

THE FRAUD CAVEAT TO AGENCY PREEMPTION

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INTRODUCTION: THE FRAUD CAVEAT

Federal agencies are flexing their preemptive muscles. More and more, they are asserting control over the realms of consumer and product safety—realms that have traditionally been the province of state tort law.¹ This trend has prompted polarizing responses: critics have taken aim at what they perceive to be an illegitimate, politically unaccountable form of tort reform in disguise,² whereas supporters have embraced the opportunity to displace the jury-created, chaotic, ad hoc regulation of inherently risky products with uniform, rational, national standards.³

My focus in this Article is upon what may be the only point of agreement: the need for some regulatory mechanism to police fraud on the agency. What I term the “fraud caveat” to federal agency preemption has great intuitive appeal. Even the most ardent supporters of either the state-based regulatory compliance defense to tort claims against product manufacturers or the more powerful wholesale federal preemption of state tort law by administrative regulations concede that fraud changes the equation.⁴

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¹ For a discussion of recent efforts by federal agencies to wield preemptive authority, see Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 229–42 (2007).

² See, e.g., Nina A. Mendelson, *A Presumption Against Agency Preemption*, 102 NW. U. L. REV. 695, 695 (2008) (“Federal agencies are increasingly taking aim at state law, even though state law is not expressly targeted by the statutes the agencies administer.”); Margaret H. Clune, *Stealth Tort Reform: How the Bush Administration’s Aggressive Use of the Preemption Doctrine Hurts Consumers* 1 (Ctr. for Progressive Regulation, White Paper No. 403, 2004), available at <http://www.progressiveregulation.org/articles/preemption.pdf> (“[A] much less visible aspect of these activities is the contribution [that FDA Chief Counsel David Troy’s] substantive legal arguments are making to the Administration anti-consumer tort reform agenda.”).

³ See, e.g., Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda*, J. TORT L., Dec. 2006, at 23–25, <http://www.bepress.com/jtl/vol1/iss1/art5> (“What possible reason is there not to preempt litigation which on balance is worse than useless?”).

⁴ Moreover, the canonical *Products Liability Restatement*—which endorses the jury’s consideration of evidence of the defendant’s regulatory compliance as part of its inquiry into whether a product is defective—accords “little or no weight” to such compliance where “the deliberative process that led to the safety standard with which the defendant’s product complies was tainted by the supplying of false in-

State legislatures that have adopted regulatory compliance provisions immunizing manufacturers of FDA-approved prescription drugs from liability for damages (either entirely or just for punitive damages) have, without exception, included the fraud caveat.⁵ Courts that interpret these immunity statutes echo the caveat mantra: “If Plaintiff comes forward with evidence that the FDA was somehow misled, Plaintiff has . . . rebutted a presumption that the manufacturer is not liable.”⁶ Indeed, the FDA itself, in the very same breath in which it proclaimed its authority to preempt state-based tort claims “that a drug’s sponsor breached an obligation to plaintiff by making statements that FDA approved for inclusion in the drug’s label,” added the obligatory caveat: “*unless . . . the sponsor withheld material information relating to the statement.*”⁷

Not only does the concession for fraud have a universally moderating effect upon ardent proponents of agency preemption, it also lies at the heart of many detractors’ vociferous resistance. In a recent decision that could be read as an exegesis on the perils of agency preemption, Judge Jack Weinstein turned the usual fraud caveat on its head, suggesting that pervasiveness of fraud undermines any theoretical soundness of regulatory preemption: “A reasonable national public policy—in the absence of *fraud*—would give a pharmaceutical manufacturer protection against tort

formation to, or the withholding of necessary and valid information from, the agency that promulgated the standard or certified or approved the product.” RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4(b) cmt. e (1998).

⁵ Michigan alone has adopted a broad statutory regulatory compliance defense. Texas has adopted similar legislation that provides for a presumption that FDA-approved warnings on pharmaceutical products are adequate. Six additional states—Arizona, New Jersey, North Dakota, Ohio, Oregon, and Utah—bar punitive damages for FDA-approved drugs. See *infra* notes 36–38 and accompanying text.

Nor is the “fraud caveat” exclusively the province of state legislation. When Congress enacted the National Childhood Vaccine Injury Compensation Act of 1986, it premised immunity from punitive damages on the absence of fraud. See 42 U.S.C. § 300aa-23(d)(2) (2000) (“[T]he manufacturer shall not be held liable for punitive damages unless the manufacturer engaged in—(A) fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine . . . , (B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or (C) other criminal or illegal activity relating to the safety and effectiveness of vaccines, which activity related to the vaccine-related injury or death for which the civil action was brought.”).

⁶ *Ackermann v. Wyeth Pharms.*, 471 F. Supp. 2d 739, 749 (E.D. Tex. 2006), *aff’d on other grounds*, No. 06-41774, 2008 WL 1821379 (5th Cir. Apr. 24, 2008); see also *Dusek v. Pfizer Inc.*, No. Civ.A. H-02-3559, 2004 WL 2191804, at *7 (S.D. Tex. Feb. 20, 2004) (rejecting plaintiff’s allegation that “Pfizer did not provide the necessary cooperation and information to the agency,” reasoning that “many of the instances of allegedly incomplete information given to the FDA are not persuasive”); *Abramowitz v. Cephalon, Inc.*, 2006 WL 560639, at *3 (N.J. Super. Ct. Law Div. Mar. 3, 2006) (“[T]he court finds that there is no evidence to suggest that the defendants attempted to hide or suppress [postmarketing risk] information.”).

⁷ Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3936 (Jan. 24, 2006) (emphasis added).

liability for failure to warn when the FDA had approved the accused warnings.”⁸

The fraud caveat is an undertheorized but highly revealing and consequential aspect of overall preemption debates. I am not the first to highlight the centrality of fraud to the agency preemption debate. In a recent piece, Richard Nagareda argues that “[f]raud on the FDA should turn off preemption.”⁹ More specifically, Nagareda claims that “a showing of [fraud on the FDA] should suffice to defeat the preemptive effect that a given FDA assessment of a device or drug otherwise might have on garden-variety actions for product liability.”¹⁰ So far, so good. But the fraud caveat Nagareda proposes fails to address a core institutional question: who should police fraud on the FDA—the agency itself or private litigants?¹¹ Embroiled within this institutional question, moreover, is a separate doctrinal one, namely the proper scope and interpretation of the Supreme Court’s decision in *Buckman Co. v. Plaintiffs’ Legal Committee*, which held that state law fraud-on-the-agency claims are preempted by the federal Food, Drug, and Cosmetics Act (FDCA), given the uniquely federal interest at stake.¹² The Court was set to take up this question this Term in *Warner-Lambert Co. v. Kent*, but in an equally divided (4-4) per curiam decision with no precedential value, the Court left resolution for another day.¹³ The resulting federalism conundrum (as aptly stated by a federal court judge) is that “[s]tates may not be concerned about protecting federal agencies, but states have a strong interest in protecting their citizens from fraud and personal injuries.”¹⁴

⁸ *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 240–41 (E.D.N.Y. 2007) (emphasis added).

⁹ Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, J. TORT L., Dec. 2006, at 47, <http://www.bepress.com/jtl/vol1/iss1/art4>.

¹⁰ *Id.* at 46–47.

¹¹ Here, Nagareda refused to weigh in. *Id.* at 46 (“I leave to others the broader question of whether statutory reform should embrace stand-alone actions for fraud on the FDA or whether, as the *Buckman* Court believed, they would disrupt the regulatory regime.” (footnote omitted)).

¹² 531 U.S. 341, 348 (2001) (holding that “plaintiff’s state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law” because the FDA was empowered by statute to punish the fraud against it).

¹³ 128 S. Ct. 1168 (2008) (mem.).

¹⁴ *In re Medtronic, Inc., Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886, 899 (D. Minn. 2006).

The institutional question is at the front and center of this Article.¹⁵ In Part I, I argue that the FDA must take the lead in policing fraud perpetrated upon it by product manufacturers. Once the FDA has made a finding of such fraud, however, private litigants should be able to wield such findings offensively to pursue damages against manufacturers in their state law tort litigation and, where necessary, to disarm regulatory immunity or preemption. In essence, I provide a model of complementary agency-court action in combating fraud. This model resolves any federalism paradox by ensuring that the federal agency is the ultimate arbiter of infringements upon its federal prerogatives, whereas state courts are not disabled from pursuing complementary enforcement based upon the antecedent federal finding of fraud. This institutional model is based on a doctrinal approach gleaned from Justice John Paul Stevens's concurrence in *Buckman*.

Part II applies the model of complementary agency-court action in combating fraud to current preemption controversies. In terms of doctrinal payoff, the model stands to resolve a circuit split on the question whether the fraud exceptions to state immunity provisions are themselves preempted by *Buckman*—the precise issue taken up by the Supreme Court in *Kent*, but left unresolved.¹⁶ This question implicates three distinct layers of law: state law tort causes of action invoked by plaintiffs; state law statutory “fraud caveat” provisions that turn off statutory immunity from liability if there has been fraud in the agency approval process; and finally, the parameters of federal preemption of state law fraud-on-the-agency claims, delineated by Supreme Court jurisprudence.¹⁷ At a more conceptual level, the model sheds light on the question whether “parallel requirements” imposed by state and federal law may coexist harmoniously, an issue at the core of the most pressing issues of implied conflict preemption in the realm of products liability.

No account of agency-court interaction can ignore the FDA's institutional shortcomings. Part III attends to the reality that, while the agency that became the FDA “was originally conceived to be a science-based pro-

¹⁵ Of late, institutional accounts of preemption seem to be gaining the upper hand over more conventional statutory interpretation approaches. See, e.g., Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449 (2008); see also Thomas W. Merrill, *Preemption and Institutional Choice*, 102 NW. U. L. REV. 727 (2008); Peter H. Schuck, *Qualified Regulatory Preemption by the FDA: Finding the Sweet Spot*, 13 ROGER WILLIAMS U. L. REV. (forthcoming 2008) (manuscript at 6–9, on file with the Northwestern University Law Review) (drawing upon Merrill's and Sharkey's accounts to argue that the “criterion of comparative institutional competence” should determine implied preemption questions including whether there has been fraud on the FDA).

¹⁶ *Kent*, 128 S. Ct. 1168.

¹⁷ The preemption question implicated here—whether state law is preempted to the extent that it requires a determination of fraud on the FDA—is separate and distinct from the much broader preemption inquiry regarding the extent to which the FDA's approval of a drug impliedly preempts state law claims. I take up this broader issue in Sharkey, *supra* note 15, at 502–20.

tector of the public from contamination fraud,¹⁸ in practice it has often fallen short of its lofty goals. I argue that reforms should be designed with the aim of prodding the FDA to bolster its capacity to police fraud, while reserving a role for state law tort claims to handle enforcement and remedial responsibilities in the event of fraud.

I. POLICING FRAUD ON THE FDA: AN INSTITUTIONAL MODEL OF AGENCY-COURT INTERACTION

The holding of *Buckman Co. v. Plaintiffs' Legal Committee* is straightforward: state law fraud-on-the-FDA claims are impliedly preempted by the Medical Devices Amendment (MDA) to the FDCA.¹⁹ But the import of that holding is far less clear. Construed narrowly, *Buckman* speaks only to circumstances in which a plaintiff raises a stand-alone state-based claim of fraud on the agency. *Buckman* itself involved such a procedural posture, coupled with a somewhat idiosyncratic factual scenario in which the product manufacturer had settled with the plaintiffs, leaving as the sole defendant an FDA consultant to the manufacturer who allegedly made fraudulent representations to the FDA in the course of obtaining approval to market a particular medical device.²⁰ Taking a much broader view, *Buckman* would

¹⁸ James T. O'Reilly, *Losing Deference in FDA's Second Century: Judicial Review Sharpens as Political Constraints Diminish a Legacy of Expertise*, 93 CORNELL L. REV. (forthcoming 2008) (manuscript at 9, on file with the Northwestern University Law Review).

¹⁹ 531 U.S. 341, 344 (2001). Although the district court decision in the case held that the MDA's express preemption provision provided an additional source of preemption, *id.* at 347, the Supreme Court did not undertake an express preemption analysis. *Id.* at 348 n.2 (“[W]e express no view on whether these claims are subject to express preemption . . .”).

While *Buckman* itself addressed medical devices, it has been applied in the pharmaceutical context as well. *See, e.g.,* Bouchard v. Am. Home Prods. Corp., 213 F. Supp. 2d 802, 812 (N.D. Ohio 2002) (“The Court does not need to engage in searching analysis of *Buckman* to determine that claims of fraud on the FDA are preempted with respect to pharmaceuticals.” (citing *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 236 (6th Cir. 2000)); *Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342, 349 (Minn. Ct. App. 2001) (“Like the claims of fraudulent procurement of medical device approval at issue in *Buckman*, the existence of the federal regulations is critical to appellant's claims that those regulations were violated and caused her injuries. Moreover, the *Buckman* Court's observation that 50 state law causes of action for violation of the FDA's detailed regulations would increase the burdens placed on applicants for FDA approval applies to drug manufacturers as well as to medical-device manufacturers.”); *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 965–66 (6th Cir. 2004) (“This case, however, presents a somewhat different legal regime from the one invalidated in *Buckman*. . . . This difference, however, is immaterial in light of *Buckman*.”); *Dusek v. Pfizer Inc.*, No. Civ.A. H-02-3559, 2004 WL 2191804, at *8 n.30 (S.D. Tex. Feb. 20, 2004) (“Although *Buckman* was a decision involving an orthopedic bone screws' manufacturer's application for an exception under § 501(k) for devices that were already on the market when the Medical Devices Amendments to the FDCA were enacted in 1976, the issues are comparable to those at bar.”).

²⁰ Plaintiffs claimed to have suffered injuries from implantation of orthopedic bone screws. The plaintiffs claimed that the FDA would not have approved the screws had the regulatory consultant for the manufacturer not made fraudulent representations regarding the screws' intended use. In other words, the claim of damages did not rest on the allegation of defective design or manufacture of the

wipe out not only stand-alone fraud-on-the-agency claims, but also any other state-based tort claims—whether for misrepresentation or fraud, or even for garden-variety design defect or failure to warn—that relied upon evidence of fraud perpetrated against the FDA.

The shortcomings of either extreme interpretation are readily discernible. The narrow view confines *Buckman* to a thin slice of field preemption—taking the position that the Court was content to treat the FDA as the master of this limited domain of agency fraud claims only because policing fraud against federal agencies is not “a field which the States have traditionally occupied.”²¹ Support for this narrow view can certainly be gleaned from the Court’s opinion, particularly in how it distinguished its prior products liability decision in *Medtronic, Inc. v. Lohr*, which held that the MDA did not expressly preempt the plaintiff’s common law design, manufacturing, and labeling claims.²² In addition to the fact that *Lohr* involved express, not implied, preemption, the Court further distinguished the case by the fact that the claims in *Lohr* arose “not solely from the violation of FDCA requirements” but from “traditional state tort law which had predated the federal enactments in question.”²³ In other words, state interests were at stake in *Lohr* that reached beyond the exclusive federal interest in policing agency fraud implicated in *Buckman*.

But an exclusive field preemption lens misses a significant portion of the Court’s reasoning in *Buckman*. Switching to more of a conflict preemption analysis, the Court held that “State-law fraud-on-the-FDA claims inevitably conflict with the FDA’s responsibility to police fraud consistently with the Administration’s judgment and objectives.”²⁴ Buttressing this point, the Court emphasized the functional consequences of allowing such a state law claim to proceed: “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”²⁵

screws, but on their fraudulent approval and subsequent existence in the market. *Buckman*, 531 U.S. at 343.

²¹ *Id.* at 347–48 (“To the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character; the relationship originates from, is governed by, and terminates according to federal law.”). For this reason, too, the presumption against preemption need not rear its head. *Id.* at 348.

²² 518 U.S. 470, 487–89 (1996) (explaining that Congress’s intent in enacting the MDA was specific preemption of contradictory statutes, not broader general preemption). Lora Lohr was implanted with a Medtronic pacemaker that later failed. Lohr filed suit against Medtronic claiming that the medical device had been negligently manufactured, that Medtronic had failed to warn Lohr or her physicians of the risk of the device failing, and that the device had been defectively designed. Medtronic contended that all of Lohr’s claims were expressly preempted by the MDA. *Id.* at 480–81.

²³ *Buckman*, 531 U.S. at 352–53.

²⁴ *Id.* at 350.

²⁵ *Id.* The Court continued: “Would-be applicants may be discouraged from seeking . . . approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer or its associates . . . to unpredictable civil liability.” *Id.*

Fraud-on-the-agency claims, moreover, “would exert an extraneous pull on the [federal] scheme”²⁶ leading to second-guessing by state courts of the FDA’s determinations and overburdening the agency:

[F]raud-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. Applicants would then have an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA’s evaluation of an application.²⁷

Buckman’s holding, then, rests in substantial part on the majority’s conclusion that de novo review of fraud-on-the-FDA claims would directly consume the time of FDA officials and complicate the approval process by inducing companies to produce and submit more information, thereby frustrating the FDA’s attempts to reach a delicate balance between safety and innovation.

In terms of practical effect, the narrow view would countenance easy end runs around *Buckman* preemption. So long as plaintiffs avoid framing their cases in terms of stand-alone fraud-on-the-agency claims, *Buckman* would not interfere with attempts to plead such fraud by a different name. For example, plaintiffs may elect to pursue failure-to-warn claims premised upon incomplete disclosures by a drug manufacturer to the FDA of a risk that materialized in harm to consumers of the drug. Such a view would relegate *Buckman* to the annals of fairly idiosyncratic cases—there, regulating disclosure between a consultant and federal agency. It would also leave in full force state-based tort claims premised upon fraud on the agency, with the very same deleterious effects of second-guessing the FDA’s determinations and overburdening the agency that the *Buckman* Court aimed to prevent.

At the same time, the broadest view would wipe out all state-based tort claims premised upon any evidence of fraud on the agency—not to mention

This precise concern regarding “off-label” uses for medical devices would not seem to pertain to pharmaceuticals. See, e.g., *Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166, 1173 (D. Ariz. 2005) (“[T]he practice of off-label usage has no analog in the context of drug manufacturing.”). Unlike drug manufacturers, which are precluded from discussing the risks associated with possible off-label uses, the FDA “encourag[es] the inclusion of information about the risks of off-label [device] use on the label itself.” James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 89 (1998). According to the Pharmaceutical Research and Manufacturers of America, this duty to enumerate all foreseeable uses when requesting FDA approval means “[p]laintiffs . . . could (and likely would) allege, as here, that the manufacturer subjectively intended the device to be put to that use—either in lieu of, or in addition to, the listed ‘intended use’—and defrauded the FDA by failing to disclose such intent.” Brief of Amicus Curiae Pharmaceutical Research and Manufacturers of America in Support of Petitioner at 21–22, *Buckman*, 531 U.S. 341 (No. 98-1768), 2000 WL 1339143, at *21–22 (footnote omitted).

²⁶ *Buckman*, 531 U.S. at 353.

²⁷ *Id.* at 351.

prevent any and all evidence of such fraud from coming before the jury—and also preclude such claims even in the face of an antecedent finding of fraud by the FDA.²⁸ The United States urged this expansive interpretation of *Buckman* before the Supreme Court this Term in *Kent* on the ground that “a rule that made preemption turn on the presence or absence of a decision by FDA could create its own potential for interference with the federal scheme.”²⁹ Moreover, the United States asserted that “[t]he federal government alone has responsibility to determine the appropriate remedy under the FDCA when it approved a product and later learned of misrepresentations that might have led it not to approve the product.”³⁰ It is difficult to square the government’s position here with the FDA’s seeming embrace of the “fraud caveat” in its preamble to a recent rule on drug labeling.³¹

Justice Stevens’s concurring opinion in *Buckman* offers a more promising compromise approach—one that I argue provides the seeds of a conceptually sound model for complementary agency-court policing of fraud: state courts should decide fraud-on-the-agency claims only when such claims are supported by an antecedent agency determination of fraud. Justice Stevens opined:

This would be a different case if, prior to the instant litigation, the FDA had determined that petitioner had committed fraud during the [medical devices approval] process. . . . Under those circumstances, respondent’s state-law fraud claim would not depend upon speculation as to the FDA’s behavior in a counterfactual situation but would be grounded in the agency’s explicit actions. In such a case, a plaintiff would be able to establish causation without second-guessing the FDA’s decisionmaking or overburdening its personnel, thereby alleviating the Government’s central concerns regarding fraud-on-the-agency claims.³²

The wisdom of this middle-ground approach lies in its accommodation of federalism concerns. Viewed through a federalism lens, *Buckman* strikes a balance between state and federal interests—sometimes overlapping,

²⁸ See, e.g., *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 28 (1st Cir. 1995) (“We hold that Congress did not intend to provide an exception to the MDA’s preemption clause where a manufacturer fails to comply with the provisions of the MDA by fraudulently obtaining approval of its device from the FDA.”); *id.* at 29 (“Nothing in [the statutory express preemption clause] suggests that the state requirements are somehow revived by this failure to comply with the federal standard.”). In *Talbott*, the FDA had previously initiated a criminal prosecution against the manufacturer of a medical device for conspiring to defraud the FDA. *Id.* (“The FDA has the broad power . . . to initiate criminal prosecutions against manufacturers, as it did in this case against Bard.”). The manufacturer pled guilty and paid civil and criminal fines. *United States v. C.R. Bard, Inc.*, 848 F. Supp. 287, 288–89 (D. Mass. 1994).

²⁹ Brief for the United States as Amicus Curiae Supporting Petitioners at 23, *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008) (No. 06-1498), 2007 WL 4218889, at *23 [hereinafter *Amicus Brief for the United States in Kent*].

³⁰ *Id.* at 24.

³¹ See *supra* note 7 and accompanying text.

³² *Buckman*, 531 U.S. at 353–54 (Stevens, J., concurring in the judgment).

sometimes conflicting—in regulating products governed by federal regulations and state tort law (in that case, medical devices). By requiring an antecedent determination of fraud by the FDA, the approach effectively eliminates the substantial federal interest in adjudicating state claims that entail interpreting the FDCA.³³ In essence, it accords the FDA primary jurisdiction over a claim of fraud on the agency and effectively substitutes the federal agency for the courts as the forum of first resort for consumer complaints. But, once the FDA has made a definitive finding of fraud, the door is thereby opened to state law tort claims to “supplement and facilitate[] the federal enforcement scheme.”³⁴

In sum, the approach laid out in Justice Stevens’s concurring opinion in *Buckman* provides a conceptually sound and eminently workable solution, relying upon the ability of federal agencies and state law to work in tandem. When liability rests on an agency determination of fraud on the FDA, state law supplements, rather than encroaches upon, the federal enforcement scheme. The next Part takes up some concrete applications.

II. APPLICATIONS: PREEMPTION CONTROVERSIES IN PHARMACEUTICAL LITIGATION

The middle ground interpretation of *Buckman* has a practical payoff in a host of contemporary controversies in pharmaceutical litigation, including the extent to which fraud exceptions to state immunity statutes are preempted—an issue that has divided the federal circuits and remains unresolved in the wake of the Supreme Court’s “nondecision” in *Kent*.³⁵ The *Buckman* interpretive issue, moreover, lies at the heart of a more fundamental conceptual controversy in the products liability field—namely, the ex-

³³ See *id.* at 354 (noting that plaintiff’s claims “would not depend upon speculation as to the FDA’s behavior in a counterfactual situation”).

³⁴ *Id.* A recent case provides an apt illustration. According to the federal district court in *Wawrzynek v. Statprobe, Inc.*, Civil Action No. 05-1342, 2007 WL 3146792 (E.D. Pa. Oct. 25, 2007), “this case essentially fits into the *Buckman* concurrence’s exemption.” *Id.* at *11. In that case, prior to the state court litigation, the FDA determined that the product manufacturer committed fraud during the regulatory approval process; indeed, the manufacturer entered a guilty plea based, in part, on its submission of false and misleading information to the FDA. *Id.* at *4. Although no formal action had been taken against the contract research organization working in tandem with the manufacturer, the court concluded that “[b]ecause the FDA found that fraud and wrongdoing occurred during the [medical device] approval process, the door to the *Buckman* concurrence was opened wide enough to allow both [the product manufacturer] and [the contract research organization] to pass through.” *Id.* at *11 (emphasis omitted).

³⁵ Compare *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004) (“[T]he [fraud] exemptions are invalid as applied in some settings (*e.g.*, when a plaintiff asks a state court to find bribery or fraud on the FDA) but not in others (*e.g.* claims based on federal findings of bribery or fraud on the FDA).”), with *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 94–95 (2d Cir. 2006) (disagreeing with *Garcia* in holding that *Buckman* did not preempt traditional state law tort claims that triggered the statute’s fraud exemption), *aff’d per curiam by an equally divided Court sub nom.* Warner-Lambert Co. v. Kent, 128 S. Ct. 1168 (2008) (mem.).

tent to which state tort law dictates and federal requirements work in tandem, or at odds, in the regulation of health and safety.

A. Fraud Exception to State Immunity Statutes

As part of myriad state tort reform efforts, several legislatures enacted statutory immunity provisions to protect pharmaceutical manufacturers—either from liability altogether, or else only from punitive damages—so long as their drugs were fully approved by the FDA and they complied with all regulations. Michigan stands alone in having adopted a complete, blanket immunity based upon federal regulatory compliance.³⁶ Several additional states—Colorado, Indiana, Kansas, Kentucky, New Jersey, Tennessee, Texas, and Utah—provide a weaker form of protection in the form of a rebuttable presumption that FDA-approved warnings are adequate in the face of failure-to-warn claims.³⁷ And several states—Arizona, Colorado, New Jersey, North Dakota, Ohio, Oregon, and Utah—bar punitive damages against drug manufacturers who have complied with FDA guidelines.³⁸ Without exception, all of these state statutes contain a fraud exception, disabling immunity where the drug manufacturer has deceived or defrauded the FDA. Indeed, the existence of the fraud exception may encourage broad immunity statutes in the first place.

While all would agree that drug manufacturers with unclean hands should not be able to reap the advantages of immunity, these fraud exceptions nonetheless present a thorny doctrinal issue: are they themselves preempted under *Buckman*, which forecloses state court adjudication of fraud-on-the-agency claims? From an institutional perspective, it is the FDA's prerogative to monitor, assess, and police fraud committed upon it by drug manufacturers. However, so long as the FDA has made a prior finding of fraud, there should be no problem with private litigants using such findings as swords in state tort litigation—either to buttress claims or, where provided by statute, to disable a defendant drug manufacturer's immunity.

The Sixth Circuit has staked out exactly this position. In *Garcia v. Wyeth-Ayerst Laboratories*,³⁹ a case against a pharmaceutical manufacturer applying Michigan law, the court partially invalidated the statutory fraud exception, ruling that it was preempted insofar as it allowed plaintiffs independently to make a showing of fraud on the agency (as opposed to relying

³⁶ MICH. COMP. LAWS ANN. § 600.2946(5) (West 2007).

³⁷ COLO. REV. STAT. § 13-21-403(1)(b) (2007); IND. CODE ANN. § 34-20-5-1(2) (West 1999); KAN. STAT. ANN. § 60-3304(a) (2005); KY. REV. STAT. ANN. § 411.310(2) (West 2005); N.J. STAT. ANN. § 2A:58C-4 (West 2000); TENN. CODE ANN. § 29-28-104 (2007); TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(a) (Vernon 2005); UTAH CODE ANN. § 78-15-6(3) (2005).

³⁸ ARIZ. REV. STAT. ANN. § 12-701(a)(1) (2003); COLO. REV. STAT. § 13-64-302.5(5)(a) (2007); N.J. STAT. ANN. § 2A:58C-5(c) (West 2000); N.D. CENT. CODE § 32-03.2-11(6) (2007); OHIO REV. CODE ANN. § 2307.80(c)(1) (West 2006); OR. REV. STAT. § 30.927(1)(a) (2005); UTAH CODE ANN. § 78-18-2(1) (2002).

³⁹ 385 F.3d 961.

upon a prior determination by the FDA).⁴⁰ According to the court, *Buckman* commanded the result: “*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims.”⁴¹ The court, moreover, fully appreciated the federalism implications:

Doubtless, *Buckman* prohibits a plaintiff from invoking the exceptions on the basis of *state court* findings of fraud on the FDA. Such a state court proceeding would raise the same inter-branch-meddling concerns that animated *Buckman*. But the same concerns do not arise when the FDA itself determines that a fraud has been committed on the agency during the regulatory-approval process. Thus, in this setting, it makes abundant sense to allow a State that chooses to incorporate a federal standard into its law of torts to allow that standard to apply when the federal agency itself determines that fraud marred the regulatory-approval process. In the final analysis, the exemptions are invalid as applied in some settings (e.g., when a plaintiff asks a state court to find bribery or fraud on the FDA) but not in others (e.g., claims based on federal findings of bribery or fraud on the FDA).⁴²

The court thereby staked out the middle position, preempting claims whereby state courts would be called upon to adjudicate fraud on the agency in the first instance while allowing claims where the FDA has itself made the antecedent finding of fraud.⁴³

Garcia has attracted a substantial following among courts.⁴⁴ They have recognized the similarity between the fraud-on-the-agency claim preempted

⁴⁰ In *Garcia*, it was the plaintiff who claimed that the fraud exception was preempted and, thus, that the entire immunity statute should be nullified. *Id.* at 967 (“[T]he Plaintiff [urges the situation] where drug manufacturers would enjoy no immunity at all.”). The court, however, determined that the fraud exception—which it held was partially void by preemption—could be severed from the remainder of the immunity statute. *Id.* (“[S]evering the preemption exemptions will not give license to drug manufacturers to use bribery or fraud as a means of obtaining FDA approval, then rely on that approval as a shield from products liability: it will merely place responsibility for prosecuting bribery or fraud on the FDA in the hands of the Federal Government rather than state courts.”). *Garcia*’s reasoning strongly suggests that the court would preempt failure-to-warn negligence per se claims based on allegations of fraud on the agency or failure to disclose risk information as required by the FDCA, unless the FDA has itself made such a determination. *Id.* at 966.

⁴¹ *Id.* at 966 (citing *Garcia v. Wyeth-Ayerst Labs.*, 265 F. Supp. 2d 825 (E.D. Mich. 2003)).

⁴² *Id.* (citations omitted).

⁴³ Though *Garcia* cites the *Buckman* majority, the position derives from Justice Stevens’s concurrence, which is nowhere incorporated by the majority. Nor does *Garcia* explicitly weigh in on the relevance of the presumption against preemption—although the *Desiano* court did attempt to distinguish its reasoning on this basis. *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 94 n.6 (2d Cir. 2006) (“[T]he Sixth Circuit’s holding in *Garcia* was based on the assumption that no presumption against preemption applied.”), *aff’d per curiam by an equally divided Court sub nom.* *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008).

⁴⁴ Federal district courts in Michigan have had occasion to apply *Garcia*’s holding. *See, e.g.*, *Zammit v. Shire U.S., Inc.*, 415 F. Supp. 2d 760, 768 (E.D. Mich. 2006) (“[T]he Court finds that this proposed avenue of proof is foreclosed by . . . *Garcia* [because] . . . plaintiff has neither alleged nor produced any evidence that the FDA itself has found any fault with Defendant’s conduct or submissions

in *Buckman* and the statutory fraud exceptions, in terms of the potential federalism clash between state court and agency adjudication. In the words of a federal district court in Arizona (interpreting an immunity statute barring punitive damages in the face of regulatory compliance):

Both a common law fraud-on-the-FDA claim and an immunity statute that requires a plaintiff to prove fraud on the FDA in order to collect punitive damages place state courts, as finders of fact, in the uncomfortable and difficult position of having to answer the question of what role, if any, the allegedly withheld information would have played in the FDA's complicated approval process.⁴⁵

But this equilibrium balance—a kind of cooperative federalism approach by courts and federal agencies to health and safety regulation in the face of fraud—is threatened by a rival approach. In *Desiano v. Warner-Lambert & Co.*,⁴⁶ a recent opinion penned by Judge Guido Calabresi, the Second Circuit (in a pharmaceutical case likewise applying Michigan law) staked out an opposing position.⁴⁷ In the Second Circuit's hands, the fraud exceptions in state immunity statutes escape preemption; the court adopts

during the course of the company's applications for agency approval . . ."); *Ammend v. Bioport, Inc.*, Nos. 5:03-CV-31, 1:03-CV-254, 1:03-CV-809, 1:05-CV-182, 2006 WL 1050509, at *3–4 (W.D. Mich. Apr. 19, 2006) (applying *Garcia* retroactively to support summary judgment of plaintiff's claim for fraud in the approval of an anthrax vaccine). Michigan state courts have also affirmed this interpretation. *See, e.g.,* *Duronio v. Merck & Co.*, No. 267003, 2006 WL 1628516, at *5–6 (Mich. Ct. App. June 13, 2006) (“[W]e agree with [*Garcia*'s] holding that the fraud-on-the-[FDA] exception is preempted by federal law unless the FDA itself determines that it was defrauded.”). For courts outside Michigan interpreting Michigan law and invoking *Garcia*, see, for example, *Henderson v. Merck & Co.*, No. 04-CV-05987-LDD, 2005 WL 2864752, at *1 (E.D. Pa. Oct. 31, 2005); *Alli v. Eli Lilly & Co.*, 854 N.E.2d 372, 378–80 (Ind. Ct. App. 2006); *Norris v. Pfizer Inc.*, 839 N.Y.S.2d 434, 2007 WL 969431, at *4 (N.Y. Sup. Ct. 2007) (unpublished table decision).

Moreover, *Garcia*'s reach extends further afield to other jurisdictions' laws. *See, e.g., In re Aredia & Zometa Prods. Liab. Litig.*, No. 3:06-MD-1760, 2007 WL 649266, at *9 n.17 (M.D. Tenn. Feb. 27, 2007) (“[T]he FDA itself must make this finding of fraud.”); *Ledbetter v. Merck & Co.*, Nos. 2005-59499 & 2005-58543, 2007 WL 1181991, at *5 (Tex. Dist. Ct. Apr. 19, 2007) (preempting fraud exception to Texas immunity statute “to the extent that someone other than the FDA is being asked to make the determination”); *cf. Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166, 1174–75 (D. Ariz. 2005) (“While the Court agrees with *Garcia* that no preemption need occur where the FDA has made a finding that it has been defrauded, . . . that is not the case here.”).

⁴⁵ *Kobar*, 378 F. Supp. 2d at 1173.

⁴⁶ 467 F.3d 85.

⁴⁷ *Id.* at 93–96. The federal district court below had, by contrast, followed the spirit of *Garcia*. *Id.* at 89. The district court, moreover, laid out a federalism-inflected argument for preventing courts from interfering with centralized, agency enforcement of federal standards:

If plaintiffs covered by the Michigan statute were able to litigate claims of fraud on the FDA in individual personal injury suits, whether in state courts or in federal courts, the potential would exist for the FDA's personnel to be drawn into those controversies on a case-by-case basis over and over again. . . . [T]he exception in the Michigan statute is preempted, except where the plaintiff relies on a finding by the FDA, or in an action brought by the FDA, of material fraud in the new drug approval process absent which approval would not have been granted.

Id.

the narrow view of *Buckman* that only stand-alone fraud-on-the-agency claims are foreclosed.⁴⁸ Here, by contrast, according to the court:

[T]he plaintiffs' complaints allege a wide range of putative violations of common law duties long-recognized by Michigan's tort regime. These pre-existing common law claims survive [the Michigan immunity provision] because there is also evidence of fraud in FDA disclosures. But, unlike the claims in *Buckman*, they are anything but based *solely* on the wrong of defrauding the FDA.⁴⁹

Desiano thereby adopted the narrower, field preemption view of *Buckman*, where the "field" is limited to stand-alone fraud-on-the-agency claims.⁵⁰ Judge Calabresi emphasized the relevance of the "presumption against preemption" where the state interest—"to regulate and restrict when victims could continue to recover under preexisting state products liability law"—arguably distinguishes the immunity statutes from the pure federal interest at stake in the fraud-on-the-agency context of *Buckman*.⁵¹ According to Judge Calabresi, the presumption is enough to overcome whatever conflict might exist between the immunity statute and the FDCA's enforcement mechanism.⁵²

The *Desiano* opinion is by no means an anomaly; at least one federal district court has adopted its analysis.⁵³ This Term, the U.S. Supreme Court granted certiorari in the case (denominated *Warner-Lambert Co. v. Kent*) to resolve the intercircuit disagreement; but its split per curiam decision left

⁴⁸ Judge Calabresi argued that the immunity statute does not make common law claims conditional on a determination of fraud on the agency. Instead, according to Judge Calabresi, the statute creates an affirmative defense for drug manufacturers. *Id.* at 96 ("[T]he Michigan law in question does no more than create a defense that drug makers may invoke, if they so decide, and . . . it is not up to the plaintiff to prove fraud as an element of his or her claim."). This creative interpretation, however, does not address the potential conflict whereby the court finds fraud where the FDA has not.

⁴⁹ *Id.* at 95; see also *id.* ("Given *Buckman's* explanation of *Medtronic [v. Lohr]*, *Buckman* cannot be read as precluding such preexisting common law liability based on other wrongs, even when such liability survives only because there was *also* evidence of fraud against the FDA.").

⁵⁰ See *supra* notes 21–23 and accompanying text.

⁵¹ *Desiano*, 467 F.3d at 94. Judge Calabresi would require a clear signal from Congress to depart from the narrowest interpretation of *Buckman*: "Until and unless Congress states explicitly that it intends invalidation of state common law claims merely because issues of fraud may arise in the trial of such claims, we decline to read general statutes like the FDCA and the MDA as having that effect." *Id.* at 96. In other words, the danger, according to Judge Calabresi, should preemption operate when fraud is merely used for its evidentiary significance, is that preemption would thereby swallow up the general presumption against preemption of state tort law causes of action absent clear-cut congressional specification.

⁵² *Id.* at 94 n.6.

⁵³ *Ackermann v. Wyeth Pharms.*, 471 F. Supp. 2d 739, 749 (E.D. Tex. 2006) (echoing *Desiano* in holding that the Texas immunity statute "creates nothing more than a presumption which the Defendant is free to raise" and "does not create a cause of action where none existed before"), *aff'd on other grounds*, No. 06-41774, 2008 WL 1821379 (5th Cir. Apr. 24, 2008).

the issue open.⁵⁴ Just as the federal circuits are evenly split, so too is academic opinion. Judge Calabresi's opinion in *Desiano* elicited vociferous criticism from Richard Epstein,⁵⁵ but an equal measure of praise from Richard Nagareda.⁵⁶

Viewed from an institutional federalism framework, *Desiano* suggests that the Second Circuit will countenance state (and federal) court interference with the FDA's standard-setting and enforcement functions in the fraud arena—at least so long as such intermeddling takes place within the context of adjudicating traditional common law tort claims. Indeed, the court defends this position as conforming to the status quo of interbranch meddling:

So long as a court or jury is allowed to consider evidence of fraud against the FDA in an ordinary common law tort suit, and so long as juries are likely to react to such evidence, there will be substantial inducements on the pharmaceutical industry to provide the federal agency with just the kind of information that troubled the *Buckman* and *Garcia* Courts.⁵⁷

Desiano's position here is arguably at odds with the “frustration of purpose” variety of implied conflict preemption as articulated by the U.S. Supreme Court, which “has spoken of pre-empting state law that ‘under the circumstances of the particular case . . . stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress’—whether that ‘obstacle’ goes by the name of ‘conflicting; contrary to; . . . repugnance; difference; irreconcilability; inconsistency; violation; curtail-

⁵⁴ Warner-Lambert Co. v. Kent, 128 S. Ct. 1168 (2008) (mem.). Although the circuit split is shallow (i.e., a 1-1 split between the Sixth and Second Circuits) and narrow (i.e., it implicates a disagreement regarding the interpretation of the Michigan immunity statute), presumably the Court was persuaded that important interests were at stake. See, e.g., Petition for a Writ of Certiorari at 11, *Kent*, 128 S. Ct. 1168 (No. 06-1498), 2007 WL 1420562, at *11 (“[T]he issues reach beyond the Michigan statute on which the Sixth and Second Circuit are in conflict. As part of tort reform efforts throughout the country, other states have enacted statutes limiting claims or damage recoveries for FDA-approved drugs unless the finder of fact determines under state law that there was fraud-on-the-FDA.”); *id.* at 25 (“The conflict also will inject forum shopping considerations into the [multi-district litigation] process, which today handles much of the pharmaceutical product liability litigation.”); Brief of the Product Liability Advisory Council as Amicus Curiae in Support of Petitioner at 14, *Kent*, 128 S. Ct. 1168 (No. 06-1498), 2007 WL 2126024, at *14 (“The pressing need for this Court’s guidance stems not only from the cases where courts have already addressed the scope of *Buckman*, but also from thousands of other cases where the issue is pending or necessarily will arise.”).

⁵⁵ Epstein, *supra* note 3, at 13–14 (“[I]f [Judge Calabresi’s] position is that fraud-on-the-FDA can be proved in order to rehabilitate the common law action, then the FDA will inevitably be enmeshed in state law litigation on the very matters that *Buckman* held were within the exclusive competence of the FDA.”).

⁵⁶ Nagareda, *supra* note 9, at 46–47; *id.* at 52 (“A world in which fraud on the agency threatens to blow up preemption from the industry’s vantage point stands to be [a] world in which there will be less fraud itself.”).

⁵⁷ *Desiano*, 467 F.3d at 97 (emphasis omitted).

ment; . . . interference,’ or the like.”⁵⁸ And as to whether *Desiano* aptly characterizes the intermeddling status quo, much turns on the implicit assumption (not validated in the opinion) that most states permit the introduction of fraud-on-the-FDA evidence, at least so long as it is offered to support traditional common law claims—an issue taken up in the next Section.

What is key for present purposes is to acknowledge that the *Buckman* interpretive issue here reverberates widely, affecting far more than just the fraud exceptions to state immunity statutes. It has far-reaching implications for the pursuit of common law tort claims—fraud, misrepresentation, design defect, failure to warn—in all states, given that no medical device or pharmaceutical drug can reach the market without FDA approval, which is based upon manufacturer’s disclosure of data and information to the FDA.

B. “Parallel” State-Federal Requirements in Pharmaceutical Cases

A complete inquiry into the scope of *Buckman* preemption entails not only an analysis of what precisely constitutes a fraud-on-the-FDA claim sufficient to trigger preemption, but also an inquiry into the scope of admissible evidence of fraud in garden-variety tort suits. These interpretive issues, moreover, lie at the heart of a core conceptual controversy in products liability preemption cases: namely how to delineate the regulatory roles to be played by courts and federal agencies.

A key question for courts is when is a state common law tort claim—whether for misrepresentation or fraud, or for design defect or failure to warn—essentially a fraud-on-the-FDA claim that would be impliedly preempted by *Buckman*? The Supreme Court did not provide a definitive answer. Focusing on the case at hand, the Court emphasized that the “fraud claims exist solely by virtue of the FDCA disclosure requirements” and reasoned that “were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in question.”⁵⁹ Instead, the Court explained, “the existence of these federal enactments is a *critical* element in their case.”⁶⁰ While central to the Court’s preemption determination, the contours of “critical element” were not further spelled out, although the Solicitor General had taken a stab at doing so in his argument before the Court:

The fraud claim is preempted, but if there is negligent design, negligent manufacturing, failure to warn, common law malpractice, all of those claims are available, but insofar as they would be asserting an *essential* element of the

⁵⁸ *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000) (alteration in original) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

⁵⁹ *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 352–53 (2001).

⁶⁰ *Id.* at 353 (emphasis added).

claim would be that the FDA was defrauded, that is an area of exclusive Federal concern, and the State common law cause of action would be preempted.⁶¹

Several lower courts have responded by being on the lookout for fraud-on-the-agency claims masquerading as garden-variety tort claims.⁶² Recently, a Minnesota state court held that state law claims of negligent misrepresentation and fraud, based upon the violation of FDCA provisions governing disclosure of adverse drug experiences and the content of labeling, were preempted.⁶³ The court reasoned: “Like the claims of fraudulent procurement of medical device approval at issue in *Buckman*, the existence of the federal regulations is critical to appellant’s claims that those regulations were violated and caused her injuries.”⁶⁴

While there is near consensus on the view that *Buckman* forecloses a claim predicated solely upon failure to disclose material information to the FDA in violation of FDCA regulations, the extent of its further reach is fraught with controversy. As discussed above, Judge Calabresi in *Desiano* adopted the narrowest possible reading of *Buckman*, which would leave intact a host of state law tort claims premised upon fraud, so long as fraud were not the sole pillar of the claim.⁶⁵ Taking a more aggressive posture, a California federal district court rebuffed a fraud allegation embedded within a failure-to-warn claim: “Plaintiffs’ allegation that [the drug manufacturer] withheld material cardiovascular risk data from the FDA does not change the preemption analysis.”⁶⁶ The court elaborated: “The law is well established that a claim premised on a drug manufacturer’s failure to provide data to the FDA is preempted.”⁶⁷

Subsumed within the preemption question is a corresponding evidentiary one, namely whether evidence of the inadequacy of the defendant’s representations to the FDA is admissible in support of common law claims (other than fraud-on-the-agency claims). Here, the narrow preemption view maps onto a broadly permissible view of allowable evidence, whereas the broadest view of preemption leads to the most restrictive evidentiary ap-

⁶¹ Transcript of Oral Argument at 21, *Buckman*, 531 U.S. 341 (No. 98-1716), 2000 WL 1801621, at *21 (emphasis added).

⁶² See, e.g., *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005) (“Granting leave to amend on [the negligence per se count] would be futile because that count is a disguised fraud on the FDA claim.”).

⁶³ See *Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342, 348–49 (Minn. Ct. App. 2001) (citing 21 C.F.R. § 314.80–.81 (2000); 21 C.F.R. § 201.57 (2000)).

⁶⁴ *Id.* at 349.

⁶⁵ See *supra* notes 46–52 and accompanying text; see also *Brown v. DePuy Spine, Inc.*, Nos. BRCV2006-00208, 00209, 00211, 00630, 2007 WL 1089337, at *12–13 (Mass. Super. Ct. Apr. 9, 2007) (“[T]here is no merit to [defendant’s] argument that [*Buckman*] forecloses a claim predicated upon failure to disclose material information to the FDA in violation of the FDA regulations.”).

⁶⁶ *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. M: 05-1699 CRB, 2006 WL 2374742, at *10 (N.D. Cal. Aug. 16, 2006).

⁶⁷ *Id.*

proach. Seemingly following this latter approach, an Ohio federal district court, in a decision that ruled out any and all private actions premised on fraud on the FDA, claimed that evidence would be excluded outright not only “when it is offered . . . to show that the FDA was misled, or that information was intentionally concealed from the FDA,” but also when “[e]xclusion of further evidence may be necessary to prevent confusion of the jury as to the nature of [plaintiff’s] claims.”⁶⁸ It is more typical, however, for courts to take an approach that forecloses causes of action that require proof of fraud rather than prohibiting the use of fraud evidence full stop. In one court’s words: “While plaintiff may not offer evidence simply to show misrepresentations to or concealment from the FDA, such evidence may be relevant to showing the defendant’s knowledge relating to the adequacy of the warning or the truth of information represented to or concealed from plaintiff or her physician.”⁶⁹ The critical distinction is that “plaintiffs may use evidence—if they are able to produce it—of [defendant’s] efforts to manipulate the regulatory process in order to prove their negligence and strict liability claims, but they may not bring an independent claim for relief based on fraud-on-the-FDA.”⁷⁰

Each of these *Buckman* interpretive debates—regarding the scope of *Buckman* preemption and the corresponding breadth of evidentiary restrictions—implicates a deeper conceptual issue regarding the allocation of authority between courts and federal agencies that extends well beyond the fraud arena. The issue of when state law can enforce “parallel requirements” to federal violations without thereby encroaching upon federal requirements confounds jurists facing questions of preemption in the products liability context. Moreover, this question has been left open by the Court this Term; both in its split decision in *Kent*⁷¹ as well as in its earlier decision

⁶⁸ *Bouchard v. Am. Home Prods. Corp.*, 213 F. Supp. 2d 802, 812 (N.D. Ohio 2002).

⁶⁹ *Globetti v. Sandoz Pharm. Corp.*, No. CV98-TMP-2649-S, 2001 WL 419160, at *3 (N.D. Ala. Mar. 5, 2001); see also *Brown*, 2007 WL 1089337, at *13 (“A state claim alleging negligence based on a failure to disclose known risks to the FDA and, thereafter, to patients is not impliedly preempted because liability does not exist solely by proof of a violation of FDA disclosure requirements.”).

⁷⁰ *In re Medtronic, Inc., Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886, 900 (D. Minn. 2006); see also *In re Baycol Prods. Litig.*, 495 F. Supp. 2d 977, 1000 (D. Minn. 2007) (“[T]o the extent Dr. Kapit’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. The Court will leave to 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 Bayer’s alleged failure to submit information to the FDA.”); *Eve v. Sandoz Pharm. Corp.*, No. IP 98-1429-C-Y/S, 2002 WL 181972, at *3 (S.D. Ind. Jan. 28, 2002) (“[E]vidence of [defendant’s] interaction with the FDA may be pertinent to proving the [plaintiff’s] claim, but it is not the basis for the claim itself.”).

⁷¹ *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008) (mem.). During the *Kent* oral arguments, the Justices probed whether allowing a cause of action that included a fraud-on-the-FDA element would swamp the agency with discovery requests. Compare, e.g., Transcript of Oral Argument at 37–38, *Kent*, 128 S. Ct. 1168 (No. 06-1498), 2008 WL 495030, at *37–38 (Alito, J., questioning whether allowing state courts to make this inquiry would permit invasive and time-consuming examination of FDA’s in-

this Term in *Riegel v. Medtronic, Inc.*⁷² Recall that in *Buckman* Justice Stevens concluded that fraud-on-the-agency claims (and those in which fraud is a critical element) are preempted unless the FDA has made a prior finding of fraud.⁷³ In reaching this result, Justice Stevens was guided by the principle that claims should be preempted only when they would “encroach upon” as opposed to “supplement and facilitate[] the federal enforcement scheme.”⁷⁴

A similar theme of complementary federal-state regulation was sounded by Justice Stevens in *Bates v. Dow Agrosciences LLC*, where the Court was called upon to construe the express preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).⁷⁵ FIFRA directs that states “shall not impose or continue in effect any requirements for labeling or packaging *in addition to or different from* those required under this subchapter.”⁷⁶ In the face of this seemingly stringent express preemption provision, the Court allowed state tort claims to proceed, as long as the elements of the state causes of action are substantially equivalent to FIFRA’s prohibition on the sale of “misbranded” products.⁷⁷ Sounding the theme of complementary state-federal enforcement, the Court reiterated that “a state-law labeling requirement must in fact be equivalent to a requirement under FIFRA in order to survive pre-emption.”⁷⁸

But contrast the Court’s approach in *Bates* with the accommodation reached by Justice Stevens in *Buckman*. The genius of Justice Stevens’s resolution in *Buckman* lies in his attention to the oft-overlooked institutional dimension of the federalism inquiry on “parallel” state and federal requirements; that is, who should decide when state tort requirements are “equivalent” to federal dictates? In *Bates*, Justice Stevens is content to leave this inquiry in the hands of state and federal courts; whereas in *Buckman* the resolution is lodged squarely within the federal agency. Of course, there are some obvious distinctions one could make: namely that the FDA’s prerogative to police fraud against itself (at issue in *Buckman*) is not tantamount to the EPA’s prerogative to regulate information included on product labels (at issue in *Bates*). But conceptually, the same issue arises—to what

ternal procedures), *with, e.g., id.* at *22, 27 (Stevens, J., expressing skepticism regarding the magnitude of the potential problem).

⁷² 128 S. Ct. 999, 1011 (2008) (“Although the [plaintiffs] now argue that their lawsuit raises parallel claims [they did not address the issue in earlier briefs]. We decline to address that argument in the first instance here.”).

⁷³ *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 353–54 (2001) (Stevens, J., concurring) (“This would be a different case if, prior to the instant litigation, the FDA had determined that petitioner had committed fraud.”).

⁷⁴ *Id.* at 354.

⁷⁵ 544 U.S. 431, 434–36 (2005).

⁷⁶ 7 U.S.C. § 136v(b) (2000) (emphasis added).

⁷⁷ *Bates*, 544 U.S. at 447.

⁷⁸ *Id.* at 453.

extent should state and federal courts have free rein to put federal agency decisionmaking processes on trial? Do courts have the competence to decide—absent input from the relevant federal agency—whether, and to what extent, state tort law claims complement federal regulatory schemes? Do agencies alone?

The inquiry must be a comparative institutional one, which in turn is guided by functional as well as practical considerations.⁷⁹ For example, a functional preemption policy for nationally regulated products might prohibit state and federal courts from determining whether federal standards have been met, so long as the relevant federal agency has ample authority to enforce the standards and those standards are intended by the federal government to be optimal regulation.⁸⁰ Such a functional policy might, however, allow courts to premise liability on prior federal determinations of violations if added enforcement would complement federal enforcement.

Very quickly, such a comparative institutional inquiry turns from the abstract and theoretical to the concrete and practical. The remainder of this Article returns to the role of the FDA, both as it operates presently to combat fraud and as it might be reformed to enhance its role along the lines of the agency-court model sketched out above.

III. FDA AS GATEKEEPER: INSTITUTIONAL SHORTCOMINGS

Having sketched in broad brushstrokes a model for agency-court interaction that vests significant a priori regulatory authority over disclosure of information to the FDA in the FDA itself, it is time to subject that institution to scrutiny. Some questions come to the fore: How likely is the FDA to detect a fraud upon itself? How many injured plaintiffs that deserve compensation would be deprived if the FDA's supremacy in this field demands that it be protected from the intrusion of fraud-on-the-FDA trials?⁸¹

⁷⁹ Elsewhere, I develop what I term an “agency reference model” for judicial decisionmaking in the realm of products liability preemption. Sharkey, *supra* note 15, at 477–502.

⁸⁰ As Lars Noah has pointed out, “[w]ith the proliferation of more or less detailed (and often ambiguous) regulatory requirements, gauging compliance may be difficult. . . . [E]fforts to determine whether a device manufacturer has complied fully with the requirements found in a premarket approval and any generally applicable regulations could present serious difficulties.” Lars Noah, *Reconceptualizing Federal Preemption of Tort Claims as the Government Standards Defense*, 37 WM. & MARY L. REV. 903, 954 (1996). During the *Kent* oral arguments, several of the Justices acknowledged the potential sweep of the claim for privileging agency determinations of fraud in the *Buckman* context, which might logically extend to an agency’s prerogative to determine whether a federal regulatory standard has been violated, or complied with, in the context of common law negligence per se claims and regulatory compliance defenses. *See, e.g.*, Transcript of Oral Argument at 14, *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008) (No. 06-1498), 2008 WL 495030, at *14 (Scalia, J., questioning whether a jury should be allowed to determine whether the drug had complied with the FDA approval process); *id.* at *17–19 (Souter, J., suggesting that the issue of FDA approval arises more generally in the contexts of offensive and defensive uses of compliance with federal regulations in state tort claims).

⁸¹ The FDA is subjected to one-sided institutional scrutiny here, given that the model I present above tips in favor of the agency’s exclusive prerogative to determine fraud in this context. A true com-

In considering these questions, at the outset it is important to observe that the FDA's aggressiveness on the preemption front has forged a gap at the remedial end. At present, the sword wielded by the FDA in policing and preventing fraud is dwarfed by the shield of immunity promised to drug manufacturers by FDA approval. As a formal matter, the FDA wields robust policing authority—the ability to recall products, withdraw approval, impose fines against manufacturers, and assign criminal penalties against executives. In practice, however, a wide discretionary berth separates the FDA's formal powers and actual enforcement activity. At a time when the FDA has seized the preemption reins—arguing fairly aggressively for power to preempt common law tort actions—the agency has retreated from the enforcement front. After reviewing the status quo powers and track record of the FDA, I turn to a blueprint for reform, in line with the conceptual model laid out above.

A. *Status Quo*

The FDA polices fraud in the regulatory approval process for medical devices and drugs.⁸² There is no private right of action to enforce the FDCA. “The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device [and drug] provisions.”⁸³ Private citizens

parative institutional analysis would of course investigate the opposite side of the coin: How badly would the FDA drug approval process be skewed if state and federal courts took the lead in determining the sufficiency of information disclosure to the FDA, in light of concerns of public health and safety? It is difficult, however, to do much more than speculate given the dearth of state and federal court experience independently prosecuting fraud on the FDA through the tort system. Nonetheless, one might impugn as a general matter the competence of juries to make decisions in the FDA drug regulation context. *See, e.g.*, Schuck, *supra* note 15, at 13–14 (arguing that juries are at a comparative disadvantage vis-à-vis the FDA with respect to “the ability to process detailed scientific research information and complex risk-risk tradeoffs, and to make or second-guess technocratic decisions about drug design and labeling”).

⁸² *Buckman* describes in detail the federal enforcement mechanism created by the FDCA and MDA governing medical devices. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348–50 (2001). The FDA has similar enforcement powers with respect to regulating prescription drugs, though the nature of the statutory regime differs.

Several scholars, nonetheless, contrast the FDA's ability to regulate medical devices with its ability to police prescription drugs. *See, e.g.*, Michael D. Green & William B. Schultz, *Tort Law Deference to FDA Regulation of Medical Devices*, 88 GEO. L.J. 2119, 2145 (2000) (“[A] regulatory compliance defense for medical devices is even more undesirable [than one for FDA-approved drugs].”); Nagareda, *supra* note 9, at 53 (“For medical devices that have undergone full-scale premarket approval, the FDA gets its preemption stance right but its characterization of the underlying regulatory regime wrong. Preemption flows from a federal command in the nature of required forbearance from product change, even while the basic substantive standard for device approval sounds more in minimal, rather than optimal, regulation. For prescription drug labeling, by contrast, optimal regulation—here, the FDA's repeated assessments of the science on SSRIs—has produced a confused array of judicial conclusions about preemption.”).

⁸³ *Buckman*, 531 U.S. at 50 n.4 (quoting 21 U.S.C. § 337(a) as requiring “[a]ll such proceedings for the enforcement, or to restrain violations, of this chapter [to] be by and in the name of the United States”).

may, nonetheless, petition the FDA to take action against wrongdoing;⁸⁴ and the FDA must respond in a timely manner to such petitions.⁸⁵

Among its statutory powers, the FDA may compel disclosure and retains the power to investigate suspected fraud.⁸⁶ The statutory scheme is flexible and dynamic,⁸⁷ and gives wide berth to the FDA to sanction device and drug manufacturers. The FDA may seek injunctive relief,⁸⁸ civil penalties,⁸⁹ or criminal prosecution.⁹⁰ The FDA may also seize a medical device⁹¹ or have a prescription drug removed from the marketplace.⁹² The FDA has authority both to enforce federal rules against defrauding the FDA and to reverse its findings of safety and efficacy by withdrawing approval where it finds that the drug company or its agent made material omissions or false statements.⁹³ The FDA can also institute enforcement actions against manufacturers for issuing false or misleading labels.⁹⁴

The FDA's enforcement track record, however, does not quite live up to its lofty formal powers. To begin, the number of enforcement actions declined by sixty-six percent between 2000 and 2005.⁹⁵ It is of course diffi-

⁸⁴ 21 C.F.R. § 10.30 (2007); *see also* *Eve v. Sandoz Pharm. Corp.*, No. IP 98-1429-C-Y/S, 2002 WL 181972, at *1 (S.D. Ind. Jan. 28, 2002) (“[C]itizens may report wrongdoing to the FDA and petition the Agency to take action under 21 C.F.R. § 10.30.”).

⁸⁵ 21 C.F.R. § 10.30(e)(1) (“The Commissioner shall . . . rule upon each petition filed . . . taking into consideration (i) available agency resources for the category of subject matter, (ii) the priority assigned to the petition considering both the category of subject matter involved and the overall work of the agency, and (iii) time requirements established by statute.”). Response time is typically 180 days. *Id.* § 10.30(e)(2).

⁸⁶ 21 U.S.C. § 372 (2000); 21 C.F.R. § 5.35 (2000).

⁸⁷ *See Buckman*, 531 U.S. at 349 (“This flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives.”).

⁸⁸ 21 U.S.C. § 332.

⁸⁹ *Id.* § 333(g)(1) (“[A]ny person who violates a requirement of this Act which relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed \$15,000 for each such violation, and not to exceed \$1,000,000 for all such violations adjudicated in a single proceeding.”); *id.* § 333(f)(3)(A) (imposing civil monetary penalties for submission of false or misleading clinical trial information).

⁹⁰ *Id.* § 333(a); *see also* Amicus Brief for the United States in *Kent*, *supra* note 29, at 24 n.7 (“When necessary and appropriate, the government has secured formal relief, including criminal convictions, against drug or device manufacturers who defrauded the agency.”). This is in addition to the general criminal proscription on making false statements to the federal government, *see* 18 U.S.C. § 1001 (2000).

⁹¹ 21 U.S.C. § 334(a)(2)(D).

⁹² *Id.* § 334(a)(1).

⁹³ *Id.* § 355(e) (providing for withdrawal of FDA approval where “the application contains any untrue statement of material fact”); *id.* § 331(jj)(3) (prohibiting the submission of false or misleading clinical trial information).

⁹⁴ *Id.* § 352.

⁹⁵ SPECIAL INVESTIGATIONS DIV., U.S. HOUSE OF REPRESENTATIVES, PRESCRIPTION FOR HARM: THE DECLINE IN FDA ENFORCEMENT ACTIVITY 8–9 (2006) [hereinafter PRESCRIPTION FOR HARM]. The only enforcement measure that increased significantly over this five-year period was the number of

cult to infer, from this fact alone, whether the root cause is lax enforcement or rather heightened levels of regulatory compliance by manufacturers.⁹⁶ But the fact that the number of regulatory violations identified by field FDA inspectors did not decline over the same five-year period casts considerable doubt on the latter optimistic explanation.⁹⁷ Instead, the picture that emerges is one of the FDA pulling back on enforcement, contrary to the recommendations of its field operators.⁹⁸ To add to this picture of lax enforcement, a recent study by the Institute of Medicine called into question the ability of the FDA to compel clinical trials following drug approval.⁹⁹

B. Reform

Scholarly and judicial resistance to a regulatory compliance defense (and, by extension, the blunter instrument of federal preemption) has often been tethered to dissatisfaction with lax FDA enforcement in practice. Michael Green has taken aim at the FDA's inability to monitor unexpected adverse side effects following drug approval:

[I]f we could freeze time (and our knowledge of risk) at the point of FDA approval of [a new drug application], we might be inclined to opt for an FDA compliance defense. But we cannot freeze time; it marches on and with it our storehouse of information changes, often radically. And it is the post-approval period that raises the most serious questions about the viability of a regulatory compliance defense because additional significant information is uncovered, manufacturers undertake marketing activity that affects the benefit-risk ratio of the drugs that are promoted, and the FDA has inadequate resources to enforce regulatory compliance.¹⁰⁰

Green does not put too fine a point on it: “The FDA is woefully underfunded for its mandate, which includes regulatory oversight of products that account for more than twenty-five percent of all American consumer pur-

FDA-regulated products on the market that had to be recalled, which increased by forty-four percent. *Id.* at 9.

⁹⁶ Settlements may also play a significant role, exacerbating the difficulty of gauging FDA enforcements. *See, e.g.*, Amicus Brief for the United States in *Kent*, *supra* note 29, at 24 (“When FDA suspects fraud, it often reaches a settlement with the applicant in which the applicant pays a fine or takes corrective action (such as changes in labeling) without admitting liability.”).

⁹⁷ PRESCRIPTION FOR HARM, *supra* note 95, at 10.

⁹⁸ *See, e.g.*, Brief of the National Conference of State Legislatures et al., as Amicus Curiae Supporting Respondents at 24, *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008) (No. 06-1498), 2008 WL 194280, at *24 (“FDA officials in Washington repeatedly reject[ed] the recommendations of career field officials urging enforcement actions, even in cases involving death and serious injury.” (quoting PRESCRIPTION FOR HARM, *supra* note 95, at 6)).

⁹⁹ INST. OF MED., THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 4–9 (2006); *see also* U.S. GOV'T ACCOUNTABILITY OFFICE, DRUG SAFETY: IMPROVEMENT NEEDED IN FDA'S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS 27–29 (2006).

¹⁰⁰ Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 495–96 (1997).

chases.”¹⁰¹ Robert Rabin has echoed a similar critique: “There is the all-too-familiar pattern of underfunded or myopic regulators who fail to monitor effectively once regulatory standards have been set.”¹⁰²

Judge Weinstein inverts the typical critique, provocatively asserting that “[w]ere the courts in a position to rely on the adequacy and candor of representations to the FDA and of the robustness of the inquiry and decisions of the FDA, a desirable result would be to apply preemption, excluding the state tort law.”¹⁰³ By positing robust FDA enforcement as a counterfactual, Judge Weinstein implicitly assumes that criticisms and reform proposals have fallen on tin ears at the FDA.¹⁰⁴

It is notoriously difficult to assess empirically whether the FDA’s enforcement has been too lax and, if so, the size of the problem. As Green astutely notes, “instances of withholding (or mischaracterization) of information from the FDA represent a partial numerator without a denominator—that is they reveal nothing about the rate at which such episodes occur.”¹⁰⁵ There has, nonetheless, been some indication that something is amiss. A recent study warns that “[a]mong the most worrisome signs that things are amiss within the agency are reports that FDA scientists have been discouraged by supervisors from raising questions about drug safety and sometimes have been prevented from sharing their concern with FDA advisory committees.”¹⁰⁶

Congress, after conducting numerous hearings over the past few years,¹⁰⁷ has taken recent action to buttress the FDA’s drug approval and oversight functions. The FDA Amendments Act (FDAAA), effective Oc-

¹⁰¹ *Id.* at 476 (citing John K. Iglehart, *The Food Drug Administration and Its Problems*, 325 NEW ENG. J. MED. 217, 217 (1991)); see also ADVISORY COMM. ON FOOD & DRUG ADMIN., FINAL REPORT 11 (1991) (“It is glaringly apparent that the FDA cannot now execute all of its statutory responsibilities within the limitations of existing resources, a conclusion that is repeated throughout this report.”).

¹⁰² Robert Rabin, *Poking Holes in the Fabric of Tort: A Comment*, 56 DEPAUL L. REV. 293, 301–02 (2007); see also David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA’s Efforts to Preempt Failure to Warn Claims*, 96 GEO. L.J. 461, 466 (2008) (“The reality is that the FDA does not have the resources to perform the Herculean task of monitoring comprehensively the performance of every drug on the market. Recent regulatory failures have demonstrated the FDA’s shortcomings in this regard.”).

¹⁰³ *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 241 (E.D.N.Y. 2007).

¹⁰⁴ *Id.* (“The FDA’s attempts to keep abreast of and inform the public about dangerous side effects discovered only after a drug has been approved have been decryd by many in the medical community as inadequate.”).

¹⁰⁵ Green, *supra* note 100, at 489 n.99.

¹⁰⁶ Susan Okie, *What Ails the FDA?*, 352 NEW ENG. J. MED. 1063, 1066 (2005).

¹⁰⁷ See, e.g., *Ensuring Drug Safety: Where Do We Go From Here? Hearings Before the S. Comm. on Health, Educ., Labor & Pensions*, 109th Cong. (2005); *FDA’s Drug Approval Process: Up to the Challenge? Hearings Before the S. Comm. on Health, Educ., Labor & Pensions*, 109th Cong. (2005); *Hearings on Risk & Responsibility: The Roles of the FDA and Pharmaceutical Companies in Ensuring Safety of Approved Drugs, Like Vioxx, Before the H. Comm. on Gov’t Reform*, 109th Cong. 23, 55 (2005).

tober 2, 2007,¹⁰⁸ empowers the FDA with additional authority during the postapproval period to monitor drug side effects and to impose larger fines on companies that do not conduct postmarketing studies.¹⁰⁹

The time is ripe to use this moment of political will for reform of the FDA to guide reforms in a direction that supports a conceptually sound model of agency-court interaction. The conceptual model outlined in this Article is one whereby private litigants in essence may piggyback on FDA findings of fraud. As a preliminary matter, such a model relies upon the FDA's ability to be proactive in monitoring and rooting out fraud. The FDAAA, which bolsters the FDA's ability to play an enhanced role here, is a significant step in the right direction.

But even with this beefed up FDA, there remains a critical enforcement role for private litigants and state tort claims.¹¹⁰ For years, scholars and judges have argued in favor of tort suits as catalysts for regulatory action.¹¹¹

¹⁰⁸ Food and Drug Administration Amendments Act of 2007, Pub. L. 110-85, 120 Stat. 823 (codified as amended in scattered sections of 21 U.S.C.).

¹⁰⁹ See Peter Chang, *Reauthorization of PDUFA: An Exercise in Post-Market Drug Safety Reform*, 36 J.L. MED. & ETHICS 196, 198 (2008) (arguing that pursuant to the FDAAA "post-marketing surveillance programs should experience a sizeable transformation"); Kessler & Vladeck, *supra* note 102, at 467-68 ("[T]he Act provides the agency with new resources to monitor the safety of drugs on the market, it authorizes the agency to compel manufacturers to make labeling changes if negotiations with the manufacturers are unsuccessful, it provides the agency greater power to require manufacturers to undertake safety studies after drugs have been approved, and it promises to give the agency greater resources to monitor direct-to-consumer drug advertising." (footnotes omitted)). *But see* Peter Barton Hutt, *The State of Science at the Food and Drug Administration*, in FDA SCIENCE AND MISSION AT RISK: REPORT OF THE SUBCOMMITTEE ON SCIENCE AND TECHNOLOGY app. B, at B-5 (2007), available at http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_02_FDA%20Report%20Appendices%20A-K.pdf (criticizing Congress for enacting "an unfunded FDA omnibus statute . . . that demands substantial FDA scientific resources to analyze and implement . . . with no plans for additional appropriated funds or personnel to implement it"); *see also* Margaret Gilhooley, *Addressing Potential Drug Risks: The Limits of Testing, Risk Signals, Preemption, and the Drug Reform Legislation*, 59 S.C. L. REV. 347, 350-51 (2008) ("The agency will now have express authority to require additional postmarket tests and new warnings, but the agency will have to issue regulations and guidance to establish the dispute resolution procedures needed to implement the authority, a process that could take years." (footnotes omitted)).

¹¹⁰ Preemption of state tort claims was a hotly contested issue during the House and Senate debates over the FDAAA. *See* Kimberly K. Egan & Alysson Russell Snow, *Does the FDA Amendments Act of 2007 Preempt State Law?* (DLA Piper Publ'ns, Oct. 10, 2007), <http://www.dlapiper.com/global/publications/Detail.aspx?ref=rv&pub=2696> (comparing the floor statement of Senator Tom Coburn (R-OK) asserting that the "newly expanded role of the FDA does and should preempt state law when it comes to drug safety and labeling," with the floor statement to the contrary by Senator Edward Kennedy (D-MA)—echoed by Senator Patrick Leahy (D-VT)—that "Congress has stated very clearly in the legislation that we do not intend the new authority being given to FDA to preempt common law liability for a drug company's failure to warn its customers of health risks"); *see also* Press Release, Maurice Hinchey, Statement Against FDA Amendments Act (July 11, 2007), available at http://www.house.gov/list/press/ny22_hinchey/morenews/071107FDAamendmentsAct.html ("[T]his legislation does nothing to keep the FDA from its current, misinformed policy of preempting state law on drug policy.").

¹¹¹ *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 277 (E.D.N.Y. 2007) ("State law adequacy of warning claims may alert the FDA to potential inadequacies in product labeling. The current

Even scholars who bemoan that such a system creates overdeterrence concede that tort liability has a role to play in terms of regulating information disclosure.¹¹² Kip Viscusi, for example, has argued that “tort liability provides additional and necessary economic incentives for manufacturers to provide full and complete risk information to the FDA so that the agency’s approval and labeling judgments are based on proper data.”¹¹³ Specifically, “tort law creates incentives for truthfulness above and beyond the criminal and other sanctions contained in the FDCA.”¹¹⁴

The institutional model advanced here calls for a nuanced partnership between agencies and courts, with private litigants having a role to play with respect to each. Private litigants must aggressively petition the FDA to make findings of fraud and to revisit its approval of drugs and medical devices.¹¹⁵ Indeed, they must do so as a prerequisite to bringing state-based tort claims based upon fraud perpetrated against the FDA (at least in the absence of the FDA taking action on its own). The viability of state tort liti-

litigation against Lilly may be a testament to that fact.” (citing Letter from FDA to Eli Lilly & Co. (Mar. 28, 2007)); see also *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 451 (2005) (“[L]abels will evolve over time, as manufacturers gain more information about their products’ performance in diverse settings [T]ort suits can serve as a catalyst in this process.”). This is one aspect of what Robert Rabin calls “the educational effect of tort.” Rabin, *supra* note 102, at 302 (“Pretrial discovery has frequently unearthed both industry and regulatory agency practices that might otherwise never have seen the light of day.”); see also Kessler & Vladeck, *supra* note 102, at 477 (“[T]he FDA has often acted in response to information that has come to light in state damages litigation”).

¹¹² See, e.g., W. Kip Viscusi et al., *Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1454 (1994) (“[T]he [FDA] regulatory scheme already provides excessive deterrence of risks. This suggests that further regulation of pharmaceuticals through tort liability is inappropriate, except as a means to compel regulatory compliance with regulations requiring the sharing of adverse safety information.”).

¹¹³ *Id.* at 1455 n.67; see also *id.* (“For this reason, litigation can play a useful role as an adjunct to ensure that the FDA receives truthful information.”).

¹¹⁴ *Id.*

¹¹⁵ Central to the model I propose is the existence of an appropriate administrative process for citizen petitions, because an FDA finding of fraud is necessary to get the ball rolling (absent the FDA taking initiative on its own). The precise scope of the types of FDA “action” that private citizens may request pursuant to 21 C.F.R. § 10.30 is somewhat ambiguous. In *Kent*, the United States took the position that “[w]hile FDA takes suggestions of fraudulent representations very seriously, it does not have a process for considering allegations or making explicit findings of fraud in the abstract. Citizen petitions must seek specific types of administrative action, such as withdrawal of a drug’s approval, not merely a finding of fraud.” Amicus Brief for the United States in *Kent*, *supra* note 29, at 24. But the regulation itself would seem to give citizens wider berth. See 21 C.F.R. § 10.30(A)(3) (2007) (“If the petition requests the Commissioner to take or refrain from taking *any other form of administrative action* [apart from a request to issue, amend, or revoke a regulation or order], [the petition must describe] the specific action or relief requested.” (emphasis added)). The United States, moreover, seems to have hardened its position since *Buckman*, when it appeared to countenance a more liberal understanding of the scope of citizen petitions. Brief for the United States as Amicus Curiae Supporting Petitioner at 3–4, *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001) (No. 98-1768), 2000 WL 1364441, at *3–4 (“Any citizen who believes that a submitter has committed fraud may petition FDA to take administrative action.”). The precise reforms to the administrative process—including the scope of judicial review of the agency’s fraud findings—that may be required are beyond the scope of this Article.

gation premised upon fraudulent disclosures during the regulatory approval process, in other words, depends upon the FDA first making a determination that there has been fraud perpetrated upon it. Such an approach would certainly have an effect on the political dynamics for the agency. The impact could be welfare-enhancing to the extent that it incentivizes the plaintiffs' bar (in addition to public interest watchdog organizations) to seek FDA investigation of fraud in the food and drug arena.¹¹⁶ And once the FDA has made a finding of fraud, private litigants may seek damage remedies for harms suffered.¹¹⁷ Allowing private law tort suits to piggyback on prior FDA determinations of fraud will thereby buttress enforcement in the disclosure of information.

CONCLUSION

In *Warner-Lambert Co. v. Kent*, the U.S. Supreme Court left for another day the resolution of the question whether *Buckman* preempts statutory fraud exceptions to drug manufacturer immunity statutes. The question raises a narrow doctrinal issue, but one that squarely hits a raw federalism nerve, with correspondingly wide reverberations in products liability preemption jurisprudence. A satisfactory resolution of the doctrinal issue—relying upon the FDA to police fraud in the first instance, but enlisting private litigants on the remedial and enforcement end—provides the seeds of a more generalizable model of agency-court cooperation for the regulation of nationally regulated products, such as medical devices and pharmaceuticals.

¹¹⁶ There would, of course, be corresponding costs to this approach as well, including setting up an appropriate institutional framework for the FDA to handle such an influx of petitions. Indeed, as the United States ominously predicts:

[I]f FDA were the gatekeeper for private tort liability, it could anticipate numerous petitions filed by prospective tort plaintiffs urging the agency to make a finding of fraud. The disposition of such petitions might prove every bit as burdensome for the agency as state-court litigation concerning whether FDA was defrauded.

Amicus Brief for the United States in *Kent*, *supra* note 29, at 23. *But see* Brief for Respondents at 40–41 n.11, *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008) (No. 06-1498), 2008 WL 157174, at *40–41 n.11 (“[T]he United States does not offer any evidence of a deluge of citizen petitions—or any citizen petitions—filed since [*Garcia*] by Michigan patients requesting that the FDA make such findings.”).

¹¹⁷ As aptly put by a Virginia federal district court, a formal determination by the FDA of misconduct during the regulatory approval process “holds the gate open”; moreover, as the court emphasized, where a manufacturer has pled guilty to such fraud, “[i]f the gate had not been open, that event would have opened it.” *Woods v. Gliatech Inc.*, 218 F. Supp. 2d 802, 810 (W.D. Va. 2002).

A further complication exists, given the FDA’s ability to reach settlements with offending parties without any formal finding of fraud (or any admission of liability on the part of the misfeasants). *See supra* note 96. In that respect, the FDA retains significant discretionary authority. Critics have gone so far as to suggest that such discretionary power in effect shuts out private enforcement. *See, e.g.*, Brief of Amicus Curiae AARP in Support of Respondents at 21, *Kent*, 128 S. Ct. 1168 (No. 06-1498), 2008 WL 189550, at *21 (“[R]equiring a formal FDA finding of fraud or decision to withdraw approval for a drug on the basis of safety concerns would render the [fraud caveat] provision [to statutory immunity] a dead letter.”).

This institutional approach gives primacy to the agency to decide, in the first instance, the extent to which state law requirements would encroach upon its regulatory scheme, but reserves room for private litigant enforcement of federally determined standards.

