The Supreme Court also interpreted the statute in 2001 in *Buckman Co. v. Plaintiffs’ Legal Committee*, 239 a case involving a “fraud-on-the-FDA” claim in which the plaintiffs were injured by a device that they claimed the FDA approved only because of false information submitted by the manufacturer. Even though the preemption clause in the statute did not apply, the Court held that such a claim was impliedly preempted because it conflicted with the FDA’s mission to police the medical device market and to maintain the delicate balance between protecting the public from unsafe devices and giving people access to devices that might help them. *Buckman* may not, however, immunize manufacturers from liability for misrepresentations made to consumers and physicians rather than to the FDA. 240

The Eighth Circuit has held that *Buckman* also bars a claim based on a manufacturer’s failure to report adverse events to the FDA after the FDA had approved the particular medical device. 241 The Fifth Circuit, however, allowed a failure to warn claim based on failure to report post-approval adverse events to proceed. 242 It stressed that the adverse event reports would have been disseminated to the public, not just the FDA, and that the plaintiff’s claim did not depend on speculation that the FDA would have taken some particular regulatory action in response to the adverse event reports. The Ninth Circuit has agreed that neither *Buckman* nor the Supreme Court’s other decisions require preemption of a claim based on a manufacturer’s violation of a continuing duty under Arizona law to warn of dangers and report them to third parties such as the FDA, although a concurrence notes the difficulties of proving causation. 243

**Footnotes**

239 {223} 531 U.S. 341, 353, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001). *See also* Mink v. Smith & Nephew, Inc., 860 F.3d 1319 (11th Cir. 2017) (negligence claim based on failure to report adverse events to FDA is preempted); Perez v. Nidek Co., 711 F.3d 1109 (9th Cir. 2013) (claim based on failure to inform patients that FDA had not approved device for certain uses is preempted because facts are tied to scope of FDA approval); Kapps v. Biosense Webster, Inc., 813 F. Supp. 2d 1128, 1144, 1151–1152 (D. Minn. 2011) (*Buckman* preempts claim based on manufacturer’s securing of FDA approval through incorrect procedural route); *Cf.* Zimmerman v. Novartis Pharmaceuticals Corp., 889 F. Supp. 2d 757 (D. Md. 2012) (*Buckman* precludes jury from considering whether manufacturer was liable for punitive damages because of misrepresenting information to FDA, a requirement under state law). *But cf.* Desiano v. Warner-Lambert & Co., 467 F.3d 85 (2d Cir. 2006) (common law claim not preempted even though state law made manufacturer immune unless it withheld or misrepresented information to FDA), *aff’d by an equally divided court sub nom.* Warner-Lambert Co. v. Kent, 552 U.S. 440 (2008) (per curiam).


241 {225} *In re* Medtronic, Inc., Sprint Fidelis Leads Products Liab. Litig., 623 F.3d 1200 (8th Cir. 2010). *See also* Hiesner v. Genzyme Corp., 2010 WL 8949054 (N.D. Ill. Mar. 8, 2010) (state law claim that manufacturer should have updated its label to reflect new information about adverse reactions goes beyond FDA regulation that permits, but does not require, manufacturers to do so, and therefore is preempted).

242 {226} Hughes v. Boston Scientific Corp., 631 F.3d 762 (5th Cir. 2011).

243 {227} Stengel v. Medtronic Inc., 704 F.3d 1224 (9th Cir. 2013) (en banc).