

# Prescription Drug Products Liability Litigation and Punitive Damages Preemption

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In *Wyeth v. Levine*, the Supreme Court held that FDA-approval of the brand name prescription drug Phenergan did not preempt state common law claims seeking compensatory damages for injuries allegedly caused by the drug.<sup>1</sup> The holding was informed by the fact that Congress, in enacting the Food, Drug, and Cosmetic Act (“FDCA”), “did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs” and instead “[e]vidently... determined that widely available state rights of action provided appropriate relief for injured consumers.”<sup>2</sup> This reasoning—that

allegedly injured plaintiffs should have judicial recourse to compensation—has been a consistent theme in Supreme Court arguments opposing preemption of state tort claims involving FDA-approved products.<sup>3</sup>

*Levine* did not address the separate question whether a brand name prescription drug manufacturer may be subject to *punitive damages* under state law related to the marketing of an FDA-approved drug. However, the question of punitive damages preemption in prescription drug

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<sup>1</sup> 555 U.S. 555 (2009). More recently, the Supreme Court held that all product liability claims involving *generic* prescription drugs with labels identical to their brand name counterparts are preempted because of the different federal regulations governing the labeling of generic drugs. *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

<sup>2</sup> *Levine*, 555 U.S. at 574, 579 (state tort claims “serve a distinct compensatory function”); *see also* id. at 563 (rejecting *Wyeth*’s preemption argument because “state law serves a compensatory function distinct from federal regulation”).

<sup>3</sup> *See Pliva, Inc.*, 131 S. Ct. at 2592 (Sotomayor, J., dissenting) (arguing that majority’s opinion preempting state tort-law claims improperly “strips generic drug consumers of compensation when they are injured by inadequate warnings”), *reh’g denied*, 132 S. Ct. 55; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 337 (2008) (Ginsburg, J., dissenting) (arguing that the “MDA’s failure to create any federal compensatory remedy for... consumers [injured by devices] further suggests that Congress did not intend broadly to preempt state common-law suits grounded on allegations independent of FDA requirements”).

litigation has arisen post-*Levine* in the context of state tort reform statutes that bar punitive damages against FDA-compliant drug manufacturers absent evidence that the manufacturer had defrauded the FDA. In this context, most courts have followed the Supreme Court's reasoning in *Buckman v. Plaintiffs' Legal Committee*<sup>4</sup> and have held that punitive damages claims are preempted because the required showing of fraud on the FDA would impermissibly frustrate the federal statutory scheme in which the FDA is granted plenary power to police such misconduct.<sup>5</sup> While these opinions are limited on their face to the particular state statutes under which they arise, the rulings have a potential national impact, both because of: (1) choice of law rules that call for the application of a defendant manufacturer's home state law to punitive damages claims arising from injuries taking place in other states; and (2) the legal reasoning supporting the preemption holdings in some of these cases, which would apply more broadly to punitive damages awards in

prescription drug product liability litigation even in the absence of state tort reform statutes.

The broader significance of this emerging body of prescription drug punitive damages preemption case law is demonstrated in a recent opinion secured by Novartis Pharmaceutical Corporation ("NPC") in one of the cases being defended in the Aredia® and Zometa® MDL products liability litigation.<sup>6</sup> In *Zimmerman v. Novartis Pharmaceutical*, a Maryland plaintiff brought suit against NPC (headquartered in New Jersey), alleging that her doctor's prescription of the FDA-approved drugs Aredia® and Zometa® for prevention of skeletal complications associated with her metastatic breast cancer to bone had caused a jaw condition known as osteonecrosis of the jaw. Applying the Second Restatement's "significant relationship" standard, the court held that while Maryland law governed the plaintiff's claims for compensatory damages arising from her use of the drugs and injury in Maryland, New Jersey law governed the plaintiff's claim for punitive damages because the alleged defendant misconduct at issue took place in New Jersey.<sup>7</sup> The court then held that plaintiff's claim for punitive damages was preempted by a New Jersey state statute that bars punitive damages in claims involving FDA-approved drugs absent evidence that the defendants had engaged in fraud on the FDA.<sup>8</sup>

In this article, we analyze the *Zimmerman* court's reasoning in support of both the choice-of-law and preemption parts of

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<sup>4</sup> 531 U.S. 341 (2001).

<sup>5</sup> Six states—Arizona, New Jersey, North Dakota, Ohio, Oregon, and Utah—have state statutes that insulate FDA-compliant drug manufacturers from punitive damages absent evidence of fraud on the FDA. Courts in Arizona and New Jersey and have held that the fraud-on-the-FDA exceptions in those state statutes are preempted, but Utah courts are divided with respect to the Utah statute. See *Kobar v. Novartis Corp.*, 378 F. Supp.2d 1166 (D. Ariz. 2005); *McDarby v. Merck*, 949 A.2d 223 (N.J. Super. Ct. App. Div. 2008), *appeal dismissed*, 979 A.2d 766 (2009); *Pierce v. Mylan Labs., Inc.*, No. 1:10-CV-00104, 2011 WL 2650726 (D. Utah May 18, 2011) (noting split in district court opinions interpreting Utah statute). There are no published opinions addressing preemption of the fraud-on-the-FDA exceptions in the North Dakota, Ohio, or Oregon statutes.

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<sup>6</sup> See *Zimmerman v. Novartis Pharm. Corp.*, No. 8:08-cv-02089, 2012 WL 3848545 (D. Md. Sept. 5, 2012).

<sup>7</sup> *Id.* at \*1-\*6.

<sup>8</sup> *Id.* at \*6-\*16 (citing N.J. STAT. ANN. § 2A:58C-5(c)).

its ruling and then discuss what *Zimmerman* may portend for the broader application of preemption to punitive damages claims involving FDA-approved prescription drugs throughout the country.

## I. The Zimmerman Court's Punitive Damages Preemption Analysis

*Zimmerman* was originally filed in the middle district of Tennessee, where the Aredia® and Zometa® MDL is situated, and was remanded to the district court of Maryland for case-specific pretrial proceedings and trial on July 27, 2011. On December 20, 2011, NPC filed a motion to preclude punitive damages in *Zimmerman*, arguing that the plaintiff's claim for punitive damages was preempted because it was governed by New Jersey's statutory limitation on punitive damages in prescription drug product liability litigation. In opposition, the plaintiff argued that her punitive damages claims should be governed by the law of her home state, Maryland, which has no statutory protection for sellers of FDA-approved drugs. Alternatively, the plaintiff argued that if New Jersey law did apply, her claim for punitive damages arose under New Jersey state common law, not the statutory fraud on the FDA exception, and that *Wyeth v. Levine* accordingly required that NPC's preemption defense be rejected. The court held in favor of NPC on both counts, and the plaintiff's claim for punitive damages was precluded.

### A. Application of the Rule of Depeage to the Choice of Law Analysis

Mrs. Zimmerman's jaw injury arose in Maryland and was allegedly caused by her doctor's prescription and her use of Aredia® and Zometa® in Maryland. Based

upon these facts, the parties agreed that Maryland law governed the issues of liability and compensatory damages. The parties disagreed on what law applied to the plaintiff's claim for punitive damages. The plaintiff argued that the application of Maryland law to her liability and compensatory damages claim required that Maryland law also apply to her punitive damages claim. NPC argued that the court should conduct a separate "significant relationship" analysis for the issue of punitive damages and that, because the plaintiff's allegations of NPC misconduct focused on actions taken at NPC's headquarters, New Jersey law should be applied.<sup>9</sup> The court agreed with NPC.

The court first explained that "[t]he 'significant relationship' approach allows for 'depeage,' such that a court can apply different state laws to different issues in a single case – *i.e.*, liability, compensatory damages, and punitive damages."<sup>10</sup> As explained in the Restatement (Second) of Conflicts of Law § 146 (1971), under the significant relationship test, "the local law of the state where the injury occurred determines the rights and liabilities of the parties, unless, with respect to the particular issue, some other state has a more significant relationship."<sup>11</sup> Although the rule of depeage is often overlooked, NPC

<sup>9</sup> Because *Zimmerman* was filed in the Middle District of Tennessee, the court applied Tennessee's choice of law rules. Tennessee has adopted the Second Restatement's "most significant relationship" test. See *Hataway v. McKinley*, 830 S.W.2d 53, 59 (Tenn. 1992).

<sup>10</sup> *Zimmerman*, 2012 WL 3848545, at \*3.

<sup>11</sup> (emphasis added); see also *id.* § 145 cmt. d ("courts have long recognized that they are not bound to decide all issues under the local law of a single state").

has successfully relied on this rule in numerous other cases in the Aredia® and Zometa® litigation to secure a separate choice of law analysis for punitive damages claims brought by plaintiffs allegedly injured by the drugs in a number of states.<sup>12</sup>

Turning then to the choice-of-law analysis with respect to punitive damages, the court recognized that the default rule under the Second Restatement is that courts apply the “the law of the state where the injury occurred, unless some other state had a more significant relationship to the litigation.”<sup>13</sup> The court held, however, that NPC had successfully overcome this default rule on the issue of punitive damages.<sup>14</sup> The court began by analyzing the contacts that each state had to the conduct at issue in the plaintiffs’ punitive damages claim. The court explained that “the place where the injury occurred, Maryland, is ‘simply fortuitous’

with respect to punitive damages as ‘it bears little relation to the occurrence and the parties with respect to the particular issue.’”<sup>15</sup> The court found that all of the other contacts favored application of New Jersey law. The court noted that NPC’s “primary place of business is in New Jersey and the corporate decisions with respect to labeling and packaging of Aredia and Zometa took place in New Jersey.”<sup>16</sup> The court further noted that NPC’s “New Jersey business activities, including its interactions with the FDA, form the foundation of Plaintiffs’ claim for any punitive damages award.”<sup>17</sup>

The court then addressed the other elements of the “significant relationship” test relating to the relevant state interests and party expectations. The court found that these factors likewise supported the application of New Jersey law. The court explained that “New Jersey has made a policy decision on how to impose punitive damages, and has an interest in its citizens being governed by those provisions.”<sup>18</sup> The court concluded that NPC, “having its principal place of business in New Jersey, has a justified expectation of being subject to New Jersey law for punitive damages” and that “[t]he justified expectations of the Plaintiff are met as she will be compensated under [her home state’s] law.”<sup>19</sup> Further, the court found that “[t]he basic policy underlying punitive damages is to punish and deter the

<sup>12</sup> See *Brown v. Novartis Pharms. Corp.*, No. 7:08-cv-00130-FL, 2011 WL 6318987, \*4-9 (E.D.N.C. Dec. 16, 2011) (North Carolina resident plaintiff); *Talley v. Novartis Pharms. Corp.*, No. 08-cv-361-GCM, 2011 WL 2559974 (W.D.N.C. June 28, 2011) (North Carolina resident plaintiff); *Irby v. Novartis Pharms Corp.*, Nos. MID-L-1815-08, 278, 2011 WL 5835414 (N.J. Super. Ct. Nov. 18, 2011) (Virginia resident plaintiff); *Meng v. Novartis Pharms. Corp.*, Nos. L7670-07MT, L-6072-08MT; 2009 WL 4623715 (N.J. Super. Ct. Law Div. Nov. 23, 2009) (Maine and Mississippi resident plaintiffs). As noted in JOHN J. KIRCHER AND CHRISTINE M. WISEMAN, PUNITIVE DAMAGES: LAW & PRACTICE 2d. § 23.21 (2012), the American Law Institute, as part of its Complex Litigation Project, also recommended the depeceage approach for deciding which state’s law should apply to punitive damages.

<sup>13</sup> *Zimmerman*, 2012 WL 3848545, at \*4.

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

<sup>15</sup> *Id.* (citing, *inter alia*, Restatement (Second) of Conflicts of Law § 145 cmt. e (1971)).

<sup>16</sup> *Id.*

<sup>17</sup> *Id.* at \*5.

<sup>18</sup> *Id.* at \*6 (quoting *Talley*, 2011 WL 2559974, at \*4).

<sup>19</sup> *Id.*

Defendant, whose conduct occurred in New Jersey, thus the interests of the tort field are enhanced through consistent application of New Jersey law.”<sup>20</sup>

Because New Jersey had the most significant relationship to the plaintiff’s punitive damages claim, the court held that the punitive damages claim was governed by New Jersey law.

## B. Preemption Analysis

Under New Jersey law, the imposition of punitive damages in product liability actions against drug manufacturers is governed by the New Jersey Product Liability Act.<sup>21</sup> Section 2A:58C-5(c) provides that “[p]unitive damages shall not be awarded if a drug or device ... which caused the claimant’s harm was subject to premarket approval ... by the federal Food and Drug Administration ... and was approved.” This statutory protection is subject to the following exception: “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.”<sup>22</sup> The next question for the *Zimmerman* court was whether this “fraud-on-the-FDA” exception was “preempted by federal law because it requires a jury to speculate whether Novartis misrepresented material information that was required to be submitted under the FDCA and applicable regulations.”<sup>23</sup> As the court explained,

“[t]his speculation raises a preemption concern because the FDA is charged with determining whether a new drug is safe and effective enough to be sold in the United States, and with ensuring compliance with FDCA-mandated disclosure obligations in connection with new drugs.”<sup>24</sup>

In *Buckman v. Plaintiffs’ Legal Committee*,<sup>25</sup> the United States Supreme Court held that a state tort law claim premised on alleged fraud on the FDA was impliedly preempted by the FDCA because it would serve as an obstacle to the FDA’s ability to effectively police fraud against the agency pursuant to its own expert judgment and plenary authority over regulatory submissions to the agency. In *Zimmerman*, NPC argued that *Buckman* was fully applicable to the fraud-on-the-FDA exception in Section 2A:58C-5(c), and that the preemption of the only statutorily permissible basis for punitive damages against NPC required that the plaintiff’s punitive damages claim be dismissed. The plaintiff argued in response that *Buckman* only applies to stand-alone fraud-on-the-FDA claims and that her punitive damages claims was not preempted because it was premised on traditional New Jersey common law tort causes of action. In reviewing the post-*Buckman* judicial authority addressing similar fraud-on-the-FDA statutory provisions, the *Zimmerman* court found that the case law was divided, both with respect to the New Jersey statute and with respect to other statutes that provided FDA-compliant drug manufacturers with

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<sup>21</sup> N.J. STAT. § 2A:58C-5(c) (West 2012).

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

<sup>23</sup> *Zimmerman*, 2012 WL 3848545, at \*7.

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<sup>24</sup> *Id.*

<sup>25</sup> 531 U.S. 341 (2001).

broader protection against even compensatory damages awards.<sup>26</sup>

The court engaged in its own analysis of the New Jersey fraud-on-the-FDA statutory provision to determine whether it posed an obstacle to FDA's regulatory

authority over the approval of prescription drugs. The court concluded that the statutory exception did pose such an obstacle and, accordingly, held that the exception was preempted.

The court's analysis was comprised of three parts. First, the court detailed the federal government's extensive grant of authority to FDA under the FDCA to regulate the safety and efficacy of pharmaceutical drugs. Pursuant to this statutory grant of authority, the FDA not only imposes detailed requirements on drug manufacturers setting forth exactly what information must be provided to the agency as part of the drug approval process,<sup>27</sup> but the FDA also has plenary power to enforce violations of those requirements.<sup>28</sup> The court noted that "[t]he FDA enforces violations of the drug approval process, not private litigants."<sup>29</sup> Thus, "the FDCA provides FDA with a number of enforcement options ... includ[ing] *in rem* forfeiture, injunction, and even criminal prosecutions."<sup>30</sup> The court further noted that the "FDA is vested with considerable discretion in how it chooses to deploy these enforcement tools" and that "courts have found the FDA's decision not to undertake certain enforcement actions to be non-reviewable."<sup>31</sup>

Second, the court addressed whether it should apply any presumption against preemption of the New Jersey statute's

<sup>26</sup> Three federal circuit courts of appeal have analyzed statutory immunity provisions that protect drug manufacturers against any liability in prescription drug litigation absent fraud on the FDA, with two circuits concluding that the fraud-on-the-FDA exceptions were preempted and one court holding that it was not. *Compare* Lofton v. McNeil Consumer Specialty Pharms., 672 F.3d 372 (5th Cir. 2012) (fraud-on-the-FDA exception in Texas statute preempted); *Garcia v. Wyeth-Ayerst Labs*, 385 F.3d 961, 966 (6th Cir. 2004) (same; Michigan statute) *with* *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 96 (2d Cir. 2006) (fraud-on-the-FDA exception to Michigan statute not preempted). *See also* *Emerson v. Novartis Pharms. Corp.*, 446 Fed. App'x 733 (6th Cir. 2011) (holding preempted plaintiffs' claim that manufacturer was not entitled to Florida's statutory presumption that drugs were not defective because of alleged fraud on the FDA); *In re Aredia & Zometa Prods. Liab. Litig.*, 352 Fed. App'x 994 (6th Cir. 2009) (fraud-on-the-FDA exception to Michigan statute preempted even in cases of alleged post-approval fraud). In *Warner-Lambert Co., LLC v. Kent*, 552 U.S. 440 (2008), the Supreme Court was evenly divided 4-4 on this issue, with Chief Justice Roberts recused from the case. Most courts that have addressed the issue under N.J. STAT. § 2A:58C-5(c) have held that the fraud-on-the-FDA exception for prescription drug punitive damages claims in New Jersey is preempted. *See* *Cornett v. Johnson & Johnson*, 998 A.2d 543, 566 (N.J. Super. Ct. App. Div. 2010), *aff'd on other grounds*, 2012 WL 3210943 (N.J. 2012); *McDarby*, 949 A.2d at 271-276; *Baker v. APP Pharms., LLC*, No. 09-05725, 2010 WL 4941454 (D. N.J. Nov. 30, 2010); *Stanger v. APP Pharms., LLC*, No. 09-05725, 2010 WL 4941451 (D. N.J. Nov. 30, 2010). However, one federal district court in the Second Circuit followed that court's ruling in *Desiano* and concluded that the N.J. statutory exception was not preempted. *See* *Forman v. Novartis Pharms. Corp.*, 793 F. Supp.2d 598, 608 (E.D.N.Y. 2011).

<sup>27</sup> *See Zimmerman*, 2012 WL 3848545, at \*9.

<sup>28</sup> *See id.* at \*10.

<sup>29</sup> *Id.* (citing 21 U.S.C. § 337 ("all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States").

<sup>30</sup> *Id.*

<sup>31</sup> *Id.* (citing *Heckler v. Chaney*, 470 U.S. 821, 837-838 (1985)).

fraud-on-the-FDA exception. Focusing again on the FDA's exclusive enforcement authority over the drug approval process, the court held that the presumption should not apply. The court explained that a presumption against preemption "is not triggered when the State regulates in an area where there has been a history of significant federal presence,"<sup>32</sup> and noted that the Supreme Court held in *Buckman* that there is no presumption against preemption "where a jury is asked to decide whether there has been a material fraud on the FDA during the regulatory process."<sup>33</sup> The court disagreed with other courts that nonetheless applied the presumption against preemption in the context of similar state statutory immunity provisions (on the theory that such provisions merely restrict recovery under preexisting state products liability law). The court explained that under the New Jersey statute, a plaintiff cannot recover for punitive damages unless it makes the same showing of fraud on the FDA that was the subject of the Supreme Court's no-presumption holding in *Buckman*.

Third, the *Zimmerman* court held that even if the presumption against preemption were to apply, it was rebutted "because Plaintiff's claim for punitive damages under New Jersey's statutory immunity provision poses an obstacle to the FDCA regulatory scheme and FDA enforcement prerogatives."<sup>34</sup> Citing both to *Buckman* and the Supreme Court's very recent decision in *Arizona v. United States*,<sup>35</sup> *Zimmerman*

explained that "[i]f a state claim requires a fact finder to make a determination exclusively committed by federal law to the agency, courts are likely to find this claim to be an obstacle to the purposes and objectives of a federal statute."<sup>36</sup> The court concluded that this was exactly what was required under the fraud-on-the-FDA provision of the New Jersey statute:

Simply put, Plaintiff's claim for punitive damages requires a state fact finder to determine what was required to be submitted to the FDA, whether it was submitted to the FDA, and whether the FDA would have made a different approval decision had it been provided with the correct or missing information. Plaintiff's claim thus requires a fact finder to make these types of determinations as a matter of state law even though federal law makes such determinations the exclusive province of the FDA.<sup>37</sup>

"Accordingly, Plaintiff's claim for punitive damages poses an obstacle to the objectives and purpose of the FDCA, and it is therefore preempted by the FDCA."<sup>38</sup>

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<sup>36</sup> *Zimmerman*, 2012 WL 3848545, at \*13.

<sup>37</sup> *Id.* at \*15.

<sup>38</sup> *Id.* The court also rejected the argument that the analysis in *Buckman* was inapposite because that case involved a stand-alone fraud-on-the-FDA claim whereas a New Jersey plaintiff would still need to present additional evidence of wrongdoing in support of punitive damages. The court found that the purported distinction "is meaningless because it is simply not entirely accurate. In *Buckman*, the plaintiffs not only had to prove the device maker's non-compliance with the FDCA disclosure requirements, which served as the predicate false representation in a common law fraudulent misrepresentation action, but also other common law elements of a fraudulent misrepresentation action such as injury and proximate cause." *Id.*

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<sup>32</sup> *Id.* at \*11 (citing *United States v. Locke*, 529 U.S. 89, 108 (2000)).

<sup>33</sup> *Id.*

<sup>34</sup> *Id.* at \*12.

<sup>35</sup> 132 S.Ct. 2492 (2012) (holding preempted a Arizona statute relating to unlawful aliens).

## II. Broader Implications of the Zimmerman Analysis

*Zimmerman* is one of the first cases in which a court has applied another state's statutory immunity provision for pharmaceutical manufacturers to preclude a punitive damages claim brought by a resident in the state in which the court is situated.<sup>39</sup> This fact alone makes *Zimmerman* worthy of note. But *Zimmerman*'s extensive and well-reasoned analysis of the choice of law and preemption issues posed by such a circumstance raise the possibility that the case may have implications that extend well beyond New Jersey. By correctly applying the rule of deceptage to the choice of law question, *Zimmerman* empowers New Jersey (and other states adopting similar statutory tort reform measures) to protect their FDA-compliant, domestic pharmaceutical companies from punitive damage claims not only within their state but anywhere in the country (or at least wherever the "significant relationship" conflicts-of-law rule is applied). By focusing on the fundamental principles of preemption in the context of FDA's plenary enforcement authority over the approval of prescription drugs, *Zimmerman* also sets forth a legal framework for preemption arguments against the imposition of punitive damages on FDA-compliant pharmaceutical companies even in states without statutory protections.

### A. New Jersey Product Liability Act Protects Domestic Pharmaceutical Companies From Punitive Damages Claims Brought Anywhere in the Country

The New Jersey Products Liability Act was enacted in 1987 "in order to re-balance the law 'in favor of manufacturers.'"<sup>40</sup> "The legislature intended for the Act to limit the liability of manufacturers so as to balance the interests of the public and the individual with a view towards economic reality."<sup>41</sup> "In particular, in enacting the PLA, the Legislature intended to reduce the burden on manufacturers of FDA approved products resulting from products liability litigation."<sup>42</sup> This legislative intent is reflected in the protections afforded by New Jersey Statutes Section 2A:58C-5(c) to FDA-compliant pharmaceutical corporations against the imposition of punitive damages.

New Jersey's ability to exercise its own informed judgment in regulating the in-

<sup>40</sup> *Rowe v. Hoffman-La Roche, Inc.*, 917 A.2d 767, 772 (N.J. 2007) (citation omitted).

<sup>41</sup> *Id.* (citations omitted).

<sup>42</sup> *Kendall v. Hoffman-La Roche, Inc.*, 36 A.3d 541, 554 (N.J. 2012). New Jersey has made a significant investment in building a domestic pharmaceutical industry, and is the U.S. headquarters for fifteen of the world's leading pharmaceutical companies, including Johnson & Johnson, Novartis, Merck, and Bayer HealthCare. As of the end of 2012, pharmaceutical and medical technology companies had a \$29.3 billion economic impact in New Jersey and employed more than 131,000 people in the state. See Melanie Hill, *New Jersey Pharmaceuticals Industry Writes Prescription for Growth* (Dec. 5, 2012), available at <http://businessclimate.com/new-jersey-economic-development/new-jersey-pharmaceuticals-industry-writes-prescription-growth>.

<sup>39</sup> See also *Talley*, 2011 WL 2559974.



state conduct of its pharmaceutical industry is strongly dependent on the application of New Jersey law to such conduct in connection with punitive damages claims brought by out-of-state plaintiffs. As the New Jersey Supreme Court recently noted, over a 10-year period from 1996 to 2006, “over ninety percent of mass-tort claims against New Jersey pharmaceutical companies in New Jersey courts have been brought by non-New Jersey residents.”<sup>43</sup> Presumably, the percentage of claims against New Jersey pharmaceutical companies brought by non-New Jersey residents in other states’ courts is even higher. Accordingly, greater than ninety percent of New Jersey pharmaceutical companies’ potential exposure to punitive damages arising from its in-state conduct comes in cases brought by residents of other states for injuries allegedly incurred in those states. If those plaintiffs’ punitive damages claims proceed under their home states’ laws, New Jersey’s legislative intent in adopting Section 2A:58C-5(c) will largely be thwarted, and New Jersey’s ability to set and enforce its own guidelines for in-state conduct of its domestic pharmaceutical industry will be severely curtailed.

By correctly separating the issues of compensatory and punitive damages in its deceptio conflicts of law analysis, *Zimmerman* insures that out-of-state plaintiffs will receive compensation for injuries as authorized by their home state while at the same time empowering New Jersey to regulate its pharmaceutical industry as it deems appropriate. As *Zimmerman* explains, pharmaceutical companies based in New Jersey have “a justified expectation of being subject to New Jersey law for punitive damages” and the “interests of

the tort field are enhanced through consistent application of New Jersey law” “to punish and deter” conduct in New Jersey, notwithstanding the “simply fortuitous” out-of-state location where an alleged injury might occur.<sup>44</sup> Pursuant to *Zimmerman*, New Jersey-based pharmaceutical companies are protected against the imposition of punitive damages for in-state conduct taken in compliance with FDA regulations, regardless where a legal claim is brought or where an individual plaintiff is located.

*Zimmerman*’s choice of law analysis is not limited to New Jersey or to pharmaceutical companies. A large majority of states have now adopted the Second Restatement’s “significant relationship” test,<sup>45</sup> and the rule of deceptio incorporated in that test would support the application of a defendant’s home state’s law to punitive damages claims brought by out-of-state plaintiffs based upon any manner of alleged in-state misconduct. The *Zimmerman* analysis significantly strengthens individual state legislature’s hands in setting the rules of conduct for their domestic companies (generally or for particular industry sectors), and it provides those companies with a more meaningful decision point in selecting a principal place of business and an added measure of legal protection and predictability in policing their conduct to comply with their home state’s punitive damages standards.

<sup>43</sup> *Rowe*, 917 A.2d at 771 (emphasis added).

<sup>44</sup> *Zimmerman*, 2012 WL 3848545, at \*4, \*6.

<sup>45</sup> See Symeon C. Symeonides, *Choice of Law in the American Courts in 2011: Twenty-Fifth Annual Survey*, 60 AM. J. COMP. L. 291, 308–309 (2012) (survey listing of state conflicts of law rules).

## B. *Zimmerman* is Applicable Even in the Absence of a State Immunity Statute

*Zimmerman* is expressly limited in scope to the question whether the fraud-on-the-FDA exception to the New Jersey Product Liability Act's ban on prescription drug punitive damages claims is preempted. However, the court's detailed analysis of the FDA's plenary authority to police the conduct of pharmaceutical companies in the new drug approval process raises the question whether all state law punitive damages claims against FDA-compliant drug companies should be preempted.

Punitive damages serve a fundamentally different purpose than compensatory damages. While compensatory damages "are intended to redress the concrete loss that the plaintiff has suffered by reason of the defendant's wrongful conduct," punitive damages, "which have been described as 'quasi-criminal,' operate as 'private fines' intended to punish the defendant and to deter future wrong doing."<sup>46</sup> But as *Zimmerman* correctly notes, "the FDA enforces violations of the drug approval process, not private litigants."<sup>47</sup> And the FDCA vests the FDA—not private litigants—with significant discretion in

determining when to exercise the myriad of enforcement tools at its disposal.<sup>48</sup>

The imposition of punitive damages in prescription drug liability cases almost always turns on evidence of a company's alleged improper dealings with the FDA in the drug approval process.<sup>49</sup> Because of the nature of the pharmaceuticals market, prescription drug product liability litigation does not involve direct dealings between a pharmaceutical company and an alleged injured plaintiff. Rather, under the learned intermediary doctrine, the legally relevant pathway of communication is between the pharmaceutical company and the plaintiff's prescribing physician. Under Restatement (Second) of Torts § 402A, comment k, the primary focus of a potential legal liability arising from a pharmaceutical company's communication with a prescribing physician is the drug label, which must be drafted in compliance with FDA regulations. And because of the heightened standard for punitive damages generally, plaintiffs often rely heavily on claims that the drug manufacturers acted willfully or wantonly in its dealings with the FDA so as to secure approval for the label that plaintiffs allege to be inadequate. In pursuing punitive damages, prescription drug product liability plaintiffs are asking state law juries to impose "private fines" on drug companies to punish their alleged misconduct in dealings with the FDA, notwithstanding

<sup>46</sup> *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424, 432 (2001).

<sup>47</sup> *Zimmerman*, 2012 WL 3848545, at \*10; see also *Bailey v. Johnson*, 48 F.3d 965, 967 (6th Cir. 1995) ("The language of the [FDCA] and its legislative history clearly evidence Congress' intent that it should be enforced only by the government."); *Wyeth v. Sun Pharm. Indus., Ltd.*, No. 09-11726, 2010 WL 746394, \*4 (E.D. Mich. 2010) ("it is solely the FDA's duty to investigate and prosecute allegations of misbranding or adulterating drugs") (citing cases).

<sup>48</sup> See *Chaney*, 470 U.S. at 837–838; see also *Schering Corp. v. Heckler*, 779 F.2d 683, 685–686 (D.C. Cir. 1985) (decisions by FDA whether to exercise its enforcement authority "involve a complex balancing of an agency's priorities, informed by judgments 'particularly within its expertise,' and they are therefore ill-suited for judicial review") (internal citation omitted).

<sup>49</sup> See *Zimmerman*, 2012 WL 3848545 at \*5.

the fact that the enforcement of violations of the drug approval process is the exclusive purview of the FDA. By this analysis, the vast majority of punitive damages claims in prescription drug litigation should be held preempted.<sup>50</sup>

*Levine* is not to the contrary. As noted above, *Levine* only addresses whether federal law preempts *compensatory* damage awards in prescription drug litigation. Compensatory damages do not penalize drug companies for violation of FDA regulations, they compensate plaintiffs for injuries. Because federal law does not “provide a . . . remedy for consumers harmed by unsafe or ineffective drugs,” the award of such damages under state tort law is not contrary to any power granted to FDA.<sup>51</sup> But the FDCA grants the FDA exclusive authority to enforce compliance with its new drug approval requirements. The question whether punitive damages claims are preempted thus gives rise to a fundamentally distinct preemption analysis.<sup>52</sup>

While *Levine* addresses a plaintiff’s right to seek redress for his or her own injury, “a plaintiff bringing a product liability action acts akin to a private attorney general, since any damages awarded on his punitive damages claim do not compensate him, but instead vindicate societal interests.”<sup>53</sup> As such, one of the objectives of punitive damages is to “encourage citizens to assist in the enforcement of state and federal laws.”<sup>54</sup> In connection with other statutory schemes, Congress specifically “intended punitive damages to provide incentives for citizens to act as private attorneys general to enforce the statute.”<sup>55</sup> But the idea of plaintiffs serving as “private attorneys general to enforce” the FDCA is not only nowhere contemplated in that statute, it is in direct contradiction to Congress’ decision to bestow exclusive enforcement authority on the FDA. It is this conflict between FDA’s exclusive enforcement authority and the use of punitive damages as a private enforcement tool in the hands of individual plaintiffs – which is nowhere

<sup>50</sup> See *Zimmerman*, 2012 WL 3848545, at \*13 (“[i]f a state claim requires a fact finder to make a determination exclusively committed by federal law to the agency, courts are likely to find this claim to be an obstacle to the purposes and objectives of a federal statute”) (citing *Arizona*, 132 S.Ct. at 2502–2503).

<sup>51</sup> *Levine*, 555 U.S. at 574.

<sup>52</sup> See *Arizona*, 132 S.Ct. at 2502–2503 (“Permitting the State to impose its own penalties for the federal offenses here would conflict with the careful framework Congress adopted.”); *National Meat Association v. Harris*, 132 S.Ct. 965, 972–973 (2012) (noting that express preemption savings clause provision allowing state regulation of the commercial sales activities of slaughterhouses does not save state ban on certain types of slaughterhouses from preemption because the ban “is something more than an ‘incentive’ or ‘motivator’” and acts as a command that differs

from federal regulation); *Buckman*, 531 U.S. at 347–348 (States may not impose their own punishment for fraud on the Food and Drug Administration); *Wisconsin Dept. of Industry v. Gould Inc.*, 475 U.S. 282, 288 (1986) (States may not impose their own punishment for repeat violations of the National Labor Relations Act).

<sup>53</sup> *McDarby*, 949 A.2d at 275; see also *In re School Asbestos Litigation*, 789 F.2d 996, 1003 (3rd Cir. 1986) (punitive damages “act almost as a form of criminal penalty administered by a civil court at the request of a plaintiff who serves somewhat as a private attorney general”).

<sup>54</sup> *Ogelsby v. Western Stone & Metal Corp.*, 230 F. Supp.2d 1184, 1192–1193 (D. Or. 2001).

<sup>55</sup> *Timmons v. Wal-Mart Stores, Inc.*, 33 F. Supp.2d 577, 580 (W.D. Ky. 1999) (discussing legislative history of Title VII).

at issue in *Levine* – that gives rise to preemption.<sup>56</sup>

While *Levine*, accordingly, does not address the relevant question, another Supreme Court precedent gives greater basis for pause. In *Silkwood v. Kerr-McGee*,<sup>57</sup> the Supreme Court rejected the defendant's argument that the Court should distinguish between compensatory and punitive damages in determining whether to hold preempted a punitive damages award against a federally licensed nuclear facility arising from an accidental exposure of one of the defendant's employees. In holding that the punitive damages claim was not preempted, the Court held that "punitive damages have long been a part of traditional state tort law."<sup>58</sup> The Court further held that "while the [Nuclear Regulatory Commission] is authorized to impose civil penalties on licensees when federal standards have been violated ... paying both federal fines and state-imposed punitive damages for the same incident would not appear to be physically impossible, [n]or does exposure to punitive damages frustrate any purpose of the federal regulatory scheme."<sup>59</sup> If this

reasoning was equally applicable to the FDA's authority over prescription drugs, *Levine's* holding that prescription drug compensatory damages awards are not preempted would be dispositive of punitive damages preemption as well.

*Silkwood* is distinguishable in the first instance, however, because it involves a fundamentally different regulatory scheme. "Unlike the comprehensive FDA regulatory scheme, which functions independently of any state partnership, the NRC's authority is not exclusive."<sup>60</sup> While the punitive damages claim in *Silkwood* arose from alleged misconduct in which the defendant directly exposed the plaintiff to radioactive materials on the job and at her home, a punitive damages award in a prescription drug product liability case turns instead on a proximate causation chain in which the defendant's dealings with a federal agency, the FDA, is a necessary, intermediate link. Accordingly, the interference with federal authority in policing pharmaceutical manufacturer misconduct in drug labeling is far more direct.

<sup>56</sup> Cf. *Strayhorn v. Wyeth Pharms. Co.*, Nos. 11-2058-STA-cgc, 11-2095-STA-cgc, 11-2083-STA-cgc, 11-2134-STA-cgc, 11-2060-STA-cgc, 11-2059-STA-cgc, 11-2145-STA-cgc, 2012 WL 3261377, \*10 (W.D. Tenn. Aug. 8, 2012) ("any claims in which plaintiffs attempt to enforce FDA regulations are preempted by *Buckman*, as the FDA is the only entity with power to pursue enforcement actions for violation of the FDCA").

<sup>57</sup> 464 U.S. 238 (1984).

<sup>58</sup> *Id.* at 255.

<sup>59</sup> *Id.* at 257. The Supreme Court also rejected a proposed distinction between compensatory damages and punitive damages for preemption purposes in *Exxon Shipping Company v. Baker*, 554 U.S. 471, 489 (2008), but that case involved an *express* preemption argument under the Clean

Water Act, and the Court's ruling focused on the fact that "nothing in the statutory text [of the CWA] points to fragmenting the recovery scheme this way." Exxon did not argue that the punitive damages award should be impliedly preempted based on a conflict with or frustration of federal enforcement authority under the CWA, nor would such an argument have been tenable given that the federal government had prosecuted Exxon for violations of the CWA, and Exxon had plead guilty to such violations. *Id.* at 479.

<sup>60</sup> *DOCA Co. v. Westinghouse Electric Co.*, No. 04-1951, 2011 WL 3476428, \*11 (W.D. Pa. Aug. 9, 2011) (holding that difference between NRC and FDA regulatory authority rendered *Buckman* inapposite to claims arising from fraud on the agency claims arising from NRC-regulated conduct).

*Silkwood* is also distinguishable because it was decided prior to the emergence of the Supreme Court's modern punitive damages jurisprudence, in which the Court moved away from its historical view that state law was the exclusive arbiter of punitive damages awards.<sup>61</sup> To be sure, *State Farm*, *Cooper Industries*, and *Gore* do not do away with the continuing strong state interests in punitive damages. However, the Court's new recognition of a substantive federal interest in punitive damages (while at the same time discounting any such interest in compensatory damages)<sup>62</sup> necessarily shifts the balance of federal and state interests in cases seeking punitive damages. This changes the analysis whether a state tort law punitive damages award in a prescription drug case frustrates federal interests in enforcement of FDA prescription drug regulations sufficient to give rise to implied preemption.<sup>63</sup>

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<sup>61</sup> See *State Farm Automobile Ins. Co. v. Campbell*, 538 U.S. 408, 430 (2003) (Ginsburg, J., dissenting) ("Not long ago, this Court was hesitant to impose a federal check on state-court judgments awarding punitive damages."); *BMW of North America, Inc. v. Gore*, 517 U.S. 559, 605 (1996) (Scalia, J., dissenting) (noting that the "necessary effect" of the Court's opinion "is to establish federal standards governing the hitherto exclusively state law of [punitive] damages"); see also *Cooper Industries*, 532 U.S. at 433 ("Despite the broad discretion that States possess with respect to the imposition of criminal penalties and punitive damages, the Due Process Clause of the Fourteenth Amendment to the Federal Constitution imposes substantive limits on that discretion").

<sup>62</sup> See *Cooper Industries*, 532 U.S. at 432.

<sup>63</sup> See *Farmer v. United Brotherhood of Carpenters and Joiners of America, Local 25*, 430 U.S. 290, 300 (1977) (implied frustration preemption analysis "reflect[s] a balanced inquiry into such

The question whether some or all punitive damages claims in prescription drug products liability litigation impermissibly frustrate FDA's enforcement authority is an open question, and one which, under the reasoning of *Zimmerman*, warrants close scrutiny. When plaintiffs seek punitive damages based upon alleged misconduct by a drug company in its dealings with the FDA that the FDA has not concluded were improper, those claims should be preempted.

### III. Conclusion

Pharmaceutical companies currently are subject to the risk of potentially massive punitive damages sanctions in prescription drug product liability litigation for conduct taken in full compliance with FDA regulations. In *Zimmerman*, the court laid the groundwork for significant protections for FDA-compliant companies, both by strengthening the hands of individual state legislators to establish the scope of punitive damages liability for pharmaceutical companies located in their states and by highlighting the reasons why the imposition of punitive damages for FDA-compliant conduct improvidently intrudes upon FDA's plenary enforcement authority.

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factors as the nature of the federal and state interests in regulation and the potential for interference with federal regulation").