Drug and Medical Device Litigation

# *Buckman*—Its Impact Over a Decade Later

By John W. Elder and Taylor A. Williams

**There are many reasons to consider the impact of *Buckman* when advising clients on issues of preemption, choice of law, and pretrial motions.**

For an attorney defending a pharmaceutical or medical device manufacturer in a product liability lawsuit, having a court dismiss a plaintiff's state law tort claims based on federal preemption may seem more tantalizing than other prospects. While *Wyeth v. Levine*, and *Riegel v. Medtronic, Inc.*, often steal the limelight as the cases that purportedly answer the preemption question, attorneys should not overlook another case, *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). The case sought to answer a seemingly simple question: Could a plaintiff pursue a state law tort claim premised on the fact that a medical device manufacturer made fraudulent representations to the FDA during the medical device's FDA approval process in violation of a federal regulation? *Id.* at 343. In a relatively short opinion, the Court answered with a swift and resounding "no."

Anyone who has worked on a pharmaceutical or medical device case has probably spent some time with *Buckman*. Even if you have never read the opinion, you may know its colloquial conclusion: no "fraud-on-the-FDA" state law-based claims or no "fraud-on-the-agency" state law-based claims. The theory is simple in the abstract. Most federal agencies, including the U.S. Food and Drug Administration (FDA), possess the power to police the veracity of submissions to those agencies and even impose civil and criminal liability for misrepresentations made to them. Accordingly, if the FDA, for example, reviews and approves a manufacturer's submission, the FDA has implicitly found that the manufacturer complied with FDA regulations. However, if a jury deciding a state law tort claim later concludes that the manufacturer made misrepresentations to the FDA and that the manufacturer should take economic responsibility for those misrepresentations, then a direct conflict exists between the FDA's finding and that of the jury in the state law tort lawsuit. As a result of this conflict, federal law preempts state law claims based on "fraud-on-the-agency."

Even though *Buckman*'s straightforward holding seems rather limited, defense attorneys across the country have sought to stretch its impact to the furthest reaches possible eliciting a variety of responses from courts. While some attorneys found

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courts receptive to arguments applying *Buckman* against numerous state law tort claims involving various factual scenarios, many attorneys quickly realized that *Buckman* has significant limitations. In the years since the decision, courts applying *Buckman* have come to vastly different conclusions. This article will provide a brief review of the cases applying *Buckman* over the past 11 years, the present preemptory and evidentiary effects of *Buckman*, and the future of *Buckman* in light of the increasingly popular trend of tort reform.

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### *Buckman Co. v. Plaintiffs' Legal Committee*

In *Buckman*, AcroMed Corporation retained consultant Buckman Company, Inc., "as a liaison to the FDA in its attempt to secure marketing clearance for… an orthopedic bone screw device known as the Variable Screw Placement ('VSP') Spinal Plate Fixation System in September 1984." *In re Orthopedic Bone Screw Liab. Litig.*, 159 F.3d 817, 820 (3d Cir. 1998), *rev'd by Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). The FDA had designated the VSP system a Class III medical device requiring a lengthy premarket approval process (PMA). Rather than undertaking this time-consuming burden, AcroMed, with the advice of Buckman, used the §510(k) exception to the ordinary PMA. *Id.* The §510(k) exception decreases FDA review of a medical device from an approximate 1,200 hours for a PMA to only 20 hours for devices that are "substantially equivalent" to existing medical devices. 21 U.S.C. §360e(b)(1)(B); *In re Orthopedic Bone Screw Prod. Liab. Litig.*, 159 F.3d at 820. To qualify for the §510(k) exception, the "FDA must determine that the new device has the same intended use as the predicate device and that it possesses the same technological characteristic or is as safe and effective as the predicate device." *In re Orthopedic Bone Screw Prod. Liab. Litig.*, 159 F.3d at 819 (citing 21 U.S.C. §360c(i)(1)(A)).

Before the FDA approved the VSP, AcroMed and Buckman submitted two unsuccessful §510(k) applications. In denying these applications, the FDA determined "that the device was not substantially equivalent to a predicate device and that it posed potential risks not exhibited by other spinal-fixation systems." *Id.* at 820. With the third try AcroMed and Buckman took a new approach and divided the VSP into two component parts, filed two separate applications, and changed the intended use from spinal applications to using the component parts in the long bones of the arms and the legs. *Id.* The FDA approved the two §510(k) applications. The plaintiffs in *Buckman* took issue with the "third time is the charm" approach AcroMed and Buckman undertook in obtaining approval of the VSP. The plaintiffs saw the actions by AcroMed and Buckman as intentionally deceptive and alleged that but for AcroMed's and Buckman's misleading approach to obtaining FDA approval, the FDA would not have approved the VSP, and the plaintiffs would not have been injured. *Buckman*, 531 U.S. at 343.

The U.S. District Court of the Eastern District of Pennsylvania dismissed the plaintiffs' fraud-on-the-FDA claims on the grounds that, among other things, a private right of action did not exist for Federal Food, Drug, and Cosmetic Act (FDCA) violations. *In re Orthopedic Bone Screw Prod. Liab. Litig.*, No. MDL 1014, 1997 WL 305257, at *1 (E.D. Penn. Mar. 28, 1997). However, the Third Circuit reversed the district court's decision, holding that the plaintiffs' claims were not preempted and, therefore, could not be dismissed. *In re Orthopedic Bone Screw Prod. Liab. Litig.*, 159 F.3d at 823 (citing *Medtronic Inc. v. Lohr*, 518 U.S. 470 (1996)). Despite existing Third Circuit precedent finding that the FDCA did not establish a private right of action for FDCA violations, the Third Circuit read *Lohr* as expressly allowing state law claims against medical device manufacturers that obtained FDA approval under §510(k). Accordingly, the Third Circuit disagreed with the district court, which had ruled that the plaintiffs could not maintain state law claims for FDCA violations. Such a decision, according to the Third Circuit, would amount to preemption directly contradictory to *Lohr*. *Id.*

By the time that the Supreme Court reviewed the case, Buckman remained the sole "defendant." *Buckman*, 531 U.S. at 343. With AcroMed Dismissed, the lawsuit lacked state law-based design-defect or failure-to-warn claims, and the only allegation before the Supreme Court was that Buckman had made false statements to the FDA in obtaining FDA approval, a pure paradigmatic "fraud-on-the-FDA" claim. *Id.* In addressing these claims, the Court quickly noted that "[p]olicing fraud against federal agencies is hardly a 'field which the States have traditionally occupied.'" *Id.* at 347 (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Using that statement as a springboard, the Court found that nothing warranted finding a "presumption against preemption" in the case at hand.

Without a "presumption against preemption," the Court held that the "plaintiffs' state-law fraud-on-the-FDA claims conflict with, and therefore are impliedly pre-empted by, federal law." *Id.* at 348. To elaborate,

> The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law.

*Id.*

Noting that fraud-on-the-FDA claims would "impede competition" and "delay" appropriate medical device off-label use, the Court stated that "complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants" and that "fraud-on-the-FDA claims would also cause applicants to fear that their disclosures to the

FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court." *Id.* at 351.

The Court did limit the holding, however, comparing it to previous cases and drawing a distinction between fraud-on-the-FDA claims and common law negligence actions based on product defects and claims arising from FDCA violations. *Id.* at 352. Although the Court noted that the FDCA will not preempt some state law-based causes of actions that do not arise "solely from the violation of FDCA requirements," the Court concluded that when a violation of a federal enactment "is a critical element" to a claim, then federal law would preempt the claim. *Id.* at 353. Justices Stevens, joined by Justice Thomas, entered a concurring opinion which separated from the majority opinion only to note that if the FDA found that Buckman had violated the FDCA, then the state law tort claims would not impose *a new or different standard* on Buckman in conflict with federal regulation.

#### What Qualifies as Fraud on the FDA?

While *Buckman* clearly establishes that the FDCA preempts a state law fraud-on-the-FDA claim, the Court did not spend much time discussing what constitutes a fraud-on-the-FDA claim. Naturally, defense attorneys would like courts to expand *Buckman*'s reach to encompass all claims that require proof of fraud against the FDA, including failure-to-warn claims. Unfortunately, however, most courts have found that as long as a plaintiff's claims arise from traditional tort law causes of action, federal law will not preempt state law claims.

In *Buckman*, the Supreme Court held that the decision did not affect traditional state law tort claims. *Buckman*, 531 U.S. at 352. The *Buckman* court pointed to previous precedent established in *Silkwood v. Kerr-McGee Corp.*, which found that federal law did not preempt claims based on "traditional state law tort principles of the duty of care owed by the producer of plutonium fuel pins to an employee working in its plant." 464 U.S. 238, 241 (1984). In contrast, federal law did preempt the claims in *Buckman* because a "critical element" of the plaintiff's claims required finding that a manufacturer violated a federal regulation, in particular complete and truthful reporting to the FDA.

In January of 2011, the Fifth Circuit addressed this point in *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011). In *Hughes*, the court noted that the claim preempted in *Buckman* was a "free-standing federal cause of action based on violation of the FDA's regulations [with no] assert[ions of] violations of a state tort duty." *Id.* at 775. In contrast, the claim in *Hughes* was "a Mississippi tort claim based on the underlying state duty to warn about the dangers or risks of product." *Id.* The *Hughes* court found it unimportant that the plaintiff would use evidence that the manufacturer violated regulations in proving the claim. *Id.* Other courts have reached similar conclusions. *See*, *e.g.*, *Rossum v. I-Flow Corp.*, No. 09-3714, 2011 WL 3274080 (D. Minn. Aug. 1, 2011); *Gilleon v. Medtronic USA, Inc.*, No. C01-20460, 2002 WL 31300694 (N.D. Cal. Aug. 28, 2002).

However, some courts have taken a less lenient stance on whether using fraud-on-the-FDA evidence amounts to a fraud-on-the-FDA claim. The Eleventh Circuit noted just a few months ago that under *Buckman* a plaintiff could not establish a theory of causation based solely on allegations that but for a misrepresentation to the FDA, a medication would not have been approved and injury would not have happened. *Southeast Laborers Health & Welfare Fund v. Bayer Corp.*, NO. 10-13196, 2011 WL 5061645 (11th Cir. Oct. 24, 2011). Justice Stevens' concurrence also has limited *Buckman*'s impact. Justice Stevens noted that an exception to *Buckman* would exist if the FDA itself found that a manufacturer violated federal regulation. Indeed, courts reviewing cases that fit this exception have applied Justice Stevens' reasoning. *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 943 (8th Cir. 2011) (noting that "[t]he hypothetical scenario that Justice Stevens conceived of in *Buckman* is virtually identical to the present case").

Ultimately, whether a claim constitutes a fraud-on-the FDA claim heavily depends on the facts of the case as well as the jurisdiction. The key question prevalent throughout the case law is whether the plaintiff could have pursued and sustained his or her claim if the federal regulations had not existed. If the answer is no, then under *Buckman* federal law will preempt the claim. In other words, if a plaintiff exclusively bases a required element of his or her tort claim on the fact that a manufacturer violated a federal regulation, then he or she cannot maintain the claim.

Based upon a survey of cases, courts rarely will view the fact that a plaintiff seeks to introduce evidence that a manufacturer violated an FDA regulation during approval of a medical product as sufficient to dismiss a claim. Even so, one possible way to maximize *Buckman* is to hold plaintiffs to the strict pleading requirements for fraud and misrepresentation. If a response to a request for a more definite statement contains nothing more than allegations that a manufacturer defrauded the FDA, then *Buckman* may serve to help thwart those claims.

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#### Fraud on the Agency

Attorneys have extended *Buckman*'s fraud-on-the-agency holding beyond the field of pharmaceuticals and medical devices. Attorneys have used the fraud-on-the-agency concept to argue that federal law as interpreted in *Buckman* will preempt a claim premised on the fact that a defendant made misrepresentations to a federal agency that somehow resulted in injury. Courts have favorably received this argument. *Ramirez v. E.I. Dupont De Nemours & Co.*, No. 8:09-cv-321, 2010 WL 3529509 (M.D. Fla. Sept. 3, 2010) (involving fraud-on-the-U.S. Envtl. Protect Agency); *Littel v. Bridgestone/Firestone, Inc.*, 259 F. Supp. 2d 1016 (C.D. Cal. 2003) (involving fraud-on-the-Nat'l Highway Traffic Safety Admin.); *Morgan v. Brush Wellman, Inc.*, 165 F. Supp. 2d 704 (E.D. Tenn. 2001) (involving fraud-

on-the-U.S. Dep't of Energy). However, these arguments are still subject to the weaknesses identified in *Buckman*. If a defendant can characterize a claim as a traditional state law tort claim for which fraud on the agency evidence is only support, a court will likely permit the plaintiff to use the evidence. *George v. Ford Motor Co.*, No. 03 Civ. 7643, 2007 WL 2398806 (S.D.N.Y. Aug. 17, 2007) (involving fraud-on-the-Nat'l Highway Traffic Safety Admin.).

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Additionally, a defense attorney must keep in mind the intricacies of each agency's regulations. Differences in the purposes and powers of an agency may prevent *Buckman* from applying. *DOCA Co. v. Westinghouse Electric Co., LLC*, No. 04-1951, 2011 WL 3476428 (W.D. Penn. Aug. 9, 2011) (fraud-on-the-U.S. Nuclear Regulatory Comm'n).

### Negligence Per Se for Violations of Federal Regulations

An attorney could also use *Buckman* to defend a drug or medical device manufacturer in a product liability case when a plaintiff pleads quasi-negligence per se claims grounded in FDCA violations. In deciding *Buckman*, the Supreme Court found that federal law preempted claims based exclusively on violations of the FDCA. As viewed by the Court, what defines a preempted claim is whether the claim existed before the federal regulatory framework was in place. In other words, does the sole foundation of a plaintiff's cause of action arise from a federal regulation? If so, federal law preempts the claim. The *Buckman* court used this question to discern between traditional state law tort claims and preempted claims.

Many courts have relied on *Buckman* and found that federal law preempts claims based exclusively on the FDCA because the FDCA does not establish a private right of action for FDCA violations. *Leonard v. Medtronic, Inc.*, No. 1:10-CV-03787, 2011 WL 3652311 (N.D. Ga. Aug. 19, 2011); *Kapps v. Biosense Webster*, No. 09-CV-1039, 2011 WL 4470701 (D. Minn. Sept. 27, 2011); *Mattingly v. Medtronic, Inc.*, 486 F. Supp. 2d 964 (E.D. Mo. 2007); *Vanderwerf v. SmithKline-Beecham Corp.*, 414 F. Supp. 2d 1023 (D. Kan. 2006). These cases hold that a plaintiff cannot use the FDCA in a negligence-per-se fashion to establish liability merely because someone allegedly violated a federal regulation. These claims do not have state law tort underpinnings but exclusively rely on violations of the FDCA to establish liability inapposite with *Buckman*. Unfortunately, however, it does not appear that this aspect of *Buckman* will extend to other federal regulatory frameworks. At least a few courts have held that claims attempting to establish liability through negligence per se for violations of federal regulations are not automatically preempted. *See Howard v. Sulzer Orthopedics, Inc.*, 796 F. Supp. 2d 1305, 1310 (N.D. Okla. 2011); *Harmon v. Maury Cnty., Tenn.*, No. 1:05 CV 0026, 2005 WL 2133697 (M.D. Tenn. Aug. 31, 2005).

While *Buckman* may not have a grandly sweeping effect, defense attorneys can use it to whittle away the number of a plaintiff's claims. Defense attorneys should argue that allegations in medical products cases containing nothing more than laundry lists of purportedly violated federal regulations attempt to use the FDCA for purposes of negligence per se. Under *Buckman*, courts should not allow plaintiffs to proceed with such claims. Similarly, claims which masquerade as state law tort claims but ultimately rely exclusively on violations of the FDCA, should also be preempted.

### *Buckman* as an Evidentiary Bar

Almost immediately after the Court released the *Buckman* opinion, defendants in drug and medical device litigation began citing the holding as a basis for excluding evidence of their clients' alleged interactions with the FDA, including opinions of "regulatory" experts that manufacturers violated federal regulations or otherwise misled the agency. *See Globetti v. Sandoz Pharm. Corp.*, No. CV980TMP-2649-S, 2001 WL 419160, at *1 (N.D. Ala. Mar. 5, 2001) ("This cause is before the court on several motions… based on the Supreme Court's recent decision in *Buckman Company v. Plaintiff's Legal Committee*, 531 U.S. 341, 2001 U.S. Lexis 1701."). As one court aptly noted, "The essential link among all these motions is the assertion that the *Buckman* decision precludes any claim, and indeed any evidence, relating to defendant's communications with the FDA and any other communications 'controlled' by the FDA." *Id.*

Depending on the facts of a case, the opinions an expert intends to proffer, and the view that a court takes of the *Buckman* opinion, these motions have experienced varying degrees of success. While some courts narrowly view *Buckman* as a strict preemption case that doesn't apply to evidentiary rulings, others have interpreted the holding broadly to exclude almost all evidence of interactions with the FDA. *See In re Yasmin and Yaz (Drospirenone) Marketing, Sales Practices and Prod. Liab. Litig.*, No. 3:09-md-02100-DRH-PMF, 2011 WL 6302287, at *11 (S.D. Ill. Dec. 16, 2011) ("*Buckman* is a claim preemption case focusing on fraud-on-the-FDA claims, not an evidence preemption case."). *But see Swank v. Zimmer, Inc.*, No. 03-cv-60-B, 2004 WL 5254312, at *2 (D. Wyo. Apr. 20, 2004) (granting a motion in limine to exclude evidence of defendant's interactions with the FDA based on policies outlined in *Buckman*).

Several courts have held that trial courts can properly exclude evidence offered to show that the FDA was misled or that information was concealed from the FDA. Recognizing "claims of fraud on the FDA are preempted with respect to pharmaceuticals," one court further held that "[e]vidence will be excluded outright when it is offered only to show that the FDA was misled, or that information was intentionally concealed from the FDA." *Bouchard v. Am. Home Prods. Corp.*, 213 F. Supp. 2d 802, 812 (N.D. Ohio 2002). Relying on *Bouchard*, other courts have granted motions in limine to "exclude evidence alleging that [the manufacturer] was misleading or deceptive in its dealings with the FDA and/or committed violations of the FDCA or FDA regulations." *Skibniewski v. Am. Home Prods. Corp.*, No. 99-0842-CV-W-FJG, 2004 WL 5628157, at *13 (W.D. Mo. April 1, 2004).

Not all courts assign the same weight to *Buckman*. The defendant in *In re Vioxx Products Liability Litigation* asked the United States District Court of the Eastern District of Louisiana to exclude several of the plaintiffs' tendered experts for a multitude of reasons, including that under *Buckman* the expert was "not entitled to supplant the judgment of the FDA in balancing the benefits and risks of drugs from the regulatory perspective," and evidence regarding the "inadequacy of [the manufacturer's] interactions" with the FDA was preempted. *In re Vioxx Prod. Liab. Litig.*, 401 F. Supp. 2d 565, 585, 593 (E.D. La. 2005). Although the court did prevent the plaintiffs' experts from offering opinions that it found them unqualified to offer, the *Buckman* arguments did not persuade the court. The court held that *Buckman* "would not bar a qualified expert from testifying as to their opinion on whether the FDA correctly balanced the benefits and risks of a drug from a regulatory standpoint. In *Buckman*, the Supreme Court found that state law fraud-on-the-FDA claims were preempted by federal law." *Id.* at 588. The court later stated that "*Buckman* is not applicable to this case or issue at all." *Id.* at 595.

Many of the courts that attorneys have asked to exclude evidence based on *Buckman* have taken the middle road holding that *Buckman* requires them to exclude some evidence involving a manufacturer's interactions with the FDA but not all. Often, the decision hinges on the purpose for which a party offers the evidence. For example, in *In re Baycol Products Liability Litigation*, the United States District Court of the District of Minnesota, examining motions in matters consolidated by the Judicial Panel on Multidistrict Litigation, held that "to the extent [the plaintiffs' regulatory expert's] testimony is offered only to show that the FDA was misled, or that information was intentionally concealed from the FDA, the testimony must be excluded." *In re Baycol Prod. Liab. Litig.*, 532 F. Supp. 2d 1029, 1053 (D. Minn. 2007). However, the court left to the discretion of the "respective trial courts the admissibility determination of such testimony to the extent it is offered to support a claim that the medical community, treating physicians or patients were misled by [the manufacturer's] alleged failure to submit information to the FDA." *Id.*

In deciding whether to file a motion to exclude an expert opinion or other evidence under *Buckman*, a defense attorney should consider the precise evidence that he or she seeks to exclude and what impact the court's granting of the motion may have on the overall litigation. A defense attorney should specifically take into account how a court's view of the *Buckman* holding may impact the evidence that *he or she* intends to present on behalf of *his or her* client. After citing *Buckman* for the proposition that "evidence or testimony that [the manufacturer] failed to adequately or timely provide information to the FDA pursuant to FDA reporting obligations that run to the FDA, such as §314.80, is generally irrelevant to Plaintiffs' state-law claims and thus inadmissible," the court in *In re Trasylol Products Liability Litigation* employed a similar rationale to exclude certain opinions offered by the defendants' regulatory expert. *In re Trasylol Prod. Liab. Litig.*, No. 08-md-01928, 2010 WL 4259332, at *9–10 (S.D. Fla. Oct. 21, 2010). In support of its ruling, the court held that "consistent with its prior Order, [the defendants' regulatory expert's] testimony as to compliance with reporting duties to the FDA is generally irrelevant to this Case" as well. *Id.* at *10.

Both plaintiffs and defendants commonly introduce experts armed with experience with the FDA or other government agencies and working knowledge of the applicable regulations not only in drug and medical device litigation but in other types of litigation as well. Although a plaintiff may not particularly complain of fraud on the agency, a plaintiff's experts will likely testify that the defendant interacted with the agency in less than desirable ways. Closely reading *Buckman* and its progeny may provide a defendant's counsel with an opportunity to prevent a jury from hearing such evidence. Since the courts seem split on the application of *Buckman*, however, the authors recommend closely reviewing the law in the particular jurisdiction where a defense attorney will file a motion.

### *Buckman* and Tort Reform

The importance of *Buckman* will undoubtedly increase given that several states have recently enacted tort reform. Only a few months ago, and of particular interest to the authors of this article, Tennessee enacted a new tort reform act, which modified its existing product liability statute. The reform brought Tennessee in line with a handful of other states that have legislation containing specific provisions applying to federal-agency-approved products. Many of these statutes require a plaintiff in some manner or another to show that a manufacturer withheld information from or misrepresented information to the FDA. Some statutes limit damages for FDA-approved products, while others create a presumption that a product is not unsafe or unreasonably dangerous. One state even has a statute interpreted in light of *Buckman* as completely barring pharmaceutical and medical products claims.

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The most common product liability statute for purposes of medical products limits punitive damages. States having this statute type include Arizona, New Jersey, North Dakota Ohio, Oregon, Tennessee, and Utah. Ariz. Rev. Stat. §12-701 (1989); N.J. Stat. Ann. §2A:58C-5; N.D. Cent. Code §32-03.2-11; Ohio Rev. Code §2307.80; Or. Rev. Stat. §30.927; Tenn. Code Ann. §29-39-104(d); Utah Code Ann. §78B-8-203(1). Illinois had a similar statute, but the Supreme Court of Illinois declared another provision of the public act enacting the statute unconstitutional and not severable. *Best v. Taylor Mach. Works*, 689 N.E.2d 1057 (Ill. 1997).

As structured, these statutes generally do not allow a plaintiff to recover punitive damages against the manufacturers of an FDA-approved product. An exception exists if a plaintiff can prove that a man-

ufacturer withheld information from or misrepresented information to the FDA. Obviously, presenting such an argument seemingly flies in the face of *Buckman*. The courts have split on whether plaintiffs can recover punitive damages in these states. *Forman v. Novartis Pharm. Corp.*, 793 F. Supp. 2d 598 (E.D.N.Y. 2011) (applying New Jersey law); *Stanley v. Mylan Inc.*, NO. 1:09-CV-124, 2010 WL 3718589 (D. Utah Sept. 17, 2010); *Lake-Allen v. Johnson & Johnson, L.P.*, NO. 2:08-CV-00930, 2009 WL 2242198 (D. Utah July 27, 2009); *Grange, Jr. v. Mylan Labs, Inc.*, No. 1:07-CV-107, 2008 WL 4813311 (D. Utah Oct. 31, 2008); *In re Aredia and Zometa Prod. Liab. Litig.*, No. 3:06-MD-1760, 2007 WL 649266 (M.D. Tenn. Feb. 27, 2007) (applying New Jersey law); *Kobar v. Novartis Corp.*, 378 F. Supp. 2d 116 (D. Ariz. 2005); *McDarby v. Merck & Co., Inc.*, 949 A.2d 223 (N.J. Super. Ct. App. 2008). Some courts have found that when a plaintiff does not pursue a claim solely based on fraud on the FDA, the plaintiff can introduce that evidence and recover punitive damages. Other courts have found that *Buckman* inherently preempts introducing such evidence and in effect bars punitive damages.

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Other product liability statutes create a presumption that an FDA-approved product is not defective or unreasonably dangerous. States with this type of statute include Florida and Texas. Fla. St. Ann. §768.1256(1); Tex. Civ. Prac. & Rem. §82.007. In these states, the product liability statute explicitly outlines the ways in which a plaintiff can overcome the statutory presumption. One way is to show that a medical product manufacturer withheld information from or misrepresented information to the FDA. As with the other tort reform statutes, courts have split over how *Buckman* applies to these presumption statutes. *Lofton v. O'Neil*, ___ F.3d ___, 2012 WL 579772 (5th Cir. Feb. 22, 2012); *Emerson v. Novartis Pharm.*, No. 09-6273, 2011 WL 3701835 (6th Cir. Aug. 23, 2011); *Yocham v. Novartis Pharm. Corp.*, 735 F. Supp. 2d 875 (D.N.J. 2010); (N.D. Tex. 2010); *In re Aredia & Zometa Prod. Liab. Litig.*, No. 3:06-md-1760, 2009 WL 2497229 (M.D. Tenn. Aug. 13, 2009); *In re Aredia & Zometa Prod. Liab. Litig.*, No. 3:06-MD-1760, 2008 WL 2944910 (M.D. Tenn. July 25, 2008); *Ackermann v. Wyeth Pharm.*, 471 F. Supp. 2d 739 (E.D. Tex. 2006).

Finally, the most controversial product liability statute resides in Michigan. Fodder for a direct split between the Second Circuit and the Fifth and Sixth Circuits, the Michigan statute, enacted before *Buckman*, grants immunity to a medical product manufacturer unless a plaintiff can show that the manufacturer bribed a government official or made misrepresentations during the FDA-approval process. Mich. Comp. Laws 600.2946(5). The statute makes fraud on the FDA an essential element of a product liability claim. The Sixth Circuit held that *Buckman* barred a plaintiff from introducing evidence that a manufacturer made misrepresentations to the FDA during the approval process. *Garcia v. Wyeth-Ayerst Labs*, 385 F.3d 961 (6th Cir. 2004). As a result, the Michigan statute essentially became a complete bar to recovery in medical product liability cases. Dissatisfied with this barring effect, the Second Circuit came to the opposite conclusion. *Desiano v. Warner-Lambert*, 467 F.3d 85 (2d Cir. 2006). Of the many cases addressing the Michigan statute, most, including the Fifth Circuit, the Michigan Supreme Court and the Michigan Court of Appeals, agree with the Sixth Circuit that *Buckman* prevents a plaintiff from introducing evidence that a manufacturer defrauded the FDA, and thus, serves as a complete bar to product liability claims in Michigan. *Lofton v. O'Neil*, ___ F.3d ___ , 2012 WL 579772 (5th Cir. Feb. 22, 2012); *In re Aredia & Zometa Prod. Liab. Litig.*, 352 F. App'x 994 (6th Cir. 2009); *Estate of Muniz ex rel. Muniz v. Genetech, Inc.*, No. 1:11-CV-683, 2011 WL 5089289 (W.D. Mich. Oct. 26, 2011); *Bower v. Johnson & Johnson*, 795 F. Supp. 2d 672 (N.D. Ohio 2011); *In re Trasylol Prod. Liab. Litig.*, 2010 WL 4259332 (S.D. Fla. 2010); *Hall v. Wyeth, Inc.*, No. 10-00738, 2010 WL 3860467, (E.D. Penn. Sept. 30, 2010); *White v. SmithKline-Beecham Corp.*, 538 F. Supp. 2d 1023 (W.D. Mich. 2008); *Zammit v. Shire US Inc.*, 415 F. Supp. 2d 760 (E.D. Mich. 2006); *Taylor v. SmithKlineBeecham Corp.*, 658 N.W.2d 127 (Mich. 2003); *Duronio v. Merck & Co., Inc.*, No. 267003, 2006 WL 1628516 (Mich. Ct. App. June 16, 2006).

As only a portion of states have enacted tort reform, this is clearly not an issue for the entire country. However, a defense attorney will want to know the state law on the subject when working on a product liability case. Tort reform in recent years has been an increasingly prevalent trend, and any future tort reform frameworks passed will likely address, create, or revise product liability statutes. State legislatures often turn to the statutes already in place in other states for guidance. While it seems unlikely that any other state will follow Michigan, the statutes in Florida and Texas have functioned to block several lawsuits because the plaintiffs could not overcome the presumptions against defectiveness or unreasonable dangerousness. Encouraging state legislatures to enact statutes adopting these presumptions will benefit attorneys who represent medical products manufacturers.

## Conclusion

Many attorneys have attempted to expand the applicability of *Buckman*, and many attempts have failed. In the process, some case law has developed that seems to limit *Buckman*'s usage severely. However, *Buckman* remains a useful tool for defense attorneys. Besides its primary holding regarding fraud on the FDA, *Buckman* can prevent claims of fraud on other federal agencies, can prevent plaintiffs from creating liability merely because of violations of the FDCA, and can bar expert testimony and other evidence irrelevant to state law tort claims. Further, used in conjunction with product liability statutes, *Buckman* can block punitive damages or obtain a presumption that a product was not defective or unreasonably dangerous. As a result, defense attorneys should consider the impact of *Buckman* when advising clients on issues of preemption, choice of law and dispositive and other pretrial motions.