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Should Preemption Apply in a Pharmaceutical Context? An Analysis of the Preemption Debate and What Regulatory Compliance Statutes Contribute to the Discussion

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Should Preemption Apply in a Pharmaceutical Context? An Analysis of the Preemption Debate and What Regulatory Compliance Statutes Contribute to the Discussion

Cover Page Footnote

J.D. Candidate, 2009, Fordham University School of Law; B.A., 2006, Fordham University at rose Hill. Thank you to everyone who offered me support in this process—particularly my family and friends.
Should the Food and Drug Administration (FDA)'s determination that a product is safe negate a private litigant's cause of action under state law in all circumstances, unless the FDA determines that the manufacturer withheld relevant information regarding the safety of the product? This Note concludes that such federal preemption is proper because the FDA is fully capable of making a determination regarding the adequacy of the information disclosed by a pharmaceutical manufacturer without state interference. Additionally, such interference on the state level hinders the FDA's objectives and effective functioning. Thus, determinations about the adequacy of the information provided to the FDA should remain in the Agency's sound discretion and not be questioned at the state level.

Introduction

In the past decade, there has been a radical shift in pharmaceutical tort law from a theory of regulatory compliance to one of federal preemption. Food and Drug Administration (FDA) approved pharmaceuticals provide perhaps one of the most convincing cases for the application of the regulatory compliance defense, and now, federal preemption argument. This shift, aided by several recent U.S. Supreme Court decisions including Warner-Lambert Co. v. Kent, seems only to be gaining ground as several states in recent years have adopted regulatory compliance statutes, which in some instances serve to effectively shield certain types of product manufacturers from liability. Notably, while purporting to provide blanket

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2. Id. at 1026.
immunity for manufacturers that comply with regulatory standards, some of these statutes try to preserve a state cause of action for claimants through an exception. This exception revokes the grant of immunity if the manufacturer defrauded or misrepresented information to the FDA in securing approval for its drug.4

Whether or not such an exception remains viable in light of recent jurisprudence is a matter of significant interpretative controversy.5 This debate has become particularly relevant lately with the 4-4 split of the Supreme Court on this very issue in Kent.6 This Note addresses whether FDA approval of pharmaceuticals shields their makers from tort liability under state law under a theory of federal preemption and focuses on the controversy surrounding state-adopted regulatory compliance statutes containing an exception for fraud on the FDA.

This Note proceeds in three parts. Part I analyzes the origins of the trend toward federal preemption and how recent court decisions and state-enacted regulatory compliance statutes have contributed to this debate. Part II offers an in-depth look at the varying approaches from courts and commentators to interpreting whether or not preemption should apply. Finally, Part III examines regulatory compliance statutes and will argue that state tort liability should be preempted by compliance with FDA regulation of pharmaceuticals.

I. FEDERAL PREEMPTION IN PRODUCTS LIABILITY ACTIONS

Part I.A of this Note discusses the theory of federal preemption generally and the documents that the FDA claims grant it preemptive authority. Part I.B highlights approximately twenty years of recent Supreme Court jurisprudence that addresses the scope of federal preemption. Finally, Part I.C examines the states that have adopted regulatory compliance statutes and narrows the focus of this Note to three of those states.

A. Preemptive Authority of the FDA

This section proceeds in three parts: Part I.A.1 provides general definitional guidance about the theory of federal preemption. Part I.A.2 discusses the Medical Device Amendments (MDA)—a series of amendments granting express preemptive authority to the FDA in the context of medical devices. Part I.A.3 discusses the preamble to a 1996 FDA regulation (FDA Preamble)—a document that the FDA argues grants it implied preemptive authority in the pharmaceutical context.

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5. See infra Part II.B.
1. Theory of Federal Preemption

Federal preemption has risen recently from nothing more than a "blip on the radar screen to one of the most powerful defenses in all of products liability law." As a result, it has been characterized by some as the most important doctrine of products liability law today.

As a general matter, preemption is an affirmative defense, waivable by the defendant, which arises when federal regulations conflict with state law claims. There are two types of federal preemption: (1) express preemption, which arises when a federal statute contains language that expressly preempts state regulation or legislation, and (2) implied preemption, which arises as either field preemption or conflict preemption.

Implied field preemption arises when either a pervasive regulatory scheme is already in place at the federal level or when there is such a dominant federal interest that it is assumed that enforcement of state laws on the same issue are precluded. Conversely, implied conflict preemption arises either when there is a direct conflict between federal and state provisions, thus making compliance with both impossible, or when a state obscures "the accomplishment and execution of the full purposes and objectives of Congress."

Historically, the Supreme Court has advocated for a presumption against a finding of preemption, concluding that there is an "assumption that the historic police powers of the States were not to be superceded by [a] Federal Act unless that was the clear and manifest purpose of Congress." This presumption, in essence, rests upon the notion that "the Constitution constrains the federal government, the powers of which are limited and specifically enumerated," from "cavalierly pre-empt[ing] state-law causes of action." In the past it was common for the Supreme Court to interpret product safety statutes using such a mindset. However, as observed by

8. Id.
12. Hines v. Davidowitz, 312 U.S. 52, 67 (1941); see also Owen, supra note 9, at 416.
13. Rice, 331 U.S. at 230 (discussing federal preemption of state action); see also Owen, supra note 9, at 417.
14. Owen, supra note 9, at 417.
15. Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996); see also Owen, supra note 9, at 417; Tortline & Teeter, supra note 10, at 34.
many commentators, in more recent years, the Supreme Court has started moving away from such a presumption—if not abandoning it entirely.\textsuperscript{17}

Two documents, the MDA and the FDA Preamble, provide the primary framework for the preemption debate in the pharmaceutical context. Indeed, both sides of the argument for and against preemption look to these documents for support. They are discussed below.

2. The MDA

While the primary focus of this Note is implied preemption, one cannot ignore the important impact that the MDA—an example of express preemption—has had.\textsuperscript{18} In 1976, Congress passed the MDA as a series of amendments to the Food, Drug, and Cosmetic Act (FDCA),\textsuperscript{19} thereby giving the FDA the authority to classify and monitor the safety and effectiveness of medical devices. The MDA requires screening of all medical devices seeking approval through a pre-market approval process (PMA), which on average requires 1200 hours to conduct.\textsuperscript{20} In the realm of federal preemption, pharmaceutical products pose an interesting question because, while the MDA clearly applies express preemption for medical devices, there is no such express preemption clause for prescription drugs.\textsuperscript{21} The lack of an express preemption provision for pharmaceutical products has not escaped the notice of both courts and commentators.\textsuperscript{22}

3. The FDA Preamble

In 2006, the FDA adopted a preamble to its 1996 prescription drug labeling rule, which asserted that, “FDA approval of labeling under the act

\textsuperscript{17} See Owen, supra note 9, at 417; Tortline & Teeter, supra note 10, at 34. For a thorough analysis of the Court’s move away from such a presumption, see infra Part I.B.

\textsuperscript{18} While a thorough discussion of the Medical Device Amendments (MDA) is beyond the scope of this Note, their importance has not escaped the notice of many commentators who have written amply on the subject. See generally Brad Kenneth Lindow, Medical Device Amendments Act Does Not Preempt All State Law Claims, 10 LOY. CONSUMER L. REV. 32 (1998); Gregory J. Scandaglia & Therese L. Tully, Express Preemption and Premarket Approval Under the Medical Device Amendments, 59 FOOD & DRUG L.J. 245 (2004); Michael P. DiNatale, Comment, Patients Beware: Preemption of Common Law Claims Under the Medical Device Amendments, 39 J. MARSHALL L. REV. 75 (2005).


\textsuperscript{20} 21 U.S.C. § 360. The MDA classifies medical devices into three different classes of devices each reflecting a different degree of risk to human health, with Class III devices presenting the greatest risk and Class I devices representing the lowest. Id. § 360c(a). Because of the heightened risk they pose, the Food and Drug Administration (FDA) requires Class III devices to undergo a rigorous screening process for safety and effectiveness before they are placed on the market. Medtronic, 518 U.S. at 477; see also Owen, supra note 9, at 430.

\textsuperscript{21} See W. Wylie Blair, Implied Preemption of State Tort Law Clams Against Prescription Drug Manufacturers Based Upon FDA Approval, 27 J. LEGAL MED. 289, 293 (2006).

\textsuperscript{22} See Caraker v. Sandoz Pharm. Corp., 172 F. Supp. 2d 1018, 1035 (S.D. Ill. 2001); O’Steen & O’Steen, supra note 9, at 82.
preempts conflicting or contrary State law." The FDA was adamant that state law decisions that reject the preemptive authority of FDA labeling "rely on and propagate interpretations of the Act and FDA regulations that conflict with the agency's own interpretations and frustrate the agency's implementation of its statutory mandate." Incidentally, the FDA has emphasized that its requirements set both a ceiling and a floor for manufacturer compliance. This notably is in opposition to the FDA's previous position, which as of 1997 established only minimum standards, to which states were free to add additional protections.

The FDA now proclaims that tort law claims for injuries interfere with its ability to properly regulate the market. This position stems from the fact that "safety," when discussing pharmaceutical products, is essentially different than safety in the context of other products since virtually all drugs have side effects that would lead them to be deemed "unsafe" if considered in any other context. As noted by Mary J. Davis, this recent position of the FDA "favoring preemption—that its labeling regulations establish optimal standards in some cases from which state law may not deviate—places federal preemption of prescription drug labeling actions directly" at the forefront of the preemption debate. Notably, this shifting stance of the FDA has aided in the recent changing landscape from regulatory compliance to federal preemption in the pharmaceutical arena.

B. The Shifting Stance of the Supreme Court

Over the past decade and a half, there has been a dramatic shift in the courts from an attitude of regulatory compliance to one of federal

23. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 21 C.F.R. § 201.56 (2007); see also Catherine M. Sharkey, Preemption by Preamble: Federal Agencies and the Federalization of Tort Law, 56 DEPAUL L. REV. 227, 227 (2007). This formal declaration was given by the FDA after the courts evinced "reluctance...to accept amicus briefs as a formal statement of the agency's intent." Howard L. Dorfman et al., Presumption of Innocence: FDA's Authority to Regulate the Specifics of Prescription Drug Labeling and the Preemption Debate, 61 FOOD & DRUG L.J. 585, 593 (2006).


26. See O'Steen & O'Steen, supra note 9, at 77. But see Dorfman et al., supra note 23, at 590. Howard L. Dorfman and his colleagues argue that since 1991, the FDA has asserted that its regulations set both a ceiling and a floor. In support of this proposition, they cite a statement by the former FDA chief counsel where he declares that the "FDA surely does not regard its own prescription drug labeling decisions as merely establishing a floor... On the contrary, FDA regards such labeling as fully adequate for the purpose of informing physicians of all necessary information." Id. at 590 n.49.

27. See O'Steen & O'Steen, supra note 9, at 77.


30. See O'Steen & O'Steen, supra note 9, at 77.
preemption. This shift began in the early 1990s, however as the case law (including the recent indecision in Kent) suggests, the Court has been grappling with the difficult task of trying to find the proper balance between federal regulatory compliance and the powers of the states. The following cases illustrate this shift.

1. Cipollone v. Liggett Group

Until the early 1990s, the Supreme Court, when deciding common-law tort claims, was noticeably hesitant to find preemption. Indeed, the Court was formerly so reluctant that it advocated a presumption against preemption, relying on the "assumption that the historic police powers of the States were not to be superseded by a Federal Act unless that was the clear and manifest purpose of Congress." The Court in Cipollone v. Liggett Group, thoroughly outlined the analysis for a finding of preemption:

Congress' intent may be "explicitly stated in the statute's language or implicitly contained in its structure and purpose." In the absence of an express congressional command, state law is pre-empted if that law actually conflicts with federal law, or if federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the states to supplement it.

Thus, the Court in Cipollone went on to find in favor of federal preemption, allowing it to become the landmark case "trigger[ing] a notable upsurge in the successful use of preemption as a defense to products liability lawsuits."

In Cipollone, the estate of a life-long smoker, who died of lung cancer, brought an action against three cigarette manufacturers alleging that they failed to warn about the dangers of smoking. The Court held that the Public Health and Cigarette Smoking Act of 1969 expressly preempted state failure-to-warn claims.

31. See Sharkey, supra note 1, at 1020–22.
32. See Lars Noah, Reconceptualizing Federal Preemption of Tort Claims at the Government Standards Defense, 37 WM. & MARY L. REV. 903, 906 (1996) ("In the decade before Cipollone, the Court expressed a marked reluctance to find preemption of common-law tort claims, but its [recent] decisions . . . suggest a significant reversal in this attitude.").
33. Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947); see also Tortline & Teeter, supra note 10, at 34 (explaining the Court's movement away from traditional notions of a presumption against preemption).
34. 505 U.S. 504 (1992). Though Cipollone v. Liggett Group deals with cigarettes and not pharmaceutical products or even medical devices, its inclusion here is meant to illustrate the beginnings of the Court's trend toward preemption in products liability actions more generally.
35. Id. at 516 (quoting Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977)).
36. See Noah, supra note 32, at 904.
37. Cipollone, 505 U.S. at 504.
38. Id. at 530–31.
2. Medtronic, Inc. v. Lohr

Not long after Cipollone, the Court issued a conflicting determination on preemption in the medical context in its Medtronic, Inc. v. Lohr\(^ {39}\) decision. In Lohr, a Medtronic pacemaker, which had been implanted within the plaintiff, failed, requiring her to undergo emergency surgery to remove a heart blockage.\(^ {40}\) The plaintiff initiated the suit against Medtronic alleging negligence and strict liability.\(^ {41}\) In response, Medtronic argued for summary judgment, declaring that both of the claims were preempted by § 360k(a).\(^ {42}\) Unable to reach a majority, the Court issued a plurality opinion authored by Justice John Paul Stevens,\(^ {43}\) which began by noting that “we have long presumed that Congress does not cavalierly pre-empt state law causes of action.”\(^ {44}\) Justice Stevens disagreed with Medtronic’s interpretation of § 360k, finding the notion that Congress “would... bar[] most, if not all, relief for persons injured by defective medical devices” to be implausible.\(^ {45}\) Such a reading, coupled with the lack of an overt legislative attempt to “pre-empt most, let alone all, general common-law duties enforced by damages actions,”\(^ {46}\) led to the Court’s conclusion that the design defect claims asserted by the claimant against Medtronic were not barred by the preemption clause in the MDA.\(^ {47}\) The conflicting results reached by Cipollone and Lohr, if anything, evidence a general skepticism on the part of the Court, which was not quite ready to part with its traditional presumption against preemption.\(^ {48}\)

40. Id. at 480–81.
41. Id. at 481.
42. Id.
43. Justice Stephen Breyer, concurring, noted (along with the dissent) that “the MDA will sometimes pre-empt a state-law tort suit,” but concluded that the provisions did not preempt any of the state requirements that were at issue. Id. at 503, 505 (Breyer, J., concurring in part and concurring in the judgment). Chief Justice William Rehnquist and Justices Antonin Scalia, Clarence Thomas, and Sandra Day O’Connor, in a concurrence/dissent written by Justice O’Connor, distinguish their opinion from the plurality by concluding that “a state common-law claim is pre-empted if it would impose any requirement which is different from, or in addition to, any requirement applicable to the device under the FDCA.” Id. at 514 (O’Connor, J., concurring in part, dissenting in part) (internal quotation marks omitted).
44. Id. at 485.
45. Id. at 487 (“Medtronic’s construction of § 360k would therefore have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation . . . .”).
46. Id. at 491 (“There is, to the best of our knowledge, nothing in the hearings, the Committee Reports, or the debates suggesting that any proponent of the legislation intended a sweeping pre-emption of traditional common-law remedies against manufacturers and distributors of defective devices.”).
47. Id. at 494.
48. See Tortline & Teeter, supra note 10, at 34.
3. Buckman Co. v. Plaintiffs' Legal Committee

In 2001, again faced with a medical device issue, the Court in *Buckman Co. v. Plaintiffs' Legal Committee* affirmatively stated that "no presumption against pre-emption" applies. In *Buckman*, the Court analyzed a factual situation where a defendant medical-products manufacturer hired a consultant, Buckman Co., to help obtain FDA approval for its product. This collaboration resulted in approval for its product through rather egregious acts of defrauding the Agency. Subsequently, plaintiffs, who were injured by the defendant's product, sought to bring a state tort cause of action against the defendant for their injuries. Plaintiffs alleged that the defendant made fraudulent representations to the FDA in the course of the device approval process and that, but for these misrepresentations, the device would not have been approved.

In response, the Supreme Court unanimously held that federal law impliedly preempted such state law fraud-on-the-FDA claims. To that effect, the Court stated that “[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA’s responsibility to police fraud consistently with the Administration’s judgment and objectives,” and would “cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court.” Moreover, the Court noted that the FDA is aptly empowered to pursue and prosecute fraud perpetrated against it and that “[p]olicing fraud against [a] federal agency was hardly ‘a field which the States have traditionally occupied.’” However, the Court’s *Buckman* decision has sparked more questions than it has answered, resulting in a situation where “[s]tates may not be concerned about protecting federal agencies, but states have a strong interest in protecting their citizens from fraud and personal injuries.”


The Supreme Court on March 3, 2008, issued its most recent decision impacting the pharmaceutical preemption debate in *Kent*. In *Kent*, the Court considered the recent decision of the U.S. Court of Appeals for the

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50. Id. at 346.
51. Id. Buckman Co. was retained by AcroMed to help secure approval for its spinal bone screw product. After two denials of FDA approval, the applicant split the spinal screw into its component parts and resought approval. However, this time, rather than seeking clearance for spinal use, the applicant sought approval to market the plates and screws for use in arm and leg bones. It was on this ground that AcroMed secured approval for its product. Following this approval, spinal surgeons began to use the product widely. Id.
52. Id. at 343.
53. Id.
54. Id. at 341–42.
55. Id. at 350–51.
56. Id. at 347 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).
Second Circuit in *Desiano v. Warner-Lambert & Co.*, which asked if a federal law prohibiting fraudulent disclosures and communications to a government agency preempted a state law granting plaintiffs a cause of action to sue for injuries sustained from defective products that would have reached the market absent such fraud. The Court deadlocked on the question in a 4-4 split (with Chief Justice John Roberts recusing himself from decision). Thus, while the case at the outset appeared to have the potential to shed significant light on the preemption debate and the role of state statutes against that of federal agencies, in actuality, it did no such thing. Without even issuing a written opinion, the Court in *Kent* presented more questions than answers.

C. Regulatory Compliance Statutes in the Pharmaceutical Context

Several states, through the adoption of regulatory compliance statutes, have added to the discussion of what the proper approach should be to determining whether or not preemption should apply in the pharmaceutical context. The vast majority of states are opposed to the regulatory compliance defense, with most concluding that compliance with Agency regulations is only one of many factors to be taken into account in tort actions. However, in recent years several states have adopted such statutes, which aim to shield a drug manufacturer from liability for its FDA approved drugs. Indeed, the adoption of these statutes seems to coincide with tort reform efforts throughout the country.

1. Granting (and Taking Away?) Immunity Through Exception

Some of the statutes, though purporting to provide complete immunity, declare that if the manufacturer defrauded or deceived the FDA to secure its drug approval, then the grant of immunity does not apply. The phrasing of these statutes differs slightly, but importantly. Of the enacted regulatory compliance statutes, seven states bar punitive damages against drug manufacturers of FDA-approved drugs. Eight states provide a “weaker

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58. 467 F.3d 85 (2d Cir. 2006).
59. *See infra* Part II.B.
61. *Id.*
62. *See Sharkey, supra* note 1, at 1024.
63. *See id.* at 1023.
66. *Id.* at 8 (“Arizona, New Jersey, North Dakota, Ohio, Oregon, and Utah—bar punitive damages against drug manufacturers who have complied with FDA guidelines.”); *see* ARIZ. REV. STAT. ANN. § 12-701 (2003); N.J. STAT. ANN. § 2A:58C-5 (West 2000); N.D. CENT. CODE § 32-03.2-11(6), (7)(a) (1996 & Supp. 2007); OHIO REV. CODE ANN. § 2307.80(C) (West 2003); OR. REV. STAT. ANN. § 30.927 (West 2003); UTAH CODE ANN. § 78-18-2 (2002).
form of protection in the form of a rebuttable presumption that FDA-approved warnings are adequate in the face of failure-to-warn claims."67

2. Regulatory Compliance Defense Across the Country

Though only a handful of states have effective regulatory compliance statutes, the power of the argument has not escaped the notice of defendants everywhere, thus ushering it into courts across the country to varying degrees of success.68 Indeed, courts countrywide are split on the issue, with some siding with the U.S. Court of Appeals for the Sixth Circuit’s interpretative reading of preemption arguments in light of Buckman69 and others aligning themselves with the Second Circuit’s opinion.70

Notably, as explained by Catherine Sharkey, “[s]ubsumed within the preemption question is a corresponding evidentiary one, namely whether evidence of the inadequacy of the defendant’s representations to the FDA is admissible in support of common-law claims”—a question faced by all the courts grappling with these issues, regulatory compliance statute or not.71 Indeed, some courts have become so restrictive that they have refused to allow any and all private actions premised on fraud on the FDA.72

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68. See Brief of Petitioner-Appellant, supra note 64, at 8–9; Sharkey, supra note 65 (manuscript at 14).

69. See Webster v. Pacesetter, Inc., 259 F. Supp. 2d 27, 36 (D.D.C. 2003) (holding that the “plaintiffs are precluded from arguing that defendant[]... fail[ed] to adhere to the FDA regulations... since such claims are preempted by the... Supreme Court’s holding in Buckman” (citation and internal quotation marks omitted)); Healthpoint, Ltd. v. Ethex Corp., 273 F. Supp. 2d 817, 841 (W.D. Tex. 2001) (concluding that “the ‘direct interpretation and application of’ regulations was a job better left to the FDA” (quoting Braintree Labs., Inc. v. Nephro-Tech, Inc., No. 96-2459-JWL, 1997 WL 94237, at *6 (D. Kan. Feb. 26, 1997)); Baker v. St. Jude Med., S.C., Inc., 178 S.W.3d 127, 138 (Tex. App. 2005) (noting the Buckman concerns of having the states interfere in the functioning of a federal agency, as well as the notion that the FDA was well equipped to police and deter fraud against itself without state interference).

70. See In re St. Jude Med., Inc. Silzone Heart Valves Prods. Liab. Litig., No. MDL 01-1396, 2004 WL 45503, at *5 (D. Minn. Jan. 5, 2004) (noting that “[p]reemption is disfavored in areas of historic importance to the states’ police powers—areas such as public health and safety,” and finding no implication of the Buckman concerns); Bryant v. Hoffman-La Roche, Inc., 585 S.E.2d 723, 725 (Ga. Ct. App. 2003) (holding that federal law did not preempt the claim because plaintiff was not asserting a fraud claim or a violation of federal law, but rather was asserting that defendant violated duties arising under state statutory and common law).

71. Sharkey, supra note 65 (manuscript at 14).

72. Id. (“[A]n Ohio federal district court... claimed that evidence would be excluded outright not only ‘when it is offered only to show that the FDA was misled, or that information was intentionally concealed from the FDA,’ but also when ‘[e]xclusion of further evidence may be necessary to prevent confusion of the jury as to the nature of
Professor Sharkey goes on to note, however, that "[i]t is more typical . . . for courts to take an approach that forecloses causes of action that require proof of fraud rather than prohibiting the use of fraud evidence full stop."73

D. The Three Statutes at Issue: Michigan, Texas, and New Jersey

Termed by some a "[s]tate-[s]ponsored [p]reemption," statutes that forbid lawsuits against manufacturers that complied with FDA regulations and did not defraud or deceive the Agency are a recent addition to the changing face of products liability tort actions.74 However, a determination of how to interpret these statutes—particularly those that allow for imposition of liability if such deception can be shown—is far from conclusive. While there are several states with provisions providing exceptions to immunity for deceiving the FDA, this Note focuses on three states—Michigan, Texas, and New Jersey—to help further explore the current debate on the proper role of preemption in the pharmaceutical liability context. Notably, each statute attempts to preserve liability for manufacturers deceiving the FDA in a slightly different manner.

1. The Michigan Statute and Interpretative Case Law

Michigan's statute is unique among these statutes in that it provides complete blanket immunity, but then through an exception, declares that such immunity does not apply if the manufacturer "[i]ntentionally withholds . . . or misrepresents" information to the FDA.75 Through this explicit language of fraud (which is compounded by the requirement of a showing of reliance on the misinformation by the FDA), the Michigan statute references a stand-alone crime, and is also the most contentious of the three statutes herein examined.76 The text of the statute reads 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 United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller . . . . This subsection does not apply if the defendant . . .


73. Id.
74. O'Steen & O'Steen, supra note 9, at 89.
75. MICH. COMP. LAWS ANN. § 600.2946(5) (West 2000).
76. Id. Also, though not a subject of this Note, the regulatory compliance statute of North Dakota is unique and interesting in that it also refers to a stand-alone crime. That statute explicitly refers (not to fraud) but to bribery of an agency official. N.D. CENT. CODE § 32-03.2-11(7)(b) (1996 & Supp. 2007).
(a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act . . . and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.\textsuperscript{77}

The discontent surrounding this statute emanates from a circuit split between the Sixth and Second Circuits regarding what its proper interpretation should be. Indeed, on September 25, 2007, the Supreme Court granted certiorari to help sort out some of the contention surrounding this statute.\textsuperscript{78} However, on March 3, 2008, the Supreme Court deadlocked in a 4-4 split, thus keeping the controversy alive.\textsuperscript{79}

In Garcia v. Wyeth-Ayerst Laboratories,\textsuperscript{80} an anomalous case of the preemption debate, the Sixth Circuit examined the statute.\textsuperscript{81} The court disagreed with the plaintiff’s proposed conclusion that “drug manufacturers [sh]ould enjoy no immunity at all” and instead decided to only partially invalidate the statutory fraud exception.\textsuperscript{82} In doing so, the court concluded that for the state to be allowed to prosecute instances of fraud, the FDA must make a prior determination that such fraud has occurred; otherwise the central tenets of Buckman would be violated.\textsuperscript{83}

In 2007, when the Second Circuit was given its turn to interpret the Michigan statute, it expressly refused to follow Garcia in declaring that the fraud exceptions in state immunity statutes escape preemption.\textsuperscript{84} Interpreting the Buckman decision, the Second Circuit concluded that the Supreme Court’s statements were predominantly concerned with making sure that the policing of fraud on the FDA did not interfere with how the FDA chose to police itself.\textsuperscript{85} The Second Circuit emphasized that, since Michigan’s section 600.2946(5) could not “reasonably be characterized as a

\textsuperscript{77} MICH. COMP. LAWS ANN. § 600.2946(5) (citations omitted).
\textsuperscript{80} 385 F.3d 961 (6th Cir. 2004). Garcia v. Wyeth-Ayerst Laboratories is an unusual preemption case because in that case, the plaintiff, not the defendant, advanced the preemption argument. Indeed, the plaintiff argued that under the principles of Buckman, the entire statute should be invalidated as “impliedly preempted by federal law because it requires one to prove fraud on the FDA as part of her cause of action against the Defendant.” Id. at 965.
\textsuperscript{81} Id. at 963. Garcia involved an individual who suffered severe liver failure as a result of adverse side effects she experienced while taking “Duract, a non-steroidal, anti-inflammatory prescription medication manufactured by” Wyeth-Ayerst. Id. at 963.
\textsuperscript{82} Id. at 967.
\textsuperscript{83} Id. at 966 (“Buckman prohibits a plaintiff from invoking the exceptions on the basis of state court findings of fraud on the FDA. . . . But the [Buckman] concerns do not arise when the FDA itself determines that a fraud has been committed on the agency during the regulatory-approval process.”).
\textsuperscript{85} Id. at 93.
state's attempt to police fraud against the FDA," the traditional presumption against preemption held. Thus, the Second Circuit upheld the validity of the statute based upon: (1) state regulation of tort law affecting health and safety (as to which the presumption against preemption applies), rather than an attempted use of state law to police fraud on the FDA; (2) alleged violation of state common-law duties, rather than solely the federal duty of candor to the FDA; and (3) invocation of fraud on the FDA to rebut an affirmative defense, rather than as an element in a claim.

2. The Texas Statute and Interpretative Case Law

Texas also has a statute that forbids suits against manufacturers of pharmaceuticals when those manufacturers obtain approval from the FDA for their drugs. The Texas statute provides for a rebuttable presumption that FDA-approved warnings on pharmaceutical drugs are sufficient, which can be rebutted if the defendant withheld or misrepresented information. The statute does not reference an independent crime on the FDA (like Michigan's), but rather removes protection if the plaintiff can prove general misconduct on the part of the defendant. The statute reads 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 defendants are not liable with respect to the allegations involving failure to provide adequate warnings or information if:

(1) the warnings [and products] were those approved by the [FDA] . . .

. . .

(b) The claimant may rebut the presumption in Subsection (a) as to each defendant by establishing that:

(1) 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 . . .

86. Id. at 94.
87. Id. at 92–97.
88. TEX. CIV. PRAC. & REM. CODE ANN. § 82.007 (Vernon 2005); see also Brief of Petitioner-Appellant, supra note 64, at 11.
89. TEX. CIV. PRAC. & REM. CODE ANN. § 82.007. Though not a subject of this Note, the wording of the Ohio statute also speaks to misconduct generally in that it removes protection if the harm suffered by the plaintiff was the "result of misconduct of the manufacturer or supplier... that manifested a flagrant disregard of the safety of persons who might be harmed by the product." OHIO REV. CODE ANN. § 2307.80(A) (LexisNexis 2005). Thus, the Ohio statute (by requiring "a flagrant disregard") is worded more harshly than the Texas statute, which merely requires that the defendant have "withheld from or misrepresented to the [FDA] required information that was material and relevant to the performance of the product." Compare OHIO REV. CODE ANN. § 2307.80(A), with TEX. CIV. PRAC. & REM. CODE ANN. § 82.007.
90. TEX. CIV. PRAC. & REM. CODE ANN. § 82.007.
As of yet, only the District Court of Texas, a state court, has considered the validity of the Texas statute.\textsuperscript{91} In \textit{Ledbetter v. Merck & Co.}, the Texas court, aligning itself with the position of the Sixth Circuit, concluded that the Texas statute was “preempted to the extent that someone other than the FDA is being asked to make the determination” of fraud.\textsuperscript{92} The plaintiffs in \textit{Ledbetter} tried to advance the position that the Texas statute was different from Michigan’s because it did not require an explicit finding of fraud.\textsuperscript{93} In granting summary judgment to the defendants, the court evinced a concern with the three tenets upon which \textit{Buckman} based its holding, noting that “[a]ll of the concerns raised by the Supreme Court in \textit{Buckman} would manifest themselves if the motion for summary judgment were denied.”\textsuperscript{94}

3. The New Jersey Statute and Interpretative Case Law

Finally, the New Jersey statute at issue provides relief from punitive damages if the manufacturer complied with FDA regulations, though it removes protection if the manufacturer secured such approval deceptively.\textsuperscript{95} The New Jersey statute (commonly referred to as the New Jersey Product Liability Act), in a manner seemingly in between that of the Michigan and Texas statutes, requires a showing of knowledge of the withheld information to remove the statutory protection.\textsuperscript{96} Notably, the statute only provides protection from punitive damages.\textsuperscript{97} The entirety of the statute reads as follows:

\begin{quote}
In any product liability action the manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction . . . . An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product . . . . If the warning or instruction given in connection with a drug or device . . . [has] been approved or prescribed by the [FDA] . . . a rebuttable presumption shall arise that the warning or instruction is adequate. For purposes of this section, the terms “drug”, “device”, “food”, and “food
\end{quote}

\textsuperscript{92} Id. at *10.
\textsuperscript{93} Id. at *8.
\textsuperscript{94} Id. at *9.
\textsuperscript{95} See N.J. STAT. ANN. § 2A:58C-5(c) (West 2000).
\textsuperscript{96} Id. Though outside the scope of this Note, four other statutes in a manner similar to New Jersey’s remove protection if the defendant “knowingly” withheld information from the FDA: Arizona, North Dakota, Oregon, and Utah. See ARIZ. REV. STAT. ANN. § 12-701 (2003); N.D. CENT. CODE § 32-03.2-11(7)(a) (1996 & Supp. 2007); OR. REV. STAT. ANN. § 30.927 (West 2003); UTAH CODE ANN. § 78-18-2 (2002).
\textsuperscript{97} See N.J. STAT. ANN. § 2A:58C-5(c). The statutes of Utah, Arizona, Oregon, and North Dakota similarly only protect against punitive damages and not damages more broadly. See ARIZ. REV. STAT. ANN. § 12-701; N.D. CENT. CODE § 32-03.2-11(6), (7)(a); OR. REV. STAT. ANN. § 30.927; UTAH CODE ANN. § 78-18-2.
additive" have the meanings defined in the "Federal Food, Drug, and Cosmetic Act."

(c) Punitive damages shall not be awarded if a drug or device or food or food additive which caused the claimant’s harm was subject to premarket approval or licensure by the [FDA] . . . . However, where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question, punitive damages may be awarded.98

In McDarby v. Merck & Co., the Superior Court of New Jersey recently was able to reexamine the validity of its regulatory compliance statute against the current landscape of controversy.99 The lower court in this case had already reviewed the substance of plaintiffs claims and had awarded large sums of compensatory and punitive damages to both plaintiffs, which the defendant, Merck, appealed.100 The joint plaintiffs in that case claimed that Merck knew that the drug increased the risk of heart attack but failed to warn of the risk.101 Conversely, Merck argued that since changes to a label are governed by the FDCA and its accompanying regulations, a state law cause of action based upon the warnings would conflict with the federal law and must be preempted.102 Thus, it found that the lower court improperly awarded such large amounts of damages.103

While recognizing the recent deadlock of the Supreme Court in Kent and the pendency of appeal before the Supreme Court of Levine v. Wyeth, the New Jersey Superior Court concluded that “[e]xisting New Jersey precedent clearly supports the conclusion that the FDCA does not preempt state-law tort remedies under theories of express conflict or implied preemption in [the] duty-to-warn context.”104

In finding that there was no statutory preemption, the court relied on the court's previous statement in Feldman v. Lederle Labs that “granting immunity to a drug manufacturer from liability in [failure to warn] circumstance[s] would 'conflict with Congress' well-

98. N.J. STAT. ANN. § 2A:58C-4, 5(c).
99. McDarby v. Merck & Co., 949 A.2d 223 (N.J. Super. Ct. App. Div. 2008). Notably, since the statute’s inception in 1987, the New Jersey Supreme Court had examined it once before in Feldman v. Lederle Laboratories, 592 A.2d 1176 (N.J. 1991). In that case, the New Jersey Supreme Court articulated the position that the Food, Drug, and Cosmetic Act (FDCA) does not preempt state tort remedies such as those available in New Jersey because of the state’s express purpose of protecting the health and safety of its citizens. Id. at 1189.
100. McDarby, 949 A.2d at 229.
101. Id. at 242–48.
102. Id. at 249.
103. Id.
104. Id. at 251. For more information on Levine v. Wyeth, 944 A.2d 179 (Vt. 2006), cert. granted, 128 S. Ct. 1118 (2008), see supra notes 216–17 and accompanying text.
recognized purpose in enacting the FDCA," which was the protection of consumers from dangerous products.105

The court also went on to conclude that regulatory preemption did not apply for two reasons: (1) the labeled changes sought by the plaintiff did not conflict with the blackletter provisions of the FDA Preamble106 and (2) the preamble applies to “circumstances in which state law appear[s] to mandate warnings that [the] FDA ha[s] specifically considered and rejected as scientifically unsubstantiated.”107 Thus, because “the ‘balance of risks and benefits set by the FDA when it approves a drug label’” are not affected by the proposed labeling sought, the state cause of action was not preempted by federal regulations.108 Regardless of this lack of conflict, the court offered a general analysis of the FDA Preamble, in which the court determined that the preamble itself did not carry preemptive weight.109

II. THE PREEMPTION DEBATE: THE STATE OF THE ISSUE

As the above conflicting interpretations between the regulatory compliance statutes indicate, scholars and courts are relatively divided on the issue of whether or not preemption should apply in the pharmaceutical context. This part explores the arguments for and against preemption coming from a variety of sources. Part II.A addresses arguments from courts and commentators in favor of preemption, while Part II.B addresses arguments against preemption.

A. Arguments for Preemption from Courts and Commentators

The FDA, as a federal agency, is amply empowered and able to regulate and monitor the pharmaceutical drug market. Indeed, it is effective to the point that state tort law interference in policing the pharmaceutical market is not only unnecessary, it is counterproductive to the Agency’s effective operation.110 As detailed below, preemption in the pharmaceutical context is the best way to ensure the optimal performance of the FDA.

105. McDarby, 949 A.2d at 251 (quoting Feldman v. Lederle Labs., 529 A.2d 1176, 1196 (N.J. 1991)).
106. Id. at 252 (explaining why the labeling sought by the plaintiff is not in conflict with the provisions of the preamble because “a sponsor is permitted to add risk information to the FPI [full prescribing information] without first obtaining FDA approval . . . and the labeling remains subject to enforcement action if the added information makes the labeling false or misleading”).
107. Id. at 253 (internal quotation marks omitted).
108. Id.
109. Id. at 253–54.
110. W. Kip Viscusi et al., Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense, 24 SETON HALL L. REV. 1437, 1480 (1994) (“Tort law in the pharmaceutical context has proven to be an extraordinarily expensive regime that suffers from institutional constraints limiting its accuracy . . . [W]here the manufacturer has complied with the FDCA and its implementing regulations, tort law does not appear to have significant ability to generate safer drugs.”).
Part II.A.1 explains why the preemptive weight of federal regulations means that congressional silence on the issue is irrelevant. Part II.A.2 discusses the effective and efficient nature of the FDA. Part II.A.3 addresses the FDA’s competency as an institution. Finally, Part II.A.4 explains why FDA standards should not be questioned in state courts.

1. Irrelevance of Congressional Silence

Undoubtedly, the MDA only refers to “medical devices” and is silent on what preemptive effect should be afforded to pharmaceutical products. As a result, the strongest argument for granting the FDA regulations for prescription drugs preemptive force comes from the FDA Preamble. However, the question becomes “whether it is appropriate to defer to an agency statement in a preamble.” The Supreme Court has long advocated the position that “federal regulations have no less preemptive effect than federal statutes.” In Lohr, Justice Stephen Breyer in his concurrence “cast a wide net for relevant sources of preemptive intent,” including “regulations, preambles, interpretative statements, and responses to comments,” as well as through the exercise of its explicitly designated power to exempt state requirements from pre-emption.

Some commentators do not see congressional silence on the pharmaceutical front as a problem at all. As observed by W. Wylie Blair, in enacting the MDA, Congress was responding to a specific concern related directly to medical devices, not to prescription drugs. Blair goes on to argue that,

[T]he inclusion of an express preemption clause does not equate to an intent to exclude preemption of prescription drug tort suits . . . . An equally plausible interpretation is that, if Congress had the opportunity to speak directly on the issue of FDA’s approval of prescription drugs, an express preemption clause would be included . . . .

111. 21 U.S.C. § 360(e), (g) (2000).
112. See supra Part I.A.3.
113. Sharkey, supra note 1, at 1040.
114. Hillsborough County, Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985) (“We have held repeatedly that state laws can be pre-empted by federal regulations as well as by federal statutes.”). For a general discussion of Hillsborough County, Florida v. Automated Medical Laboratories, Inc. and its progeny, see Davis, supra note 29, at 1115–20, which discusses modern implied preemption cases.
115. Sharkey, supra note 1, at 1040.
118. Blair, supra note 21, at 296.
119. Id.
However, "[e]ven if Congress did not intend to preempt the claim[s]" against drug manufacturers, "the intent of the FDA could provide grounds for preemption" alone.\(^\text{120}\)

Furthermore, scholars have urged the importance of keeping in mind distinctions between express and implied conflict preemption.\(^\text{121}\) "Congress undeniably has shown that it intends ordinary conflict-preemption principles to apply to [the] FDA's actions under the FDCA. Section 202 of the 1962 Amendments to the FDCA . . . expressly invalidates any state law that creates a 'direct and positive conflict' with any amendments to the FDCA."\(^\text{122}\) Working from such grounds, scholars argue that the FDA Preamble should be given preemptive effect because of the provisions of the Supremacy Clause.\(^\text{123}\)

2. Effective and Efficient Nature of the FDA

As noted by the Supreme Court in \textit{Buckman}, the FDA is extensively involved in every step of the approval process.\(^\text{124}\) Every manufacturer seeking FDA approval for a new product must submit a large volume of information to the FDA to aid in the Agency's meticulous determination of safety.\(^\text{125}\) Through this entire "new drug application" (NDA) process, the FDA is "required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards."\(^\text{126}\) Indeed, the application process requires the submission of "full reports of investigations which have been made to show whether or not such [a] drug is safe for use."\(^\text{127}\) This rigorous "premarket approval" (PMA) process requires that the "[m]anufacturer . . . submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission."\(^\text{128}\) Indeed, the Supreme Court has viewed the FDA's process as so effective that one of its central concerns expressed in \textit{Buckman} was not to hinder this "speedy" and effective process.\(^\text{129}\)

\(^{120}\) \textit{Id.} at 297.

\(^{121}\) Dorfman et al., \textit{supra} note 23, at 609.


\(^{123}\) \textit{Id.} at 610 ("Even though the Preamble is a regulatory advisory opinion . . . the Supremacy Clause requires courts to give full deference to FDA labeling determinations, including its interpretation that the regulations provide both a floor and a ceiling and therefore preempt contrary state law.").


\(^{126}\) Approval of an Application and an Abbreviated Application, 21 C.F.R. § 314.105(c) (2007).

\(^{127}\) 21 U.S.C. § 355(b)(1); \textit{Buckman}, 531 U.S. at 344 ("[A]n application must include all known reports pertaining to the device's safety and efficacy . . . .")


\(^{129}\) \textit{See Buckman}, 531 U.S. at 351. The Court held that
Notably, several other courts considering the *Buckman* concerns have determined that maintaining the efficiency and effectiveness of the FDA approval process was a paramount concern of the Supreme Court. For example, the District Court of Texas in *Ledbetter*, in concluding that the statutory exception was federally preempted, stated that "[t]he logic of *Buckman* was that the FDA promulgates detailed data submission requirements and is fully empowered to investigate wrongful withholding by manufacturers."  

The court went on to articulate the *Buckman* Court's concern that "manufacturers might 'deluge' the FDA with information it neither needed nor wanted in order to defend state tort claims."  

In an effort to protect the integrity of this process and the health and safety of the American public, the FDA has the power to conduct its own independent examinations and investigations for all NDAs and is similarly empowered with the requisite tools to punish and deter instances of fraud and misrepresentation against itself as soon as such problems arise. To that end, the FDA has established its own enforcement policy of premarket submissions, which articulates available remedies. Thus, the FDA is aptly equipped to make a "measured response to suspected fraud" perpetuated upon it. However, if a citizen is concerned about an instance of uninvestigated fraud, she is statutorily empowered to report that wrongdoing and petition the Agency to take action.  

Likewise, while the Supreme Court has recognized the traditional role of the states in guarding the health and safety of its citizens, it has been adamant in declaring that “[p]olicing fraud against federal agencies is

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131. *Id.* at *6 (noting that “[t]he *Buckman* concern of deluging the FDA could well come true if manufacturers were forced to make data submissions defensively in order to ensure that the presumption of the Texas Act remained in place”).


133. *Id.*; see also 18 U.S.C. § 1001 (2000) (allowing the FDA to criminally pursue and punish a wrongdoer who falsifies information); 21 U.S.C. § 332 (allowing FDA to address fraud against itself by seeking civil penalties in the form of injunctive relief); *Id.* § 355(e)(5) (allowing the FDA to withdraw drug approval if it is discovered that the manufacturer falsified or misrepresented information in its New Drug Application (NDA)).


135. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001) (“In addition to the general criminal proscription on making false statements to the Federal Government, the FDA may respond to fraud by seeking injunctive relief, civil penalties, seizing the device, and pursuing criminal prosecutions.” (citations omitted)).


hardly 'a field which the States have traditionally occupied.'” Indeed, the Court has considered the interference of the states in such federal regulation to be unnecessary since “the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and . . . this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives.”

3. The FDA’s Institutional Competency to Conduct a Cost/Benefit Analysis for Mass Market Drugs

The FDA determination about an NDA is premised on a cost/benefit analysis, which the FDA alone possesses the institutional competency to conduct. Indeed, the Supreme Court has exhibited concern that state policies do not hinder the “comparatively speedy” and effective process of the FDA. Any requirements that states might want to impose on manufacturers, in addition to those required by the Agency, could result in an overburdening of the Agency, impairing its proper functioning.

Moreover, the fact that the FDA leaves drugs on the market that have some adverse side effects is not indicative of the fact that the FDA is absent from regulating drugs once they are on the market. Often the FDA will leave drugs on the market even if they do cause risks because there are no safer product alternatives that produce the same level of benefit.

This cost/benefit consideration is especially necessary because all of the ill effects of a drug are not immediately apparent at the clinical level. Thus, the FDA requires meticulous reporting on the effects of a drug once it is being used in society and requires removal of the drug from the market if a manufacturer refuses to comply. Indeed, the FDA has asserted that “permitting jury verdicts based on approved labeling will encourage manufacturers to warn physicians of unsubstantiated risks [which will]

139. Id. at 348.
141. Buckman, 531 U.S. at 351.
142. Id. (noting that “fraud-on-the FDA claims would . . . cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court [thus causing them] . . . to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA’s evaluation of an application”).
143. See Epstein, supra note 117, at 23.
144. See id.
145. 21 C.F.R. § 314.80(b) (2004) (requiring the reporting of information from “any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/ surveillance studies, reports in the scientific literature, and unpublished scientific papers”).
146. Id.
147. Id. § 314.80(j).
negatively impact medical treatment,” thus upsetting the careful cost/benefit balance that the FDA tries to maintain.\textsuperscript{148}

Far from overly careful in its regulation, the FDA has been criticized as too stringent in its scrutiny of drugs, which sometimes results in beneficial drugs being kept off of the market because they do not pass the Agency’s cost/benefit analysis.\textsuperscript{149}

4. No State Court Questioning of FDA Standards

The FDA itself has explicitly said that its regulations are meant to achieve optimal safety.\textsuperscript{150} Indeed, the FDA has made it abundantly clear “that its stamp of approval should preempt state tort law claims.”\textsuperscript{151} Indeed, when Scott Gottlieb, the FDA’s Deputy Commissioner for Medical and Scientific Affairs, spoke on the issue of the supremacy of FDA standards, he stated,

We think that if your company complies with the FDA processes, if you bring forward the benefits and risks of your drug, and let your information be judged through a process with highly trained scientists, you should not be second-guessed by state courts that don’t have the same scientific knowledge.\textsuperscript{152}

Furthermore, as noted by Howard Dorfman and his colleagues, the FDA has stressed that certain “[r]isk minimization measures, such as labeling warnings and market withdrawal, may actually present substantial disadvantages. More warnings can discourage appropriate product use.”\textsuperscript{153} Dorfman goes on to discuss the \textit{Motus v. Pfizer, Inc.} case where the U.S. Department of Justice filed an amicus brief explaining the importance of the fact that the “FDA considered and rejected the inclusion of an additional warning relating to suicide in the [drug’s] labeling as scientifically untenable and, therefore, a state tort law-required suicide warning would result in misbranding of the drug in violation of federal regulations.”\textsuperscript{154}

\textsuperscript{148} Davis, supra note 29, at 1135.
\textsuperscript{150} See Epstein, supra note 117, at 23 (“Another misunderstanding . . . is that FDA labeling requirements represent a minimum safety standard. In fact, FDA interprets the act to establish both a ‘floor’ and a ‘ceiling’ . . .” (citing Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934–35 (Jan. 24, 2006) (codified at 21 C.F.R. § 201.56 (2007)))).
\textsuperscript{151} Blair, supra note 21, at 297.
\textsuperscript{153} Dorfman et al., supra note 23, at 592 (citation omitted).
\textsuperscript{154} Id. In the briefs in \textit{Motus v. Pfizer, Inc.}, the FDA went on to assert that preemption was required for two reasons: (1) allowing a claim that the defendant should have provided
The courts are split in their responsiveness to the institutional competency argument. Notably, however, some courts, such as those in Michigan, have determined that deferring to the sound judgment of regulatory agencies is a primary goal of the regulatory compliance statutes. For example, as articulated by the Michigan Supreme Court in consideration of the constitutionality of the state's regulatory compliance statute,

[T]his statute only establishes that a determination of independent significance, here the FDA finding that a drug is safe and effective, will be the measure in Michigan of whether the duty of reasonable care has been met by a drug manufacturer or seller in a tort case. . . . [T]he FDA, for its own reasons that are independent of Michigan tort law, simply makes a factual finding regarding the safety and efficacy of drugs.

Indeed, as commentators have suggested, the propreemption position "strike[s] just the right balance between protecting consumers from harmful products and preserving manufacturers' ability to sell therapeutic products—including those with known health and safety risks and side effects." From that basis, the presumption in the drug context should be in favor of federal preemption, for that is the only way to preserve this delicate balance.

Furthermore, some courts have concluded that the "exceptions" to fraud on the FDA interfere with the efficiency of the Agency and should just be severed from the statute as a whole. The dominant case in this line of

alternative warnings other than those required by the FDA would require a manufacturer to choose between tort liability or compliance with the FDCA, and (2) "imposition of liability on the basis of a failure to warn would thwart the FDCA's objectives of ensuring a drug's optimal use by requiring that manufacturers disseminate only truthful information as to its effects." Id. (quoting Amicus Brief for the United States in Support of Defendant-Appellee and Cross-Appellant, and in Favor of Reversal of the District Court's Order Denying Partial Summery Judgment of Defendant-Appellee and Cross-Appellant at 14–15, Motus v. Pfizer, Inc., 358 F.3d 659 (9th Cir. 2004) (Nos. 02-55372, 02-55498)). For a thorough discussion of Motus, see Davis, supra note 29, at 1095–98.


156. Taylor v. Smithkline Beecham Corp., 658 N.W.2d 127, 134 (Mich. 2003). Taylor v. Smithkline Beecham Corp. marks the only time that the Michigan Supreme Court has examined the state's regulatory compliance statute. In that case, the plaintiffs, who suffered injuries resulting from use of the Fen-phen diet drug, sought to establish that the regulatory compliance statute violated the state constitution. Id. at 130. The court upheld the constitutionality of the statute and found for the defendant, holding that the statute provided an "absolute defense to a products liability claim if the drug and its labeling were in compliance with the FDA's approval at the time the drug left the control of the manufacturer." Id. at 131.


158. See id.

reasoning is *Garcia*, in which the Sixth Circuit, interpreting the Michigan statute,\textsuperscript{160} concluded that, insofar as the statute required plaintiffs to independently prove fraud on the FDA, it was preempted under federal law.\textsuperscript{161} However, the court went on to determine that this partially invalidated fraud exception could be severed from the remainder of the immunity statute. This would preserve the regulatory compliance portion while removing the exception that conflicted with *Buckman*.\textsuperscript{162} The court reasoned that if the Michigan legislature were "given a choice between immunity absent a finding of bribery or fraud by the Federal Government and no immunity, the . . . [l]egislature would prefer the former option."\textsuperscript{163} Thus, the court deferred entirely to the sound judgment of the Agency in concluding that instances of fraud could be brought to light in subsequent trials if, and only if, the FDA had in fact made a prior determination that such fraud had occurred.\textsuperscript{164}

**B. Arguments Against Preemption from Courts and Commentators**

Having preemption apply across the board would interfere with the delicate balance of state and federal interests and trample on the traditional constitutional powers of the states—namely ensuring the health and safety of its citizens. Indeed, legislatures that have adopted regulatory compliance statutes (particularly those worded very broadly) have placed their citizens in the dubious position of not being able to seek redress for their injuries.\textsuperscript{165} Some commentators argue that preemption should not apply broadly to these pharmaceutical drugs because the FDA has exhibited an inability to effectively monitor drugs and thus the states need to take individual actions to protect the health and safety of their citizens.

\textsuperscript{160} See supra Part I.D.1.

\textsuperscript{161} *Garcia*, 385 F.3d at 965.

\textsuperscript{162} Id. at 967 ("[S]evering the preemption exemptions will not give license to drug manufacturers to use bribery or fraud as a means of obtaining FDA approval, then [allow them to] rely on that approval as a shield from products liability: it will merely place responsibility for prosecuting bribery or fraud on the FDA in the hands of the Federal Government rather than state courts.").

\textsuperscript{163} Id.

\textsuperscript{164} Id. at 966. Another, more recent case with a similar, though more limited line of reasoning, is *Colacicco v. Apotex Inc.*, 521 F.3d 253 (3d Cir. 2008). In *Colacicco*, the U.S Court of Appeals for the Third Circuit looked at the very narrow issue of circumstances in which the FDA has publicly rejected the need for heightened warnings on pharmaceutical products, and concluded that, when the Agency had made such a definitive judgment, its conclusion was not to be questioned by state courts. *Id.*

\textsuperscript{165} See O'Steen & O'Steen, supra note 9, at 90–91 (noting that the result of what the Michigan legislature did is that "residents injured by dangerous drugs like Vioxx are prevented from pursuing claims against the manufacturers").
1. Congress’s Explicit Removal of Pharmaceutical Drugs from the Ambit of Preemption

The MDA is specific in its grant of preemptive force only for “medical devices”—not for prescription drugs. Indeed, the statutory language indicates that Congress did not intend for the FDCA to occupy the field of pharmaceutical regulation to the point that it would impliedly preempt state claims. As noted by McDonald v. Ortho Pharmaceutical Corp., “[t]he regulatory history of the FDA requirements belies any objective to cloak them with preemptive effect.” Indeed, Congress has in the past adopted a FDA compliance defense for products that it has found to be particularly beyond the purview of state tort considerations.

Moreover, the presumption against preemption should continue to apply in areas that are traditionally within the state police powers: notably ensuring the health and safety of its citizens. As the Supreme Court articulated, “[P]articularly in [instances] in which Congress has ‘legislated . . . in a field which the States have traditionally occupied,’ we ‘start with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.’”

Working from this premise, the Second Circuit, interpreting the Michigan statute, disagreed with the Sixth Circuit and found that no part of the statute should be federally preempted. In Desiano, the Second Circuit concluded that where there is such a clear state interest “to regulate and restrict when victims could continue to recover under preexisting state products liability law,” the consideration falls squarely within the traditional regulatory powers of the state. The Second Circuit also emphasized the significance of congressional silence on the issue, observing that “[u]ntil and unless Congress states explicitly that it intends invalidation of state common law claims merely because issues of fraud

169. In 1986, the notable products in this area were childhood vaccines. See 42 U.S.C. §§ 300aa-22(b), 300aa-23(d); Noah, supra note 33, at 957.
172. For a discussion of the circuit split, see supra Part I.D.1.
may arise in the trial of such claims, we decline to read general statutes like the FDCA and the MDA as having [preemptive] effect.”174

Several courts have adopted this position, notably, the Superior Court of New Jersey. In McDarby, the court, considering the current judicial landscape of federal preemption and looking to New Jersey precedent,175 determined that Congress did not intend to preempt state tort law in failure to warn cases for pharmaceuticals, and affirmed the district court’s ruling for the plaintiff.176 In finding there was no statutory preemption, the court concluded that “granting immunity to a drug manufacturer from liability in [failure-to-warn] circumstance[s] would ‘conflict with Congress’ well-recognized purpose in enacting the FDCA,’” which was the protection of consumers from dangerous products.177

Furthermore, commentators discourage an extension and enlargement of Buckman principles, noting that “Congress has not entirely displaced state regulation over the matter in question.”178 Thomas McGarity speaks extensively on the “weak link” in the Buckman decision, which he concludes is the notion that “Congress believed that federal agencies are by-and-large willing and able to police fraud against themselves.”179 To the contrary, McGarity argues that congressional silence in this area is extremely relevant and notes “one should not lightly presume a congressional determination that the federal government is sufficiently capable of dealing with fraud without the reinforcing incentives that state tort law can provide.”180

2. Inability of FDA to Conduct the Approval Process Properly

The inability of the FDA to conduct the approval process in an effective and efficient manner is exhibited in several respects. The first involves the ease of manipulation of the regulatory process, which stems in part from the misrepresentation and concealment of relevant scientific data from a regulatory agency.181 Indeed, scholars have observed that there is a “strong incentive for the regulatee to paint the most benign possible picture of the product at the time” the application is submitted in order to obtain approval to manufacture the product.182 The most frequent instance of fraud committed against an agency involves instances where entities withhold

174. Id. at 96.
175. See supra notes 98–106 and accompanying text.
177. Id. at 55 (quoting Feldman v. Lederle Labs, 592 A.2d 1176, 1196 (1991)).
179. Id. at 564.
180. Id.
181. See id. at 558–63 (noting that this problem especially affects “permit and licensing regimes like those administered by the FDA for approving new drugs, medical devices and food additives”).
182. Id. at 558–59.
relevant scientific data.\footnote{183} Often agencies are manipulated through false reports and publications by “scientists” whose sole purpose in writing is the distortion of the truth.\footnote{184} It has been argued that the “pervasiveness of fraud undermines any theoretical soundness of regulatory preemption.”\footnote{185} Thus, instances of “[f]raud on the FDA should turn off preemption.”\footnote{186}

Most troubling is that it appears that FDA concern about these problems arises only periodically, when news of such manipulation results in public outcry.\footnote{187} These problems of misrepresentation “represent[] a serious threat to the integrity of the federal regulatory process.”\footnote{188}

Many scholars assert that even aside from instances of deception upon the Agency, the FDA is incapable of effectively monitoring and scrutinizing every drug before granting it mass-market approval.\footnote{189} Notably, scholars take issue with the information that the Agency actually uses and to which it has access.\footnote{190} Indeed, scholars note the irony of the fact that “the advisory committees to which the FDA looks for guidance on scientific questions have included researchers paid by the manufacturer of the product for committee consideration.”\footnote{191}

3. FDA Inability to Regulate Approved Drugs Once They Enter the Market

One of the major flaws of the FDA concerns its inability to conduct meaningful postmarket surveillance of the drugs it approves.\footnote{192} Many commentators have noted that once a drug obtains FDA approval for sale, the FDA no longer regulates the drug and merely takes reactionary measures after problems with the drug become blatant.\footnote{193} Some scholars

\footnote{183. See id. at 559.}
\footnote{184. See id. at 562 (“Another way that a regulated industry can manipulate an agency is by paying for scientific consultants to write critiques of scientific studies that indicate that the industry’s products may cause adverse health or environmental effects.”).}
\footnote{185. Sharkey, supra note 65 (manuscript at 2) (“A reasonable national public policy—\textit{in the absence of fraud}—would give a pharmaceutical manufacturer protection against tort liability for failure to warn when the FDA had approved the accused warnings.”) (quoting \textit{In re Zyprexa Prods. Liability Litig.}, 489 F. Supp. 2d 230, 240 (E.D.N.Y. 2007) (Weinstein, J.) (emphasis added))).}
\footnote{186. Richard A. Nagareda, \textit{FDA Preemption: When Tort Law Meets the Administrative State}, 1 J. TORT L. 4, 46-47 (2006) (“[A] showing of [fraud on the FDA] should suffice to defeat the preemptive effect that a given FDA assessment of a device or drug otherwise might have on garden-variety actions for products liability.”).}
\footnote{187. McGarity, supra note 178, at 563.}
\footnote{188. Id.}
\footnote{189. See Nagareda, supra note 186, at 41 (“One central concern about the according of preemptive force to regulatory action in any setting speaks to the information on which the federal agency acts. Agencies have expertise in the subject areas in which they regulate, but important information about those areas often rests outside of the agencies themselves.”).}
\footnote{190. Id. at 42 (expressing a concern with “information within the control of industry”).}
\footnote{191. See id. at 43–44; O’Steen & O’Steen, supra note 9, at 85 (“Drug manufacturers possess strong leverage in rejecting efforts by the FDA to strengthen warnings on labels.”).}
\footnote{193. See O’Steen & O’Steen, supra note 9, at 85.}
have cited the FDA’s emphasis on “rushing drugs to the market”\textsuperscript{194} as a major contributor to the compromised state of the Agency’s regulative abilities.\textsuperscript{195}

To support the claim that the FDA tends to rush drugs to market, scholars frequently focus on the “fast track” approval process that the Agency initiated in 1992 for certain medications.\textsuperscript{196} The drugs that are considered under this “fast track” process are evaluated for only six months before they are approved for market use—a time period far too short to truly gauge the effects that these drugs can have.\textsuperscript{197} Indeed, Vioxx gained FDA approval through such a fast track process, which, scholars argue, indicates the FDA’s severe lack of judgment in discerning which drugs should and should not be considered for fast track approval.\textsuperscript{198}

Considering the rapidity with which scientific knowledge goes out of date, the FDA’s lack of scrutiny once the drug is on the market is particularly troubling.\textsuperscript{199} Part of this may result from the fact that “[a]pproximately half [of] the FDA’s drug evaluation budget comes directly from pharmaceutical companies in the form of fees for expedited approval of drugs,” and some believe that these budgetary concerns have caused the FDA to “lose control over the drug industry.”\textsuperscript{200} Additionally, because of the speed of the entrance of new drugs into the market, “it becomes increasingly difficult for the FDA to perform its other functions—including monitoring drug safety, ensuring manufacturing standards, and regulating marketing.”\textsuperscript{201}

Scholars assert that far too frequently the FDA responds too slowly to serious concerns reported about its approved drugs.\textsuperscript{202} Indeed, even when the FDA officially recognizes the harmful effects of certain drugs, it seems unwilling to rapidly withdraw those drugs from mass-market sales.

\textsuperscript{194} See id. at 86.
\textsuperscript{195} See MARCIA ANGELL, THE TRUTH ABOUT DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT 209–10 (2004) (“As drugs enter the market faster, it becomes increasingly difficult for the FDA to perform its other functions—including monitoring drug safety, ensuring manufacturing standards, and regulating marketing.”); O’Steen & O’Steen, supra note 9, at 86.
\textsuperscript{196} See O’Steen & O’Steen, supra note 9, at 86.
\textsuperscript{197} See id.
\textsuperscript{198} See id. at 86–87 (“The fast-track approval process was created to facilitate quick approval of pharmaceuticals used for treatment of cancer, AIDS, and other life-threatening conditions. It is doubtful that Congress intended the FDA to use this tool for a drug like Vioxx, which was developed to relieve pain caused by arthritis.”).
\textsuperscript{199} See Nagareda, supra note 186, at 47 (“Preemptive FDA action at a given time should not operate as a get-out-of-jail-free card good forever, for any agency assessment of science at a given time is merely a snapshot of a process in motion.”).
\textsuperscript{200} See O’Steen & O’Steen, supra note 9, at 85.
\textsuperscript{201} See ANGELL, supra note 195, at 210.
\textsuperscript{202} See O’Steen & O’Steen, supra note 9, at 87 (“Many physicians and health care providers blame the FDA for failing to warn the public of serious risks as evidence of the harmful side effects of Vioxx began to accumulate.”).
consumption. With the FDA lacking the gumption to ensure public safety above all else, scholars argue, state tort causes of action are necessary to protect consumers from harmful drugs and to ensure that manufacturers are deterred from releasing the drugs without adequate testing.

4. Lack of FDA Resources to Set and Ensure Optimal Standards of Safety

The substantial lack of resources at the FDA's disposal heavily contributes to its inability effectively to set and maintain such optimal levels of safety. Indeed, scholars exhibit criticism that the number of resources available to the Agency hinder it from functioning effectively, noting that "[a]s programs and responsibilities have increased, enforcement budgets have not increased accordingly." Many scholars take issue with the fact that due to a lack of resources, the FDA's NDA process has been streamlined such that it no longer focuses on ensuring optimal levels of safety. As noted by Michael D. Green, after the completion of his comprehensive study on the Bendectin litigation, the "FDA does not have the resources to monitor and ensure universal compliance of a large, technologically complex, and informationally massive industry." Professor McGarity also notes that the biosearch monitoring program—an FDA initiative responsible for conducting inspections of clinical investigators—is so thinly staffed that in 1999, "the FDA inspected only 468 out of more than 14,000 clinical investigators actually conducting trials during that time period." McGarity goes on to discuss how this has been a problem of the FDA since the 1990s and that as a result it has learned to adapt to working with a severe lack of resources. "Currently, the FDA

203. See id. at 88 (noting that the thirty-two-member advisory board of the FDA recommended to return Vioxx to the market even after all members "unanimously agreed that Vioxx ‘significantly increases the risk of cardiovascular events’" (quoting Celebrex, Bextra, Vioxx Can Stay, CNNMONEY.COM, Feb. 18, 2005, http://money.cnn.com/2005/02/18/news/fortune500/merck_drugs/)).

204. See McGarity, supra note 178, at 567; O'Steen & O'Steen, supra note 9, at 88.

205. McGarity, supra note 178, at 567.

206. Id. (noting the statement by "[a] high-level EPA enforcement official who complained that '[t]he widening gap between government's compliance assurance mandate and the resources it can apply to it means there will simply never be enough inspectors and government attorneys to achieve significant levels of compliance through enforcement actions alone'" (quoting Clifford Rechtschaffen, Competing Visions: EPA and the States Battle for the Future of Environmental Enforcement, 30 ENVTL. L. REP. 10,808, 10,810 (2000))).

207. See Rosen, supra note 149, at 254–55.

208. MICHAEL D. GREEN, BENDECTIN AND BIRTH DEFECTS 342 (1996); see also McGarity, supra note 178, at 568.


210. Id. at 568–69. Thomas McGarity writes, In the early 1990s, the FDA launched what it characterized as an aggressive "enforcement enhancement" campaign aimed at restoring the agency's "credibility
lacks the resources to monitor drugs and their promotion after initial approval.”

Additionally, a survey by the Union of Concerned Scientists found that 70% of FDA scientists who participated in the survey believed that the Agency lacked the resources necessary to function properly. Furthermore, 81% of those surveyed said that the Agency needed to strengthen its oversight of drugs after they are approved for mass-market distribution.

Courts have taken issue with the FDA’s position articulated in the FDA Preamble that state courts have an undermining effect on its authority. For example, in Jackson v. Pfizer, Inc., the U.S. District Court for the District of Nebraska concluded that the preamble is not preclusive because it was not adopted under appropriate administrative law polices nor was there any public input in its adoption.

The district court in Nebraska is not alone in this conclusion, as the Vermont Supreme Court also asserted (contrary to the preamble) that “federal labeling requirements create a floor, not a ceiling, for state regulation.”

"The FDA’s and integrity.” Budgetary constraints, however, continued to plague the agency throughout the 1990s. At the same time, Congress added to the FDA’s responsibilities without increasing its enforcement resources. Agency officials have acknowledged that they will have “to do more with less” in exercising its enforcement authorities. In fact, the FDA, in the mid-1990s, argued in court that constraints on enforcement resources justified a decision to shirk its statutory responsibilities to promulgate regulations under the recently enacted Nutrition Labeling and Education Act of 1990.

Id. (citations omitted).

211. Mitchell Oates, Facilitating Informed Medical Treatment Through Production and Disclosure of Research into Off-Label Uses of Pharmaceuticals, 80 N.Y.U. L. REV. 1272, 1300 (2005) (discussing the insufficient resources at the FDA to monitor postapproval uses since the primary focus of the Agency is new drug approval).


213. Id.


215. Jackson, 432 F. Supp. 2d. at 968 & n.3 (noting that “[t]he FDA failed to comply with its requirements to communicate with the states and to allow the states an opportunity to participate in the proceedings prior to a preemption decision”).


217. See id. at 185 (quoting 21 C.F.R. § 314.70(c) (2004)). In Levine, the Vermont Supreme Court quoted the relevant part of the FDA regulation, which provides,

(6) The agency may designate a category of changes for the purpose of providing that, in the case of a change in such category, the holder of an approved application may commence distribution of the drug product involved upon receipt
approved label . . . can therefore be said to set the minimum labeling requirement, and not necessarily the ultimate label where a manufacturer improves the label to promote greater safety.”218 Thus, “[s]ection 314.70(c) allows, and arguably encourages, manufacturers to add and strengthen warnings that, despite FDA approval, are insufficient to protect consumers.”219 The threat of state tort liability “simply give[s] these manufacturers a concrete incentive to take this action as quickly as possible.”220

Further still, the New Jersey Superior Court has also joined this position by asserting that the FDA Preamble does not carry preemptive weight.221 In McDarby, the New Jersey Superior Court articulated five reasons for denying the preamble preemptive effect:222 (1) presumption against preemption in fields of traditional state dominance; (2) absence of any requirement of deference under principals articulated by numerous Supreme Court precedents addressing the subject of preemption; (3) the failure of the regulations to provide notice and opportunity for comment; (4) the conflict between the preamble and longstanding FDA policy; and (5) the trampling effect of the preamble on the state’s police powers.223

Great emphasis overall is thus placed on the federal government not “cavalierly pre-empt[ing]” aspects of governance traditionally within the province of state authority.224 As the issues here relate fundamentally to powers traditionally reserved to the states, the state should be able to regulate drug manufacturers through statute.

III. APPLYING PREEMPTION

Part III proceeds in three sections: Part III.A argues that the FDA is fully capable of ensuring that pharmaceutical products are safe for public use.

by the agency of a supplement for the change. These changes include, but are not limited to:

(iii) Changes in the labeling . . . to accomplish any of the following:
(A) To add or strengthen a contraindication, warning, precaution, or adverse reaction . . . [or]

(C) To add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product . . . .

21 C.F.R. § 314.70(c)(6).
219. Id.
220. Id.
222. The court actually articulates six reasons for denying preemptive weight to the preamble, but the sixth (“the absence of any actual conflict between the FDCA or FDA regulations and plaintiffs’ failure-to-warn cause of action”) is specific to the precise facts of McDarby v. Merck & Co. and thus omitted here. See id. at 254–55.
223. Id.
Part III.B argues that exceptions to regulatory compliance statutes should be preempted because they conflict with agency objectives. Finally, part III.C argues that the specific wording of each of the statutes must be scrutinized against the backdrop of the Buckman principles.

A. The FDA's Capability to Ensure Safety

The Supreme Court has on numerous occasions advocated the position that "federal regulations have no less preemptive effect than federal statutes."\footnote{225. Hillsborough County, Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985) ("We have held repeatedly that state laws can be pre-empted by federal regulations as well as by federal statutes.").} Furthermore, not only has the Court articulated sound ground for finding that the FDA regulation of pharmaceuticals preempts state tort law causes of action, but the Agency has expressly stated such a position in the 2006 preamble.\footnote{226. See supra Part I.A.3.} Courts that have ignored the preemptive weight that should be accorded to this Agency statement are acting in direct opposition to the furtherance of the Agency’s objectives and thus hinder its efficient operation,\footnote{227. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 n.7 (Jan. 24, 2006) (codified at 21 C.F.R. § 201.56 (2007)); see also Buckman Co. v. Plaintiffs’ Legal Comm., 531 U.S. 341, 341-42 (2001); supra Part I.A.3.} even when they declare that they are not.\footnote{228. See McDarby, 949 A.2d at 234. In McDarby the court found, in part, that the state cause of action could not be preempted because the state statute did not affect "'the balance of risks and benefits set by the FDA when it approves a drug label.'" Id. at 253 (quoting David A. Kessler & David C. Vlacleck, A Critical Examination of the FDA’s Efforts to Preempt Failure-to-Warn Claims, 96 Geo. L.J. 461, 465 (2008)). Additionally, when the court enumerated its factors for not giving preemptive weight to the preamble, the final factor was incredibly fact-specific to the case. See supra note 223 and accompanying text. These two elements, taken together, suggest that perhaps the court could find preemption if the FDA declared that the balance of risks and benefits was upset or in any other factually dissimilar situation.}

Thus, despite the Supreme Court’s recent deadlock on the issue, there is good reason to give the Agency’s determinations preemptive effect in this area, primarily because it is in the best position to evaluate all of the considered factors about whether to market (or keep on the market) any given drug.\footnote{229. See supra Part II.A.3.} While critics argue that the FDA is actually ineffective in ensuring the health and safety of the public,\footnote{230. See supra Part II.B.3.} these are all hindsight critiques that fail to consider the careful cost/benefit analysis that the Agency conducted.

The institutional competency of the FDA should not be second-guessed by juries, who do not possess the same scientific knowledge that the FDA had when it made its determination about the safety of the drug.\footnote{231. See supra Part II.A.3.} Having the sound judgment of the FDA questioned at the state level would destroy the Agency’s goals of pursuing a cost/benefit analysis with respect to the
products that it maintains on the market. Thus the careful cost/benefit consideration that the Agency conducts would be rendered useless if it could be abrogated by juries that are sympathetic to the plight of the injured plaintiff. Additionally, allowing the states to weigh in on the discussion about what is adequate representation to the FDA would “dramatically increase the burdens facing potential applicants,” which might discourage them from seeking FDA approval for a universally beneficial drug.

Moreover, the Supreme Court has praised the FDA approval process numerous times for being not only efficient but also effective. Indeed, in Buckman, the Court indicated that one of its central reasons for finding preemption was the concern that if additional state tort requirements were added to the current FDA requirements they might overburden the industry.

Granted, instances of fraud present a difficult situation, because as a result of the misrepresentation, the FDA did not have the proper basis of knowledge to make an accurate determination. However, the FDA is adequately empowered to effectively police and monitor the integrity of the pharmaceutical production process and to punish and deter fraud without state intervention. Moreover, the states should not be allowed to judge the adequacy or inadequacy of disclosures made to the FDA, but rather such a task must remain in the sound discretion of the Agency.

This Note agrees with the Sixth Circuit and Professor Sharkey in concluding that the FDA should take a more aggressive role in prosecuting such fraud. Once the FDA has independently made the determination that fraud exists, the states are then in a better position to allow private litigants to seek personal redress. However, without that determination, Buckman’s concerns are implicated—notably, if states are pursuing causes of action against manufacturers without independent findings of fraud, then the states act outside the traditional purview of their police powers. It is the FDA’s role (not that of the states) to determine what kind of information it needs from the manufacturer and whether such necessary information was misrepresented or withheld from it. Once the FDA has made this determination, then the states can use that prior conclusion to redress the

232. See supra Part II.A.3.
233. See supra Part II.A.3.
234. Buckman Co. v. Plaintiffs’ Legal Comm., 531 U.S. 341, 350–51 (2001) (noting that “[a]s a practical matter, complying with the FDA’s detailed regulatory regime in the shadow of 50 States’ torts regimes will dramatically increase the burdens facing potential applicants”).
235. See supra Part I.B.3.
236. Buckman, 531 U.S. at 350.
237. See supra Part II.B.2.
238. See Buckman, 531 U.S. at 347–50.
239. See Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961, 967 (6th Cir. 2004); Sharkey, supra note 65 (manuscript at 7).
240. See Sharkey, supra note 65 (manuscript at 7).
241. See supra Part II.A.2.
242. See supra Part II.A.2.
wrongs committed upon their citizens. Indeed, this position has not escaped the notice of the Court; it was precisely the position that Justice Stevens articulated in his concurrence in Buckman.

This issue stands poised for Supreme Court consideration in the near future. At that later date, the Court should reevaluate the sound view articulated by Justice Stevens in Buckman and consider it to be a middle ground approach of preventing the states from policing Agency fraud, while allowing citizens private causes of action after such fraud has been positively determined by the Agency. Adopting such a position strikes a balance between conflicting state and federal interests as expressed by the opponents of federal preemption.

B. Exceptions to Regulatory Compliance Statutes in Conflict with Agency Objectives

This Note argues that, because of the institutional competency of the FDA, exceptions in regulatory compliance statutes should be struck from the statute, as advocated by the Sixth Circuit. The Sixth Circuit, looking at the relevant Michigan statute, concluded that this was the proper choice because it conformed to legislative intent. The Sixth Circuit’s interpretation was more sound than the Second Circuit’s, primarily because the Second Circuit ignored Buckman’s concern that the efficient functioning of the Agency should not be hindered.

While Judge Guido Calabresi of the Second Circuit in Desiano premised his conclusion on three central points, all of them dismiss the central concern of Buckman: notably the adverse impact that state law

243. See supra notes 81–84 and accompanying notes (discussing Garcia).

244. Buckman Co. v. Plaintiffs’ Legal Comm., 531 U.S. 341, 354 (2001) (Stevens, J., concurring) (“This would be a different case if, prior to the instant litigation, the FDA had determined that petitioner had committed fraud during the [approval] process . . . . Under those circumstances, respondent’s state-law fraud claim would not depend upon speculation as to the FDA’s behavior in a counterfactual situation but would be grounded in the agency’s explicit actions. In such a case, a plaintiff would be able to establish causation without second-guessing the FDA’s decision-making or overburdening its personnel, thereby alleviating the Government’s central concerns regarding fraud-on-the-agency claims.”).

245. Levine is currently being considered by the Supreme Court and should be decided shortly after this Note’s publication. See Wyeth v. Levine, 128 S. Ct. 1118 (2008).

246. See supra note 237 and accompanying text.

247. See Sharkey, supra note 65 (manuscript at 7).

248. See supra note 81–84 (discussing Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961 (6th Cir. 2004)).

249. Garcia, 385 F.3d at 967.

250. “State-law fraud-on-the-FDA claims inevitably conflict with the FDA’s responsibility to police fraud . . . .” Buckman Co. v. Plaintiffs’ Legal Comm., 531 U.S. 341, 350 (2001). Additionally, the Court feared that a potential overburdening of the FDA would occur, since applicants might begin to fear that their FDA disclosures were not sufficient and thus would want to “submit a deluge of information that the Administration neither wants nor needs.” Buckman, 531 U.S. at 351; see also supra Part I.D.1.

251. For a discussion of the tenets of the holding of the U.S. Court of Appeals for the Second Circuit, see Part I.D.1.
determinations of fraud-on-the-FDA could have on the FDA's internal operations and the regulatory process as a whole. The Second Circuit's holding threatens to upset the "equilibrium" that the Garcia court strikes between state and federal interests by adopting a narrow reading of Buckman that forecloses only stand-alone fraud-on-the-FDA claims.

Of the three statutes on which this Note focuses, Michigan's most clearly violates Buckman's principles because it most clearly references fraudulent activity. Notably, it requires that the manufacturer "intentionally withhold[] from or misrepresent[] [information] to the [FDA]." Furthermore, the Michigan statute requires not only a finding of intentionality on the part of the manufacturer, but also a finding that the Agency relied on the misinformation.

In providing a rebuttable presumption, the Texas statute varies slightly from the blanket immunity that the Michigan statute purports to give. The Texas statute varies from the Michigan statute in that it does not require such a finding of intentionality. Moreover, the Texas statute, unlike the Michigan statute, does not require any finding of reliance on the part of the FDA. Despite the lack of intentionality and reliance, the Texas court interprets its own statute to be indistinguishable in intent and purpose from the Michigan statute and hence implicates the concerns of Buckman. Indeed, such a finding was appropriate, as the Supreme Court has indicated that the proper focus is on the legislative intent behind the statute.

Finally, the New Jersey statute differs from the other two statutes in that it does not provide broad protection for the manufacturer in compliance with FDA regulations but rather just protects them narrowly against a punitive damages judgment. While the New Jersey statute does not require a standard of intentionality, it does require a lesser standard of "knowingly with[holding] . . . information" on the part of the manufacturer. Additionally, while not requiring a finding of reliance on the part of the FDA, the New Jersey statute requires that the withheld information be causally related to the harm suffered by the plaintiff.
C. The Differences Among the Statutes and the Proper Interpretation of Buckman

To date, no court has pinned down the proper interpretation of *Buckman* as it applies to the slight variations of these regulatory compliance statutes. Indeed, assessing the slight differences among the statutes is particularly relevant. A statute like Michigan's that explicitly refers to instances of fraud most clearly implicates the central concerns of *Buckman*, to the extent that such statutes are trying to police the communications to which the Agency had access. However, such a reading is not dispositive, as evinced by the Second Circuit, the New Jersey Superior Court, and other courts handing down similar decisions. Thus, the crucial issue is the application of the *Buckman* principles to the pros and cons of Agency deference, and how the variations of regulatory compliance statutes show attempts by state legislatures to strike a balance between federal deference and state province.

If one reads *Buckman* narrowly, statutes speaking to any lesser form of concealment (and probably even bribery) would not invoke the *Buckman* concerns, which, the Second Circuit (and others) argue, were principally about fraud. However, reading *Buckman* so narrowly is unduly restrictive. A more plausible reading of *Buckman* articulates a concern about policing any forms of communication to which the Agency has access. If read that way—a reading more in line with the Sixth Circuit's view—a statute like Michigan's quite clearly implicates *Buckman* concerns, as would statutes that deal with any lesser form of concealment. The policing of any lesser form of concealment (as the Texas and New Jersey statutes strive to do) also deals with the regulation of the communications at the Agency's disposal, because the statutes consider information to which the Agency had access and judge whether there was concealment, misrepresentation, or incompleteness. The desire to regulate this information conflicts with the central tenets of *Buckman*, because each statute tries to impose a state judgment on the information to which the Agency had access. Thus, assuming that the broader reading of

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2008] PREEMPTION IN A PHARMACEUTICAL CONTEXT 361

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264. See supra Part I.D.1.
265. See supra Part I.D.1.
266. See supra Part I.D.2-3.
267. While not the subject of this Note, statutes like those of Kansas, see KAN. STAT. ANN. § 60-3304(a)(1994), and Colorado, see COLO. REV. STAT. ANN. § 13-21-403(1), which remove protection for noncompliance with Agency regulations (but do not reference concealment, misrepresentation, or other forms of misconduct), also conceivably implicate the *Buckman* concerns. They trigger these concerns because they too seek to make a determination about the sufficiency of the information that the FDA had when it made its determination. Thus, these statutes seek to determine noncompliance with Agency standards, without first requiring that the Agency itself make such a determination, which (assuming the broader...
Buckman is viable, the only statutes that should not be preempted are those that do not regulate any form of concealment or judge compliance with Agency standards.

Additionally, the Buckman concerns with respect to the proper functioning of the FDA are implicated by the statutes because the FDA, in its preamble, has explicitly articulated its belief that any additional state regulations will inhibit the proper functioning of the Agency. Despite the arguments against the preemptive effect of the preamble, it carries weight because the Supreme Court has long advocated the position that "federal regulations have no less preemptive effect than federal statutes."

As articulated by the preamble, "FDA approval of labeling under the act . . . preempts conflicting or contrary State law." Thus, the FDA was adamant that state law decisions that reject the preemptive authority of FDA labeling "rely on and propagate interpretations of the act and FDA regulations that conflict with the agency's own interpretations and frustrate the agency's implementation of its statutory mandate." Incidentally, the FDA has emphasized that its requirements set both a ceiling and a floor for manufacturer compliance. Furthermore, the FDA has declared that tort law claims for injuries "interfere with its ability" to properly regulate the market.

The interpretation that the FDA sets out optimal protections is a sound conclusion given the fact that "safety" when discussing pharmaceutical products is different than "safety" in the context of other products, since virtually all drugs have side effects that would lead them to be deemed "unsafe" when considered in any other context. The FDA's shifting stance has placed almost all of these regulatory compliance statutes in a reading of Buckman) touch on the concern of policing the communication at the FDA's disposal.

268. See supra Part I.A.3.

269. Hillsborough County, Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985) ("We have held repeatedly that state laws can be pre-empted by federal regulations as well as by federal statutes."). For a general discussion of Hillsborough and its progeny, see Davis, supra note 29, at 1115. See also Medtronic, Inc. v. Lohr, 518 U.S. 470, 506 (1996) (Breyer, J., concurring in part and concurring in the judgment) (noting that the Court has a history of being overinclusive regarding the sources of preemptive intent and extends that list to "'regulations, preambles, interpretative statements, and responses to comments' as well as . . . the exercise of [an agency's] explicitly designated power to exempt state requirements from pre-emption." (quoting Hillsborough, 471 U.S. at 718)).

270. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (codified at 21 C.F.R. § 201.56 (2007)); see also Sharkey, supra note 23, at 227. This formal declaration was given by the FDA after the courts evinced "reluctance . . . to accept amicus briefs as a formal statement of the agency's intent." Dorfman et al., supra note 23, at 593.


273. See O'Steen & O'Steen, supra note 9, at 77.

274. Dorfman et al., supra note 23, at 590.
preemptive position, especially with regard to the FDA’s interpretation of its powers.

**CONCLUSION**

In the pharmaceutical context, preemption should apply because the FDA is the most capable body to make determinations of the safety of pharmaceutical drugs, and its premarket approval and monitoring processes are effective and efficient. Allowing juries to second-guess FDA decisions takes the monitoring of the health and safety of the American public out of the hands of the most knowledgeable agency and places it into the hands of individual citizens with limited or no expertise in the area.

Several states (like Michigan, Texas, and New Jersey) have moved this evaluative process in the right direction, by aiming to place the decisions in the capable hands of the FDA. However, for the reasons that this Note has articulated, the exceptions contained in these and similar regulatory compliance statutes that allow juries to make independent findings of fraud or misrepresentation, should be severed or qualified by requiring an independent finding of fraud or misconduct by the Agency itself, for the exception to be viable. Removing these determinations from juries keeps the decision-making power in the hands of the most capable agency and maintains the effectiveness and efficiency of the regulatory process.

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275. While not a subject of this Note directly, the statutes of Indiana, Kentucky, and Tennessee would undoubtedly not be considered to interfere with the Agency’s objectives, as all three provide blanket immunity for compliance with FDA regulations, which is not removed by any exception for misrepresentation, fraud, etc. See Ind. Code. Ann. § 34-20-5-1 (LexisNexis 1998); Ky. Rev. Stat. Ann. § 411.310 (LexisNexis 2005); Tenn. Code Ann. § 29-28-104 (2000).

276. See O’Steen & O’Steen, supra note 9, at 77.