–19 (2001).
50. *Id.*
51. *Id.* at 1019.
52. *Id.* at 1018–19.
53. *Id.* at 1018.
54. *Id.* at 1017.
55. *Id.*
56. *See also* Broderick v. Sofamor Danek Group, Inc., No. 95–8644, 1999 WL 1062135, at *7 (S.D. Fla. Apr. 9, 1999) (noting that products liability plaintiffs "do not represent the interests of the FDA").

all patients' health and welfare, both by ensuring the relative safety and efficacy of drugs and medical devices and by making sure that those products are made available in a manner that will not impede necessary medical care. As Congress recently instructed in drafting a mission statement for the FDA: "[T]he agency should be guided by the principle that expeditious approval of useful and safe new products enhances the health of the American people. Approving such products can be as important as preventing the marketing of harmful or ineffective products."[57] In pursuing this mission, the FDA has been charged by Congress to "promptly and efficiently review[] clinical research and tak[e] appropriate action on the marketing of regulated products in a manner which does not unduly impede innovation or product availability."[58] Accordingly, to the extent that state tort law claims stand as an obstacle to the FDA's balanced mission, implied preemption applies.

III. THE IMPLICATIONS OF *BUCKMAN* ON PRODUCTS LIABILITY CLAIMS INVOLVING FDA-REGULATED PRODUCTS

Although the U.S. Supreme Court's holding in *Buckman* addressed a specific "fraud on the FDA" claim under the MDA, the Court's implied preemption analysis is applicable to a wide variety of state tort law allegations involving all types of FDA-regulated products. At the very least, *Buckman* should preclude any reliance on "fraud on the FDA" allegations, whether in support of specifically entitled "fraud on the FDA" claims or in support of differently labeled state tort law claims that rely on those allegations. But the plain import of the Court's reasoning reaches well beyond "fraud on the FDA." Particularly with regard to prescription drugs, Class III medical devices, and other products subject to FDA safety and efficacy determinations, the FDA routinely dictates much of the conduct that later forms the basis for state tort law claims. These claims conflict with specific FDA regulatory determinations and, under the reasoning of *Buckman*, should be preempted.

A. *State Tort Law Claims Premised on "Fraud on the FDA" Allegations*

"Fraud on the FDA" allegations are based on the premise that but for alleged misrepresentations to or concealments from the FDA, the FDA would have taken action that would have prevented a private litigant from being injured by a drug or medical device. Plaintiffs can package such allegations in a number of ways. First, they can bring a claim expressly styled "fraud on the FDA." Second, they can bring claims of indirect fraud,

57. Food and Drug Administration Modernization Act of 1997, S. REP. No. 105–43, 106th Cong. (enacted), *reprinted in* 1997 WL 394244, at *8 (1997).
58. *Id.* at *2.

negligent misrepresentation, or concealment with respect to their physicians. To support such claims, plaintiffs will argue that physicians were misled because the physicians relied upon communications made through the defrauded FDA. Third, plaintiffs can bring inadequate-warning claims, arguing that but for the "fraud on the FDA," the FDA would not have approved the label at issue.

As a practical matter, these differently named causes of action are indistinguishable. Any argument that plaintiffs can avoid *Buckman*'s preemption analysis simply by placing a different label on their "fraud on the FDA" arguments would render *Buckman* a nullity. The key danger giving rise to conflict with federal law is not the existence of a "fraud on the FDA" claim per se, but the possibility that a jury will impose damages under state tort law premised on the argument that the FDA was defrauded.[59]

A simple example can demonstrate why preemption is required under *Buckman* for all claims premised on "fraud on the FDA" allegations. Suppose that a plaintiff alleges that a manufacturer defrauded the FDA by concealing postmarketing "adverse drug experience reports"[60] from the FDA, and that "but for" this "fraud on the FDA," the FDA would have required stronger warning language on the drug's label. *Buckman* expressly precludes such "but for" reasoning.[61] In such cases, plaintiffs' "fraud on the FDA" claim is plainly preempted. But what if the plaintiff instead brings a claim for failure to warn? For a jury to find for the plaintiff based on allegedly concealed ADEs, for example, it would be required to decide the very same questions at issue in the "fraud on the FDA" claim: Was the FDA defrauded; "but for" the fraud, would the FDA have required a stronger warning; and what action should be taken against the drug company in response to the fraud? Likewise, each of the conflicts discussed in *Buckman* will remain. Drug manufacturers faced with these failure-to-warn claims will, as a practical matter, be forced to report all ADEs, including those that federal regulations instruct not be reported, so as to comply with tort regimes in the fifty states. Such a reporting requirement will "dramatically increase the burdens" accompanying the marketing of a prescription drug.[62] The FDA will be flooded with ADEs "it neither wants nor needs," and will be frustrated in its ability to assess the properly reportable ADEs. Further, the FDA will be deprived of its "critical . . . flexibility" in

59. *See* Cipollone v. Liggett Group, Inc., 505 U.S. 504, 521 (1992) ("[S]tate regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." (quoting San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236, 247 (1959))).

60. Hereinafter ADE.

61. *See* Buckman Co. v. Plaintiffs' Legal Comm., 121 S. Ct. 1012, 1015 (2001).

62. *See* 21 C.F.R. § 314.80 (1999) (establishing limitations on which ADEs should be reported).

addressing claims of inadequate ADE reporting, determining the significance (or lack thereof) of the alleged inadequate reporting, and balancing the importance of including this information on the label against its regulatory responsibility to not "unduly impede . . . product availability."[63]

The fallacy of any argument distinguishing specific "fraud on the FDA" claims from the failure-to-warn claim, or from similar tort claims premised on alleged FDA fraud, is explained in *Kemp v. Medtronic, Inc.*,[64] the only lower court preemption opinion cited in *Buckman*.[65] In *Kemp*, plaintiffs alleged that the defendant failed to submit certain information to the FDA, including animal studies and clinical data, regarding a Model 4004M pacemaker lead that the FDA initially deemed as safe and effective.[66] In their complaint, the plaintiffs did not bring a claim entitled "fraud on the FDA"; instead, they brought a claim of fraud on plaintiffs and their physicians. In finding that federal law expressly preempted these claims, the court found this distinction to be irrelevant:

> [T]o prove the falsity of Medtronic's representation . . . plaintiffs must establish that the Model 4004M was falsely represented to be safe and effective—the very determination made by the FDA in granting PMA approval. Consequently, although plaintiffs' Count VII claim does not expressly allege "fraud on the FDA," such claim is necessarily implied in plaintiffs' allegations.[67]

The court further held in *Kemp* that the same "fraud on the FDA" preemption analysis precluded plaintiffs' warnings claim: "[T]o the extent that plaintiffs' claim is premised on the adequacy of the warnings reviewed and approved by the FDA, our analysis of the 'fraud on the FDA' claim applies equally to the failure to warn claim, and that claim is similarly preempted."[68]

The FDA has reached the same conclusion. In *Buckman*, the U.S. Supreme Court invited the solicitor general to appear as amicus curiae to

63. *See Buckman*, 121 S. Ct. at 1018–19; Food and Drug Administration Modernization Act of 1997, S. Rep. No. 105–43, 106th Cong. (enacted), *reprinted in* 1997 WL 394244, at *8 (1997).

64. 231 F.3d 216 (6th Cir. 2000).

65. *Buckman*, 121 S. Ct. at 1017.

66. *Kemp*, 231 F.3d at 234.

67. *Id.* at 234 n.14.

68. *Id.* at 236. Other federal courts have likewise recognized that claims styled "fraud on the FDA" cannot be separated, in the context of a preemption analysis, from claims of misrepresentations or inadequate warnings to physicians or the public that are dependent on or derivative of federally regulated dealings with the FDA. *See* King v. Collagen Corp., 983 F.2d 1130, 1140 n.8 (1st Cir. 1993) ("Plaintiff similarly presents a claim for misrepresentation, both to the public and to plaintiff's physician. As the record shows no statements to the public or physicians that go beyond those approved by the FDA, this claim collapses into that of fraud on the FDA."), *cert. denied*, 510 U.S. 824 (1993); Carey v. Shiley, Inc., 32 F. Supp. 2d 1093, 1106–08 (S.D. Iowa 1998) (holding that claims alleging "fraud on the FDA," physicians, and the general public during and after the premarket approval process preempted).

present the FDA's view on the proper scope of preemption, if any, in claims based on "fraud on the FDA" arguments. During oral argument, the U.S. Supreme Court pressed the solicitor general specifically on the question of whether preemption should be limited solely to claims styled "fraud on the FDA." The solicitor general made clear the FDA's position that all state tort law claims premised on alleged fraudulent dealings with the FDA should be preempted:

> Q: Assume the FDA concluded that its processes had been corrupted by the acts of fraud, and so forth and so on. Is there any way the FDA could give a remedy to people who were injured by that fraud?
>
> . . .
>
> A: Well, let me just continue. The fraud claim is preempted, but if there is negligent design, negligent manufacturing, failure to warn, common law malpractice, all those claims are available, but insofar as they would be asserting an essential element of the claim . . . that the FDA was defrauded, that is an area of exclusive Federal concern, and the State common law cause of action would be preempted.[69]

The Court has previously held that the FDA's preemption analysis is entitled to significant deference.[70] The analysis that the solicitor general offered on the FDA's behalf should guide future court opinions applying *Buckman*.

B. *State Tort Law Claims Premised on a Second-Guessing of FDA Determinations*

Buckman holds that federal law impliedly preempts "fraud on the FDA" allegations because a defendant's "dealings with the FDA [a]re prompted by the MDA and the very subject matter of [defendant's] statements [a]re dictated by that statute's provisions."[71] This same reasoning applies to a variety of state tort law claims involving FDA-regulated products that would require a jury to second-guess a specific regulatory determination through which the FDA dictated the very conduct alleged to be tortious. Such claims should also be preempted under *Buckman*.[72]

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69. *Buckman* Oral Arg. Official Transcript, 2000 WL 1801621, at *20–*21.

70. *See* Geier v. Am. Honda Motor Co., 529 U.S. 861, 882–83 (2000) (agency position as expressed by solicitor general in amicus brief entitled to deference); *see also* Hillsborough County v. Automated Med. Lab., Inc., 471 U.S. 707, 714 (1985) (considering FDA understanding of preemptive effect of its regulations "dispositive").

71. Buckman Co. v. Plaintiffs' Legal Comm., 121 S. Ct. 1012, 1017 (2001).

72. The U.S. Supreme Court's 1996 decision in *Lohr* is not to the contrary. The Court's rejection of the express preemption argument in that case was based on the general nature of the § 510(k) regulatory scheme there at issue. As the plurality opinion explained in voicing the views of the four Justices most strongly opposed to preemption:

Returning to the example of failure to warn, suppose that the plaintiffs do not premise their claim on "fraud on the FDA" but do allege that a drug label that the FDA approved is inadequate under state tort law. As *Buckman* recognizes, in approving the drug label, the FDA engaged in a "delicate balancing of statutory objectives," which ensures both the safety and efficacy of the drug and the drug's timely availability in a fashion that will not "intrud[e] upon [medical] decisions statutorily committed to the discretion of health care professionals."[73] A jury considering state tort law is not guided by this same balancing of regulatory objectives. Even if it were, it would not balance the objectives in the same way as the FDA. Furthermore, the manufacturer defending the adequacy of its drug warnings will be faced with the prospect of inconsistent jury verdicts in fifty states. By their very nature, such verdicts will conflict with the FDA's objective of creating uniform, nationwide standards for regulated products.[74] As a result, a drug manufacturer's labeling decision will no longer be guided by the FDA or by the balanced regulatory objectives that Congress has set forth. Instead, a drug company will base its labeling decision, at least in part, on state tort law, to the detriment of the FDA's regulatory authority and flexibility.[75]

This same conflict analysis has led numerous courts to hold that the MDA's preemption provision expressly preempts state tort law claims involving medical devices regulated under the strict PMA review. The provision requires preemption of state common law claims that are "different from, or in addition to, any requirement applicable under this chapter."[76]

> The generality of those requirements make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.

Medtronic, Inc. v. Lohr, 518 U.S. 470, 501 (1996). *See infra* note 48 (courts applying *Lohr* in cases involving the more stringent PMA regulatory scheme have repeatedly preempted many, if not all, of plaintiffs' state tort law claims).

73. *Buckman*, 121 S. Ct. at 1017–18.

74. Talbott v. C.R. Bard, Inc., 63 F.3d 25, 29 (1st Cir. 1995), *cert. denied*, 517 U.S. 1230 (1996); *see also Geier*, 529 U.S. at 871 ("the rules of law that judges or juries create or apply in such suits may themselves create uncertainty and even conflict, say, when different juries in different States reach different conclusions on similar facts").

75. *See Buckman*, 121 S. Ct. at 1018 ("As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA and the MDA.").

76. 21 U.S.C. § 360k(a); *see Lohr*, 518 U.S. at 507–08 (Breyer, J., concurring) (finding that MDA express preemption provision should be read in light of basic conflict preemption principles). *See, e.g.*, Kemp v. Medtronic, Inc., 231 F.3d 216 (6th Cir. 2000) (negligence per se, fraud, and warning claims preempted); Mitchell v. Collagen Corp., 126 F.3d 902 (7th Cir. 1997) (strict liability, negligence, mislabeling, misbranding and adulterating, fraud, implied

The argument for implied preemption of state tort law claims involving FDA-regulated products is now stronger than the express preemption argument relied upon in those cases. Although the express preemption cases depended on a parsing of the U.S. Supreme Court's sharply divided *Lohr* decision, the argument for implied preemption builds on a unanimous ruling in *Buckman*, and the clear and sweeping language of a seven-Justice opinion. In addition, while defendants arguing for express preemption had to overcome a presumption against preemption, no such presumption follows under the *Buckman* holding.[77] Also, as the U.S. Supreme Court recognized in *Geier*, the implied preemption doctrine often sweeps more broadly than that of express preemption, which is limited by the language of the express preemption provision.[78]

A defendant can argue that all state tort law claims involving FDA products subject to specific FDA regulatory determinations should be impliedly preempted because they "stand[] as an obstacle of the full purposes and objectives of Congress" in empowering the FDA to pursue its delicate balance of regulatory objectives. The argument for implied preemption following *Buckman* will be particularly strong where a plaintiff's common law cause of action would require a state jury to second-guess a specific FDA regulatory determination. Therefore, for example, the case for implied preemption of an inadequate-warning claim may be stronger where evidence exists that the FDA was engaged in ongoing discussions regarding the labeling with the drug manufacturer and did not require the changes that plaintiffs allege were necessary. Likewise, a state tort law claim for fraud on a physician should be preempted if it is based on a drug advertisement or a "Dear Doctor" letter that the FDA approved.

Given the extensive nature of FDA regulations, the circumstances under which such direct conflicts will occur are legion. With respect to prescription drugs, for example, FDA regulations dictate a drug manufacturer's actions throughout a drug's life. To obtain FDA approval to market and sell a prescription drug in the United States, a drug manufacturer must submit voluminous documents to the agency in accordance with statutory

warranty, and warning claims preempted), *cert. denied*, 523 U.S. 1020 (1998); *Talbott*, 63 F.3d at 25 (claims for negligence, breach of implied and express warranties, punitive damages, negligent infliction of emotional distress, fraudulent misrepresentation and concealment, and civil conspiracy preempted); Martello v. Ciba Vision Corp., 42 F.3d 1167 (8th Cir. 1994) (state law claims of strict liability; breach of express and implied warranties; misrepresentation; failure to warn; and negligence in design, manufacture, and labeling preempted), *cert. denied*, 515 U.S. 1161 (1995); *see also* Papike v. Tambrands, Inc., 107 F.3d 737 (9th Cir.), *cert. denied*, 522 U.S. 862 (1997) (failure-to-warn claim against tampon manufacturer preempted under MDA because federal regulation governed labeling).

77. *See Buckman*, 121 S. Ct. at 1017.

78. *See Geier*, 529 U.S. at 862 (finding that state tort law claim impliedly preempted despite inapplicability of express preemption provision).

requirements set forth in the FDCA.[79] New drug applications are subject to detailed reporting requirements addressing, inter alia, the application's format and organization, pharmacological and toxicological studies, clinical investigation data, case report forms, patent information, and marketing exclusivity issues.[80] Once the FDA has approved a drug, the manufacturer remains subject to regulations that dictate which ADEs, scientific studies, and other pieces of information should be reported to the FDA pursuant to the FDA's oversight and continued approval of the drug.[81] The FDA maintains continuing regulatory control over drug label content and format.[82] Furthermore, the FDA regulates what manufacturers are permitted to say and do in communicating with physicians about drugs, and it circumscribes manufacturers' advertising and marketing activities.[83]

Plaintiffs should not be allowed to avoid preemption due to conflicts with this regulatory scheme by arguing that FDA regulations set only minimum standards of conduct. Although such arguments have been successfully pressed in some cases in the past,[84] *Buckman* makes clear that the FDA regulatory determinations are based on a balancing of different and often competing regulatory goals. Thus, for example, in dictating the language of warning labels on a prescription drug, the FDA is charged not only with appropriately disclosing potential product health risks, but with avoiding excessive warnings that could unduly impede the availability of a drug that may provide the best possible medical care. *Buckman* thus recognizes that FDA regulations reflect not *minimum* standards but *balanced* standards that appropriately reflect the FDA's competing regulatory goals.[85]

IV. CONCLUSION

In *Buckman*, the U.S. Supreme Court made clear that state common law tort claims must yield when they conflict with the FDA's balanced regu-

79. *See* 21 U.S.C. § 355.

80. *See* 21 C.F.R. § 314.50 (2000).

81. *See* 21 C.F.R. § 314.80-.81 (2000).

82. *See* 21 C.F.R. § 201.57 (2000); *see also* 21 C.F.R. § 201 (2000).

83. *See* 21 C.F.R. § 200.5 ("Mailing of important information about drugs"), § 202 ("Prescription Drug Advertising"), and § 203 ("Prescription Drug Marketing") (2000).

84. *See* Motus v. Pfizer Inc., 127 F. Supp. 2d 1085 (C.D. Cal. 2000) (rejecting implied preemption claim based on argument that FDA regulations allow drug manufacturer to increase safety warnings without prior FDA approval). *But see* Mitchell v. Collagen Corp., 126 F.3d 902, 911 (7th Cir. 1997) (holding that failure-to-warn claim expressly preempted under MDA despite identical regulation regarding manufacturer's ability to strengthen safety warnings).

85. *See* Geier v. Am. Honda Motor Co., 529 U.S. 861, 884–85 (2000) (rejecting similar minimum standards argument and holding that state tort law claim that would require installation of airbags in all cars would stand as an obstacle to the federal government's regulatory determination to allow "a gradually developing mix of alternative passive restraint devices").

latory objectives. The Court's holding does not mean, however, that manufacturers of FDA-regulated products will not be held accountable for misconduct relating to their products. As the Court in *Buckman* explained, the FDA has significant authority to penalize such misconduct, including the authority to seize a product and pursue criminal prosecution of the wrongdoers.[86] *Buckman* holds, however, that where a state tort law claim alleges "fraud on the FDA," or would require a second-guessing of a specific FDA determination, the FDA, not a private litigant, is the proper party to determine whether the manufacturer's conduct was appropriate, and, if not, what penalties are warranted. State tort law claims that deprive the FDA of this authority and flexibility stand as an obstacle to the FDA's regulatory charge to protect the health and welfare of all Americans, and accordingly must be preempted.

86. *See* Buckman Co. v. Plaintiffs' Legal Comm., 121 S. Ct. 1012, 1018 (2001).