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# Buckman Extended: Federal Preemption of State Fraud-on-the-FDA Statutes

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***Buckman* Extended: Federal Preemption of State Fraud-on-the-FDA Statutes**

*Christine A. Gaddis*\*

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## I. INTRODUCTION

It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.<sup>1</sup>

Justice Brandeis' statement is true, except where Congress has stood in that courageous state's way and preempted state law via federal statute.<sup>2</sup> A number of states have enacted statutes that provide protection to drug manufacturers in product liability actions.<sup>3</sup> Additionally, several of these states have enacted "fraud-on-the-FDA" statutory provisions, which remove statutory protection afforded to drug manufacturers in product liability actions if plaintiffs can provide evidence that the drug manufacturer made misrepresentations to the United States Food and Drug Administration ("FDA") during the process of obtaining marketing approval for the drug.<sup>4</sup> Currently, the federal circuits are in disagreement over whether these state "fraud-on-the-FDA" statutes should be federally preempted and thus invalidated. The Sixth and Fifth circuits have held that Michigan's and Texas's fraud-on-the-FDA statutes, respectively, were federally preempted, while the Second Circuit found the same Michigan statute considered by the Sixth Circuit to be constitutional.<sup>5</sup>

This issue warrants resolution, and the Supreme Court did grant *certiorari* to hear the appeal of the Second Circuit's decision in *Desiano v. Warner-Lambert & Co.*<sup>6</sup> Unfortunately

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<sup>1</sup> *New State Ice Co. v. Liebmann*, 285 U.S. 262, 286–87 (1932) (Brandeis, J., dissenting).

<sup>2</sup> See U.S. CONST. art. VI, cl. 2.

<sup>3</sup> See *infra* notes 127–29 and accompanying text.

<sup>4</sup> See *infra* note 130 and accompanying text.

<sup>5</sup> Compare *Garcia v. Wyeth Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004), and *Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 380 (5th Cir. 2012), with *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 97 (2d Cir. 2006); see *infra* text accompanying note 156 (explaining the procedural history that led the Second Circuit to consider a case involving Michigan state law).

<sup>6</sup> *Warner-Lambert Co. v. Kent*, 128 S.Ct. 31 (2007).

however, the Court issued a 4-4 decision without an opinion, which affirmed the *Desiano* holding, but has no precedential value.<sup>7</sup> Thus, drug manufacturers, private citizens, and state legislatures have been left without a conclusive interpretation of the constitutionality of state fraud-on-the-FDA statutes. Conflicts in interpretation are likely to continue until the Supreme Court resolves the issue.

This Comment proceeds as follows: Part II will discuss the history and role of the FDA's authority in drug and medical device regulation; Part III will discuss federal preemption generally and the Supreme Court's decisions that considered whether state law failure to warn claims are federally preempted in the context of drugs and medical devices; Part IV will discuss the Supreme Court's decision in *Buckman v. Plaintiffs' Legal Committee*, where the Court held that claims that a medical device manufacturer made fraudulent representations to the FDA were federally preempted because such claims interfered with the relationship between the FDA and the entities it regulated<sup>8</sup>, state fraud-on-the-FDA statutory provisions, and the existing circuit split regarding whether those statutes should be federally preempted; Part V will discuss the potential resolutions to the circuit split; and Part VI will conclude and advocate that the Supreme Court's *Buckman* holding be applied to federally preempt state fraud-on-the-FDA statutes because such statutes involve the relationship between a federal agency and the entity it regulates and thus undermine the FDA's authority.

## II. FEDERAL DRUG AND DEVICE OVERSIGHT

### A. Food, Drug, and Cosmetic Act

Historically, states have regulated matters of health and safety through their police

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<sup>7</sup> *Warner-Lambert Co. v. Kent*, 128 S.Ct. 1168 (2008) (*per curiam*); See Mark Hermann, et al. *The Meaning of the Parallel Requirement Exception under Lohr and Riegel*, 65 N.Y.U. ANN. SURV. AM. L. 545, 546 n. 12 (2010).

<sup>8</sup> *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 343 (2001).

powers.<sup>9</sup> Since the Food and Drug Act of 1906 however, the federal government’s role in health and safety regulation has been expanding.<sup>10</sup> In the Food and Drug Act of 1906 Congress prohibited the transport of adulterated or misbranded drugs in interstate commerce.<sup>11</sup> In 1938, the Food Drug and Cosmetic Act (“FDCA”) was passed.<sup>12</sup> The premarket approval process (“PMA”) for new drugs was implemented through the FDCA.<sup>13</sup> The FDCA required drug manufacturers to submit new drug applications to the FDA, and the FDA conducted *inter alia*, safety and efficacy review.<sup>14</sup> The FDA had the authority to reject a new drug application if the agency considered a drug to be “not safe as labeled.”<sup>15</sup> In 1962, amendments to the FDCA required drug manufacturers, not the FDA, to provide evidence that a proposed drug was safe and effective as part of a New Drug Application (“NDA”), thus shifting the burden of proof from the FDA to the drug manufacturer.<sup>16</sup>

If a drug manufacturer becomes aware of new safety information associated with a drug following the drug’s approval the FDCA requires that the drug’s warning label be appropriately revised to reflect that new information.<sup>17</sup> In 2008, the FDA set forth a regulation that allows drug manufacturers to make some changes to a drugs label prior to obtaining FDA approval

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<sup>9</sup> See *Hillsborough County. v. Automated Med. Laboratories*, 471 U.S. 707, 719 (1985) (describing the “regulation of health and safety matters [as] primarily and historically a matter of local concern”) (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)); see also *Metro. Life Ins. Co. v. Mass.*, 471 U.S. 724, 756 (1985) (noting “[s]tates traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.”) (quoting *Butchers’ Benevolent Ass’n of New Orleans v. Crescent City Live–Stock Landing and Slaughter House Company (Slaughter House Cases)* 83 U.S. 36, 62 (1872) (internal quotation marks omitted).

<sup>10</sup> See *Medtronic Inc. v. Lohr* 518 U.S. 470, 475 (1996).

<sup>11</sup> PETER B. HUTT ET AL., *FOOD AND DRUG LAW* 10 (3d ed. 2007).

<sup>12</sup> HUTT, *supra* note 11 at 13.

<sup>13</sup> Federal Food Drug and Cosmetic Act 21 U.S.C. § 555 (2012).

<sup>14</sup> *Id.*

<sup>15</sup> *Wyeth v. Levine*, 555 U.S. 555, 567 (2009) (citing FDCA, 52 Stat. 1052 (current version at 21 U.S.C. § 355 (2012))).

<sup>16</sup> *Id.* (citing FDCA, 76 Stat. 781, 784 (current version at Food Drug and Cosmetic Act, 21 U.S.C. § 355 (2012))).

<sup>17</sup> See 21 U.S.C. § 355(o) (2012).

through the Changes Being Effected Process (“CBE”).<sup>18</sup> Under the CBE process drug manufacturers can make changes to a brand name drug’s label for several reasons including adding or strengthening existing warnings or adverse reactions and adding or strengthening dosage or administration instructions to increase a drug’s safety.<sup>19</sup>

In 1976 the Medical Device Amendments (“MDA”) to the FDCA were passed.<sup>20</sup> The MDA classifies medical devices based on risk into three categories.<sup>21</sup> Each category is subject to regulation proportional to its perceived risk.<sup>22</sup> Class I devices are subject to the least significant regulation of the three classes of devices.<sup>23</sup> Class II devices are potentially more harmful and subject to more federal regulation than Class I devices.<sup>24</sup> Class III devices are subject to the most significant federal regulation of the three classes of medical devices, and are defined as devices that are “purported or represented to be for a use in sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.”<sup>25</sup>

To gain FDA approval, Class III devices must be approved either through the premarket approval (“PMA”) or § 510(k) processes.<sup>26</sup> The PMA process is time consuming, and the FDA spends approximately 1,200 hours reviewing each application.<sup>27</sup> Medical device manufacturers seeking approval of a device through the PMA process are required to provide comprehensive safety and efficacy data to the FDA.<sup>28</sup> Approximately 1% of all medical devices entering the

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<sup>18</sup> *Wyeth*, 555 U.S. 555, 568 (2009).

<sup>19</sup> 21 C.F.R. § 314.70(c)(6)(iii)(A) (2008).

<sup>20</sup> HUTT, *supra* note 11, at 14.

<sup>21</sup> *Medtronic*, 518 U.S. at 476.

<sup>22</sup> *Id.*

<sup>23</sup> *Id.* at 476–77 (citing 21 U.S.C. § 360c(a)(1)(A) (2012)).

<sup>24</sup> *Id.* at 476 (citing U.S.C. § 360c(a)(1)(B) (2012)).

<sup>25</sup> 21 U.S.C. § 360c(a)(1)(C)(ii)(I)–(II) (2012).

<sup>26</sup> *See Medtronic*, 518 U.S. at 477–78.

<sup>27</sup> *Id.* at 477.

<sup>28</sup> 21 U.S.C. § 360e (2012); *Medtronic*, 518 U.S. at 477.

market do so through the PMA process.<sup>29</sup>

Class III medical devices can be approved through the § 510(k) process if a manufacturer demonstrates that the device is “substantially equivalent” to a previously approved medical device.<sup>30</sup> A device is considered substantially equivalent if it has the same use and technological characters as a previously approved device or if the device has the same use, different technological characteristics, so long as the data submitted by the manufacturer does not indicate that the new device has additional safety and effectiveness concerns than a previously approved device.<sup>31</sup> The § 510(k) process is less cumbersome than the PMA process, and § 510(k) clearance is completed by the FDA in approximately 20 hours.<sup>32</sup> Approximately one third of all medical devices entering the market each year do so through the § 510(k) process, and the remaining 67% of medical devices entering the market each year without PMA or § 510(k) clearance do so without any review.<sup>33</sup>

In 1984 another significant change to the FDCA was made when Congress passed the Drug Price Competition and Patent Term Restoration Act (“Hatch-Waxman Amendments”).<sup>34</sup> Through the Hatch-Waxman Amendments manufacturers may obtain approval for generic drugs by submitting an abbreviated new drug application (“ANDA”), which demonstrates that the generic drug is the same as another drug previously approved by the FDA.<sup>35</sup> Through the ANDA process, generic drug manufacturers are required to submit a drug application that demonstrates the proposed drug’s label will be the same as a corresponding brand name drug’s

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<sup>29</sup> INSTITUTE OF MEDICINE, *MEDICAL DEVICES AND THE PUBLIC’S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS* 4 (2011).

<sup>30</sup> 21 U.S.C. §§ 360(k), (o) (2012).

<sup>31</sup> 21 U.S.C. § 360c(i)(1)(A)(i)-(ii) (2012).

<sup>32</sup> *Medtronic*, 518 U.S. at 478.

<sup>33</sup> INSTITUTE OF MEDICINE, *supra* note 28, at 4.

<sup>34</sup> *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567, 2574 (2011).

<sup>35</sup> *Id.* (citing 21 U.S.C. § 355(j)(2)(A)).

label.<sup>36</sup> In contrast, NDAs submitted by brand name drug manufacturers must demonstrate that the proposed drug’s label will contain accurate and sufficient warnings.<sup>37</sup> Brand name drug manufacturers can modify the labels of drugs approved through the NDA or CBE processes, or by sending “Dear Doctor” letters which contain “additional warnings to prescribing physicians and other healthcare professionals” without first receiving approval from the FDA.<sup>38</sup> Generic drug manufacturers cannot modify the labels of drugs approved through the ANDA process using the CBE process unless the modification is necessary to make the generic drug’s label match the corresponding brand name drug’s label.<sup>39</sup> The Hatch-Waxman Amendments benefit generic drug manufacturers “[b]y eliminating the need for generic manufacturers to prove their drugs’ safety and efficacy independently[,]” thereby lowering the cost to obtain approval for generic drugs.<sup>40</sup>

#### B. The FDCA’s Preemption Provision

The effect of the FDCA on state laws involving drugs and medical devices has been significantly impacted by the statute’s preemption provision.<sup>41</sup> The MDA include an express preemption provision relating to medical devices.<sup>42</sup> The provision states in pertinent part:

[e]xcept as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement – a) which is different from, or in addition to, any requirement applicable under this chapter to the device, and b) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.<sup>43</sup>

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<sup>36</sup> *PLIVA*, 131 S.Ct. at 2574 (citing 21 U.S.C. § 355(j)(2)(A)(v) (2012); 21 U.S.C. § 355(j)(4)(G) (2012); and 21 CFR §§ 314.94(a)(8), 314.127(a)(7) (2012)).

<sup>37</sup> *Id.* (citing 21 U.S.C. §§ 355(b)(1), (d); *Wyeth*, 555 U.S. at 570–571).

<sup>38</sup> *Id.* at 2576.

<sup>39</sup> *Id.* at 2575.

<sup>40</sup> *Id.* at 2574.

<sup>41</sup> *See infra* Part III.B.

<sup>42</sup> 21 U.S.C. § 360k(a) (2012).

<sup>43</sup> 21 U.S.C. § 360k(a) (2012).



The FDCA does not include an express preemption provision relating to drugs.<sup>44</sup> As discussed in the next section, the Supreme Court has relied on Congress’s explicit inclusion of a preemption provision for medical devices but not for drugs within the FDCA’s text.<sup>45</sup>

### III. FEDERAL PREEMPTION

#### A. Supremacy Clause –Federal Preemption

The Supremacy Clause states “[t]his Constitution, and the Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.”<sup>46</sup> Under the Supremacy Clause if state laws “interfere with, or are contrary to the laws of Congress . . . the act of Congress . . . is supreme; and the law of the State . . . must yield to it.”<sup>47</sup> Both federal laws and federal regulations can preempt state laws.<sup>48</sup> “Federal regulations have no less preemptive effect than federal statutes.”<sup>49</sup>

There are two general types of federal preemption: express and implied.<sup>50</sup> Implied preemption is classified further into three subtypes – conflict, obstacle, and field preemption.<sup>51</sup> A federal law or regulation expressly preempts a state law if either the intent of Congress or a regulatory agency is “explicitly stated in the statute’s [or regulation’s] language.”<sup>52</sup> A federal law or regulation preempts state law through implied conflict preemption if “compliance with

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<sup>44</sup> See 21 U.S.C. § 360 (2012); see also *Wyeth*, 555 U.S. at 574.

<sup>45</sup> See *infra* Part III.B.

<sup>46</sup> U.S. CONST. art. VI, cl. 2.

<sup>47</sup> *Gibbons v. Ogden*, 22 U.S. 1, 211 (1824).

<sup>48</sup> *Hillsborough*, 471 U.S. at 713.

<sup>49</sup> *Fidelity Fed. Sav. & Loan Ass’n v. de la Cuesta* 458 U.S. 141, 153 (1982); See also *United States v. Shimer* 367 U.S. 374, 381–82 (1961); See also *Capital Cities Cable, Inc., v. Crisp*, 467 U.S. 691, 699 (1984).

<sup>50</sup> See *infra* text accompanying notes 52–55.

<sup>51</sup> See *infra* text accompanying notes 53–55.

<sup>52</sup> *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977).

both federal and state regulations [or statutes] is a physical impossibility.”<sup>53</sup> A federal law or regulation preempts state law through implied obstacle preemption if the federal legislation “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”<sup>54</sup> Finally, a federal law or regulation preempts state law through implied field preemption in circumstances where federal legislation occupies “a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.”<sup>55</sup>

#### B. Preemption in the Pharmaceutical and Medical Device Context

Following the passage of the FDCA, the Supreme Court has considered the application of express preemption regarding medical devices approved via the 501(k) and PMA processes and implied preemption in the context of brand name and generic pharmaceuticals. The body of case law that has developed has resulted in distinct holdings regarding federal preemption based upon industry and market entry method involved.<sup>56</sup> The Court has held that state law failure to warn claims *are* preempted in cases involving medical devices entering the market through the PMA process and in cases involving generic pharmaceuticals.<sup>57</sup> In contrast, state law failure to warn claims *are not* preempted in cases involving medical devices entering the market through the § 510(k) process and cases involving brand name pharmaceuticals.<sup>58</sup>

##### i. *Medtronic, Inc. v. Lohr*

In *Medtronic Inc. v. Lohr*, the Supreme Court considered “whether . . . [the MDA] preempts a state law negligence action against the manufacturer of an allegedly defective medical

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<sup>53</sup> Fla. Lime and Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142–43 (1963).

<sup>54</sup> Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

<sup>55</sup> Rice, 331 U.S. at 230.

<sup>56</sup> See *infra* Figure 1.

<sup>57</sup> See *infra* Parts III.B.ii and III.B.iv.

<sup>58</sup> See *infra* Parts III.B.i and III.B.iii.

device approved through the 510(k) process.”<sup>59</sup> In *Medtronic*, the plaintiff filed a claim against a medical device manufacturer, Medtronic, alleging negligence and strict products liability in Florida state court for injuries suffered as the result of the failure of a pacemaker.<sup>60</sup> Medtronic removed the action to federal court and asserted that the plaintiff’s claims were expressly preempted by 21 U.S.C. § 360(k)(a).<sup>61</sup> The Supreme Court was not persuaded by Medtronic’s argument and reasoned that because the medical device at issue was approved under the 510(k) process, which is “focused on *equivalence*, not safety,”<sup>62</sup> the pacemaker had not “been formally reviewed under the MDA for safety or efficacy.”<sup>63</sup> Thus, the statutory language and legislative history of the § 510(k) process “included the possibility that the manufacturer of the device would not have to defend itself against state-law claims of negligent design.”<sup>64</sup> The Court reasoned that federal legislation should preempt state law “where a particular state requirement threatens to interfere with a specific federal interest.”<sup>65</sup> Additionally, a state law must “relate to the safety and effectiveness of [a] device,” and be “different from or in addition to federal requirements” in order to be federally preempted.<sup>66</sup> The Court reasoned that Florida could enforce common law duties that “parallel[ed] federal requirements.”<sup>67</sup> Ultimately, the Court held that none of the plaintiff’s claims were preempted under § 360k.<sup>68</sup>

ii. *Riegel v. Medtronic, Inc.*

In *Riegel v. Medtronic, Inc.*, the Supreme Court considered whether the MDA’s preemption

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<sup>59</sup> *Medtronic*, 518 U.S. at 474.

<sup>60</sup> *Id.* at 481.

<sup>61</sup> *Id.*

<sup>62</sup> *Id.* at 493 (quoting *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1348 (11th Cir. 1995)) (internal quotation marks omitted).

<sup>63</sup> *Id.*

<sup>64</sup> *Id.* at 494.

<sup>65</sup> *Medtronic*, 518 U.S. at 500.

<sup>66</sup> *Id.* (internal quotation marks omitted).

<sup>67</sup> *Id.* at 495.

<sup>68</sup> *Id.* at 502.

clause, 21 U.S.C. § 360(k), expressly preempted state law claims that challenged the safety and efficacy of medical devices approved through the PMA process.<sup>69</sup> In *Riegel*, the plaintiff claimed that he was injured because the Evergreen Balloon Catheter, manufactured by Medtronic and approved by the FDA through the PMA process, was “designed, labeled, and manufactured” in a manner that violated New York State law.<sup>70</sup>

The Court distinguished the PMA process from the § 510(k) process because the PMA process is focused on the safety and effectiveness, while the § 510(k) process is focused on medical device equivalence.<sup>71</sup> The Court specifically noted that PMA “is specific to individual devices . . . and it *is* federal safety review.”<sup>72</sup> Thus, if a state law imposed requirements that were “different from or in addition to federal requirements and . . . relate[d] to the safety or effectiveness of the device,” such state laws would be expressly federally preempted by § 360(k).<sup>73</sup> The Court held that because the New York common law claims at issue related to the safety and effectiveness of the Evergreen Balloon Catheter, and imposed requirements that were different from those required under the PMA process, those claims were expressly federally preempted.<sup>74</sup>

The Supreme Court’s reasoning in *Lohr* and *Riegel* demonstrates that the federal requirements of a medical device’s market entry determine whether or not state law claims alleging that a device is unsafe survive a federal preemption challenge. If a medical device is approved through the PMA process any state law claims challenging the device’s safety are expressly preempted by the FDCA.<sup>75</sup> However, if a medical device is cleared through the §

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<sup>69</sup> *Riegel v. Medtronic*, 552 U.S. 312, 315 (2008).

<sup>70</sup> *Id.* at 320.

<sup>71</sup> *Id.* at 322–23.

<sup>72</sup> *Id.* at 323.

<sup>73</sup> *Id.*

<sup>74</sup> *Id.* at 330.

<sup>75</sup> *See supra* Part III.B.ii.

510(k) process, so long as a state law claim is parallel to the FDCA's requirements, such claims are not federally preempted.<sup>76</sup> In considering federal preemption in the context of state law failure to warn claims involving brand name and generic pharmaceuticals, the Supreme Court's reasoning has similarly been tied to the specific statutory language of the FDCA.<sup>77</sup>

iii. *Wyeth v. Levine*

In *Wyeth v. Levine*, the Supreme Court considered “[w]hether the FDA’s drug labeling requirements preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use.”<sup>78</sup> In *Wyeth*, the plaintiff was injured after receiving a Phenergan injection.<sup>79</sup> Phenergan is an antihistamine drug approved through the NDA process.<sup>80</sup> The plaintiff asserted a products liability claim and a negligence claim against Wyeth alleging that the manufacturer failed to adequately provide warnings on Phenergan’s label regarding drug administration risks.<sup>81</sup> Wyeth argued that the plaintiff’s claims were federally preempted through both implied conflict preemption and implied obstacle preemption.<sup>82</sup>

Wyeth maintained that the plaintiffs’ state law claims were preempted through implied conflict preemption “because it [was] impossible for it to comply with both the state-law duties underlying those claims and its federal labeling duties.”<sup>83</sup> Specifically, Wyeth noted that it could not modify Phenergan’s label to comply with state law without first obtaining FDA approval under the FDCA.<sup>84</sup> The Court reasoned that while generally modifications to labels for drugs

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<sup>76</sup> See *supra* Part III.B.i.

<sup>77</sup> See *infra* Parts III.B.iii and III.B.iv.

<sup>78</sup> *Wyeth*, 555 U.S. at 563.

<sup>79</sup> *Id.* at 560.

<sup>80</sup> *Id.* at 555.

<sup>81</sup> *Id.* at 559–60.

<sup>82</sup> *Id.* at 563.

<sup>83</sup> *Id.* at 568 (citing *de la Cuesta*, 458 U.S. at 153).

<sup>84</sup> *Wyeth*, 555 U.S. at 568.

approved through the NDA process required approval from the FDA before the label was altered, under certain circumstances a drug manufacturer could modify a drug's label before obtaining FDA approval.<sup>85</sup> The FDA's CBE process allows modifications to drug labels after a supplemental application has been filed with the FDA, but prior to the manufacturer receiving FDA approval for the changes, if the modifications "add or strengthen a contraindication, warning, precaution, or adverse reaction," or if the modifications "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug."<sup>86</sup> The Court reasoned that the plaintiff's claims were not preempted through implied conflict preemption because Wyeth could comply with both federal and state laws.<sup>87</sup>

Wyeth argued that Levine's state law claims were preempted through implied obstacle preemption because the claims "interfere[d] with Congress's purpose to entrust an expert agency to make drug labeling decisions."<sup>88</sup> The Court reasoned that the lack of an express preemption provision for drugs approved through the NDA process in the FDCA was an indication that Congress did not believe such state law claims "posed an obstacle to its objectives."<sup>89</sup> Wyeth's implied obstacle preemption argument relied on the text of the FDA's 2006 preamble in which the FDA maintained that the FDCA preempted state laws related to pharmaceutical labeling.<sup>90</sup> The Court reasoned that the 2006 preamble did "not merit deference" because the FDA published the preamble without first "offering States and other interested parties notice or opportunity for comment."<sup>91</sup> Additionally, the Court noted that the 2006 preamble conflicted

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<sup>85</sup> *Id.*

<sup>86</sup> *Id.* (quoting 21 C.F.R. §§ 314.70(c)(6)(iii) (A), (C) (2012)).

<sup>87</sup> *Id.* at 573.

<sup>88</sup> *Id.* ("requiring...[Wyeth]...to comply with state-law duty to provide a stronger warning about IV-push administration would obstruct the purpose and objectives of federal drug labeling regulation") (internal quotation marks omitted).

<sup>89</sup> *Id.* at 574.

<sup>90</sup> *Wyeth*, 555 U.S. at 573-74.

<sup>91</sup> *Id.* at 577.

with the FDA's previous position that state law served as an *additional* method to regulate the pharmaceutical industry.<sup>92</sup> Thus, the Court concluded that the plaintiff's state law claims were not preempted through implied conflict or implied obstacle preemption.<sup>93</sup>

iv. *PLIVA, Inc. v. Mensing*

In *PLIVA v. Mensing*, the Supreme Court considered "whether, and to what extent generic [drug] manufacturers may change their labels *after* FDA approval."<sup>94</sup> In *PLIVA*, the plaintiffs claimed that they developed neurological disorders after taking metoclopramide, a generic drug approved through the ANDA process, and that their injuries were caused by metoclopramide's manufacturers failure to "provide adequate warning labels."<sup>95</sup> The metoclopramide manufacturers argued that the plaintiffs' claims were federally preempted through implied conflict preemption.<sup>96</sup>

Under the state laws applicable to the plaintiffs' claims, drug manufacturers are required to provide labels that render a drug "reasonably safe."<sup>97</sup> The Supreme Court reasoned that the state laws requiring all drug manufacturers, including those of generic drugs, to modify their drug labels to make those labels safer conflicted directly with generic drug manufacturer's federal obligations to ensure that generic drug label are the same as the labels on corresponding brand-name drugs.<sup>98</sup> Therefore, the Court held that the plaintiffs' state law claims were federally preempted via implied conflict preemption.<sup>99</sup>

Thus, the Supreme Court's reasoning in *Wyeth* and *PLIVA* indicates that based on the language of the FDCA individuals *may* assert failure to warn claims against brand name

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<sup>92</sup> *Id.* at 577–78.

<sup>93</sup> *Id.* at 581.

<sup>94</sup> *PLIVA*, 131 S.Ct. at 2574.

<sup>95</sup> *Id.* at 2572.

<sup>96</sup> *Id.* at 2573.

<sup>97</sup> *Id.* at 2570.

<sup>98</sup> *Id.* at 2578.

<sup>99</sup> *Id.* at 2581.

pharmaceutical manufacturers, but *may not* assert the same claim against generic drug manufacturers.<sup>100</sup> In his concurrence to the *PLIVA* opinion, Justice Thomas noted, “Congress and the FDA retain the authority to change the law and regulations if they so desire.”<sup>101</sup> Subsequent to the Court’s *PLIVA* opinion, identical bills were introduced in both the United States Senate and the United States House of Representatives on April 18, 2012 that would allow generic drug manufacturers to modify drug labels using the CBE process by adding “the holder of an approved application under this subsection [(ANDA)] may change the labeling of a drug so approved in the same manner authorized by regulation for the holder of an approved new drug application under subsection (b)” and “[i]n the event of a labeling change made under subparagraph (A), the Secretary may order conforming changes to the labeling of the equivalent listed drug and each drug approved under this subsection that corresponds to such listed drug” to 21 U.S.C. § 355(j).<sup>102</sup> If passed, either bill would allow generic drug manufacturers to change the warning labels on drugs through the same CBE process currently applicable to brand name drug manufacturers.<sup>103</sup> Additionally, either bill’s passage would overrule the Court’s holding in *PLIVA* by allowing individuals to assert state law failure to warn claims against both brand name *and* generic pharmaceutical manufactures who failed to sufficiently update drug safety labels. Figure 1 below summarizes the Supreme Court’s preemption precedent in state law failure to warn cases involving drugs and medical devices.

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<sup>100</sup> See *supra* Parts III.B.iii and III.B.iv.

<sup>101</sup> *PLIVA*, 131 S.Ct. at 2582 (Thomas, J., concurring).

<sup>102</sup> Patient Safety and Generic Labeling Improvement Act, S. 2295, 112 Cong. (2nd Sess. 2012) (as referred to Comm. on Health, Educ., Labor, and Pensions); Patient Safety and Drug Labeling Improvement Act, H.R. 4384, 112 Cong. (2nd Sess. 2012) (as referred to House Comm. on Energy and Commerce, Apr. 18, 2012) (as referred to Subcomm. on Health, Apr. 20, 2012).



**Figure 1: Supreme Court Federal Preemption Precedent Regarding Failure to Warn**

Case	Industry/Market Entry	Express/Implied Preemption	Outcome
<i>Medtronic, Inc. v. Lohr</i>	Medical Device/§ 510(k)	Express	No Preemption – where state law claims parallel federal requirements
<i>Riegel v. Medtronic, Inc.</i>	Medical Device/PMA	Express	Express Preemption
<i>Wyeth v. Levine</i>	Brand Name Pharmaceutical/NDA	Implied	No Obstacle or Conflict Preemption
<i>PLIVA, Inc. v. Mensing</i>	Generic Pharmaceutical/ANDA	Implied	Conflict Preemption

#### IV. FEDERAL PREEMPTION – FRAUD ON THE FDA CAUSES OF ACTION AND STATE STATUTES

In addition to considering state failure to warn claims in the drug and medical device context, the Supreme Court has additionally considered whether another distinct cause of action was preempted in the medical devices context. In *Buckman*, the Supreme Court addressed whether “fraud-on-the-FDA” claims were preempted by the FDCA.<sup>104</sup> The following section describes the Supreme Court’s reasoning in *Buckman*, current state fraud-on-the-FDA statutes that exist to provide liability protection to pharmaceutical companies in failure to warn cases, and the current circuit split that exists over whether the Supreme Court’s reasoning in *Buckman* should be extended to federally preempt these statutory provisions.

##### A. *Buckman Co. v. Plaintiff’s Legal Committee*

In *Buckman*, the plaintiffs filed a claim alleging a violation of state tort law against a consulting company affiliated with the manufacturer of orthopedic bone screws, which were classified as Class III medical devices that had been approved through the § 510(k) process.<sup>105</sup> Specifically, the plaintiffs claimed that the defendant, “made fraudulent representations to the . . . FDA . . . in the course of obtaining approval to market the screws.”<sup>106</sup> Additionally, the

<sup>104</sup> *Buckman*, 531 U.S. at 343.

<sup>105</sup> *Id.* at 343, 346 (quoting *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817, 820 (3d Cir. 1998)).

<sup>106</sup> *Id.* at 343.

plaintiffs claimed that the fraudulent representations caused their alleged injuries.<sup>107</sup> Thus, “[h]ad the representations not been made, the FDA would not have approved the devices, and the plaintiffs would not have been injured.”<sup>108</sup> The Court considered whether the plaintiffs’ fraud-on-the-FDA claims were preempted by the FDCA.<sup>109</sup>

The Supreme Court reasoned that the “presumption against preemption”<sup>110</sup> that generally arises in cases dealing with matters of health and safety did not exist in *Buckman* because the claim’s asserted . . . “involved the relationship between a federal agency and the entity it regulates.”<sup>111</sup> Such relationships are “inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law.”<sup>112</sup> The Court noted that “the federal statutory scheme amply empowers the FDA to punish and deter fraud against the . . . [FDA,] . . . and this authority is used by the . . . [FDA] to achieve a somewhat delicate balance of statutory objectives.”<sup>113</sup> As a result of this federal scheme and the FDA’s authority, the “balance sought by the . . . [FDA] . . . can be skewed by allowing fraud-on-the-FDA claims under state tort law.”<sup>114</sup>

The Court noted that allowing state fraud-on-the-FDA claims would “dramatically increase the burdens facing potential applicants,” who would be subject to liability under both the FDCA and each individual state’s laws.<sup>115</sup> As a result of allowing such claims, potential “applicants may be discouraged from seeking § 510(k) approval<sup>116</sup> of devices with potentially

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<sup>107</sup> *Id.*

<sup>108</sup> *Id.*

<sup>109</sup> *Id.*

<sup>110</sup> *Buckman*, 531 U.S. at 348.

<sup>111</sup> *Id.* at 347.

<sup>112</sup> *Id.*

<sup>113</sup> *Id.* at 348.

<sup>114</sup> *Id.*

<sup>115</sup> *Id.* at 350.

<sup>116</sup> *But see* Joyce B. Margarce & Michelle R. Schieffele, “*Is the Preemption Defense for PMA-Approved Medical Devices in Jeopardy?*” 75 DEF. COUNS. J. 12, 15 (2008) (noting that while the PMA process indicates that a medical

beneficial off-label uses for fear that such use might expose the manufacturer . . . to unpredictable civil liability.”<sup>117</sup> The Court also expressed concern that, should state law fraud-on-the-FDA claims be allowed, it could result in applicants submitting a “deluge of information” to the FDA because of “fear that their disclosures to the FDA, although deemed appropriate by the . . . [FDA could] . . . later be judged insufficient in state court.”<sup>118</sup> The § 510(k) process could be slowed as a result of the increased information.<sup>119</sup>

Additionally, the Court distinguished the claims at issue in *Buckman* from the claims addressed in *Medtronic* because in *Buckman* the claims “exist[ed] solely by virtue of the FDCA disclosure requirements,” while the claims in *Medtronic* “arose from the manufacturer’s alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements.”<sup>120</sup> The Court held that “[s]tate-fraud-on-the-FDA claims inevitably conflict with the FDA’s responsibility to police fraud consistently with the Administration’s judgment and objectives,” and therefore the plaintiff’s claims were preempted through implied conflict preemption.<sup>121</sup>

In his concurrence, Justice Stevens, joined by Justice Thomas, reasoned that if the FDA had determined prior to the litigation that the drug manufacturer had committed fraud during the course of gaining approval for the device, and the FDA had begun the process of removing the device from the market, the plaintiff’s claim would not have been preempted.<sup>122</sup> Justice Stevens reasoned further that preemption would not prohibit the plaintiffs’ claim because the “claim would not depend upon speculation as to the FDA’s behavior in a counterfactual situation but

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device has been approved by the FDA, the § 510(k) process is a clearance process not an approval process).

<sup>117</sup> *Buckman*, 531 U.S. at 350.

<sup>118</sup> *Id.* at 351.

<sup>119</sup> *Id.*

<sup>120</sup> *Id.* at 353.

<sup>121</sup> *Id.* at 348, 350.

<sup>122</sup> *Id.* at 354 (Stevens, J., concurring).

would be grounded in the agency’s explicit actions.”<sup>123</sup> If the FDA determined that fraud had been committed in the course of the approval process, “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.”<sup>124</sup> Under those circumstances, “state damages remedies would not encroach upon, but rather would supplement and facilitate the federal enforcement statute.”<sup>125</sup> Figure 2 below, summarizes Supreme Court drug and medical device precedent, while specifically distinguishing the claim at issue in *Buckman* from the state failure to warn claims previously considered by the Court in the context of drug and medical devices.

**Figure 2: Supreme Court Federal Preemption Precedent**

Case	Industry/Market Entry	Claim	Express/Implied Preemption	Outcome
<i>Medtronic, Inc. v. Lohr</i>	Medical Device/§ 510(k)	Failure to warn	Express	No Preemption – where state law claims parallel federal requirements
<i>Riegel v. Medtronic, Inc.</i>	Medical Device/PMA		Express	Express Preemption
<i>Wyeth v. Levine</i>	Brand Name Pharmaceutical/ NDA		Implied	No Obstacle or Conflict Preemption
<i>PLIVA, Inc. v. Mensing</i>	Generic Pharmaceutical/ANDA		Implied	Conflict Preemption
<b><i>Buckman v. Plaintiffs’ Legal Committee</i></b>	<b>Medical Device/§ 510(k)</b>	<b>Fraud-on-the-FDA</b>	<b>Implied</b>	<b>Conflict Preemption</b>

B. State Law Fraud-on-the-FDA Statutes

A number of states have passed legislation that provides different types of liability protection for drug manufacturers in state tort law cases, so long as the drug manufacturer

<sup>123</sup> *Buckman*, 531 U.S. at 354 (Stevens, J., concurring).

<sup>124</sup> *Id.* (Stevens, J., concurring).

<sup>125</sup> *Id.* (Stevens, J., concurring).

involved in the litigation followed the FDCA's requirements to obtain approval to market the drug.<sup>126</sup> In Michigan, drug manufacturers are never liable in product liability suits, provided the manufacturer met all FDCA requirements.<sup>127</sup> In some states, drug manufacturers are afforded a rebuttable presumption against liability in tort cases if a drug was approved according to FDA standards.<sup>128</sup> In some states, drug manufacturers are not liable for punitive damages in product liability cases so long as the manufacturer adhered to the FDCA's requirements.<sup>129</sup> Yet, in other states, liability protection for drug manufacturers is removed if a plaintiff can provide evidence that the manufacturer made misrepresentations to the FDA in the course of gaining approval for the drug involved in the litigation.<sup>130</sup>

A disagreement currently exists among the federal circuits regarding whether the provisions of those statutes that remove liability protection when a plaintiff can provide evidence that a pharmaceutical company made misrepresentations to the FDA during the application process should be federally preempted.<sup>131</sup> Case law in the lower federal courts, as well as state courts, continues to emerge on both sides of the preemption issue regarding whether these "fraud-on-the-FDA" statutory provisions should be federally preempted by the FDCA.<sup>132</sup> Thus

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<sup>126</sup> See *infra* notes 127–30.

<sup>127</sup> MICH. COMP. LAWS. ANN. § 600.2946(5) (1995).

<sup>128</sup> KY. REV. STAT. ANN. § 411.310(2) (1978); KAN. STAT. ANN. § 60–3304(a) (1981); N.J. STAT. ANN. § 2A:58C–4 (West 1987); COLO. REV. STAT. § 13–21–403(1)(b) (2003); TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(a) (2003); TENN. CODE ANN. § 29–28–104(a) (2011); UTAH CODE ANN. § 78B–6–703 (West 2008).

<sup>129</sup> N.J. Stat. Ann. § 2A:58C–5(c) (West 1987); OR. REV. STAT. § 30.927(1) (1987); OHIO REV. CODE ANN. § 2307.80(C)(1)(1988); ARIZ. REV. STA. ANN. § 12–701(a) (1989); UTAH CODE ANN. § 78B–8–203(1) (2008); N.D. CENT. CODE § 32–03.2–11(6) (2009); COLO. REV. STAT. § 13–64–302.5(5)(a) (2010); TENN. CODE ANN. § 29–39–104(d)(1) (2012).

<sup>130</sup> N.J. Stat. Ann. § 2A:58C–5(c) (West 1987); OHIO REV. CODE ANN. § 2307.80(C)(2)(1988); ARIZ. REV. STA. ANN. § 12–701(b) (1989); MICH. COMP. LAWS. ANN. §§ 600.2946(5)(a)–(b) (1995); TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(b) (2003); UTAH CODE ANN. § 78B–6–703(2) (West 2008); N.D. CENT. CODE § 32–03.2–11(7) (2009); TENN. CODE ANN. § 29–39–104(d)(2) (2012).

<sup>131</sup> See *supra* note 5.

<sup>132</sup> See *Zimmerman v. Novartis Pharm. Corp.*, No. RWT 08cv2089, 2012 WL 3848545, at \*16 (D. Md. Sept. 5, 2012) (holding that N.J. Stat. Ann. § 2A:58C–5(c) was federally preempted); see also *Murthy v. Abbott Labs.*, 847 F.Supp.2d 958 (S.D. Tex. 2012) (holding that TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(b) was federally preempted); see also *Forman v. Novartis Pharm. Corp.*, 793 F.Supp.2d 598, 599 (E.D.N.Y. 2011) (holding that N.J.

far, three Circuit Courts of Appeal have considered the issue.<sup>133</sup> The Second and Sixth Circuits created a split regarding the issue of preemption of Michigan’s “fraud-on-the-FDA” statutory provision exception.<sup>134</sup> The split was deepened this year when the Fifth Circuit considered a similar provision of a Texas statute and held that it was preempted by the FDCA.<sup>135</sup> Unless and until the Supreme Court issues an opinion on the issue, increased litigation and disagreement among the circuits regarding the proper interpretation of these statutes is likely.

i. *Garcia v. Wyeth-Ayerst Laboratories*: Sixth Circuit Finds Federal Preemption

In *Garcia v. Wyeth-Ayerst Laboratories*, the Sixth Circuit considered whether MICH. COMP. LAWS. §§ 600.29469(5)(a) or (b) were federally preempted, and if so, whether the “preemption . . . require[d] . . . [the court] . . . to invalidate § 600.29469(5) in its entirety”<sup>136</sup> or if the preempted portions of the statute were severable from the remainder of the statute.<sup>137</sup> The Michigan statute considered by the Sixth Circuit states in pertinent part:

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 [F]ood and [D]rug [A]dministration’s approval at the time the drug left the control of the manufacturer or seller.<sup>138</sup>

The immunity afforded to drug manufacturers under § 600.29469(5) is subject to several

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Stat. Ann. § 2A:58C–5(c) was not federally preempted); *see also* *Yocham v. Novartis Pharm. Corp.*, 736 F.Supp.2d 875, 889 (D.N.J. 2010) (holding TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(b) was not federally preempted); *see also* *Henderson v. Merck & Co.*, No. 04–CV–05987–LDD, 2005 WL 2600220 (E.D. Pa. Oct. 11, 2005) (holding that MICH. COMP. LAWS. ANN. §§ 600.2946(5)(a)–(b) were federally preempted); *see also* *Kobar v. Novartis Corp.*, 378 F.Supp.2d 1166, 1177 (D. Ariz 2005) (holding that ARIZ. REV. STA. ANN. § 12–701(b) was federally preempted); *see also* *McDarby v. Merck & Co.*, 401 N.J.Super 10, 99 (N.J. Super. Ct. App. Div. 2008) (holding that N.J. Stat. Ann. § 2A:58C–5(c) was federally preempted).

<sup>133</sup> *See supra* note 5 and accompanying text.

<sup>134</sup> *Compare Garcia*, 385 F.3d at 966, *with Desiano*, 467 F.3d at 97.

<sup>135</sup> *Lofton*, 672 F.3d at 380.

<sup>136</sup> *Garcia*, 385 F.3d at 966.

<sup>137</sup> *Id.* at 963.

<sup>138</sup> MICH. COMP. LAWS. ANN. § 600.2946(5) (1995).

exceptions.<sup>139</sup> Drug manufacturers are not provided immunity if a plaintiff can provide evidence that a defendant drug manufacturer:

Intentionally [withheld] from or misrepresent[ed] to the United States [F]ood and [D]rug [A]dministration information concerning the drug that is required to be submitted under the federal [F]ood, [D]rug, and [C]osmetic act . . . and the drug would not have been approved, or the [FDA] . . . would have withdrawn approval for the drug if the information was accurately submitted.<sup>140</sup>

Additionally, drug manufacturers are not provided immunity under § 600.29469(5)(a) if a plaintiff can provide evidence that in the process of obtaining FDA approval to market a drug, the defendant drug manufacturer made “an illegal payment to an official or employee of the . . . [FDA] . . . for the purpose of securing or maintaining approval of the drug.”<sup>141</sup>

In *Garcia*, the plaintiff filed a state tort law claim in federal court against the manufacturer of the prescription drug Duract.<sup>142</sup> The plaintiff alleged that Duract’s manufacturer had manufactured and sold an unsafe drug, and that the manufacture and sale of the drug caused the plaintiff to suffer from liver failure and require liver transplant.<sup>143</sup> The plaintiff “argued . . . that Section 600.2945(5) conflicts and is 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.”<sup>144</sup> The district court agreed with the plaintiff that § 600.2945(5) was preempted by federal law, but also held that the preempted portion of the statute could be severed from the remainder of the Michigan statute, thereby maintaining the drug manufacturer’s statutory immunity.<sup>145</sup>

On appeal, the Sixth Circuit agreed with the district court’s reasoning that “in analyzing implied preemption, a court must begin with the assumption that a state law *is* valid and should

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<sup>139</sup> See MICH. COMP. LAWS. ANN. § 600.2946(5)(a), (b) (1995).

<sup>140</sup> MICH. COMP. LAWS. ANN. § 600.2946(5)(a) (1995).

<sup>141</sup> MICH. COMP. LAWS. ANN. § 600.2946(5)(b) (1995).

<sup>142</sup> *Garcia*, 385 F.3d at 963.

<sup>143</sup> *Id.*

<sup>144</sup> *Id.* at 965.

<sup>145</sup> *Id.*

be reluctant to resort to the Supremacy Clause.”<sup>146</sup> The Sixth Circuit noted that in *Buckman* the Supreme Court held that “[s]tate law fraud-on-the-FDA claims inevitably conflict with the FDA’s responsibility to police fraud consistently with the Agency’s judgment and objectives.”<sup>147</sup> The Sixth Circuit asserted that the plaintiff’s claim in *Garcia* differed from the claim considered in *Buckman* because § 600.29469(5) was not a specific cause of action alleging fraud-on-the-FDA. Nevertheless, the Sixth Circuit found this difference “immaterial” and agreed with the district court’s reasoning that “*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims.”<sup>148</sup>

The Sixth Circuit opined further however, that “it makes abundant sense to allow a State that chooses to incorporate a federal standard into its law of torts to allow that standard to apply when the federal agency *itself* determines fraud marred the regulatory-approval process.”<sup>149</sup> Thus, the Sixth Circuit held that § 600.29469(5)(a) and (b) are impliedly federally preempted unless the plaintiff can provide evidence that the FDA itself has found that a drug manufacturer engaged in bribery or fraud-on-the-FDA in the course of obtaining approval for a drug.”<sup>150</sup>

Additionally, the Sixth Circuit held that while §§ 600.2946(5)(a) and (b) are federally preempted under certain circumstances, these portions of Michigan’s statute were severable from the remainder of § 600.2946(5).<sup>151</sup> Consequently, if a court holds that a portion of a statute is unconstitutional it can be severable from the rest of the statute “unless such construction would be inconsistent with the manifest intent of the legislature.”<sup>152</sup> The Sixth Circuit reasoned that “it

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<sup>146</sup> *Id.* (emphasis added) (internal quotation marks omitted).

<sup>147</sup> *Id.* (quoting *Buckman*, 531 U.S. at 350) (internal quotation marks omitted).

<sup>148</sup> *Garcia*, 385 F.3d at 965 (quoting *Garcia v. Wyeth–Ayerst Labs*, 265 F.Supp.2d 825 (E.D. Mich. 2003)) (internal quotation marks omitted).

<sup>149</sup> *Id.* at 966 (emphasis added).

<sup>150</sup> *Id.*

<sup>151</sup> *Id.*

<sup>152</sup> *Id.* (quoting MICH. COMP. LAWS. ANN. § 8.5 (2012)) (“If any portion of an act . . . shall be found to be invalid by a court, such invalidity shall not affect the remaining portions . . . of the act.”).



appears that the Michigan legislature was concerned that unlimited liability for drug manufacturers would threaten the viability of many enterprises and could add substantially to the cost and unavailability of many drugs.”<sup>153</sup> Additionally, “severing the preemption exceptions . . . [would] . . . not give license to drug manufacturers to use bribery or fraud as a means of obtaining FDA approval . . . [but] . . . would merely place responsibility for prosecuting bribery or fraud on the FDA in the hands of the Federal Government rather than the state courts.”<sup>154</sup> The Sixth Circuit has since affirmed its holding in *Garcia*.<sup>155</sup>

ii. *Desiano v. Warner-Lambert & Co.*: Second Circuit Finds No Federal Preemption

In *Desiano v. Warner-Lambert & Co.*, the Second Circuit considered whether MICH. COMP. LAWS. § 600.29469(5)(a) was federally preempted.<sup>156</sup> The plaintiffs in *Desiano* were Michigan residents who filed claims against the manufacturers of the type-2 diabetes drug, Resulin, in Michigan and California state courts.<sup>157</sup> The plaintiffs filed a number of claims including breach of warranty, negligence, and fraud.<sup>158</sup> The defendants, Resulin manufacturers, removed the cases to federal court and the Judicial Panel on Multidistrict Litigation consolidated the claims and transferred them to the Southern District of New York.<sup>159</sup> At the district court level the defendant’s filed a motion for judgment on the pleadings and argued that they were not liable under § 600.29469(5).<sup>160</sup> The district court held that § 600.29469(5)(a) was impliedly federally preempted and should be severed from the remainder of § 600.29469(5), “except where the plaintiff relies on a finding by the FDA, or in an action brought by the FDA, of material fraud in

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<sup>153</sup> *Id.* at 967 (citing State Fiscal Agency, Revised Bill Analysis, S.B. 344 & H.B. 4508 (Mich. 1996)).

<sup>154</sup> *Garcia*, 385 F.3d at 967.

<sup>155</sup> *See* Marsh v. Genentech Inc., Nos. 11–2373, 11–2385, 11–2419, 11–2417, 2012 WL 3854780 (6th Cir. Sept. 6, 2012); *See also*, In re Aredia & Zometa Prods. Liab. Litig., 352 F. App’x 994 (6th Cir. 2009).

<sup>156</sup> *Desiano*, 467 F.3d at 87.

<sup>157</sup> *Id.* at 88.

<sup>158</sup> *Id.*

<sup>159</sup> *Id.*

<sup>160</sup> *Id.*

the new drug approval process absent which approval would not have been granted.”<sup>161</sup>

On appeal, the Second Circuit reasoned that the plaintiff’s claim in *Desiano* differed from the claim asserted in *Buckman* in three ways.<sup>162</sup> First, a presumption against federal preemption that did not exist in *Buckman* existed in *Desiano*. The court noted that the Supreme Court has previously described that, “because the states are independent sovereigns in our federal system, . . . Congress does not cavalierly pre-empt state-law causes of action.”<sup>163</sup> In *Buckman*, the presumption against preemption did not exist because the claim being asserted involved the relationship between a federal agency and the entity that agency regulated, which the Court posited was not an area historically controlled by state law.<sup>164</sup> In *Desiano*, the Second Circuit asserted that the claim could not “reasonably be characterized as a state’s attempt to police fraud against the FDA.”<sup>165</sup> The Second Circuit reasoned that because the plaintiff’s claim involved the “Michigan state legislature’s desire to rein in state-based tort liability” it fell “squarely within . . . its [the legislature’s] . . . prerogative to regulate matters of health and safety” and the presumption against preemption applied.<sup>166</sup>

Second, the Second Circuit noted that the claims asserted in *Desiano* were based on state tort law in contrast to the fraud-on-the-FDA claims asserted in *Buckman*.<sup>167</sup> The claims asserted in *Desiano* and *Buckman* were based on two distinct sets of duties.<sup>168</sup> The claims in *Desiano* were based on “duties between a product manufacturer and a Michigan consumer,” while the claims asserted in *Buckman* were based on “a duty between a manufacturer and a federal

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<sup>161</sup> *Id.* at 88–89.

<sup>162</sup> *Desiano*, 467 F.3d. at 93.

<sup>163</sup> *Id.* (quoting *Medtronic*, 518 U.S. at 485.) (internal quotation marks omitted).

<sup>164</sup> *Id.* (quoting *Buckman*, 531 U.S. at 347) (“Policing fraud against federal agencies is hardly a field which the States have traditionally occupied.”).

<sup>165</sup> *Id.* at 94.

<sup>166</sup> *Id.*

<sup>167</sup> *Id.*

<sup>168</sup> *Desiano*, 467 F.3d at 95.

agency.”<sup>169</sup> The Second Circuit opined that finding the plaintiff’s claims preempted in *Desiano* would mean that “Congress . . . modified traditional state tort law duties between pharmaceutical companies and their consumers.”<sup>170</sup> Additionally, the Second Circuit noted that in *Buckman* proving “fraud against the FDA [was] *alone sufficient* to impose liability.”<sup>171</sup> *Desiano* was distinguishable, as *Medtronic* was from *Buckman*, because the plaintiff’s complaints (in *Desiano* and *Medtronic*) “allege[d] a wide range of putative common law duties long-recognized by Michigan’s tort regime,” and those claims were not “based *solely* on the wrong of defrauding the FDA,” as the claims in *Buckman* were.<sup>172</sup>

Finally, the Second Circuit noted that “unlike *Buckman* . . . proof of fraud against the FDA is not even an *element* of a products liability claim” asserted by the plaintiffs in *Desiano*.<sup>173</sup> In *Desiano*, “properly-obtained FDA approval becomes germane *only* if a defendant company chooses to assert an affirmative defense made available by the Michigan legislature.”<sup>174</sup> The Second Circuit reasoned that finding preemption in *Desiano* would “result in preemption of a scope that would go far beyond anything that has been applied in the past.”<sup>175</sup>

The Second Circuit concluded that § 600.29469(5)(a) was not federally preempted because the claim did not implicate the presumption against preemption, the Michigan statute did not “implicate the concerns” discussed in *Buckman*, and the plaintiff’s claim involved traditional tort law.<sup>176</sup>

### iii. *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*: Fifth Circuit Finds Federal Preemption

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<sup>169</sup> *Id.*

<sup>170</sup> *Id.* at 95.

<sup>171</sup> *Id.*

<sup>172</sup> *Id.*

<sup>173</sup> *Id.* at 96.

<sup>174</sup> *Desiano*, 467 F.3d at 96.

<sup>175</sup> *Id.*

<sup>176</sup> *Id.* at 97.

Recently, the Fifth Circuit deepened the circuit split created by the Second Circuit's *Desiano* decision. In *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, the Fifth Circuit considered whether TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(b)(1) was federally preempted.<sup>177</sup> The Texas statute considered by the Fifth Circuit states in pertinent part:

In a product liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a *rebuttable presumption* that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if: the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act...or the warnings provided were those stated in monographs developed by the United States Food and Drug Administration for pharmaceutical products that may be distributed without an approved new drug application.<sup>178</sup>

A plaintiff may rebut the presumption *inter alia* by “establishing that the defendant . . . 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 claimants injury.”<sup>179</sup>

In *Lofton*, the plaintiffs filed negligence and products liability claims against McNeil Consumer and Specialty Pharmaceuticals (“McNeil”), the manufacturer of Motrin.<sup>180</sup> The claims alleged that McNeil “had failed to warn consumers about the risk of . . . severe autoimmune allergic reactions” associated with Motrin.<sup>181</sup> McNeil raised § 82.007(a)(1) as an affirmative defense because in obtaining FDA approval for Motrin it had “complied with all

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<sup>177</sup> *Lofton*, 672 F.3d at 373.

<sup>178</sup> TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(a)(1)–(2) (West 2003) (emphasis added).

<sup>179</sup> TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(b)(1) (West 2003).

<sup>180</sup> *Lofton*, at 373–74.

<sup>181</sup> *Id.*

FDA requirements governing the labels of over-the-counter ibuprofen.”<sup>182</sup> The district court concluded that “§ 82.007(b)(1), which allows plaintiffs to attempt to rebut the presumption established by § 82.007(a)(1), was federally preempted . . . including . . . where Plaintiffs ask the court to reach the conclusion opposite of that reached by the FDA, that the Defendant did not withhold information or mislead it.”<sup>183</sup>

On appeal, the Fifth Circuit reasoned that it needed to determine whether the claim at issue was more analogous to *Wyeth*, where the Supreme Court “held that state common law failure to warn claims are not preempted by FDA approval of drug labels[,]”<sup>184</sup> or *Buckman*, where the Supreme Court held “that state law fraud-on-the-FDA claims are preempted because they conflict with the FDA’s responsibility to police fraud consistently with the Administration’s judgment and objectives.”<sup>185</sup> When the Sixth Circuit decided *Garcia* and the Second Circuit decided *Desiano*, the Supreme Court had not yet issued its *Wyeth* opinion, and therefore, neither the Sixth nor Second Circuits were able to consider the Supreme Court’s reasoning that state law failure to warn claims were not always federally preempted within the context of brand name pharmaceutical labels.<sup>186</sup>

The Fifth Circuit noted that the claim at issue bore similarities to both the claim considered in *Buckman* and the claim considered in *Wyeth*.<sup>187</sup> The Fifth Circuit reasoned that the claim in *Lofton* was similar to the claim asserted in *Buckman* because fraud-on-the-FDA was required by both claims.<sup>188</sup> The court reasoned that the plaintiff’s claim in *Lofton* was similar to the claim asserted in *Wyeth* because “the tort covered by the statute is a failure to warn products liability

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<sup>182</sup> *Id.* at 374–75 (citing *Lofton v. McNeil Consumer & Pharm.*, 682 F.Supp.2d 662, 673 (N.D. Tex. 2010).

<sup>183</sup> *Id.* at 375 (quoting *Lofton*, 82 F.Supp.2d at 675) (internal quotation marks omitted).

<sup>184</sup> *Id.* at 375 (citing *Wyeth*, 555 U.S. 555).

<sup>185</sup> *Id.* (quoting *Buckman*, 531 U.S. at 350) (internal quotation marks omitted).

<sup>186</sup> *See Wyeth*, 555 U.S. at 581 (2009); *See Desiano*, 467 F.3d at 85 (2006); *See Garcia*, 385 F.3d at 961 (2004).

<sup>187</sup> *Lofton*, 672 F.3d at 376.

<sup>188</sup> *Id.* at 376–77.

claim,” as was the plaintiff’s claim in *Wyeth*.<sup>189</sup> Yet, the Fifth Circuit noted that, through *Wyeth*, the Supreme Court “preserve[d] common law state tort claims that parallel or reinforce the . . . [FDA’s] . . . efforts but *do not* involve the relationship between the federal regulator and the regulated entity.”<sup>190</sup> In fact, the relationship between the “federal regulator and the regulated entity” was “the dispositive factor *for* federal preemption in *Buckman*.”<sup>191</sup> The court concluded that not applying *Buckman* to the plaintiff’s claims in *Lofton* would be “denying that the Texas statute is what it is – a requirement to prove fraud on the FDA.”<sup>192</sup>

The Fifth Circuit continued its analysis by noting that in some preemption cases the Supreme Court “has occasionally stated that a preemption inquiry starts with the assumption that the historic police powers of the states were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”<sup>193</sup> Nevertheless, because the Supreme Court’s opinion in *PLIVA* did not discuss the presumption against preemption, the Fifth Circuit reasoned that the “value or relevance a presumption against preemption of state tort law is uncertain.”<sup>194</sup>

Regardless of the effect of the presumption against preemption, the Fifth Circuit asserted that “the primacy of the state’s police powers is not universal” and that “the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law.”<sup>195</sup> Additionally, the Fifth Circuit agreed with the Supreme Court’s conclusion that “disclosures to the FDA are uniquely federal and thus beyond the states’ traditional police power.”<sup>196</sup> The Fifth Circuit reasoned that both the plaintiff’s and the Second Circuit’s attempts to distinguish the

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<sup>189</sup> *Id.* at 377.

<sup>190</sup> *Id.* (emphasis added).

<sup>191</sup> *Id.* (emphasis added).

<sup>192</sup> *Id.*

<sup>193</sup> *Lofton*, 672 F.3d at 378 (citing *Hillsborough Cnty.*, 471 U.S. at 715) (internal quotation marks omitted).

<sup>194</sup> *Id.* (citing *PLIVA Inc.*, 131 S.Ct. at 2567).

<sup>195</sup> *Id.* at 379 (quoting *Buckman*, 531 U.S. at 347) (internal quotation marks omitted).

<sup>196</sup> *Id.* (quoting *Buckman*, 531 U.S. at 347) (internal quotation marks omitted).

plaintiff's claims as traditional state law tort claims, separate and distinct from the federally preempted claim considered in *Buckman*, were unpersuasive because the issue being considered by the court was whether the "Texas fraud-on-the-FDA exception to a presumption, is preempted."<sup>197</sup> Additionally, while the Supreme Court has held that "the Supremacy Clause to permit some parallel state law tort suits, the current case [did not] raise that issue."<sup>198</sup> The Fifth Circuit found the plaintiff's argument - that because proving fraud-on-the-FDA was a "rebuttal to a defendant's affirmative defense" and not an element of the plaintiff's claim that the statute was not federally preempted - unpersuasive.<sup>199</sup> The Fifth Circuit articulated that "where the FDA has not found fraud, the threat of imposing state liability on a drug manufacturer for defrauding the FDA intrudes on the competency of the FDA and its relationship with regulated entities."<sup>200</sup>

Thus, the Fifth Circuit concluded that the Sixth Circuit's reasoning in *Garcia* was more consistent with the Supreme Court's reasoning and holding *Buckman* than the Second Circuit's reasoning was in *Desiano* and held "§ 82.007(b)(1) is a fraud-on-the-FDA provision analogous to the claim considered in *Buckman*, . . . [and] it is preempted by the FDCA unless the FDA itself finds fraud."<sup>201</sup>

## V. ANALYSIS – RESOLVING THE CIRCUIT SPLIT

The circuit split initially created by the Sixth and Second Circuits' decisions in *Garcia* and *Desiano*, respectively, and further deepened this year by the Fifth Circuit's decision in *Lofton* requires resolution. State statutes constructed similarly to the Texas and Michigan statutes, considered at the federal appellate level, should be uniformly interpreted and provide conclusive

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<sup>197</sup> *Id.* ("the plaintiff's artful reasoning overlooks the reality of trial practice and the precise statutory language.")

<sup>198</sup> *Id.*

<sup>199</sup> *Lofton*, 672 F.3d at 380.

<sup>200</sup> *Id.*

<sup>201</sup> *Id.*

guidance to state legislatures to allow them to construct statutes that will not be federally preempted. There are three potential resolutions to this circuit split. First, the split could be resolved using the *Buckman* holding, which would result in the conclusion that state immunity exceptions are federally preempted.<sup>202</sup> Second, the split could be resolved using Justice Steven’s concurrence in *Buckman*, which is the opinion advocated by the Second and Fifth Circuits.<sup>203</sup> Under this reasoning, state law immunity exceptions are preempted unless the FDA has itself found fraud. The third solution involves determining that *Buckman* does not apply to state immunity exception statutes because the claims at issue are traditional state law tort claims, and therefore, are not federally preempted. This is the position advocated by the Second Circuit in *Desiano*.<sup>204</sup>

Applying the Supreme Court’s rationale in *Buckman* is the best resolution to the circuit split because the Michigan and Texas statutes considered by the Second, Fifth, and Sixth Circuits require the plaintiff to provide evidence that a drug manufacturer made misrepresentations to the FDA, which was a part of the plaintiffs’ federally preempted claims in *Buckman*. While the Court’s holding in *Wyeth* indicated that state failure to warn claims are not necessarily federally preempted, the particular issues considered by the Second, Fifth, and Sixth Circuits were distinct from the question the Court was considering in *Wyeth*.<sup>205</sup> These cases involved the use of a state statute that implicates the relationship between drug manufacturers and the FDA, and thus, should be analyzed and considered based upon the Supreme Court’s holding in *Buckman*.

#### A. Applying *Buckman*: Federal Preemption

In *Buckman*, the Supreme Court held that state “fraud-on-the-FDA” claims are impliedly

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<sup>202</sup> See *Buckman*, 531 U.S. at 350.

<sup>203</sup> See *id.* at 354 (Stevens, J., concurring); see also *Lofton*, 672 F.3d 380, and *Garcia*, 385 F.3d at 966.

<sup>204</sup> See *Desiano*, 467 F.3d at 97.

<sup>205</sup> Compare *Wyeth*, 555 U.S. at 581, with *Lofton*, 672 F.3d at 373, and *Desiano*, 467 F.3d at 87, and *Garcia*, 385 F.3d at 966.



preempted by federal law.<sup>206</sup> The holding in *Buckman* should be expanded to federally preempt the state statutes at issue in the present circuit split. The portions of statutes at issue in this circuit split involve the relationship between the FDA and drug manufacturers. According to *Buckman*'s rationale, "the relationship between a federal agency and the entity it regulates is inherently federal in character."<sup>207</sup> Both the Sixth Circuit and Fifth Circuits noted that MICH. COMP. LAWS. § 600.29469(5)(a) and TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(b)(1) involved a state attempting to regulate the relationship between the FDA and drug manufacturers.<sup>208</sup> In *Lofton*, the court articulated that the Texas statutory provision at issue "re-treads the FDA's administrative ground both to conduct discovery and to persuade a jury."<sup>209</sup> The court noted that it is important to preserve the FDA's discretion.<sup>210</sup> Using similar rationale the United States District Court for the District of Maryland has reasoned that a New Jersey statute, similar to the Texas and Michigan statutes considered by the courts of appeals, was federally preempted because the statutory language "require[d] a fact finder to make a determination under state law that federal law leaves exclusively to the FDA."<sup>211</sup>

Indeed, the FDA has the necessary expertise and authority to exclusively police fraud by the drug manufacturers that it regulates. The FDA has exclusive authority to initiate enforcement proceeding against those drug companies that fail to comply with the FDCA and applicable regulations.<sup>212</sup> The FDA has the authority to respond to a finding of fraud by making criminal allegations,<sup>213</sup> imposing imprisonment or financial penalties,<sup>214</sup> issuing an injunction,<sup>215</sup>

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<sup>206</sup> *Buckman*, 531 U.S. at 348.

<sup>207</sup> *Id.* at 347.

<sup>208</sup> *See Lofton*, 672 F.3d at 376; *see also Garcia*, 385 F.3d at 965.

<sup>209</sup> *Lofton*, 672 F.3d at 380.

<sup>210</sup> *Id.*

<sup>211</sup> *Zimmerman*, 2012 WL at \*16.

<sup>212</sup> 21 U.S.C. § 337(a) (2012).

<sup>213</sup> 18 U.S.C. § 1001 (2006).

<sup>214</sup> 21 U.S.C. § 333 (2012).

imposing civil penalties,<sup>216</sup> and withdrawing abbreviated drug applications.<sup>217</sup> Additionally, private citizens have the ability to file a petition with the FDA, requesting that the agency take administrative action regarding any regulated entity.<sup>218</sup> Although ultimately rejected by the FDA, prior to the Fifth Circuit’s decision in *Lofton*, individuals had in fact filed a Citizen’s Petition, which alleged that Motrin manufacturers “had withheld information from the FDA” related to certain risks of taking the drug.<sup>219</sup>

A strict application of the *Buckman* holding to state law fraud-on-the-FDA statutes is not without limitations. As a result of preempting state statutes, which require plaintiffs to provide evidence of a drug manufacturer’s fraud-on-the-FDA, individuals in certain jurisdictions may be unable to bring failure to warn claims against drug manufacturers. States, however, as the primary regulators of health and safety could modify state legislation to allow failure to warn claims against drug manufacturers, which, based on the Supreme Court’s holding in *Wyeth* are not necessarily federally preempted.<sup>220</sup> Despite the lack of judicial remedies available to private citizens, resolving the split by applying *Buckman* does preserve the states’ traditional authority to regulate matters of health and safety.

B. Applying Justice Stevens’ *Buckman* Concurrence: Federal Preemption except where the FDA has found fraud

The second potential solution to resolve the circuit split is to apply Justice Stevens’ concurrence in *Buckman* to state fraud-on-the-FDA statutes.<sup>221</sup> This solution was supported by the Fifth and Sixth Circuits’ holdings in *Lofton* and *Garcia*, respectively. Under this solution, the state fraud-on-the-FDA statutes would be preempted unless the FDA has determined that a drug

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<sup>215</sup> 21 U.S.C. § 334 (2012).

<sup>216</sup> 21 U.S.C. § 335(b) (1953).

<sup>217</sup> 21 U.S.C. § 335(c) (1953).

<sup>218</sup> 21 C.F.R. § 10.30 (2000).

<sup>219</sup> *Lofton*, 672 F.3d at 373–74.

<sup>220</sup> *Wyeth*, 555 U.S. at 581.

<sup>221</sup> *Buckman*, 531 U.S. at 353–54 (Stevens, J., concurring).

manufacturer has made a fraudulent misrepresentation to the FDA.<sup>222</sup> Justice Stevens articulated that in situations where “the FDA had determined that the petitioner had committed fraud during 510(k) process and had then taken the necessary steps to remove the harm-causing product from the market” the state law claim at issue would “be grounded in the agency’s explicit actions” and “a plaintiff would be able to establish causation without second-guessing the FDA’s decisionmaking or overburdening its personnel.”<sup>223</sup> In *Garcia*, the Sixth Circuit held that the exceptions to the state statute were preempted except in cases where “claims based on federal findings of bribery or fraud on the FDA.”<sup>224</sup> Several legal scholars have supported this view.<sup>225</sup> Likewise, in *Lofton*, the Fifth Circuit reasoned that state law claims are preempted unless the FDA has found fraud.<sup>226</sup>

In addition to invoking the same concerns raised by resolving the split by strictly applying *Buckman*’s holding, the application of Justice Stevens’ *Buckman* concurrence creates an additional issue. Neither the Fifth nor the Sixth Circuit’s holdings specifically articulate the evidence a plaintiff would need to provide to demonstrate that the FDA had in fact found fraud. In *Garcia* and *Lofton*, the Fifth and Sixth Circuits attempted to rewrite state health and safety legislation rather than interpret such legislation, which is its role within the government.<sup>227</sup> Ultimately, state legislatures, if they so chose, should be left to design legislation that would not interfere with or attempt to regulate the relationship between drug manufacturers and the FDA, but would also provide redress to private citizens seeking to file failure to warn claims against

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<sup>222</sup> *Id.* at 354 (Stevens J., concurring); *Lofton*, 672 F.3d at 380; *Garcia*, 385 F.3d at 966.

<sup>223</sup> *Id.* (Stevens, J., concurring).

<sup>224</sup> *Garcia*, 385 F.3d at 966.

<sup>225</sup> See Jennifer A. Suprenant, *Should Preemption Apply in a Pharmaceutical Context? An Analysis of the Preemption Debate and what Regulatory Compliance Statutes Contribute to the Discussion*, 77 FORDHAM L. REV. 327 (2008); Catherine M. Sharkey, *The Fraud Caveat to Agency Preemption*, 102 NW. U. L. REV. 841 (2008).

<sup>226</sup> *Lofton*, 672 F.3d at 380.

<sup>227</sup> Patrick M. Garry, *The Unannounced Revolution: How the Court Has Indirectly Effected A Shift in the Separation of Powers*, 57 ALA. L. REV. 689, 694 (2006).

drug manufacturers.

### C. Applying *Desiano*: No Federal Preemption

The third potential solution to the circuit split is to find that statutes requiring plaintiffs to provide evidence that a drug manufacturer made misrepresentations to the FDA are not federally preempted. In its decision in *Desiano*, the Second Circuit advocated against preemption and for a narrow interpretation of *Buckman*.<sup>228</sup> The Second Circuit reasoned that “the presumption against preemption should apply to interpreting the Michigan statute because the claim involved an area (health/safety) that was traditionally regulated by the states, and the presumption has not been overcome.”<sup>229</sup> Additionally, the court reasoned that the Michigan statute at issue was distinct from the claim considered by the Supreme Court in *Buckman* because the plaintiff’s claim in *Desiano* was not a “stand-alone” fraud-on-the-FDA claim, but rather, a traditional state law tort claim.<sup>230</sup> Proof of fraud is not an element of the claim in the Michigan statute, like it was in the *Buckman*.<sup>231</sup>

The view that *Buckman*’s holding should be narrowly interpreted and not applied to the state law claims at issue in the circuit split has been supported by legal scholars.<sup>232</sup> Additionally, in the wake of the Supreme Court’s decision in *Wyeth*, where the Supreme Court found that federal preemption did not apply to a failure to warn claim involving brand-name pharmaceuticals, one such scholar has advocated that the circuit split should be resolved using the Second Circuit’s reasoning in *Desiano*, thus holding that such state statutes are not federally

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<sup>228</sup> *Desiano*, 467 F.3d at 98.

<sup>229</sup> *Id.* at 94.

<sup>230</sup> *Id.*

<sup>231</sup> *Id.* at 92.

<sup>232</sup> See Louis M. Bograd & Andre M. Mura, *Buckman Stops Here! Limits on Preemption of State Tort Claims Involving Allegations of Fraud on the PTO or FDA*, 41 RUTGERS L.J. 309, 334 (2009) (advocating “[w]here a plaintiff seeks to use evidence of fraud or other misconduct on an agency to support a traditional recognized state cause of action, such use should be permitted; but where a plaintiff seeks damages based on agency fraud alone, such a claim will be preempted”).

preempted.<sup>233</sup> Resolving the circuit split in this way is beneficial to plaintiffs because it increases the possibility that they will have a successful cause of action against drug manufacturers in states where statutory protection has been provided to those manufacturers in failure to warn cases. In Michigan, plaintiffs in failure to warn cases are without private rights of action against such drug companies unless Michigan's fraud-on-the-FDA statute is not federally preempted.

Resolving the circuit split using the Second Circuit's reasoning in *Desiano* would involve a number of limitations. In *Buckman*, the Supreme Court described a number of practical concerns that could arise should plaintiffs have the ability to allege that a drug manufacturer made misrepresentations to the FDA.<sup>234</sup> First, the Court had concerns that drug and medical device manufacturers would be overburdened by potential tort liability in each of the fifty states.<sup>235</sup> Additionally, manufacturers may be deterred from seeking approval for certain products because of the potential for increased liability.<sup>236</sup> Allowing these types of statutes could result in the FDA being inundated with more information than required by its approval processes, which would place increased burdens on the agency.<sup>237</sup> Both the logistical and constitutional concerns articulated by the Supreme Court in *Buckman* are applicable to the state statutes that allow plaintiffs to provide, law immunity exceptions at issue regarding the current circuit split.

## VI. CONCLUSION

After describing the power of states to experiment with their own individual laws, Justice

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<sup>233</sup> See Jason Murdey, *Preemption and the "Fraud on the FDA" Exception to Michigan's Tort Immunity Statute for Drug Manufacturers: Reconsidering Garcia and Desiano After Levine*, 66 FOOD DRUG L.J. 85 (2011) (asserting that based on the Supreme Court's ruling in *Wyeth*, *Buckman* should be read narrowly, and apply only to stand alone fraud-on-the-FDA claims).

<sup>234</sup> See *infra* text accompanying notes 235–37.

<sup>235</sup> *Buckman*, 531 U.S. at 351.

<sup>236</sup> *Id.* at 350.

<sup>237</sup> *Id.* at 351.

Brandeis stated that, “[t]his Court has the power to prevent an experiment.”<sup>238</sup> In the case of state fraud-on-the-FDA statutes, the Supreme Court should do precisely that. Since the FDA’s inception the regulation of health and safety has increasingly been governed by federal statutes and regulations. Nevertheless, the states retain the police power. In recent history, the Supreme Court has resolved a number of conflicts existing between state law and federal drug and medical device regulation. In certain circumstances, the Supreme Court has held that state laws regulating drugs and medical devices can coincide with federal laws and regulations doing the same. The circuit split created by *Garcia* and *Desiano*, and deepened by *Lofton*, requires resolution by the Supreme Court to solve a source of tension between the states and the federal government. To resolve the split, the Supreme Court’s holding in *Buckman* should be extended to all state laws involving fraud or misrepresentation to the FDA as an element. Such statutes interfere with the authority and expertise of the FDA and should be federally preempted. This resolution preserves the states’ rights to enact laws in health and safety, so long as those laws do not interfere with the FDA’s relationship with the drug and medical device manufacturers that it has the authority to regulate.

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<sup>238</sup> *New State Ice*, 285 U.S. at 387 (Brandies, J., dissenting).