

# RECONSIDERING THE TRADITIONAL ANALYSIS: SHOULD *BUCKMAN* ALONE SUPPORT PREEMPTION OF FRAUD-ON-THE-FDA EXCEPTIONS TO TORT IMMUNITY?

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## INTRODUCTION

On July 2, 2012, The U.S. Department of Justice (DOJ) announced that British healthcare company GlaxoSmithKline agreed to plead guilty and pay a record three billion dollars—the “largest health care fraud settlement in U.S. history”—to settle its criminal and civil liabilities arising from its illegal off-label promotion of Paxil and Wellbutrin, as well as its failure to report safety data about Avandia to the U.S. Food and Drug Administration (FDA).<sup>1</sup> Since 2009, the Department of Justice has recovered well over \$10 billion in relation to allegations of health care fraud under the False Claims Act and the Federal Food, Drug and Cosmetic Act (FDCA).<sup>2</sup> However, while coordinated governmental efforts between the DOJ, the FDA, and various other agencies to identify and curtail fraudulent behavior can be effective, as the GlaxoSmithKline agreement illustrates,<sup>3</sup> affected private individuals may find themselves without a legal remedy against a manufacturer whose fraudulent behavior may have caused their injuries.

Every year, U.S. consumers spend hundreds of billions of dollars on health care products ancillary to the care itself.<sup>4</sup> Manufacturers are under intense pressure to develop, and acquire FDA approval for, drugs and health care products.<sup>5</sup> As such, the profit-based incentives to engage in research manipulation—which could amount to a fraud on the FDA—are extant and powerful.<sup>6</sup> This fact notwithstanding, in *Buckman Co. v. Plaintiffs’ Legal Committee*, the Supreme Court fore-

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1. Press Release, Office of Pub. Affairs, U.S. Dep’t of Justice, GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data (July 2, 2012), *available at* <http://www.justice.gov/opa/pr/2012/July/12-civ-842.html>.

2. *Id.*

3. *Id.*; *see also, e.g.*, Press Release, Office of Pub. Affairs, U.S. Dep’t of Justice, Danish Pharmaceutical Novo Nordisk to Pay \$25 Million to Resolve Allegations of Off-Label Promotion of Novoseven (June 10, 2011), *available at* <http://www.justice.gov/opa/pr/2011/June/11-civ-764.html>; Press Release, Office of Pub. Affairs, U.S. Dep’t of Justice, Two Johnson & Johnson Subsidiaries to Pay Over \$81 Million to Resolve Allegations of Off-Label Promotion of Topamax (Apr. 29, 2010), *available at* <http://www.justice.gov/opa/pr/2010/April/10-civ-500.html>.

4. *See, e.g.*, U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-12-371R, DRUG PRICING: RESEARCH ON SAVINGS FROM GENERIC DRUG USE 1 (2012) (“Prescription drug spending in the United States reached \$307 billion in 2010[.]”).

5. *See* Abigail Brown, *Understanding Pharmaceutical Research Manipulation in the Context of Accounting Manipulation*, 41 J.L. MED. & ETHICS 611, 613 (2013).

6. *Id.* (“Combine these extraordinary financial pressures with the inherent ambiguity of medical research and one creates an incentive to manipulate data . . . [P]eople make decisions that obscure bad news and amplify good news. Each decision on its own may be reasonable, but the aggregate can create a highly misleading picture.”).

closed the possibility of a stand-alone fraud-on-the-FDA claim under state common law against manufacturers of health care products on the grounds that allowing private consumers to bring such actions would disturb the “delicate balance” the FDA attempts to maintain between protecting consumers and making needed drugs and medical devices available.<sup>7</sup> Currently, the federal circuit courts of appeals are split as to whether *Buckman* preempted broadly all state-law tort claims dependent on evidence of fraud on the FDA or, at the narrowest end, only common law fraud-on-the-FDA claims.<sup>8</sup> A significant number of states have enacted provisions granting varying levels of protection from liability to pharmaceutical manufacturers so long as the product is fully FDA-approved and compliant with FDA regulations.<sup>9</sup> Critical to this Note is the fact that many of these states have also enacted exceptions that nullify the protections if the manufacturer has committed fraud on the FDA during the approval process.<sup>10</sup>

This Note is concerned with the cases in which evidence of a fraud on the FDA is used to help prove traditional tort claims (rather than prove a stand-alone fraud-on-the-FDA claim), particularly in states providing statutory protections for products that have received FDA approval. The question this Note addresses is whether *Buckman*—by preempting state law fraud-on-the-FDA claims—also preempted these states’ fraud exceptions. In 2008, The Supreme Court

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7. 531 U.S. 341, 348, 353 (2001).

8. *Compare* *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004), with *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), *aff’d by an equally divided court sub nom. Warner-Lambert Co. v. Kent*, 552 U.S. 440 (2008). The courts in these cases considered the same Michigan statutory provision, MICH. COMP. LAWS § 600.2946(5), and came to opposite conclusions regarding whether to apply *Buckman*’s holding.

9. Michigan’s statute, the subject of controversy between the Second and Sixth Circuits, provides complete immunity for manufacturers whose product has received FDA approval. MICH. COMP. LAWS § 600.2946(5) (2014). At least nine other states have provided a rebuttable presumption against liability for compliance with agency regulations. COLO. REV. STAT. § 13-21-403(1)(b) (2014); FLA. STAT. § 768.1256(1) (2014); 34 IND. ADMIN. CODE 34-20-5-1(2) (2014); KAN. STAT. ANN. § 60-3304(a) (2013); KY. REV. STAT. ANN. § 411.310(2) (West 2014); N.J. STAT. ANN. § 2A:58C-4 (West 2014); TENN. CODE ANN. § 29-28-104 (2014); TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(a) (West 2013); UTAH CODE ANN. § 78B-6-703(2) (West 2014).

10. Only Michigan, Texas, and Utah expressly include a fraud exception to immunity or the presumption against liability. MICH. COMP. LAWS § 600.2946(5)(a) (2014); TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(b)(1) (2013); UTAH CODE ANN. § 78B-8-203(2) (West 2014). However, for the states where the exception is not expressly stated, the exception is likely implied by the requirement of compliance with federal law to get the statute’s benefit, because compliance with FDCA disclosure requirements are predicated on non-fraudulent and properly represented disclosures. *See, e.g.*, 21 U.S.C. § 355(q)(1)(H) (2013) (mandatory certification of a petition for review of a new drug).

was poised to answer the *Buckman* issue in *Warner-Lambert Co. v. Kent*;<sup>11</sup> however, a 4-4 decision has delayed its resolution. In examining this question, I also consider whether it may be appropriate for the courts to consider broadening the traditional preemption analysis, especially in these cases where state interests are intertwined with the preemption question.

Part I briefly introduces the Court's preemption doctrine. Part II provides a summary of the *Buckman* decision itself. Part III provides an in-depth analysis of the reasoning of the circuit court cases that have decided the issue, i.e., the Second, Sixth, and Fifth Circuits. Part IV describes the growing influence of the *Buckman* decision under different statutes, such as statutory bars on punitive damages. Part IV also briefly discusses applications of *Buckman* in other administrative contexts, such as fraud on the Coast Guard. Finally, Part V considers how the Court could expand its preemption analysis in traditional state tort actions where evidence of fraud on the FDA is provided to counter manufacturers' immunity defense under state law, rather than form the basis of liability. I argue courts should give some deference to states' legislative processes in the preemption analysis, as well as consider other policy factors, such as institutional competence, given the strong state interests present in these cases and the potential for courts, in effect, to undermine a state's legislative process.

## I.

### THE TRADITIONAL PREEMPTION ANALYSIS

Broadly defined, federal preemption is the displacement of state law by federal law.<sup>12</sup> Federal authority to preempt state law is rooted in the Supremacy Clause.<sup>13</sup> As the Supreme Court has consistently

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11. 552 U.S. 440 (2008). Chief Justice Roberts abstained in the judgment.

12. It should be noted that an entire body of scholarship can and has been written on the Court's preemption analysis. This Note only scratches the surface, by laying out only those factors that are most relevant to *Buckman* and the fraud-exception cases. For additional reading, see 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 (2008); Richard A. Nagareda, *FDA Preemption: When Tort Law Meets The Administrative State*, 1 J. TORT L. 4 (2006); Karen A. Jordan, *The Shifting Preemption Paradigm: Conceptual and Interpretive Issues*, 51 VAND. L. REV. 1149 (1998). See generally THOMAS O. MCGARITY, *THE PREEMPTION WAR: WHEN FEDERAL BUREAUCRACIES TRUMP LOCAL JURIES* (2008); *Preemption of State Common Law Claims*, 122 Harv. L. Rev. 405 (2008); Caleb Nelson, *Preemption*, 86 VA. L. REV. 225 (2000).

13. U.S. CONST. art. VI, cl. 2 ("This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.").

recognized, “state laws that conflict with federal law are without effect” under the Constitution.<sup>14</sup>

The Court has recognized two umbrella categories of preemption: express preemption and implied preemption. Express preemption occurs when the text of a federal statute or regulation expressly preempts state law.<sup>15</sup> Even in the absence of an express preemption provision, the Court may find that a state law is impliedly preempted in two situations: first, where Congress has regulated an area “so pervasively that there is no room left for the states to supplement federal law” (also known as field preemption),<sup>16</sup> and second, where state law unavoidably conflicts with federal law.<sup>17</sup>

Two types of implied conflict preemption have emerged: “impossibility” and “obstacle.” Impossibility preemption occurs when state law is preempted because it is “impossible for a private party to comply with both state and federal requirements;”<sup>18</sup> obstacle preemption occurs when state law is preempted because it stands as an obstacle to accomplishment of federal objectives or purposes.<sup>19</sup> Obstacle preemption, in particular, is relevant to this Note because the *Buckman* Court’s decision to preempt relied in large part on the FDA’s need to maintain a “delicate balance of statutory objectives,” a balance which

14. *E.g.*, *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2472–73 (2013).

15. *See, e.g.*, *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323–24 (2008) (preempting the plaintiffs’ negligence and strict liability claims by interpreting the phrase “‘any requirement’ . . . that is ‘different from, or in addition to’” in § 360k(a) of the Medical Devices Amendments of 1976 to encompass those common law causes of action).

16. *See, e.g.*, *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 236 (1947) (determining that a “less pervasive” federal regulatory plan preempted a more stringent Illinois regulatory scheme because of the declared policy of Congress to regulate grain storage in the 1916 Warehouse Act).

17. *See, e.g.*, *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 861, 881 (2000) (preempting the plaintiff’s claims for negligence and defective design because they “actually conflicted” with the federal Department of Transportation’s 1984 standard requiring automobile manufacturers to place driver-side airbags in some, but not all, automobiles).

It should be noted that, as an analytical matter, it is difficult in practice to distinguish between and among the types of implied preemption. *E.g.*, Note, *Preemption as Purposivism’s Last Refuge*, 126 HARV. L. REV. 1056, 1062 (2013) (“[F]ield preemption is analytically indistinguishable from obstacle preemption[.]”). As discussed below, the framing of the type of preemption at work can affect the outcome in a given case. *See infra* Parts IV.A.2, IV.B.

18. *E.g.*, *Bartlett*, 133 S. Ct. at 2473 (“In the instant case, it was impossible for Mutual to comply with both its state-law duty to strengthen the warnings on sulindac’s label and its federal-law duty not to alter sulindac’s label. Accordingly, the state law is pre-empted.”).

19. *See Geier*, 529 U.S. at 881; *see also* *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 347–48 (2001).

“can be skewed by allowing fraud-on-the-FDA claims under state tort law.”<sup>20</sup>

In addition to these considerations, the Court has often cited two “cornerstones” of preemption jurisprudence: first, “the purpose of Congress is the ultimate touchstone in every preemption case,” and second, “[i]n all pre-emption cases, and particularly in those in which Congress has legislated . . . in a field which the States have traditionally occupied . . . we start with the assumption that the historic powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”<sup>21</sup>

This second principle is known commonly as the “presumption against preemption.” While the presumption does appear to play some role in the Court’s analysis, the Court’s treatment of the doctrine is inconsistent from case to case, as many scholars have noted.<sup>22</sup> In *Medtronic v. Lohr*, for example, the Court advanced a strong-form version of the presumption against preemption by narrowing the scope of an express preemption provision under the FDCA concerning medical devices,<sup>23</sup> citing “federalism concerns” and the “historic primacy of state regulation of matters of health and safety.”<sup>24</sup> On the other hand, in *Buckman*, the Court commenced its preemption analysis by noting the following:

Policing fraud against federal agencies is hardly a field which the States have traditionally occupied, such as to warrant a presumption against finding federal pre-emption of a state-law cause of action . . . [I]n contrast to situations implicating ‘federalism concerns and the historic primacy of state regulation of matters of health and safety,’ no presumption against pre-emption obtains in this case.<sup>25</sup>

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20. *Buckman*, 531 U.S. at 348. For a summary of federal preemption in the pharmaceutical and medical devices context, see Christine A. Gaddis, *Buckman Extended: Federal Preemption of State Fraud on the FDA Statutes*, 69 FOOD & DRUG L.J. 113, 117–125 (2014).

21. *Wyeth v. Levine*, 555 U.S. 555, 564–65 (2009) (alterations in original) (internal quotations omitted).

22. See, e.g., Mary J. Davis, *The “New” Presumption Against Preemption*, 61 HASTINGS L.J. 1217, 1251–52 (2010) (recognizing the uncertainty of the operation of the presumption in implied conflict preemption cases); see also *infra* notes 65–66, 90. For an examination of the application (and non-application) of the presumption against preemption in the Roberts Court, see Ernest A. Young, “*The Ordinary Diet of the Law*”: *The Presumption Against Preemption in the Roberts Court*, 2011 SUP. CT. REV. 253–344.

23. 21 U.S.C. § 360k(a) (2013).

24. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

25. *Buckman*, 351 U.S. at 347–48 (internal citations and quotations omitted).

Finally, the Court has also provided some (albeit, elusive) guidance on the deference to be afforded to an agency's determinations of a statute's preemptive scope. "Preemption by preamble," as this deference is sometimes called, occurs where the federal agency seeks to make its own preemption determination in its rulemaking when directions from Congress are scant or nonexistent—as opposed to simply commenting on the preemptive scope of the underlying statute.<sup>26</sup> The Court stated in *Wyeth v. Levine* that it gives "'some weight' to an agency's views about the impact of tort law on federal objectives when 'the subject matter is technical[1] and the relevant history and background are complex and extensive.'"<sup>27</sup> Under the *Levine* analysis, the exact "weight" accorded the agency interpretation appears akin to *Skidmore* deference, meaning the level of deference depends on the "thoroughness, consistency, and persuasiveness" of the agency's explanation.<sup>28</sup>

In *Levine*, however, the Court held the agency determination, found in the preamble to a 2006 FDA regulation governing the content and form of prescription drug labels,<sup>29</sup> was entitled to no deference at all.<sup>30</sup> According to the Court, the agency's position failed to "reflect the agency's own view at all times relevant to this litigation," and the agency had, "without offering States or other interested parties notice or opportunity for comment, articulated a sweeping position on the FDCA's pre-emptive effect in the regulatory preamble."<sup>31</sup> These failings, the Court stated, meant that the agency's views on the preemptive effect of the federal statute were "inherently suspect."<sup>32</sup> The possibility remains open, however, that the Court may provide some deference to an agency interpretation where that interpretation is thor-

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26. See Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 242–47 (2007) ("Controversy surrounds the appropriate weight to be accorded agency views: Should courts grant *Chevron* deference, weaker *Skidmore* deference, or no deference at all to agency preemption determinations . . . ?").

27. 555 U.S. 555, 576 (2009) (alteration in original).

28. *Id.* at 577; see also *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944) ("We consider that the rulings, interpretations and opinions of the [agency], while not controlling upon the courts by reason of their authority, do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance.").

29. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) (codified at 21 C.F.R. pts. 201, 314, 601).

30. *Levine*, 555 U.S. at 577.

31. *Id.*

32. *Id.*

ough, valid in its reasoning, consistent with earlier interpretations, and persuasive.

In Part V, this Note proposes two additional factors—(1) deference to state legislative processes and (2) institutional competence—that are relevant and deserving of consideration to supplement the traditional preemption analysis outlined above.

## II.

### THE *BUCKMAN* DECISION

The Supreme Court in *Buckman* decided that stand-alone fraud-on-the-FDA claims under state law were preempted by the Food, Drug and Cosmetic Act.<sup>33</sup> The theory of the fraud-on-the-FDA claim was simply this: “Had the [fraudulent] representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured.”<sup>34</sup> In *Buckman*, the Court held that such claims were impliedly preempted by the FDCA on the grounds that they would erect an obstacle to the agency’s ability to police fraud. The Court reasoned that fraud-on-the-FDA claims conflict with the FDA’s mandate to police fraud “consistently with the Administration’s judgment and objectives.”<sup>35</sup> In particular, the Court found compelling the need to protect the “delicate balance” sought by the FDA in achieving its statutory objectives—i.e., to protect consumers without interfering with the practice of medicine.<sup>36</sup> According to the Court, allowing these claims to proceed would increase the burdens on manufacturers in complying with FDA regulations “in the shadow of 50 states’ tort regimes.”<sup>37</sup> Moreover, the Court stated, applicants for FDA approval would have an incentive to submit “a deluge of information” to the FDA to avoid a finding of insufficient disclosure in state courts, which would increase the burdens placed on the FDA in reviewing manufacturers’ applications.<sup>38</sup>

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33. 21 U.S.C. §§ 301–399f (2013).

34. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 343 (2001).

35. *Id.* at 350.

36. *Id.* at 348–50.

37. *Id.* at 350.

38. *Id.* at 351. *Cf.* Samuel Issacharoff & Catherine M. Sharkey, *Backdoor Federalization*, 53 UCLA L. REV. 1353, 1368 (2006) (“Contrary to the dismissive assertion that the preemption cases are simply a political battleground in the struggle between an overweening federal power and a beleaguered state authority, we advance instead a functionalist account, focusing on interests in promoting national uniformity and protecting against spillover effects.”).

This “deluge” dilemma is cited by all courts finding preemption in fraud-exception cases; however, in states where the exception operates, unlike in states where fraud-on-the-FDA claims could previously be brought, state law by virtue of tort re-

Of course, the Court acknowledged that the preemptive scope of the FDCA did not reach *all* individual causes of action against manufacturers like the defendant in *Buckman*—just those causes solely dependent on proving a fraud was perpetrated on the FDA during the approval process. The Court recognized its prior decision in *Medtronic, Inc. v. Lohr* as a case in which a “traditional” state-law tort action could proceed, because the cause of action in *Medtronic* was a common-law negligence action.<sup>39</sup> Unlike *Buckman*, the *Medtronic* case did not arise “solely from the violation of FDCA requirements.”<sup>40</sup>

### III.

#### THE FRAUD-EXCEPTION CONTROVERSY AFTER *BUCKMAN*

Following *Buckman*, a number of federal circuits have addressed the fraud-on-the-FDA exception in the context of products liability tort suits where manufacturer-defendants have raised FDA-compliance statutes as a defense. To date, the Second, Fifth, and Sixth Circuits have had occasion to decide the issue—reaching different conclusions. The Sixth Circuit was the first circuit to decide the issue, finding preemption under Michigan’s immunity statute in *Garcia v. Wyeth-Ayerst Laboratories*,<sup>41</sup> followed by the Second Circuit in *Desiano v. Warner-Lambert & Co.*, which came to the opposite result analyzing the same Michigan statute.<sup>42</sup> Most recently, the Fifth Circuit, agreeing with the Sixth Circuit, decided *Lofton v. McNeil Consumer & Specialty Pharmaceuticals* under a similar Texas statute that

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form is already providing additional protections to pharmaceutical and drug manufacturers. Moreover, it would seem that in states with no such immunity-conferring statutes where no fraud exception exists, plaintiffs would already be incentivized to provide evidence of fraud perpetrated on the FDA, if they could present such evidence, given that this evidence might bolster, for example, a claim of negligence. Though this is an empirical question beyond the scope of this Note, I am preliminarily skeptical of the great extent to which the Court seems to think fraud evidence would burden the FDA.

39. 518 U.S. 470 (1996). In *Medtronic*, the plaintiff brought negligence and strict liability claims in a Florida state court against the manufacturer of a pacemaker—a Class III medical device under the Medical Devices Amendments (MDA) to the FDCA—alleging that the device had failed. Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified in scattered sections of 21 U.S.C. §§ 301–399f). *Medtronic* removed to federal court and argued that the claims were preempted by the FDCA. The Supreme Court held the claims were not preempted, concluding that the FDCA did not preempt state or local duties “equal to, or substantially identical to” federal requirements, 518 U.S. at 497, nor did the state duty threaten to interfere with a “specific federal interest,” *id.* at 500–02.

40. *Buckman*, 531 U.S. at 352.

41. 385 F.3d 961 (6th Cir. 2004).

42. 467 F.3d 85 (2d Cir. 2006), *aff’d by an equally divided court sub nom.* Warner-Lambert Co. v. Kent, 552 U.S. 440 (2008).

provides a rebuttable presumption of non-liability, rather than complete immunity as in Michigan.<sup>43</sup> This Section discusses the reasoning behind each decision.

A. *Garcia v. Wyeth-Ayerst Laboratories (2004)*

In *Garcia*, the plaintiff brought a products liability suit against the manufacturer of the prescription drug Duract, alleging the drug was a defective product and not reasonably safe.<sup>44</sup> Because under Michigan law manufacturers and sellers of drugs cannot be held liable for drugs approved by the FDA,<sup>45</sup> the *plaintiff* argued,<sup>46</sup> in the hopes of bypassing the immunity statute, that the immunity provision conflicted with and was impliedly preempted by the FDCA as a result of *Buckman*.<sup>47</sup> The district court did find the statute partly preempted, though not in the way the plaintiff hoped; *only* the fraud exception to the statute was held preempted.<sup>48</sup>

On appeal, the plaintiff argued that finding preemption of only the fraud exception would contravene the intent of the Michigan legislature, because the effect would be to give manufacturers absolute immunity even where FDA approval has been procured by fraud.<sup>49</sup> The Sixth Circuit queried whether the legislature “would have preferred the situation where drug manufacturers would enjoy immunity in the absence of a federal finding of bribery or fraud on the FDA, or the

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43. 672 F.3d 372 (5th Cir. 2012).

44. *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 963 (6th Cir. 2004). Ms. Garcia was prescribed the medication for pain in her neck and shoulders. The medication caused liver failure in the plaintiff, necessitating a transplant to save her life.

45. MICH. COMP. LAWS § 600.2946(5) (2014). The relevant statutory language is provided, as follows: “In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the [FDA], and the drug and its labeling were in compliance with the [FDA’s] approval at the time the drug left the control of the manufacturer or seller . . . . This subsection does not apply if the defendant at any time before the event that allegedly caused the injury . . . [i]ntentionally withholds from or misrepresents to the [FDA] information concerning the drug that is required to be submitted under the [FDCA].”

46. This move was somewhat unusual, because typically it is the defendant who raises a preemption argument in response to a plaintiff’s claim, arguing that the claim is preempted by federal law and, therefore, the defendant is entitled to judgment as a matter of law. *See infra* text accompanying notes 170–171.

47. *Garcia v. Wyeth-Ayerst Labs.*, 265 F. Supp. 2d 825, 830 (E.D. Mich. 2003), *aff’d*, 385 F.3d 961 (6th Cir. 2004).

48. *Id.* at 831–32.

49. Final Brief of Appellant at 14–18, *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (2004) (No. 03-1712).

situation . . . where drug manufacturers would enjoy no immunity at all” and concluded the former, affirming the district court’s decision.<sup>50</sup>

Construing *Buckman*’s holding somewhat broadly, the district court reasoned that “*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims.”<sup>51</sup> The Sixth Circuit adopted this language, adding, “Doubtless, *Buckman* prohibits a plaintiff from invoking the exceptions on the basis of state court findings of fraud on the FDA.”<sup>52</sup>

Neither the district court nor the Sixth Circuit found occasion to address in-depth whether a presumption against preemption should apply in this case. The district court mentioned the presumption against preemption, in passing, as having not applied in *Buckman*;<sup>53</sup> the court of appeals, while giving lip service to the “assumption that state law is valid,” deferred to *Buckman*’s reasoning, finding any differences between that case and the instant case “immaterial.”<sup>54</sup> One explanation for this cursory treatment may be that, because it was the plaintiff in *Garcia* who argued in favor of finding preemption as an end-run around statutory immunity, arguments against preemption typically brought by plaintiffs in this context, such as the presumption against preemption, were not developed such that the court felt compelled to address them.<sup>55</sup>

Moreover, the courts did not address whether this case could be distinguished from *Buckman* based on the Supreme Court’s treatment of *Medtronic*, i.e., that state law causes of action that “parallel federal

50. *Garcia*, 385 F.3d at 967; see *infra* note 187 and accompanying text; see also William N. Eskridge, Jr., *The New Textualism*, 37 UCLA L. REV. 621, 643 (1990) (“[I]t is very hard for a court to figure out how a legislature ‘would have decided’ issues on which it never formally voted—it would depend very much on the order in which proposals are considered, which in turn depends on who controls the agenda.”).

51. *Garcia*, 265 F. Supp. 2d at 832.

52. *Garcia*, 385 F.3d at 966.

53. *Garcia*, 265 F. Supp. 2d at 831.

54. *Garcia*, 385 F.3d at 965–66. *But see* Zimmerman v. Novartis Pharms. Corp., 889 F. Supp. 2d 757, 772 (D. Md. 2012) (stating that courts have found preemption of fraud exceptions even when the presumption applied, citing *Garcia* as an example).

55. Compare Final Brief of Appellant, *supra* note 49, at 14–18 (agreeing with the district court that no presumption obtained, but arguing that the entire immunity statute should be preempted), with Brief for Respondent at 33–34 & n.12, *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001) (No. 98-1768) (arguing that a presumption against preemption should attach), Reply Brief of Appellants at 2, *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006) (Nos. 05-1705(L), 05-1743(CON) (L), 05-1745(CON) (L)) (same), and Reply Brief of Appellants at 4–7, *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372 (5th Cir. 2012) (No. 10-10956) (same).

safety requirements” can escape preemption.<sup>56</sup> Rather, the court employed an obstacle preemption analysis and invoked the “inter-branch-meddling concerns that animated *Buckman*,” implying the court’s reliance on broader policy considerations to avoid the “inevitable conflict with the FDA’s responsibility to police fraud consistently with the Agency’s judgment and objectives.”<sup>57</sup>

The court did narrow its interpretation somewhat, reasoning that the “inter-branch-meddling concerns” in *Buckman* are not present when the FDA itself, as opposed to a state court, determines that a manufacturer has committed fraud on the agency during the approval process.<sup>58</sup> The court’s dicta echoes Justice Stevens’ concurrence in *Buckman*, in which he wrote, “If the FDA determines both that fraud has occurred and that such fraud requires the removal of a product from the market, state damages remedies would not encroach upon, but rather would supplement and facilitate, the federal enforcement scheme.”<sup>59</sup>

#### B. *Desiano v. Warner-Lambert & Co. (2006)*

In *Desiano*, the Second Circuit examined both *Buckman* and the Sixth Circuit’s analysis in *Garcia* and came to the opposite result, concluding that *Buckman* only preempted the narrow “field” of stand-alone fraud-on-the-FDA claims.<sup>60</sup> In holding that Michigan’s fraud

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56. See *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 348–52 (2001).

57. *Garcia*, 385 F.3d at 965–66 (quoting *Buckman*, 531 U.S. at 341, 350). In stark contrast, in *Desiano v. Warner-Lambert & Co.*, the Second Circuit relies heavily on the presumption against preemption and the fact that the claims are traditional common law claims in order to adopt a narrower field-preemption view, somewhat eschewing the policy concerns compelling the Sixth Circuit’s contrary decision. See *infra* notes 62–66 and accompanying text.

58. *Garcia*, 385 F.3d at 966.

59. *Buckman*, 531 U.S. at 354 (Stevens, J., concurring) (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)); see also Catherine M. Sharkey, *The Fraud Caveat to Agency Preemption*, 102 Nw. U. L. REV. 841, 844 (2008) (arguing for a model of “complementary agency-court action in combating fraud” based on the reasoning of Justice Stevens’ concurrence).

60. *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 92–98 (2d Cir. 2006) (Calabresi, C.J.), *aff’d by an equally divided court sub nom.* *Warner-Lambert Co. v. Kent*, 552 U.S. 440 (2008); see also Sharkey, *The Fraud Caveat*, *supra* note 59, at 853 (“*Desiano* . . . adopted the narrower, field preemption view of *Buckman*, where the ‘field’ is limited to stand-alone fraud-on-the-agency claims.”).

The plaintiffs originally brought suit in state courts in Michigan and California. The defendant drug companies removed to federal court, and all of the claims were subsequently consolidated and transferred by the Judicial Panel on Multidistrict Litigation to the U.S. District Court for the Southern District of New York, which ruled in favor of the defendants on the pleadings. *Desiano*, 467 F.3d at 88.

exception was *not* preempted by the FDCA, Judge Calabresi distinguished *Buckman* on three “crucial” grounds.<sup>61</sup>

First, the court reasoned that the claim obtained the benefit of the presumption against preemption in part because the causes of actions pleaded—traditional state law tort claims—“cannot reasonably be characterized as a state’s attempt to police fraud against the FDA.”<sup>62</sup> Moreover, unlike in *Buckman*, the court argued that the presumption applied because the state in this case was acting within its right to regulate matters of health and safety, “which is a sphere in which the presumption against preemption applies, indeed, stands at its strongest.”<sup>63</sup> Throughout the opinion, the court seemed to put substantial weight on the role of the presumption in the determination of the outcome.<sup>64</sup> Arguably, Judge Calabresi overstated the significance of the presumption’s role in the Supreme Court’s preemption analysis.<sup>65</sup> Scholars have not been shy about recognizing the Court’s “haphazard application” of the presumption in products liability cases.<sup>66</sup> In any event, the court offered two additional arguments to buttress its finding that there is no preemption.

*Desiano*’s second ground for distinguishing *Buckman* was that traditional common law liability controlled the case. Unlike in *Buckman*, the arguments in this case were premised exclusively on “traditional duties between a product manufacturer and Michigan consumers,” none of which were “derive[d] from, or . . . based on, a newly-concocted duty between a manufacturer and a federal agency.”<sup>67</sup> In other words, to preempt in this case would have been to construe a congressional modification of traditional state law duties

61. *Desiano*, 467 F.3d at 93.

62. *Id.* at 94.

63. *Id.*

64. *See id.* at 97 n.9 (“Because we find that a presumption against preemption applies in the instant case, it may also be argued that even in the face of an FDA statement asserting preemption, the common law claims preserved by Michigan’s immunity exception cannot be preempted by federal law absent a clear statement from Congress.”); *id.* at 93 (“In the absence of any presumption against preemption, the Court found that fraud-on-the-FDA claims conflicted with, and were therefore impliedly preempted by, federal law.”).

65. *See, e.g.*, Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 454 (2008) (“[T]he preemption rate actually *increases* to greater than sixty percent when considering preemption of state common-law tort claims—a realm in which the putative anti-preemption presumption should be at its zenith, given the historic role of the states in matters of health and safety.”).

66. *E.g., id.* at 454, 458 (“[T]he presumption against preemption . . . breaks down in the products liability realm, rearing its head with gusto in some cases, but oddly quiescent in others.”); *see also infra* note 90 and accompanying text.

67. *Desiano*, 467 F.3d at 94–95.

without evidence of Congress's intent to do so, which would have been contrary to the presumption against preemption.<sup>68</sup> Citing *Buckman*, the court analogized the instant case to *Medtronic* on the basis that the plaintiffs' negligence and products liability claims "are anything but based *solely* on the wrong of defrauding the FDA"—unlike a stand-alone fraud-on-the-FDA claim where proof of fraud is alone sufficient to impose liability.<sup>69</sup>

The court's third base is a procedural point. The immunity provided by Michigan's statute is an affirmative defense; thus, proof of FDA compliance only becomes an issue if the *defendant* chooses to raise it.<sup>70</sup> The court argued that preemption in this context would "go far beyond anything that has been applied in the past" if it were to invalidate traditional common law claims "where fraud is not even a required element."<sup>71</sup> Falling back on the presumption against preemption, the Second Circuit asserted, "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."<sup>72</sup>

Finally, Judge Calabresi rebutted the Sixth Circuit's practical concerns of an information "deluge" by theorizing that as long as a court or jury is permitted to consider evidence of fraud on the FDA, pharmaceutical manufacturers will have an incentive to flood the FDA with more and unnecessary information.<sup>73</sup> His argument presupposes that for causes of action in which evidence of fraud alone is insufficient to impose liability—as in traditional tort claims—such evidence is still permitted.<sup>74</sup> However, many courts seem to be growing reluc-

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68. *See id.* at 95 n.7 ("This may be seen as another way of saying that, unlike the situation in *Buckman*, the presumption against preemption is at its strongest in the instant case.").

69. *Id.* at 95.

70. *Id.* at 96 ("[I]t is not up to the plaintiff to prove fraud as an element of his or her claim.").

71. *Id.*

72. *Id.* (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

73. *Id.* at 97 ("So long as a court or jury is allowed to consider evidence of fraud against the FDA in an ordinary common law tort suit . . . 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.").

74. *See id.* ("In terms of deluging the FDA, there is little difference between (a) causes of action, like the instant one . . . and (b) causes of action where proof of fraud against the FDA is permitted but not conclusive (as it was under the precursor to the Michigan law at issue here . . . and as it presumably is in most states in the country).").

tant to even consider such evidence after *Buckman*.<sup>75</sup> On the other hand, some courts have adopted a more lenient evidentiary approach holding that, while evidence offered *solely* to show the manufacturer defrauded the FDA will be excluded, “evidence concerning what information was an[d] was not provided to the FDA might still be relevant” for claims based on fraud against the plaintiff *herself or her physician*.<sup>76</sup> Picking up on this distinction, Warner-Lambert, appealing the *Desiano* decision to the Supreme Court, argued, “[T]he Michigan statutory exception is not regulating disclosures owed to the public. It instead seeks to enforce matters entirely reserved to the agency.”<sup>77</sup>

The plaintiff’s challenge, then, is demonstrating the relevance of the fraud evidence specifically to her state-law claim. At least for one district court, using a manufacturer’s “failure to comply with federal reporting requirements [as] evidence of its failure to act as a reasonable prudent company” was not a reason sufficient for admission.<sup>78</sup> Although Judge Calabresi’s hypothesis regarding manufacturers’ incentives to deluge the FDA may hold true while courts continue to allow consideration of fraud evidence, the admission of this evidence

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75. See *Covert v. Stryker Corp.*, No. 1:08CV447, 2009 WL 2424559, at \*16 (M.D.N.C. Aug. 5, 2009) (“Although . . . in some instances, express breach of warranty claims may not be subject to MDA pre-emption, . . . it would seem that these claims are subject to express pre-emption under that statute . . . and/or implied pre-emption under *Buckman*, to the extent they are based on an alleged violation of an FDA disclosure requirement.”); *Grange v. Mylan Labs., Inc.*, No. 1:07-CV-107 TC, 2008 WL 4813311, at \*7 (D. Utah Oct. 31, 2008) (holding that the fraud exception for Utah’s statutory bar on punitive damages is preempted “where a plaintiff puts on his or her own independent evidence of information being withheld from the FDA”); *Webster v. Pacesetter, Inc.*, 259 F. Supp. 2d 27, 36 (D.D.C. 2003) (“[P]laintiffs are precluded from arguing that defendant’s alleged ‘failure to adhere to the FDA regulations . . .’ supports a defective warning case, since such claims are preempted by the [FDCA].” (citations omitted)).

76. *Bouchard v. Am. Home Prods. Corp.*, 213 F. Supp. 2d 802, 812 (N.D. Ohio 2002); see also *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1053 (D. Minn. 2007) (implying that testimony offered to show the FDA was misled may be admissible “to the extent it is offered to support a claim that the medical community, treating physicians or patients were misled”); *Globetti v. Sandoz Pharm. Corp.*, No. CV98-TMP-2649-S, 2001 WL 419160, at \*1 (N.D. Ala. Mar. 5, 2001) (“Although *Buckman* precludes a plaintiff from seeking damages because the defendant lied to the FDA, it is something completely different to contend that plaintiff is precluded from seeking damages for injuries due to lies to her.”).

77. Reply Brief of Petitioners at 12, *Warner-Lambert Co. v. Kent*, 552 U.S. 440 (2008) (No. 06-1498).

78. *In re Trasylol Prods. Liab. Litig.*, 763 F. Supp. 2d 1312, 1317 (S.D. Fla. 2010) (applying *Buckman* to grant a drug manufacturer’s motion to exclude evidence of misrepresentations to the FDA offered to demonstrate the manufacturer’s negligence because it was irrelevant to the plaintiff’s state-law claims).

may be becoming an increasingly difficult proposition, especially given the absence of a clear test for admissibility.<sup>79</sup>

C. *Lofton v. McNeil Consumer & Specialty  
Pharmaceuticals (2012)*

Following the Supreme Court's 4-4 affirmance of *Desiano* without an opinion, the Fifth Circuit addressed a similar statutory scheme under Texas law. In *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, the Fifth Circuit queried whether the fraud exception of a Texas statute<sup>80</sup> similar to Michigan's statute was preempted by the FDCA.<sup>81</sup> Mr. Lofton died after suffering a rare allergic reaction to over-the-counter pain medication.<sup>82</sup> Alleging common law negligence and strict products liability, Mr. Lofton's wife and children argued that the defendants had failed to warn consumers about the risk of these reactions.<sup>83</sup> To rebut the defendant's statutory presumption against liability, plaintiffs could show the defendants had withheld material and relevant information from the FDA.<sup>84</sup>

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79. *See, e.g.,* *Brown v. DePuy Spine, Inc.*, No. BRCV2006-00208, 2007 WL 1089337, at \*13 (Mass. Super. Ct. Apr. 9, 2007) (quoting *In re Medtronic, Inc., Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886, 900 (D. Minn. 2006)) ("The 'plaintiffs may use evidence—if they are able to produce it—of [the manufacturer's] efforts to manipulate the regulatory process in order to prove their negligence . . . claims, but they may not bring an independent claim for relief based on fraud-on-the-FDA.'").

80. TEX. CIV. PRAC. & REM. CODE ANN. § 82.007 (West 2011). The relevant statutory language is provided, as follows:

(a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if . . . the warnings or information that accompanied the product in its distribution were those approved by the [FDA] for a product approved under the [FDCA].

(b) The claimant may rebut the presumption in Subsection (a) as to each defendant by establishing that . . . the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the [FDA] required information that was material and relevant to the performance of the product and was causally related to the claimant's injury[.]

81. *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372 (5th Cir. 2012) (Jones, C.J.).

82. *Id.* at 373.

83. *Id.* at 374.

84. *Id.* at 373–75; *see also* TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(a)(1) (West 2013).

Examining both the *Garcia* and *Desiano* decisions, the court found *Garcia*'s reasoning "more faithful to *Buckman*" and held the fraud exception preempted "unless the FDA itself has found fraud."<sup>85</sup> Analyzing the issue in three parts, the court first considered whether the Supreme Court's recent decision in *Wyeth v. Levine*<sup>86</sup> affected the preemption analysis of the fraud exception. The court recognized similarities in the present case to both *Buckman* (because the plaintiff's claim required proof of fraud on the FDA to survive) and *Levine* (because the plaintiffs alleged a state common law failure-to-warn claim).<sup>87</sup> Though the court noted that *Levine* "preserves common law state tort claims that parallel or reinforce the agency's efforts," it ultimately found *Buckman* to be a more apt analog.<sup>88</sup> The dispositive factor for the court was seemingly that *Levine* "[did] not involve the relationship between the federal regulator and the regulated entity" at issue in *Buckman*, i.e., the relationship between the FDA and pharmaceutical manufacturers.<sup>89</sup>

After briefly summarizing the reasoning of the *Garcia* and *Desiano* decisions, the court analyzed whether *Buckman* applied to the statute by directly addressing Judge Calabresi's arguments in *Desiano*. The court first examined the presumption against preemption, asserting at the outset that the presumption's value is "uncertain," given the Supreme Court's sporadic application.<sup>90</sup> Contrary to the Second Circuit's framing of the issue as one implicating states' authority to regulate matters of health and safety,<sup>91</sup> the *Lofton* court concluded "with

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85. *Lofton*, 672 F.3d at 380.

86. *Wyeth v. Levine*, 555 U.S. 555 (2009). In *Wyeth*, the plaintiff had been injected with the defendant's anti-nausea drug using a method of injection known as "IV-push." As a result, she developed gangrene and was required to have her forearm amputated. She sued on a state law theory that the defendant had failed to provide adequate warning of the risks associated with the IV-push method. The Supreme Court held the plaintiff's failure-to-warn claims were neither expressly nor impliedly preempted by federal law.

87. *Lofton*, 672 F.3d at 377–78.

88. *Id.* at 377 ("Only by denying that the Texas statute is what it is—a requirement to prove fraud on the FDA—can *Levine* prevail or *Buckman* be distinguished.").

89. *Id.*

90. *Id.* at 378 ("[W]hatever value or relevance a presumption against preemption of state tort law should play is uncertain"); see also, e.g., *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (upholding implied conflict preemption of state-law failure to warn claim without any mention of the presumption against preemption); Thomas W. Merrill, *Preemption and Institutional Choice*, 102 Nw. U. L. REV. 727, 738 (2008) ("The doctrine is also dominated by maxims about the importance of congressional intent and the presumption against preemption, neither of which seems to play a consistent role in determining how particular controversies are resolved.").

91. See *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 94 (2d Cir. 2006), *aff'd by an equally divided court sub nom. Warner-Lambert Co. v. Kent*, 552 U.S. 440 (2008).

confidence” that the “primacy of the state’s police powers is not universal,” putting particular emphasis on the federal character of the FDA-manufacturer relationship and FDA disclosures.<sup>92</sup> The Fifth Circuit framed its rule broadly: “State laws that depend on [FDA disclosures] are not entitled to a presumption against preemption.”<sup>93</sup> Indeed, it may be that the court’s constrained view of the presumption against preemption is the safer approach.<sup>94</sup> The court’s reluctance to apply the presumption seems to stem largely from the unsettled state of the presumption doctrine.<sup>95</sup>

After disposing of the presumption argument, the court reasoned that the application of the statute’s fraud exception is predicated on a manufacturer’s failure to comply with federal disclosure requirements.<sup>96</sup> It stated that the state tort law claims are impermissible under *Buckman* if they “exist solely by virtue of the FDCA disclosure requirements.”<sup>97</sup> Turning to the Second Circuit’s second base,<sup>98</sup> the court found unpersuasive *Desiano*’s reasoning that such claims are distinguishable from *Buckman* because they are traditional tort claims not based on a duty between the FDA and a drug manufacturer. Even though the claim may be a failure-to-warn claim, the court argued, there would have been no way for the plaintiff to recover damages unless she establishes “what amounts to fraud on the agency.”<sup>99</sup> The court similarly rejected *Desiano*’s third base—that preemption is improper when FDA compliance is an affirmative defense and proving fraud is not an “element” of the tort claim<sup>100</sup>—because the plaintiff would still have to show a violation of the FDA’s disclosure requirements and would “necessarily re-tread[ ] the FDA’s administrative ground both to conduct discovery and persuade a jury.”<sup>101</sup>

Finally, the court takes issue with the Judge Calabresi’s reasoning that allowing claims to proceed under the fraud exception would not result in an over-disclosure deluge on the FDA. The court offered

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92. *Lofton*, 672 F.3d at 379.

93. *Id.*

94. *See, e.g., Merrill, supra* note 90, at 741 (“The presumption is at the very least overbroad, as the Court seems to have recognized in recent decisions.”).

95. *See Lofton*, 672 F.3d at 379 (“Even with the benefit of *Levine* and *PLIVA*, this court is unable to assess the current scope or existence of the presumption against preemption.”).

96. *Id.*

97. *Id.* (quoting *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 353 (2001)).

98. *See supra* notes 67–69 and accompanying text.

99. *Lofton*, 672 F.3d at 379–80.

100. *See supra* notes 70–72 and accompanying text.

101. *Lofton*, 672 F.3d at 380.

two arguments in rebuttal. First, allowing state courts to “interject varying views on what disclosures are sufficient” would result in uncertainty, compelling manufacturers to deluge the FDA in future cases to retain their presumption against liability.<sup>102</sup> Thus, this deluge would cause the FDA to lose control of its ability to “prescribe—and intelligently limit—the scope of disclosures necessary for its work.”<sup>103</sup> Second, the application of the fraud exception would require an “invasion” into the agency’s processes in close cases, further burdening the FDA.<sup>104</sup> Concluding that *Garcia*’s approach is “more faithful to *Buckman*,” the Fifth Circuit held that the fraud exception was preempted with the important caveat, as in *Garcia*, that if the FDA itself has first made a finding of fraud, the case could proceed.<sup>105</sup>

#### IV.

##### APPLICATIONS OF *BUCKMAN* IN TRIAL COURTS AND OTHER CONTEXTS

Though the stage is set for the Supreme Court to decide the fate of states’ fraud-on-the-FDA exceptions to tort immunity, whether the Court will find the approach advanced by *Garcia* or *Desiano* more persuasive is still unclear considering the court’s equal division in *Warner-Lambert Co. v. Kent*.<sup>106</sup> Numerous district courts independent of the Second, Fifth, and Sixth Circuits’ jurisdictions have addressed this issue and, unsurprisingly, have emerged on both sides of the debate.<sup>107</sup>

District courts appealing to the Second, Fifth, and Sixth Circuits have consistently applied their respective circuit’s reasoning to similar fraud-exception preemption cases.<sup>108</sup> One anomalous case worth men-

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102. *Id.*

103. *Id.*

104. *Id.*

105. *Id.* (“[W]here the FDA has not found fraud, the threat of imposing state liability on a drug manufacturer for defrauding the FDA intrudes on the competency of the FDA and its relationship with regulated entities . . . . Thus, § 82.007(b)(1), is preempted unless the FDA itself has found fraud.”).

106. 552 U.S. 440 (2008).

107. *See infra* note 117.

108. *Cf. Bower v. Johnson & Johnson*, 795 F. Supp. 2d 672, 675–77 (N.D. Ohio 2011) (holding the plaintiff’s products liability claims preempted by Michigan statute applying *Garcia*’s reasoning). *Compare, e.g., Forman v. Novartis Pharm. Corp.*, 793 F. Supp. 2d 598, 601–03 (E.D.N.Y. 2011) (holding that the FDCA did not preempt the fraud exception to New Jersey’s statutory bar on punitive damages), and *Yocham v. Novartis Pharm. Corp.*, 736 F. Supp. 2d 875, 885–89 (D.N.J. 2010) (holding that the FDCA did not preempt the fraud exception to Texas’s rebuttable presumption-against-liability statute), with *Del Valle v. Qualitest Pharm. Inc.*, No. B-11-113, 2012 WL 2899406, at \*3 (S.D. Tex. June 22, 2012) (holding that the plaintiff’s products

tioning, *Hall v. Wyeth, Inc.*,<sup>109</sup> adopted *Desiano*'s reasoning to reject the argument that Michigan's fraud exception was preempted when the plaintiff had alleged that the defendant committed fraud during the application process. In doing so, the court made a curious assertion that "[t]he Sixth Circuit itself has since adopted the Second Circuit's reading of *Buckman*."<sup>110</sup> It seems the court misinterpreted a post-*Garcia* opinion, *Wimbush v. Wyeth*,<sup>111</sup> as applying to tort claims dependent on evidence of fraud on the agency, something never intended by the Sixth Circuit. The *Wimbush* court does adopt *Desiano*'s reasoning, in part, for the proposition that parallel state law tort claims are not preempted where they complement—rather than interfere with—a federal scheme,<sup>112</sup> but the issue of fraud-on-the-FDA was not invoked, except in passing,<sup>113</sup> nor was *Buckman* ever mentioned in the opinion or the parties' briefs. Rather, the *Wimbush* decision turned on application of *Wyeth v. Levine*, not *Buckman*, to garden-variety state law tort claims.<sup>114</sup> Moreover, the Sixth Circuit has since reaffirmed its position in *Garcia* in *Marsh v. Genentech, Inc.*, holding that a consumer's allegations that a drug manufacturer failed to comply with FDA's post-marketing requirements is preempted by the FDCA.<sup>115</sup>

The fraud exception debate has also arisen in other statutory schemes. For example, much debate has revolved around the fraud exception in the context of punitive damage statutes. As with FDA-compliance statutes, certain states have also enacted statutes prohibiting the recovery of punitive damages against manufacturers in a products liability action for an FDA-approved drug.<sup>116</sup> In similar fashion, under these statutes a plaintiff who can show fraud on the FDA nullifies the bar on punitive damages. At first blush, *Garcia* seems to have swayed a majority of courts "independent" of the Second, Fifth, or

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liability claim preempted absent a federal finding of fraud), and *Tiefenthal v. Genentech, Inc.*, No. 1:11-CV-689, 2011 WL 5089468, at \*4–5 (W.D. Mich. Oct. 26, 2011) (same). *But see* *Ackermann v. Wyeth Pharm.*, 471 F. Supp. 2d 739, 749–50 (E.D. Tex. 2006) (refusing to find preemption of the fraud exception merely "based on a presumption"), *aff'd on other grounds*, 526 F.3d 203 (5th Cir. 2008).

109. No. 10-00738, 2010 WL 3860467 (E.D. Pa. Sept. 30, 2010), *cert. granted*, No. 10-738, 2010 WL 4925258 (E.D. Pa. Dec. 2, 2010).

110. *Id.* at \*2.

111. 619 F.3d 632 (6th Cir. 2010).

112. *Id.* at 644.

113. *See* Brief for the Appellees at 20, *Wimbush*, 619 F.3d 632 (No. 09-3380).

114. *See supra* notes 86–89 and accompanying text.

115. *See* 693 F.3d 546, 550 (6th Cir. 2012).

116. ARIZ. REV. STAT. ANN. § 12-701(a)(1) (2014); COLO. REV. STAT. § 13-64-302.5(5)(a) (2014); N.J. STAT. ANN. § 2A:58C-5(c) (West 2014); N.D. CENT. CODE § 32-03.2-11(6) (2013); OHIO REV. CODE ANN. § 2307.80(c)(1) (West 2014); OR. REV. STAT. § 30.927(1)(a) (2014); UTAH CODE ANN. § 78B-8-203(1) (West 2014).

Sixth Circuit's jurisdictions that have dealt with these and similar fraud-exception statutes.<sup>117</sup> But whether there is indeed safety in numbers has yet to be seen.

A. *Competing Interpretations Applied: New Jersey's Punitive Damage Statute*

In a recent case, *Zimmerman v. Novartis Pharmaceuticals Corporation*,<sup>118</sup> the U.S. District Court for the District of Maryland examined at length whether the FDCA preempted the plaintiff's claim against a pharmaceutical manufacturer for punitive damages under New Jersey's fraud exception provision.<sup>119</sup> The court performed a rigorous analysis and did not rely wholly on the reasoning of either *Desiano* or *Garcia*—though ultimately, the court concluded the FDCA preempted the exception. An examination of the court's analysis may help shed some light on issues facing district courts in their attempts to reconcile *Buckman*'s competing interpretations.

The district court first examined the history of the FDCA, the FDA's role in regulating pharmaceutical drugs, and the approval process for new drugs.<sup>120</sup> The court paid special attention to the fact that

117. For example, the following are independent courts applying *Garcia*: *Zimmerman v. Novartis Pharm. Corp.*, 889 F. Supp. 2d 757, 779 (D. Md. Sept. 5, 2012); *In re Aredia & Zometa Prods. Liab. Litig.*, No. 3:06-MD-1760, 2009 WL 2497229, at \*2 (M.D. Tenn. Aug. 13, 2009) (holding Florida's fraud exception to statutory presumption against liability preempted by *Buckman*); *Grange v. Mylan Labs., Inc.*, No. 1:07-CV-107 TC, 2008 WL 4813311, at \*6–7 (D. Utah Oct. 31, 2008) (holding Utah's fraud exception to punitive damages statute preempted, applying *Garcia*'s reasoning); *In re Baycol Prods. Litig.*, Nos. 1431, 03-3596 (MJD/SRN), 2008 WL 8797727, at \*3–4 (D. Minn. Sept. 9, 2008) (holding Michigan's fraud exception to immunity statute preempted, applying *Garcia*'s reasoning); *Kobar ex rel Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166, 1170–75 (D. Ariz. 2005) (holding Arizona's fraud exception to punitive damages statute preempted, applying *Garcia*'s reasoning); cf. *In re Trasylol Prods. Liab. Litig.*, 763 F. Supp. 2d 1312, 1323–27 (S.D. Fla. 2010) (granting drug manufacturers' motion to exclude evidence of fraud on the FDA, applying *Garcia*'s reasoning).

The following are independent courts applying *Desiano*: *Hall v. Wyeth, Inc.*, CIV.A. 10-00738, 2010 WL 3860467, at \*2 (E.D. Pa. Sept. 30, 2010) (holding Michigan fraud exception not preempted, applying *Desiano*'s reasoning), *perm. app. granted*, CIV.A.10-738, 2010 WL 4925258 (E.D. Pa. Dec. 2, 2010); *Stanley v. Mylan Inc.*, No. 1:09-CV-124 TS, 2010 WL 3718589, at \*6 (D. Utah Sept. 17, 2010) (holding Utah's fraud exception to punitive damages statute not preempted, applying *Desiano*'s reasoning); *Lake-Allen v. Johnson & Johnson, L.P.*, No. 2:08CV00930DAK, 2009 WL 2252198, at \*3–4 (D. Utah July 27, 2009) (same).

118. 889 F. Supp. 2d 757 (D. Md. Sept. 5, 2012).

119. N.J. STAT. ANN. § 2A:58C-5(c) (West 2014) (barring an award of punitive damages if the product received FDA-approval but providing an exception if the manufacturer defrauded the agency).

120. *Zimmerman*, 889 F. Supp. 2d at 768–69.

the FDA—and not the private litigant—is specifically authorized by the FDCA to investigate and enforce fraud by drug manufacturers, and that the FDA is given considerable discretion in exercising its enforcement authority.<sup>121</sup> The court distinguished *Wyeth v. Levine* on this basis, noting that the Supreme Court had emphasized that the manufacturer in *Levine* could not “identify a specific federal statute . . . which precludes the possibility of two separate but parallel determinations.”<sup>122</sup> According to the district court, such a statute could be identified in this case—the FDCA.<sup>123</sup>

### 1. *The Presumption Against Preemption*

As in *Lofton*, the district court in *Zimmerman* concluded that no presumption against preemption applied in this case. In *Lofton*, the Fifth Circuit broadly concluded that all state tort claims dependent on FDA disclosures are not entitled to a presumption against preemption.<sup>124</sup> The *Zimmerman* court unpacked this conclusion, citing *Buckman* as support for its reasoning. Although recognizing that the presumption has traditionally applied in cases implicating a state’s regulation of health and safety, the district court rebutted this premise by arguing that the Supreme Court and other courts have declined to apply the presumption in cases involving areas of “significant federal concern,” even when the state law tort claims implicate health and

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121. *Id.* at 769 (citing 21 U.S.C. §§ 332–34, 336–37, 372).

122. *Id.* at 774.

123. *See id.* at 774–76 (“Plaintiff’s claim for punitive damages under New Jersey’s statutory immunity provision poses an obstacle to the FDCA regulatory scheme because it requires a fact finder to make a determination that a federal law leaves exclusively to the agency.”).

124. *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 379 (5th Cir. 2012).

safety concerns.<sup>125</sup> *Zimmerman*, the court contended, was such a case.<sup>126</sup>

Finally, even if the presumption did apply, the court found that the presumption would nonetheless be overcome because of the conflict between requiring proof of fraud and the FDA's regulatory scheme. The court cites the Sixth Circuit's decision in *Garcia* to support its assertion that the presumption is "hardly outcome-determinative"—i.e., that courts have found preemption even where the presumption did apply.<sup>127</sup> One interesting disagreement between the courts in *Zimmerman* and *Desiano* concerns whether the *Garcia* court actually applied the presumption against preemption. The *Zimmerman* court asserted that it did,<sup>128</sup> while *Desiano* contended that *Garcia*'s "persuasive effect" should be diminished because it did not apply the presumption.<sup>129</sup> This confusion may have arisen because of the Sixth Circuit's cursory treatment of the presumption. Though the court did give lip service to the presumption against preemption, it is unclear whether it had any bearing on the court's decision.<sup>130</sup> Likewise, it is unclear what effect, if any, a clear answer to this issue would have had on the *Zimmerman* decision itself, given that the district court's line of reasoning (i.e., even if the presumption against preemption were to apply, the claim is still preempted) was an alternative basis for finding preemption as it had already decided the presumption did not apply.<sup>131</sup> It does beg the question, however, whether the presumption against preemption analysis has any significance at all in cases where FDA

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125. *Zimmerman*, 889 F. Supp. 2d at 770–72 (“[T]he presumption against preemption applies to state tort claims implicating health and safety generally, the Court concludes that such a presumption does not apply to that part of Plaintiff’s claim, which . . . conditions any recovery of punitive damages on a showing that a defendant-drug manufacturer ‘knowingly withheld or misrepresented information required to be submitted . . .’”); see also *Boyle v. United Techs. Corp.*, 487 U.S. 500, 504–05 (1988) (declining to apply the presumption against preemption in an area involving “uniquely federal interests”). But see *id.* at 517–19 (Brennan, J., dissenting) (asserting that the presumption against preemption applied and the majority improperly created a new category of “uniquely federal interests”).

This reasoning was later cited by the *Buckman* majority as support for the proposition that the relationship between the FDA and the drug manufacturer it regulates is “inherently federal in character.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 347–48 (2001); see also discussion *infra* Part V.A.

126. *Zimmerman*, 889 F. Supp. 2d at 772.

127. *Id.*

128. *Id.*

129. *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.”).

130. See *supra* note 53–55 and accompanying text.

131. *Zimmerman*, 889 F. Supp. 2d at 770–72.

disclosure evidence is necessary, given that district courts can seemingly dispose of the presumption by merely invoking the federal interest in maintaining an agency's regulatory scheme.<sup>132</sup>

The district court ultimately held that the exception was preempted by the FDCA for reasons not unlike those articulated by the *Garcia* court:

Simply put, Plaintiff's claim for punitive damages requires a state fact finder to determine [(1)] what was required to be submitted to the FDA, [(2)] whether it was submitted to the FDA and, [(3)] whether the FDA would have made a different approval decision had it been provided with the correct or missing information. Plaintiff's claim thus requires a fact finder to make these types of determinations as a matter of state law even though federal law makes such determinations the exclusive province of the FDA. Accordingly, Plaintiff's claim for punitive damages poses an obstacle to the objectives and purpose of the FDCA, and is therefore preempted by the FDCA.<sup>133</sup>

## 2. *Framing the Preemption Question: Conflicting Views*

The *Zimmerman* court recognized disagreement between its decision and *Forman v. Novartis Pharmaceuticals Corporation*—another district court case in the Eastern District of New York—which had adopted the reasoning of *Desiano* to find the same fraud exception to the New Jersey punitive damages statute *not* preempted by the FDCA.<sup>134</sup> As such, the court dutifully offered a rebuttal to the *Forman* court's reasoning, which is useful for illuminating the present morass in this area of the law.<sup>135</sup> It seems the problem, in part, is that different conversations are occurring, in which the courts are not directly addressing the arguments of the others.

The *Forman* court focused on two arguments, which comprise the two prongs of *Desiano*'s second basis for its decision.<sup>136</sup> The first argument is the following: “[T]he fact that fraud in FDA disclosures is necessary for the pre-existing common law punitive damages claim to survive [under New Jersey law], is not equivalent to a [fraud on the FDA] claim ‘based *solely* on the wrong of defrauding the FDA.’”<sup>137</sup>

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132. See *supra* note 125 and accompanying text.

133. *Zimmerman*, 889 F. Supp. 2d at 776.

134. *Forman v. Novartis Pharms. Corp.*, 793 F. Supp. 2d 598, 606–08 (E.D.N.Y. 2011).

135. *Zimmerman*, 889 F. Supp. 2d at 767.

136. See *supra* notes 67–69 and accompanying text.

137. *Zimmerman*, 889 F. Supp. 2d at 776 (quoting *Forman*, 793 F. Supp. 2d at 605 (alterations and emphasis in original)).

To this argument, the *Zimmerman* court concluded the “distinction is meaningless” because the *Buckman* plaintiffs too had to prove common law elements of fraud other than violations of FDCA disclosure requirements, such as causation and injury.<sup>138</sup>

If, however, the issue is framed such that *Buckman* only concerned the preemption of the narrow field of stand-alone fraud-on-the-FDA claims, *Desiano* would be correct in saying that “*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.”<sup>139</sup> Under this framing, *Zimmerman*’s criticism—that as between fraud-on-the-FDA claims and other state law tort claims dependent on fraud evidence, the distinction is meaningless—would miss the mark, because Congress undoubtedly has authority to narrowly preempt a field of particular claims, i.e., state law fraud-on-the-FDA claims, without preempting others. Indeed, the *Desiano* interpretation seems to have some merit under a close reading of the *Buckman* decision:

[I]t is clear that the *Medtronic* claims arose from the manufacturer’s alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements. In the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure requirements . . . . [W]ere 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 questions. On the contrary, the existence of these federal enactments is a critical element in their case.<sup>140</sup>

In most cases, plaintiffs’ negligence and products liability claims are creatures of state common law that exist apart from the FDCA. They cannot proceed once the defendant has raised its statutory affirmative defenses, but they do not arise from or exist solely because of FDCA requirements—unlike the preempted fraud-on-the-FDA claim. Thus, a literal interpretation of the decision may support the view that these common law claims are closer to *Medtronic*<sup>141</sup> than they are to the claims preempted in *Buckman*.

In any case, part of the controversy seems to stem from conflicting framings of the issue: *Zimmerman*, on the one hand, framing the

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138. *Id.* at 776–77 (“[T]he preemption analysis does not change simply because, under New Jersey law, this Plaintiff must prove something in addition to non-compliance with a FDCA disclosure requirement.”).

139. *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 95 (2d Cir. 2006).

140. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 352–53 (2001) (emphasis added) (citations omitted).

141. See also *supra* notes 39–40 and accompanying text.

issue as one of practical impact on the regulatory scheme (obstacle preemption), and *Desiano*, on the other, as one of “formalistic differences” and of narrowly discerning congressional intent (field preemption).<sup>142</sup> The scope of *Desiano*’s field-preemption view seems to overly constrict *Buckman* by effectively ignoring the Court’s well-stated policy rationales.<sup>143</sup> *Zimmerman*, therefore, may have been right to focus on the practical impacts of a fraud-on-the-FDA claim and an ordinary tort claim dependent on fraud evidence, and to ultimately decide that there is no practical difference between the two claims. On the other hand, *Desiano* takes very seriously the idea that “Congress does not cavalierly pre-empt state-law causes of action,” and a court must “start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress,”<sup>144</sup> or in other words, the essence of the presumption against preemption.

The *Forman* court’s second argument, quoting *Desiano*, relied on the fact that in *Buckman* the claim was “based on a ‘newly concocted duty between manufacturer and a federal agency,’ whereas the plaintiff’s New Jersey punitive damages claim is based on traditional tort duties.”<sup>145</sup> The *Zimmerman* court was skeptical about drawing such a distinction:

Such a distinction might make sense if one were comparing a traditional tort claim with the claim in *Buckman* before New Jersey passed its punitive damages immunity statute . . . . *Once New Jersey passed the statutory immunity provision for punitive damages, the traditional cause of action is no more rooted in common law doctrine than the stand-alone claim in Buckman . . . . [I]n the post-statutory immunity world, a plaintiff’s punitive damages claim hinges on whether the defendant-drug maker made adequate disclosures to the agency and whether, in the face of these inadequate disclosures, the agency would have approved the drug. In this way,*

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142. The *Zimmerman* court implicitly recognizes the framing problem but nonetheless finds such differences unpersuasive and irrelevant. *Zimmerman*, 889 F. Supp. 2d at 777 (“For these reasons, this Court is convinced that the formalistic differences between Plaintiff’s punitive damages claim and the *Buckman* plaintiffs’ fraud on the FDA claim are immaterial.”).

143. See *Buckman*, 531 U.S. at 348 (“The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives.”).

144. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

145. *Zimmerman*, 889 F. Supp. 2d at 777.

New Jersey's statutory immunity provision makes fraud on the FDA a "critical element" of every punitive damages claim.<sup>146</sup>

Again the framing of the issue seems to create confusion, as the *Zimmerman* court's rebuttal does not seem to directly address *Desiano*'s argument. The *Zimmerman* rebuttal addresses the reality that fraud evidence will inevitably be necessary to allow a claim for punitive damages to survive, rebutting the argument in *Desiano* that the plaintiffs' claims are "anything but based solely on the wrong of defrauding the FDA."<sup>147</sup> However, *Desiano* seems to be more concerned with the more fundamental issue of congressional intent to preempt, i.e., that a claim based on a duty between a manufacturer and a consumer (which is only incidentally dependent on evidence of fraud on the FDA to defeat immunity or get punitive damages) should not be preempted absent a clear expression of intent from Congress specifically modifying these traditional duties<sup>148</sup>—in other words, that the presumption against preemption should control.<sup>149</sup>

Had the *Zimmerman* court recognized that this was the *Desiano* argument, the more appropriate response would have simply been, as stated in *Zimmerman* previously, that the presumption against preemption does not apply because of the significant federal interests at stake,<sup>150</sup> or, if it does apply, it is rebutted because of the burden imposed on the FDA's regulatory scheme.<sup>151</sup> In other words, Congress intended the FDCA to preempt conflicting state statutes, like the fraud exception, where they create an obstacle for the FDA's ability to regulate effectively. In any event, this exchange illustrates the confused situation in which courts find themselves as they navigate through the murky waters of *Buckman*'s wake.

### B. Navigating *Buckman*: A Summary

Fraud-on-the-FDA exceptions to states' compliance statutes introduce an added layer of complexity to the preemption analysis. Despite the doctrinal discord in the circuit courts, they all would agree that properly discerning *Buckman*'s reach is the key component to the analysis. So how should courts interpret the case? I think it is fair to say that, while *Buckman* should not be construed too narrowly as to

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146. *Id.* (emphasis added) (citations omitted).

147. *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 95 (2d Cir. 2006).

148. *Id.* at 94–95.

149. *Id.* at 95 n.7 (“[U]nlike the situation in *Buckman*, the presumption against preemption is at its strongest in the instant case.”).

150. *Zimmerman*, 889 F. Supp. 2d at 770–72.

151. *Id.* at 772–76.

impose intractable burdens or a “deluge” of superfluous information on the agency, there should be an equal measure of reluctance to interpret *Buckman*’s reasoning so broadly that any state law, claim, or decision which might result in even minimal additional burdens on the FDA is preempted—assuming there are other factors counseling against preemption. Though the cases in this context are anything but consistent, two salient and co-dependent issues clearly drive the courts’ decisions.

The first is simply a framing issue: What kind of implied preemption is really at issue here? While *Garcia* and its progeny frame the analysis as one of obstacle preemption,<sup>152</sup> *Desiano* and its line of cases seem to more narrowly construe *Buckman* as only preempting the field of stand-alone common law fraud-on-the-FDA claims. And while *Desiano*’s field preemption analysis may or may not be correct as a formalistic matter, the Second Circuit’s reasoning effectively ignores the Supreme Court’s policy concern that attempts by state courts to punish and deter fraud on the agency might disrupt the “somewhat delicate balance of statutory objectives” pursued by the FDA.<sup>153</sup> The unanswered question is whether Congress would have intended to preempt *any* state laws and claims posing a significant-enough obstacle to the maintenance of the FDA approval regime, or only those laws and claims where states have taken it upon themselves to directly police fraud on the federal agency, as in the case of preempted fraud-on-the-FDA claims. There is no clear answer.

The second related issue is whether the presumption against preemption should apply in fraud-exception cases and, if so, what value the presumption actually has. If *Zimmerman* is right and a significant federal interest should effectively neutralize the presumption, regardless of whether it attaches, then the answer is clear: the fraud excep-

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152. See *supra* note 142 and accompanying text.

153. See *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 348–49 (2001) (“This flexibility [to make a measured response to suspected fraud] is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives . . . .”); see also Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda*, 1 J. TORT L. 5, 14 (2006) (“The Calabresi opinion thus makes a huge deal out of the pedigree of the state law cause of action when the dominant concern of the Supreme Court was the entanglement of the FDA in state litigation, which remains the same no matter how state law tees up the plaintiff’s cause of action.”); cf. Ernest A. Young, *The Rehnquist Court’s Two Federalisms*, 83 TEX. L. REV. 1, 132 (2004) (“Many, if not most, preemption cases are not about the interpretation of ambiguous statutory text, but rather about how to identify the underlying purposes of federal statutes and to assess the acceptable degree of conflict between those purposes and state regulatory measures.”).

tion should be found preempted.<sup>154</sup> But, at least at first blush, this response feels unsatisfactory given, for example, that the *Zimmerman* court cited *Garcia* alone for the proposition that courts have found preemption even where the presumption applied,<sup>155</sup> when it is unclear whether *Garcia* had occasion to seriously examine the presumption at all.<sup>156</sup> Nonetheless, *Buckman*'s reasoning that the FDA-manufacturer relationship is inherently federal in nature and should terminate according to federal law should rebut the presumption even if it were to apply<sup>157</sup>—but only if it can and does extend to traditional tort fraud-exception cases with the same force as in *Buckman* with regard to stand-alone fraud-on-the-FDA claims. Again, it is not at all clear that *Buckman*'s rationale *should* impact, with equal strength, common law tort cases dependent on fraud evidence only to the extent it is needed to overcome a defendant's state law statutory defense.

With so much uncertainty in this area of law, a more inclusive analysis is needed. The more tools a court has in performing a preemption analysis, the better it can truly discern the state of affairs and come to a well-informed result. In Part V, I argue that courts should consider additional federalism and policy factors to inform the traditional preemption analysis.

### C. *Buckman Beyond Drug Preemption*

*Buckman*'s brand of obstacle preemption in the regulatory sphere has expanded into areas beyond pharmaceuticals and medical devices.<sup>158</sup> In *Nathan Kimmel, Inc. v. DowElanco*,<sup>159</sup> the Ninth Circuit analogized to *Buckman*, holding that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)<sup>160</sup> preempted the plaintiff's claim for injunctive relief. The court reasoned that, analogous to *Buckman*,

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154. See *supra* notes 127–32 and accompanying text.

155. *Zimmerman*, 889 F. Supp. 2d at 772.

156. See *supra* notes 53–55.

157. *Buckman*, 531 U.S. at 348 (citing *Boyle v. United Techs. Corp.*, 487 U.S. 500, 504–05 (1988)).

158. *But see, e.g.*, *DOCA Co. v. Westinghouse Elec. Co., LLC*, No. 04-1951, 2011 WL 3476428 (W.D. Pa. Aug. 9, 2011) (holding that the plaintiff's unfair competition and interference with prospective advantage claims, which were dependent on the defendant's alleged fraud on the Nuclear Regulatory Commission, were not preempted).

159. 275 F.3d 1199 (9th Cir. 2002). The plaintiff alleged that the defendant, a manufacturer of pesticides, submitted false information to the EPA regarding the reliability of certain nylon polymer bags to have its labeling changes approved for the purpose of excluding the plaintiff from the business of manufacturing nylon polymer bags. The plaintiff sued to compel the defendant to change its label to explicitly permit the use of his bags during fumigations with the defendant's pesticides.

160. 7 U.S.C. §§ 135–136y (2013).

the plaintiff's claim in this case was dependent on violations of FIFRA requirements.<sup>161</sup> Thus, allowing these claims to go forward would result in the same additional burdens and needless drain on agency resources that concerned the *Buckman* court.<sup>162</sup>

Similarly, in *Offshore Service Vessels, L.L.C. v. Surf Subsea, Inc.*, a Louisiana federal court held that the plaintiffs' claims of fraud on the Coast Guard "would exert an impermissible 'extraneous pull' on the comprehensive regulatory scheme established by Congress and administered by the Coast Guard to regulate federal vessel documentation and coastwide trade."<sup>163</sup> The district court declined to apply a presumption against preemption because the relationship between the Coast Guard and plaintiffs was "inherently federal in character."<sup>164</sup> In finding preemption, the court cited broad policy concerns similar to the reasoning stated in *Garcia and Lofton*.<sup>165</sup>

The growing number of *Buckman*-dependent cases implicating administrative regimes of different stripes speaks to the importance of the *Buckman* rationale for future cases, and why reevaluating the court's preemption analysis is important for individual parties, as well as state regimes providing statutory protections to federally regulated industries.

## V.

### RECONSIDERING THE TRADITIONAL ANALYSIS

In preemption cases, courts are quick to cite federalism concerns,<sup>166</sup> but there are factors relevant to such concerns that have escaped the preemption analysis in the fraud-exception context. Courts should be aware of these factors and, I argue, should consider them in

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161. *DowElanco*, 275 F.3d at 1206 ("It is the alleged fraud-on-the-EPA and abuse of the labeling process which give rise to Kimmel's damaged business claims and to his proffered cause of action.")

162. *Id.* at 1207 (citing *Buckman*, 531 U.S. at 351) (reasoning that permitting claims like the plaintiff's would "motivate potential applicants under FIFRA to 'submit a deluge of information that the [EPA] neither wants nor needs, resulting in additional burdens on the [EPA's] evaluation of an application'").

163. No. 12-1311, 2012 U.S. Dist. LEXIS 150103, at \*34 (E.D. La. Oct. 17, 2012). The plaintiffs contended that the defendant had been using a ship "ineligible to engage in coastwide trade" to illegally compete with the plaintiffs by obtaining a Certificate of Documentation from the Coast Guard by giving it fraudulent and misleading information.

164. *Id.* at \*34-35.

165. *See, e.g., id.* at \*43-44 (providing rationales such as increased costs of obtaining vessel documentation, frustration of coastwide trade, divergent state law penalties, and conflicts between a state or federal court and the agency regarding interpretations of the law).

166. *See, e.g., Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

their analysis of fraud-exception cases where the mode of displacing state law is implied obstacle preemption.<sup>167</sup> Although there are undoubtedly other factors that courts could consider,<sup>168</sup> I will discuss two considerations that I think are fundamentally important in the implied preemption analysis with regard to tort immunity statutes with fraud exceptions: deference for states' legislative processes and agency institutional competence. Within the framework of the traditional preemption analysis, courts can conceptualize these factors as buttressing or rebutting the presumption against preemption in a given case. Such an analysis makes sense because the presumption is rooted in protecting "the historic primacy of state regulation of matters of health and safety."<sup>169</sup>

A. *Deference to States' Legislative Processes:  
A Federalism Quandary*

As to the first factor, courts should be mindful of the effect of a preemption decision as it operates in conjunction with state law. I argue that where a decision to preempt all or part of a statute would undermine the state's legislative process that led to its enactment, this result counsels against a preemption. To illustrate, consider the ordinary preemption case: A plaintiff sues, for example, under a state law

167. An aside: Justice Thomas is infamous for his outright rejection of implied obstacle preemption, as revealed by his solo concurrence in *Levine*. *Wyeth v. Levine*, 555 U.S. 555, 583 (2009) ("In particular, I have become increasingly skeptical of this Court's 'purposes and objectives' pre-emption jurisprudence. Under this approach, the Court routinely invalidates state laws based on perceived conflicts with broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not embodied within the text of federal law."). See generally Catherine M. Sharkey, *Against Freewheeling, Extratextual Obstacle Preemption: Is Justice Clarence Thomas the Lone Principled Federalist?*, 5 N.Y.U. J.L. & LIBERTY 63, 110 (2010) ("What seems to animate Justice Thomas above all is a disdain for 'judicially manufactured policies.'").

168. See, e.g., Thomas O. McGarity, *Beyond Buckman: Wrongful Manipulation of the Regulatory Process in the Law of Torts*, 41 WASHBURN L.J. 549, 549–50 (2002) ("[T]he Buckman Court's preemption analysis gave short shrift to the federal statute's primary policy of protecting public health from medical devices that are not safe and effective. At the same time, the Court unduly stressed the potential for common law fraud claims to conflict with statutory policies aimed at protecting the regulated industry from regulatory burdens and at protecting the freedom of doctors to prescribe FDA-approved medical devices for unapproved uses."); Sharkey, *Products Liability Preemption*, *supra* note 65, at 479 ("Agencies can serve as a reference in determining the optimal regulatory strategy; specifically, agencies conduct context-specific cost-benefit (or risk-risk) analyses in deciding whether or not to pass regulations. This information base, moreover, can provide an empirical basis for the Court's assessment as to whether a uniform federal regulatory policy should exist in a particular area.").

169. *Medtronic*, 518 U.S. at 485.

cause of action for ordinary negligence.<sup>170</sup> The manufacturer-defendant rebuts, arguing the claim is preempted. The court then makes a preemption determination: The claim is preempted or not.

As we have seen, however, in state law fraud-exception cases, the procedure is quite different. A plaintiff sues under an ordinary negligence claim, and the defendant, rather than argue the plaintiff's claim is preempted, raises his defense of statutory immunity (or presumption of non-liability) under state law. The defendant, at this point, does not argue that the plaintiff's *claim* is preempted. Rather, the plaintiff argues under the fraud exception to immunity that the defense is rebutted because the defendant worked a fraud on the FDA to get approval for his product. *Only then* will the defendant argue that the fraud exception, rather than the plaintiff's claim, is preempted under *Buckman* because of the burdens that allowing such claims to go forward would indirectly impose on the FDA. Thus, if the court finds that federal law does preempt a state's fraud-on-the-agency exception, a plaintiff's claims would ultimately be extinguished by the operation of *state law* by providing de facto blanket immunity for products receiving FDA approval (absent some other extreme form of misconduct such as bribery).<sup>171</sup>

The significance of the procedural differences between ordinary preemption cases and the fraud-exception cases is clearly discernable upon considering the implications of preemption for the state legislative process. To illustrate, consider the Texas FDA-compliance statute and its fraud exception: Under Texas law, in failure-to-warn cases "there is a rebuttable presumption that the defendant . . . [is] not liable with respect to the allegations involving failure to provide adequate warnings or information if . . . the warnings or information that accompanied the product in its distribution were those approved by the [FDA] for a product approved under the [FDCA]."<sup>172</sup> The statute's fraud exception provides, in part, that the "claimant may rebut the presumption in Subsection (a) as to each defendant by establishing that . . . the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the [FDA] required

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170. *E.g.*, *id.* at 470.

171. *See* MICH. COMP. LAWS § 600.2946(5)(a) (2014). For states in which only a rebuttable presumption of non-liability attaches for compliance with FDA regulations (e.g., Texas and Utah), a plaintiff may be able to overcome the presumption by some other evidence, but it is unclear what kind of evidence is sufficient. *See, e.g.*, *Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 781 (S.D. Tex. 2008) (holding that evidence of "clinical wisdom" regarding the risks of certain drug interactions could not rebut the presumption of non-liability), *aff'd*, 321 F. App'x 350 (5th Cir. 2009).

172. TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(a) (West 2013).

information that was material and relevant to the performance of the product and was causally related to the claimant's injury[.]”<sup>173</sup>

The statute was part of a comprehensive tort reform package passed in 2003 in response to a “general environment of excessive litigation” in Texas.<sup>174</sup> The bill was allegedly “intended to address and correct problems that currently impair the fairness and efficiency of [the] court system,” by imposing, *inter alia*, noneconomic damages caps, limitations on attorneys’ fees arrangements, and class action reforms.<sup>175</sup> The bill was a highly contentious proposal in a legislative session mired in controversy.<sup>176</sup>

As introduced, Texas House of Representatives Bill 4 (H.B. 4) made no mention of an FDA-compliance provision.<sup>177</sup> After being read for the first time on February 17, 2003, the bill was referred to the Texas House Committee on Civil Practices.<sup>178</sup> Only after leaving committee on March 20th did the House Committee Report version of H.B. 4 include an immunity provision.<sup>179</sup> In its earliest form, the Texas compliance provision read similarly to Michigan’s statute, providing complete immunity from liability for FDA compliance, rather than a presumption of non-liability as it does currently.<sup>180</sup> No fraud exception then existed in the bill.

The bill was read for a second time on the House floor on February 17th.<sup>181</sup> On March 27th, Rep. Scott Hochberg (D-Houston) proposed the embryonic version of the fraud exception, which provided: “This section shall not apply in any products liability action alleging

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173. *Id.* § 82.007(b).

174. H. COMM. ON CIVIL PRACTICES, BILL ANALYSIS: C.S.H.B. 4, 78th Cong., Reg. Sess. (Tex. 2003), available at <http://www.capitol.state.tx.us/tlodocs/78R/analysis/pdf/HB00004H.pdf#navpanes=0>.

175. *Id.*

176. See, e.g., Paul Burka, *So Far, So Bad: It's a New Era in Texas Politics, but Republicans Have Been Too Busy Fighting Democrats - and Each Other - to Get Anything Done*, TEX. MONTHLY, May 2003, <http://www.texasmonthly.com/content/so-far-so-bad>; William Lutz, *Analysis: Process Questions Cast Shadow over Tort Reform Bill*, LONE STAR REP., Mar. 7, 2003, at 2; John Council, *Tort Reform Rocks the House*, TEXASLAWYER (Mar. 24, 2003), <http://www.texaslawyer.com/id=900005382938>; Kelley Shannon, *Democrats allege committee violated Open Meetings Act*, MYPLAINVIEW.COM (Mar. 20, 2003), [http://www.myplainview.com/article\\_0a36e968-ff25-5c71-8d10-2b51e4a6202b.html](http://www.myplainview.com/article_0a36e968-ff25-5c71-8d10-2b51e4a6202b.html).

177. H.R. 4, 78th Leg., Reg. Sess. (Tex. 2003) (Introduced).

178. H.R. JOURNAL, 78th Leg., Reg. Sess., at 328 (Tex. 2003), available at <http://www.journals.house.state.tx.us/hjrnl/78r/pdf/day31final.pdf>.

179. H.R. 4, 78th Leg., Reg. Sess. (Tex. 2003), available at <http://www.capitol.state.tx.us/tlodocs/78R/billtext/pdf/HB00004H.pdf#navpanes=0>.

180. *Id.*

181. H.R. JOURNAL, 78th Leg., Reg. Sess., at 328 (Tex. 2003), available at <http://www.journals.house.state.tx.us/hjrnl/78r/pdf/day31final.pdf>.

that the defendant or defendants had notice of the dangers, side effects or complications regarding the pharmaceutical product which were not disclosed fully to the [FDA].”<sup>182</sup> Rep. Hochberg’s amendment was soon substituted and adopted with the following language by bill co-author Rep. Phil King (R-Weatherford), which is substantially how the language exists today: “This section does not apply if the manufacturer, before or after premarket approval or licensing of the product, withheld from or misrepresented to the Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant’s injury.”<sup>183</sup>

The FDA-compliance provision and fraud exception would, however, undergo one more significant revision before being enrolled and sent to the Governor to be signed into law: After being received from the House, the bill was referred to the Senate Committee on State Affairs,<sup>184</sup> which amended the provision to its current form—granting manufacturers a rebuttable presumption of non-liability, rather than complete immunity.<sup>185</sup>

This example of the legislative process serves to illustrate the reality that bills develop over time as the result of compromise and deliberation. I believe it is fair to say that H.B. 4 was a controversial bill; it is not unreasonable to suspect that every compromise made contributed in part to the bill’s passage.<sup>186</sup> Recall that the Sixth Circuit in *Garcia* explicitly pondered whether state legislatures “would have preferred the situation where drug manufacturers would enjoy immunity in the absence of a *federal* finding of bribery or fraud on the FDA, or the situation . . . where drug manufacturers would enjoy no immunity at all.”<sup>187</sup> While there likely are legislators who would prefer the former situation, there are likely others who understood the bill

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182. H.R. JOURNAL, 78th Leg., Reg. Sess., at 938 (Tex. 2003), available at <http://www.journals.house.state.tx.us/hjrn/78r/pdf/day40final.pdf>.

183. *Id.* at 944.

184. S. JOURNAL, 78th Leg., Reg. Sess., at 755 (Tex. 2003), available at <http://www.journals.senate.state.tx.us/sjrn/78r/pdf/sj03-31-f.pdf>.

185. S. 4, 78th Leg., Reg. Sess. (Tex. 2003) (as passed by Senate, May 14, 2003), available at <http://www.capitol.state.tx.us/tlodocs/78R/billtext/pdf/HB00004S.pdf#navpanes=0>; see also H.R. 4, 78th Leg., Reg. Sess. (Tex. 2003) (Enrolled), available at <http://www.capitol.state.tx.us/tlodocs/78R/billtext/pdf/HB00004F.pdf#navpanes=0>.

186. The bill passed the House of Representatives with 110 Yeas; 34 Nays; and 2 Present, not voting. H.R. JOURNAL, 78th Leg., Reg. Sess., at 6041 (Tex. 2003), available at <http://www.journals.house.state.tx.us/hjrn/78r/pdf/day84final.pdf>. The bill passed in the Senate with 27 Yeas and 4 Nays. S. JOURNAL, 78th Leg., Reg. Sess., at 5008 (Tex. 2003), available at <http://www.journals.senate.state.tx.us/sjrn/78r/pdf/sj06-01-f.pdf>.

187. *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 967 (6th Cir. 2004) (emphasis added).

to allow state courts to make the fraud inquiry under the fraud exception and—with that understanding—voted to pass the bill.<sup>188</sup>

Intuitively, a preemption analysis which gives no deference to the state legislative process seems quite contrary to federalism values, especially in this example where (1) the result of preemption, practically speaking, is that an enacted bill is reverted to its post-committee, pre-enactment version; and (2) where the preemptive effect is to force state law itself to unravel the compromises that contributed to its enactment by providing blanket immunity where an exception was separately negotiated and adopted. It is state law that extinguishes the plaintiff's claims, yet in the fraud-exception cases before them, federal courts neither acknowledge nor accord any consideration to these realities.

*Buckman*'s outcome relied heavily on the “inherently federal” character of the relationship between the FDA and regulated entities “because the relationship originates from, is governed by, and terminates according to federal law.”<sup>189</sup> For this proposition, the Court cites to *Boyle v. United Technologies Corp.*, which held that state law could be displaced by federal common law where “uniquely federal” interests were at stake.<sup>190</sup> In *Boyle*, the Court states, “the fact that the area in question is one of unique federal concern changes what would otherwise be a conflict that cannot produce pre-emption into one that can.”<sup>191</sup> *Boyle* clearly seems to be a strong case for displacement of

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188. Assuming for a moment that the pharmaceutical lobby provided the primary impetus for passage of these protections, to simply write off those legislators who would not have voted for the bill but for the inclusion of an exception—as the *Garcia* court seems to do—is to create a default rule favoring the special-interest-backed majority. Though an interest group analysis is beyond the scope of this Note, Professor Roderick Hills argues that “the battle between groups that seek or oppose preemption of state law with federal regulatory standards is largely a struggle between pro-preemption [special interest groups] and anti-preemption [public interest groups].” Roderick M. Hills, Jr., *Against Preemption: How Federalism Can Improve the National Legislative Process*, 82 N.Y.U. L. REV. 1, 34 (2007). He argues for an anti-preemption rule of construction, contending that, as between the public interest and a special interest, the burden should be placed on the special interest group, because this would force them to “bring bills out of committee to a floor vote [that] requires them to resist [the inclination ‘to lie low’], as bills and votes on them are, under normal circumstances, in greater need of public justification than congressional inaction.” *Id.* at 35.

189. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 347 (2001).

190. *Id.*

191. *Boyle v. United Techs. Corp.*, 487 U.S. 500, 507–08 (1988). It is unclear (and beyond the scope of this Note to consider) whether *Boyle* expanded or was anomalous in relation to the traditional “enclave” theory of federal common law. See generally Jay Tidmarsh & Brian J. Murray, *A Theory of Federal Common Law*, 100 Nw. U. L. REV. 585, 585–614 (2006).

state law when the outcome directly affected the rights and obligations of the federal government with respect to its contracts.<sup>192</sup> *Buckman*, too, directly and singularly concerned the distinctly federal relationship between the FDA and its regulated entities, given that fraud-on-the-FDA claims existed only by virtue of federal duties.<sup>193</sup>

Fraud-exception cases, however, implicate more than federal interests, and, I argue, cannot be fairly characterized as “inherently federal” because the relationships at the epicenter of these cases are not the relationship between the FDA and the manufacturer, but rather those between the state and a manufacturer—by virtue of the state’s deliberated decision to provide statutory protections—and between the manufacturer and the harmed consumer. The relationship between the FDA and the manufacturer is invoked only secondarily as a way for plaintiffs to surmount a statutory bar on liability or punitive damages. Said another way, this factor of deference to state legislative processes lends support to the Second Circuit’s conclusion that the presumption against preemption should attach in fraud-exception cases,<sup>194</sup> because this situation, unlike that in *Buckman*, is one implicating “federalism concerns and the historic primacy of state regulation of matters of health and safety.”<sup>195</sup>

### B. Institutional Competence

A second factor worth considering is the institutional competence of the federal agency in policing fraud. This factor is especially important in fraud-exception cases, because circuit courts have expressly opined that fraud-exception provisions are preempted *unless* the FDA itself makes a finding of fraud.<sup>196</sup> Thus, a relevant consideration for the preemption analysis is whether the agency is competent to identify and police fraud. If so, this factor should arguably weigh in favor of preemption, because competent agency oversight should assuage any concern that the health and safety of a state’s citizens are not being protected with respect to approved drugs and devices. If the agency is not providing adequate enforcement, however, then states would appear to have a greater interest in providing complementary enforcement in their own courts.

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192. *Boyle*, 487 U.S. at 507.

193. *Buckman*, 531 U.S. at 352–53.

194. *See supra* Part III.B.

195. *Buckman*, 531 U.S. at 347 (2001) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

196. *See, e.g.*, *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004); *see also Buckman*, 531 U.S. at 354 (Stevens, J., concurring).

Critics of the FDA have been quick to point out the institutional shortcomings of the agency in its regulation of drug safety—that it has failed to strike the proper balance between safety and access.<sup>197</sup> Many have argued that these failings stem from the often-cited problems of limited resources, an enormous workload, and inadequate capacity.<sup>198</sup> Others argue, more controversially, that the agency has fallen prey to “regulatory capture.”<sup>199</sup> Given that these factors weigh against the effective performance of one of the FDA’s primary missions—that is, the review and approval of safe and effective drugs—does this fact shed any light on the FDA’s competency to police fraud on itself? If so, it would seem that the FDA’s institutional competence to police fraud should affect the preemption analysis of whether states retain the

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197. See, e.g., Sheila Weiss Smith, *Sidelining Safety—The FDA’s Inadequate Response to the IOM*, 357 *NEW ENG. J. MED.* 960, 960–63 (2007); Gardiner Harris, *Potentially Incompatible Goals at F.D.A.*, *N.Y. TIMES*, June 11, 2007, <http://www.nytimes.com/2007/06/11/washington/11fda.html>; see also Mary K. Olson, *Pharmaceutical Policy Change and the Safety of New Drugs*, 45 *J.L. & ECON.* 615, 617 (2002) (“Results show that reductions in a drug’s review times are associated with an increase in [adverse drugs reactions] that result in hospitalization and in death.”).

198. E.g., Kessler & Vladeck, *supra* note 12, at 484 (2008) (“An agency can go only so far as its resources can take it, and the FDA, like other federal regulatory agencies, faces serious resource constraints.”); Jordan Paradise et al., *Evaluating Oversight of Human Drugs and Medical Devices: A Case Study of the FDA and Implications for Nanobiotechnology*, 37 *J.L. MED. & ETHICS* 598, 615, 617 (2009) (finding that the FDA’s financial resources devoted to the development of the oversight system were insufficient and that its capacity to appropriately handle decisions was inadequate); David C. Vladeck, *The FDA and Deference Lost: A Self-Inflicted Wound or the Product of A Wounded Agency? A Response to Professor O’Reilly*, 93 *CORNELL L. REV.* 981, 983 (2008) (“The FDA is chronically underfunded, overworked, incapable of effectively tackling the massive job Congress assigned it . . . .”); Elliot Sheppard Tarloff, Note, *Medical Devices and Preemption: A Defense of Parallel Claims Based on Violations of Non-Device Specific FDA Regulations*, 86 *N.Y.U. L. REV.* 1196, 1224 (2011) (“Recent history suggests that the FDA does not have adequate time, capacity, or resources to monitor manufacturers to ensure that their postmarket conduct complies with safety requirements[.]”).

199. “‘Regulatory capture’ refers to the FDA’s loss of perceived independence from the wishes of a regulated constituency to the detriment of the public at large.” James T. O’Reilly, *Losing Deference in the FDA’s Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 93 *CORNELL L. REV.* 939, 963 n.167 (2008) (arguing that policy shifts under the Bush administration indicate that the FDA has been captured by its regulated industries); cf. Matthew Wynia & David Boren, *Better Regulation of Industry-Sponsored Clinical Trials Is Long Overdue*, 37 *J.L. MED. & ETHICS* 410, 416 (2009) (“[T]here is very strong evidence that industry-funded trials tend to produce industry-friendly results.”). *But see* Mary K. Olson, *Firm Characteristics and the Speed of FDA Approval*, 6 *J. ECON. & MGMT. STRATEGY* 377, 379 (1997) (“FDA reviewers respond systematically to the differences among firms . . . [which] suggests regulatory theories of agency behavior such as the capture theory are too general to explain FDA reviewer behavior.”).

right to provide complementary enforcement—particularly in the fraud-exception context.

The detection of fraud on the agency during the approval process presents a particularly tricky issue because, as one scholar has noted, “incidents of fraud on the FDA are, on any view, few and far between.”<sup>200</sup> The danger, then, is that fraud on the FDA will be unidentified or categorically under-enforced in the instances when it does occur. While the FDA undoubtedly makes strong efforts to reduce the likelihood of fraud during the approval process, resource limitations often force the FDA to rely on the manufacturers themselves to minimize the likelihood of fraud.<sup>201</sup> And even when FDA inspection reveals fraudulent activity occurring, FDA managers may be prevented from revealing that the data was compromised.<sup>202</sup>

Beyond the detection of fraud during the approval process, the FDA’s ability to enforce fraud at post-approval stages is open to question. One U.S. Government Accountability Office (GAO) report paints a bleak picture for fraud detection and enforcement activities:

FDA’s access to postmarket clinical trial and observational data, however, is limited by its authority and available resources . . . . In the absence of specific authority, FDA often relies on drug sponsors voluntarily agreeing to conduct such postmarket studies . . . . [O]ne study estimated that the completion rate of postmarket studies, including those that sponsors have voluntarily agreed to conduct, rose from 17 percent in the mid-1980s to 24 percent between 1991 and 2003. FDA has little leverage to ensure that these studies are carried out, for example, by imposing administrative penalties.<sup>203</sup>

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200. Epstein, *supra* note 153, at 13; accord Russell Katz, *FDA: Evidentiary Standards for Drug Development and Approval*, 1 J. AM. SOC’Y FOR EXPERIMENTAL NEUROTHERAPEUTICS 307, 310 (2004) (“Although fraud in the conduct and reporting of clinical trials is rare, it does occur.”).

201. *E.g.*, Katz, *supra* note 200, at 310 (“[R]esource limitations preclude detailed inspections of most of the clinical data generated, and the Agency relies on frequent monitoring of study sites by manufacturers and local institutional practices to minimize the possibility of fraud and to detect it in those rare instances in which it occurs.”).

202. *See, e.g.*, David B. Ross, *The FDA and the Case of Ketek*, 356 NEW ENG. J. MED. 1601, 1601–02 (2007) (describing a case in which an FDA inspection revealed fraud during the drug trials, including “complete fabrication of patient enrollment”; however, after notifying FDA criminal investigators, the FDA managers were prohibited from conveying their findings to the drug advisory committee on account of the open criminal investigation).

203. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-06-402, DRUG SAFETY: IMPROVEMENT NEEDED IN FDA’S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS 27–28 (2006) [hereinafter DRUG SAFETY].

GAO's concerns about the FDA's "authority to require drug sponsors to conduct post-market studies to collect additional data of drug safety concerns"<sup>204</sup> seems to have been somewhat ameliorated when Congress expanded the FDA's authority under the Food and Drug Administration Amendments Act of 2007.<sup>205</sup> For example, from 2007 to 2009, the FDA implemented a tracking system designed to track post-market drug safety issues as well as agency responses to those issues, and to further develop official policies and procedures for the tracking system,<sup>206</sup> which GAO had suggested in its 2006 report.<sup>207</sup>

The declining number of enforcement actions taken by the FDA also once reflected a cause for concern. One U.S. House of Representatives report indicated that from 2000 to 2005, the number of FDA enforcement actions declined by over 50 percent, while the number of violations<sup>208</sup> observed remained roughly the same.<sup>209</sup>

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204. *Id.* at 36.

205. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (codified in scattered sections of 21 U.S.C. and 42 U.S.C. § 247d-5a).

206. U.S. FOOD & DRUG ADMIN., MAPP 4121.2, TRACKING OF SIGNIFICANT SAFETY ISSUES IN MARKETED DRUGS — USE OF THE DARRTS TRACKED SAFETY ISSUES (2009), available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/UCM164967.pdf>.

207. DRUG SAFETY, *supra* note 203, at 29–31.

208. "During an inspection, ORA investigators may observe conditions they deem to be objectionable. These observations, are listed on an FDA Form 483 when, in an investigator's judgment, the observed conditions or practices indicate that an FDA-regulated product may be in violation of FDA's requirements." *Inspections, Compliance, Enforcement, and Criminal Investigations: Inspection Observations*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ICECI/EnforcementActions/ucm250720.htm> (last updated Jan. 15, 2014).

209. MINORITY STAFF OF H.R. COMM. ON GOV'T REFORM, 109TH CONG., PRESCRIPTION FOR HARM: THE DECLINE IN FDA ENFORCEMENT ACTIVITY 7–9 (2006) [hereinafter PRESCRIPTION FOR HARM] (noting a 54% total decline in warning letters issued and a 44% decline in the number of seizures of unsafe products by the FDA despite an unchanging number of observed violations).

TABLE 1: FDA ENFORCEMENT ACTIONS (2000–2005)<sup>210</sup>

<i>Year</i>	<i>Incidence of 483s issued from FDA Inspection Observations (Violations)</i>	<i>Incidence of FDA Warning Letters Issued</i>
2000	<b>6334</b>	<b>1154</b>
2001	<b>7683</b>	<b>1032</b>
2002	<b>180</b>	<b>755</b>
2003	<b>7813</b>	<b>545</b>
2004	<b>7137</b>	<b>725</b>
2005	<b>6268</b>	<b>535</b>

After publication of the House report, from 2006 to 2007 the number of observed violations dropped off slightly (from 4849 to 4161), but then steadily began increasing from 2007 to 2011 by about 36 percent (4161 to 6547).<sup>211</sup> Meanwhile, from 2006 to 2010, the number of warning letters issued by the FDA remained roughly the same,<sup>212</sup> indicating, perhaps, a variation of the same under-enforcement problem from 2000 to 2005. In 2011, the number of warning letters issued nearly tripled from 673 issued in 2010 to 1720 issued in 2011;<sup>213</sup> however, 1040 of those warning letters were issued by the FDA's newly-formed Center for Tobacco Products (CTP) for tobacco products, after Congress gave the FDA authority over tobacco products in 2009.<sup>214</sup> The CTP issued 4146 letters in 2012 and 6052 letters in 2013.<sup>215</sup>

210. U.S. FOOD & DRUG ADMIN., FY 2013 – ENFORCEMENT STATISTICS 7 (2013) [hereinafter FDA ENFORCEMENT STATISTICS 2013], available at <http://www.fda.gov/downloads/ICECI/EnforcementActions/UCM384647.pdf>. The figures in this table reflect the data described in the report of the Committee on Government Reform, *supra* n. 209.

211. See *infra* Table 2.

212. FDA ENFORCEMENT STATISTICS 2013, *supra* note 210, at 7.

213. *Id.*

214. Letter from Jeanne Ireland, Assistant Comm'r for Legislation, U.S. Food & Drug Admin., to Rep. Elijah E. Cummings, Ranking Member of the Comm. on Oversight & Gov't Reform, U.S. House of Representatives (July 23, 2012), available at <http://democrats.energycommerce.house.gov/sites/default/files/documents/Waxman-FDA-Concerns-Regarding-Makower-Study-of-Medical-Device-Regulation-2011-7-18.pdf>.

215. FDA ENFORCEMENT STATISTICS 2013, *supra* note 210, at 6; U.S. FOOD & DRUG ADMIN., FY 2012 – ENFORCEMENT STATISTICS 6 (2012), available at <http://www.fda.gov/downloads/ICECI/EnforcementActions/UCM346964.pdf>.

TABLE 2: FDA ENFORCEMENT ACTIONS (2006–2013)<sup>216</sup>

<i>Year</i>	<i>Incidence of 483s issued from FDA Inspection Observations (Violations)</i>	<i>Incidence of FDA Warning Letters Issued</i>	<i>Letters Issued by CTP</i>	<i>Warning Letters less Letters Issued by CTP</i>
2006	<b>4849</b>	<b>538</b>		
2007	<b>4161</b>	<b>471</b>		
2008	<b>3979</b>	<b>445</b>		
2009	<b>4367</b>	<b>474</b>		
2010	<b>5710</b>	<b>673</b>		
2011	<b>6547</b>	1720	1040	<b>680</b>
2012	<b>5797</b>	4882	4146	<b>736</b>
2013	<b>5050</b>	6760	6052	<b>708</b>

As compared to the data gathered from 2000 to 2005, the numbers indicate an upward trend in FDA enforcement. This ratio of inspectional observations to warning letters issued is just one simple metric in determining institutional competence. Admittedly, judgments on resource limitations, workload capacity, and “capture” may be more difficult to ascertain; however, future oversight by governmental agencies such as GAO can provide additional insights into institutional capacity.

#### CONCLUSION

The doctrine of preemption, as it exists today, is complex and unsettled. It may seem simple enough, in theory, to lay out the framework of the analysis: First, identifying the type of preemption at issue (express, obstacle, field, etc.) and, second, determining what factors the Court considers (congressional intent, the presumption against preemption, and so on). Yet, as discussed in Part I and demonstrated in Part IV of this Note, the analysis of a preemption issue in practice is not quite so straightforward. Moreover, the Supreme Court has been inconsistent in its analysis of preemption questions, for examples, sporadically applying the presumption against preemption in some cases

216. The figures in this table reflect the methodology as described in the report of the Committee on Government Reform. *PRESCRIPTION FOR HARM*, *supra* note 209, at 8, 10 (using the declining number of warning letters issued by FDA Centers from 2000 to 2005 as a metric for declining enforcement actions and comparing those numbers against the number of violations observed by FDA inspectors).

and, with little guidance, leaving open the possibility of deference to agency preambles.

The Court's decision in *Buckman v. Plaintiffs' Legal Committee* has only further confused the lower courts: *Buckman* added consideration of administrative burdens on the federal agency to the analytical mix without providing clear guidance on when their consideration is appropriate and how much weight they should be afforded. The disagreement among the federal courts of appeals in state law fraud-exception cases demonstrates the interpretive problem. As I described in Part V, one solution may be to open the preemption analysis to additional factors for consideration, including deference to states' legislative processes and institutional competence. These factors are important because they directly implicate the states' interests in ensuring that statutory immunity provisions are not being abused and that the health and safety of their citizens are adequately protected.

Though this Note has dealt primarily with the preemption analysis in the context of state fraud-on-the-agency exceptions, it is worth considering whether courts should examine other relevant factors when determining the scope of preemption. Clearly, the intent of Congress is the most important consideration in this analysis, but in close cases—especially those concerning implied preemption—other factors may be worthy of deference where significant local and state interests would be jeopardized by an adverse preemption decision.