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# BRAND NAME PREEMPTION: THE NEW FRONTIER IN PHARMACEUTICAL PRODUCT LIABILITY LITIGATION

ERIC LINDENFELD\*

## ABSTRACT

Over the past half-decade, the Supreme Court has issued a succession of opinions that have preempted all product liability claims made against the manufacturers of generic pharmaceuticals. While plaintiffs have attempted to evade these rulings through innovative legal theories, to date, they have been largely unsuccessful. As a result, lawsuits against brand name manufacturers have increased dramatically. Despite these developments, the implementation of clear preemption principles with regards to brand name products has lagged. While the Supreme Court has, on one occasion, attempted to clarify brand name preemption, the guidance was vague, cryptic and has led to a hodgepodge of conflicting judicial decisions. This confusion has led legal experts, academics, and practitioners to call upon the Court to revisit the field of brand name preemption.

This Article is an attempt to assemble, centralize, and clarify the most misunderstood areas of brand name preemption. It is also an attempt to forecast the future of some of the most uncertain areas underlying the field. It is cautioned that this Article does not attempt to offer a solution to the growing judicial inconsistencies concerning brand name preemption. Nor should this Article be read to endorse either side of the preemption debate. Rather, it is the hope of the author that the Article generate greater interest in the field of pharmaceutical product liability litigation and stimulate a deeper discussion into its ultimate fate. At the very least, the investigation conducted herein should function as a useful starting point for the academic, judge, or practitioner who has found themselves in the marsh that is brand name preemption.

## INTRODUCTION

Over the past six years, Supreme Court has displayed an increased willingness to construe the Food, Drug and Cosmetic Act (FDCA) and federal preemption principles in a manner that immunizes manufacturers of generic drugs from product liability lawsuits.<sup>1</sup> These decisions have essentially barred product liability lawsuits against

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<sup>1</sup> See *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2480 (2013); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624, 626 (2011). See generally Tony M. Diab, *Too Good to Last? Will the FDA's Proposed Rule Put an End to Generic Drug Preemption Under Mensing and Bartlett?*, 82 DEF. COUNS. J. 28 (2015); Eric Lindenfeld & Jasper L. Tran, *Beyond Preemption of Generic Drug Claims*, 45 SW. L. REV. 241, 243 (2015); Eric Lindenfeld & Jasper L. Tran, *Prescription Drugs and Design Defect Liability: Blanket Immunity*

manufacturers of generic drugs so long as they have complied with FDA approval standards.<sup>2</sup> Given that generic drugs comprise nearly 86 percent of currently filled drug prescriptions, this immunity has had rippling effects on product liability law.<sup>3</sup> Experts in the field have observed that the decisions have essentially wiped out personal injury claims involving generic drugs.<sup>4</sup> Others now predict that plaintiffs will soon cease to bring lawsuits against generic manufacturers altogether.<sup>5</sup> Defense attorneys and their experts have suggested that the average price for generic drugs has responded positively to the immunity.<sup>6</sup> In turn, attempts by plaintiffs to re-frame this price change or to avoid preemption through innovative and cutting-edge legal strategies have been met with limited success.<sup>7</sup>

Thus far, however, the development of a clear method of application of federal preemption principles to brand name drugs has lagged.<sup>8</sup> While the Supreme Court has issued some guidance in regard to brand name failure to warn claims, it has ultimately proven to be vague, unhelpful and yielding conflicting results in the courts.<sup>9</sup> Moreover, the Supreme Court has issued zero guidance with regards to brand name design defect claims.<sup>10</sup> This void in high-court precedent has led to divergent and conflicting lower

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*Approach to the Increased Costs and Unavailability of Prescription Medication*, 64 DRAKE L. REV. 111 (2016).

<sup>2</sup> See generally Arlen W. Langvardt, *Generic Pharmaceuticals and the “Unfortunate Hand” Dealt to Harmed Consumers: The Emerging State Court Resistance*, 17 MINN. J.L. SCI. & TECH. 565 (2016); Lindsey K. Peterson, *Evading Preemption: The State’s Search for Recovery for the Masses*, 9 CHARLESTON L. REV. 403 (2015); Mitchell Russell Stern, *An Adverse Reaction: FDA Regulation of Generic Drug Labeling*, 90 N.Y.U. L. REV. 2154 (2015).

<sup>3</sup> See Ann M. Thayer, *30 Years of Generics*, CHEMICAL & ENGINEERING NEWS (Sept. 29, 2014), <https://cen.acs.org/articles/92/i39/30-Years-Generics.html> [<https://perma.cc/Z4AH-C2U7>].

<sup>4</sup> See Kevin M. Zielke & Joshua H. Joseph, *The Plaintiff Bar’s Latest Attack on Generic Drug Manufacturers: How a New FDA Rule Could Dismantle Recent Legal Victories*, PHARM. COMPLIANCE MONITOR (Dec. 10, 2014), <http://www.pharmacompliancemonitor.com/plaintiff-bars-latest-attack-generic-drug-manufacturers-new-fda-rule-dismantle-recent-legal-victories/8110/> [<https://perma.cc/U5SN-QAG6>].

<sup>5</sup> See Diana J. Masters, *Mutual Pharmaceutical Co. v. Bartlett and the Demise of Recovery for Consumers of Generic Drugs*, 60 LOY. L. REV. 399, 422 (2014); Greg Ryan, *Post-Mensing Landscape a Wasteland for Plaintiffs*, LAW360 (June 25, 2012), <https://www.law360.com/articles/353077/post-mensing-landscape-a-wasteland-for-plaintiffs> [<https://perma.cc/3MYF-S5F5>].

<sup>6</sup> U.S. Gov’t Accountability Off., GAO-16-706, *Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases* 9 (2016) (claiming that the average prices for generic drugs have decreased by 14 percent since 2010).

<sup>7</sup> *Beyond Preemption of Generic Drug Claims*, *supra* note 1, at 252, 256.

<sup>8</sup> See *In re Xarelto (Rivaroxaban) Prods. Liab. Litig.*, MDL No. 2592, 2017 WL 3188456, at \*4 (E.D. La. July 21, 2017) (“The pre-emption of claims against brand-name drug manufacturers is not as clear [as generic preemption].”). See generally Erin M. Bosman & Julie Y Park, *Impossibility Preemption Possible for Brand-Name Drugs*, LAW360 (Dec. 16, 2015), <https://www.law360.com/articles/738622/impossibility-preemption-possible-for-brand-name-drugs> [<https://perma.cc/LCS8-2AZJ>].

<sup>9</sup> Richard Dean, *Guest Post – Design Defect Preemption – It’s as Simple as One, Two, Three*, DRUG & DEVICE L. (Mar. 31, 2016), <https://www.druganddevicelawblog.com/2016/03/guest-post-design-defect-preemption-its.html> [<https://perma.cc/JF2B-MBL6>]; see also *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig.*, 852 F.3d 268, 284 (3d Cir. 2017) (“[T]he number of cases applying the clear evidence standard continues to grow, yet ‘the clear evidence standard remains undefined.’”).

<sup>10</sup> See Rich Samp, *Sixth Circuit Ruling Shows Preemption Is Possible in Brand-Name Drug Design-Defect Cases*, FORBES (Dec. 28, 2015), <https://www.forbes.com/sites/wlf/2015/12/28/sixth-circuit-ruling-shows-preemption-is-possible-in-brand-name-drug-design-defect-cases/#272b51a87388> [<https://perma.cc/P27E-MJ8J>]; <https://perma.cc/FG52-GLHH>].

court decisions, convoluted legal analysis and exasperated plaintiff and defense bars.<sup>11</sup> It has also led experts to predict critical circuit splits on many of the key issues underlying brand name preemption.<sup>12</sup>

This paper proceeds in five parts. Part I briefly lays out the evolution of the preemption defense in the context of generic pharmaceuticals.<sup>13</sup> The Supreme Court decisions and litigant strategies instrumental in constructing that body of law are briefly examined.<sup>14</sup> Part II serves as an empirical analysis of the current state of brand name failure to warn claims and examines, in-depth, three of the most prominent and current legal battles in this arena.<sup>15</sup> Part III does likewise with regards to two current legal battles concerning brand name, design defect claims.<sup>16</sup> Part IV offers an analysis of preemption as it relates to over-the-counter drugs, a related and emerging area of pharmaceutical preemption.<sup>17</sup> Finally, Part V analyzes recent political developments, such as the inauguration of President Donald Trump and the confirmation of Supreme Court Justice Neil Gorsuch, and the potential impact they may have on preemption landscape.<sup>18</sup>

## I. GENERIC DRUGS – THE EVOLUTION

The doctrine of federal preemption in the context of generic pharmaceuticals has been well covered in recent scholarship.<sup>19</sup> The defense rests on the Supremacy Clause

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<sup>11</sup> See generally Jeffrey R. Pilkington & James R. Henderson, *Sidestepping Preemption: Generic Drug Litigation in the Aftermath of Mensing*, FDCC Q., Winter 2013, <https://www.dgslaw.com/images/materials/FDCC-Mensing-Pilkington-062813.pdf> [<https://perma.cc/2T2L-DJCJ>]; Derek M. Stikeleather & Brian M. Lands, *Courts Increasingly Recognize Federal Preemption of Claims Involving All FDA-Approved Medications*, FOR THE DEF., Sept. 2016, [www.gdldlaw.com/site/rte\\_uploads/files/FTD-1609-Stikeleather-Lands.pdf](http://www.gdldlaw.com/site/rte_uploads/files/FTD-1609-Stikeleather-Lands.pdf) [<https://perma.cc/A3UH-ZPTY>].

<sup>12</sup> See Adam E. Lyons, *Federal Preemption Precludes Challenge to FDA-Approved Drug*, LITIG. NEWS (Apr. 27, 2016), <http://apps.americanbar.org/litigation/litigationnews/mobile/article-preemption-fda.html> [<https://perma.cc/G9RR-P6T3>]; Frederick G. Helmsing, Jr., *Preemption of Design Defect Drug Claims Involving Brand-Name Drugs*, IN-HOUSE DEF. Q., Spring 2016, <http://www.mcdowellknight.com/wp-content/uploads/Helmsing-InHouse-Defense-Quarterly.pdf> [<https://perma.cc/3PX5-JLCP>].

<sup>13</sup> See discussion *infra* Part I.

<sup>14</sup> See discussion *infra* Part I.

<sup>15</sup> See discussion *infra* Part II.

<sup>16</sup> See discussion *infra* Part III.

<sup>17</sup> See discussion *infra* Part IV.

<sup>18</sup> See discussion *infra* Part V.

<sup>19</sup> See Marie Boyd, *Unequal Protection Under the Law: Why FDA Should Use Negotiated Rulemaking to Reform the Regulation of Generic Drugs*, 35 CARDOZO L. REV. 1525, 1527 (2014); Courtney A. Markey, *Implications of the Supreme Court's Decision in PLIVA, Inc. v. Mensing: Why Generic and Brand-Name Pharmaceuticals Must Be Treated Equally Under the Federal Food, Drug, and Cosmetic Act*, 15 MARQ. ELDER'S ADVISOR 135, 136 (2013); Diana J. Masters, *Mutual Pharmaceutical Co. v. Bartlett and the Demise of Recovery for Consumers of Generic Drugs*, 60 LOY. L. REV. 399, 422 (2014); Victor E. Schwartz, Phil Goldberg & Cary Silverman, *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects*, 81 FORDHAM L. REV. 1835, 1849 (2013); see also Jasper L. Tran & Derek Tri Tran, *(De)Regulating Neuroenhancement*, 37 U. LA VERNE L. REV. 179, 183–91 (2015) (discussing pharmaceutical enhancements); Jasper L. Tran, *Timing Matters: Prior Art's Age Infers Patent Nonobviousness*, 50 GONZ. L. REV. 189, 207–08 (2015) (discussing pharmaceutical patents). For background on patents, see generally Jasper L. Tran, *Software Patents: A One-Year Review of Alice v. CLS Bank*, 97 J. PAT. & TRADEMARK OFF. SOC'Y 532, 534–35 (2015); Jasper L. Tran, *Two Years After Alice v. CLS Bank*, 98 J. PAT. & TRADEMARK OFF. SOC'Y 354,

of the Constitution, which states that federal law “shall be the supreme law of the land.”<sup>20</sup> The Supreme Court has interpreted this clause as conferring two types of preemption, express and implied.<sup>21</sup> Because the portion of the FDCA that governs prescription drugs does not contain an express preemption clause, state tort claims can be preempted under the FDCA only if it can be demonstrated that Congress implicitly intended to preempt state law tort claims.<sup>22</sup> One of the methods this can be established is where it is impossible for a private party to comply with both state and federal law.<sup>23</sup>

*a. Generic Drugs – Failure to Warn*

FDA’s Changes Being Effected (CBE) procedure explicitly prohibits the generic manufacturer from making unilateral changes to a generic drug’s label that causes it to differ from its brand name counterpart.<sup>24</sup> This requirement has been dubbed “the duty of sameness” by courts and commentators.<sup>25</sup> Since 2011, lawyers for generic manufacturers have successfully argued that state tort law claims made against them should be preempted because manufacturers are barred by the FDCA from complying with state law tort standards through either label or drug composition changes.<sup>26</sup> The first Supreme Court case to recognize the defense in context of failure to warn claims against generic manufacturers was *PLIVA, Inc. v. Mensing*.<sup>27</sup> In *Mensing*, an injured plaintiff brought failure to warn claims against the manufacturer of the generic drug metoclopramide, alleging a permanent neurological disorder as a result of the drug.<sup>28</sup> The Court concluded that because a generic manufacturer had no ability to unilaterally alter the content of its warnings, state tort law claims based on the adequacy of its warnings were preempted.<sup>29</sup>

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358–59 (2016); Jasper L. Tran, Abstracting About “Abstract Idea,” 102 IOWA L. REV. ONLINE 60, 60–61 (2016).

<sup>20</sup> U.S. CONST. art. VI, cl. 2.

<sup>21</sup> See *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 95 (1983); *Fidelity Fed. Sav. & Loan Ass’n v. Cuesta*, 458 U.S. 141, 152–53 (1982).

<sup>22</sup> See Lesley A. Stout, Making Changes: Generic Drug Labeling and the Case Against Federal Preemption, 98 KY. L.J. 623, 630 (2010).

<sup>23</sup> *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990); *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 142–43 (1963).

<sup>24</sup> FDA regulations state that once a generic drug is approved, the manufacturer is prohibited from making any major changes to the “qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved [application].” 21 C.F.R. § 314.70(b)(2)(i) (2016).

<sup>25</sup> Danielle L. Steele, The “Duty of Sameness” As a Shield-Generic Drug Manufacturers’ Tort Liability and the Need for Label Independence After *PLIVA, Inc. v. Mensing*, 43 SETON HALL L. REV. 441 (2013); Jaime E. Moss, The Implications of the Supreme Court’s Decision Regarding Labeling and Liability of Generic Drugs, 35 T. JEFFERSON L. REV. 45, 68 (2012).

<sup>26</sup> Cassandra L. Santoro, Overdosing on Authority: Negative Side Effects of the FDA’s Proposal for Generic Label Changes May Include Increased Costs and Liabilities, 49 SUFFOLK U. L. REV. 183, 193 (2016); Matthew J. Clark, A Critical Analysis of *PLIVA, Inc. v. Mensing*, 46 IND. L. REV. 173, 200 (2013).

<sup>27</sup> *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624, 626 (2011).

<sup>28</sup> *Id.* at 608–09.

<sup>29</sup> *Id.* at 624.

### b. Generic Drugs – Design Defect

Two years later, the Supreme Court in *Mutual Pharmaceutical Co. v. Bartlett* recognized the defense in context of design defect claims.<sup>30</sup> In *Bartlett*, an injured plaintiff brought design defect claims against the manufacturer of the generic drug sulindac alleging permanent disfigurement as a result of the drug.<sup>31</sup> New Hampshire’s analysis of design defect includes the drug’s usefulness, feasibility of alternative design, and presence and efficacy of a warning.<sup>32</sup> The court determined that because generic drug manufacturers were prohibited from unilaterally altering the content or labels of a drug, the state law design defect claims made against them are preempted.<sup>33</sup> Most importantly, the Court rejected the plaintiff’s arguments that defendants could have complied with obligations under state and federal law by simply choosing to stop selling sulindac.<sup>34</sup> The Court reasoned “if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be all but meaningless.”<sup>35</sup>

### c. Generic Drugs – Sidestepping Preemption

Since the inception of *Mensing* and *Bartlett*, plaintiffs have been largely unsuccessful at utilizing strategies to sidestep the preemption principles articulated in those cases.<sup>36</sup> The most prominent of such strategies is known as “innovator liability.”<sup>37</sup> Plaintiffs proffering this theory contend that a consumer of generic drugs should be able to recover from the brand name manufacturer because it is foreseeable that prescribers of generic drugs will rely on the warning labels of its brand name counterpart.<sup>38</sup> While the strategy found initial success in a limited number of jurisdictions,<sup>39</sup> it has recently suffered a number of judicial and legislative setbacks.<sup>40</sup> Another strategy involving “parallel” federal misbranding claims has only achieved limited success.<sup>41</sup> Finally, claims that generic drug manufacturers failed to timely

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<sup>30</sup> *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2480 (2013).

<sup>31</sup> *Id.* at 2470, 2472.

<sup>32</sup> *Id.* at 2475.

<sup>33</sup> *Id.* at 2479–80.

<sup>34</sup> *Id.* at 2478.

<sup>35</sup> *Id.* at 2477.

<sup>36</sup> *Beyond Preemption of Generic Drug Claims*, *supra* note 1, at 253; Peterson, *supra* note 2, at 420.

<sup>37</sup> James Beck, *Innovator Liability*, DRUG & DEVICE L., <https://www.druganddevicelawblog.com/2016/06/breaking-news-california-supreme-court-to-consider-innovator-liability.html> [<https://perma.cc/5VDP-MXAB>]; Ashley N. Stubbs & John Dollarhide, *Alabama No Longer an Outlier State: Legislature Says “No” To Innovator Liability*, MISS. DEF. LAWS. ASS’N Q., Spring 2016, at 11.

<sup>38</sup> Beck, *supra* note 37.

<sup>39</sup> See *Colas v. Abbvie, Inc.*, No. 14 C 1452, 2014 WL 2699756, at \*1–3 (N.D. Ill. June 13, 2014); *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 670 (Ala. 2014); *Conte v. Wyeth*, 85 Cal. Rptr. 3d 299, 313 (Cal. Ct. App. 2008).

<sup>40</sup> *Coleson v. Janssen Pharm., Inc.*, No. 1:15-CV-04792-RWS, 2017 WL 1745508, at \*4 (S.D.N.Y. May 3, 2017); *In re Mirapex Prod. Liab. Litig.*, No. 07-1836 (MJD/FLN), 2016 WL 4217758, at \*5–6 (D. Minn. June 16, 2016), *report and recommendation adopted sub nom. In re Mirapex Prod. Liab. Litig. Gillette v. Boehringer Ingelheim Pharm., Inc.*, No. CV 15-3005 (MJD/FLN), 2016 WL 4203422 (D. Minn. Aug. 9, 2016), *aff’d sub nom. In re Mirapex Prod. Liab. Litig.*, 683 F. App’x 538 (8th Cir. 2017), *petition for cert. filed*, *Gillette v. Boehringer Ingelheim Pharm., Inc.* (U.S. Aug. 29, 2017) (No. 17-305), *sub nom.*; *Rafferty v. Merck & Co.*, No. 2013-04459, 2016 WL 3064255, at \*5–6 (Mass. Super. Ct. May 23, 2016).

<sup>41</sup> *Beyond Preemption of Generic Drug Claims*, *supra* note 1, at 255–56.



update their labels to match their brand name counterpart have been plagued by significant causation issues.<sup>42</sup> Given the limited success that plaintiffs' attorneys have seen in the generic arena, it is clear why lawsuits against brand name manufacturers have increased.

## II. BRAND NAME DRUGS – FAILURE TO WARN

Years prior to the holdings in *Mensing* and *Bartlett*, the Supreme Court in *Wyeth v. Levine* attempted to demarcate the preemptive scope of failure to warn claims against brand name drugs.<sup>43</sup> In *Levine*, the Court was faced with claims made against the manufacturer of the brand name drug, Phenergan, after the plaintiff was gravely injured by the intravenous use of the drug.<sup>44</sup> The plaintiff argued that the defendant manufacturer was aware of potentially devastating side effects utilizing an “IV-push” administration of the drug, and should have strengthened warnings to reflect those dangers.<sup>45</sup> The court disregarded defendant's claims of impossibility preemption, reasoning that a branded drug had the ability, under the CBE procedures, to independently add to or strengthen their warnings.<sup>46</sup> The Court ruled that absent “clear evidence” that FDA would not have approved a CBE-type labeling change, failure to warn claims against a brand name manufacturer would not be preempted.<sup>47</sup>

Since the decision in *Levine*, courts have increasingly grappled with the clear evidence legal standard.<sup>48</sup> The standard, which requires a court to determine the hypothetical answer to what FDA would have done, has confounded judges and commentators alike, and has spawned “a hodgepodge of judicial opinions that have reached varying results.”<sup>49</sup> Specifically, courts have issued inconsistent opinions with regards to whether the clear evidence standard mandates a showing that FDA previously rejected the exact warning deficiency under consideration.<sup>50</sup> Heavy debate also exists on whether the denial of a citizen petition that requests FDA mandate the label change of a specific drug, can be considered clear evidence for purposes of the

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<sup>42</sup> James M. Beck, *On Generic Plaintiffs' Preemption “Win” in New Jersey*, DRUG & DEVICE L. (Nov. 18, 2014), <https://www.druganddevicelawblog.com/2014/11/short-subjects.html#more-2205> [<https://perma.cc/9RH4-RU9Q>]; Steven J. Boranian, *Warnings Causation Sinks “Failure to Update” Claim*, LEXOLOGY (Nov. 6, 2015), <http://www.lexology.com/library/detail.aspx?g=88c9abce-6b13-4494-b677-7ae691e92255> [<https://perma.cc/TWQ5-9XPA>].

<sup>43</sup> *Wyeth v. Levine*, 555 U.S. 555, 579–81 (2009).

<sup>44</sup> *Id.* at 558–59.

<sup>45</sup> *Id.* at 560.

<sup>46</sup> *Id.* at 570–73.

<sup>47</sup> *Id.* at 570.

<sup>48</sup> See Michael M. Gallagher, *Clear Evidence of Impossibility Preemption After Wyeth v. Levine*, 51 GONZ. L. REV. 439, 440–42 (2016); Malcolm E. Wheeler, *The Case for Preemption: Why the U.S. Supreme Court and the Administration Are Wrong to Curtail Implied Conflict Preemption*, 8 IND. HEALTH L. REV. 317, 328–29 (2011).

<sup>49</sup> Diane E. Lifton & Danielle Rosen, *Seufert v. Merck and Cerveny v. Aventis: The Intersection of Science and Federal Preemption in Pharmaceutical Product Liability Litigation*, BLOOMBERG BNA, PROD. SAFETY & LIAB. REPORTER (Nov. 19, 2016), <https://www.hugheshubbard.com/index.php?p=actions/vmgHhrUtils/download/asset&id=45316> [<https://perma.cc/9MNF-D97Z>].

<sup>50</sup> See discussion *infra* Part II.A.

*Levine* preemption standard.<sup>51</sup> Finally, significant debate has recently emerged concerning whether the clear evidence standard is a question of fact for a jury, or a question of law for a judge.<sup>52</sup>

*a. FDA Previously Rejected Exact Label Change*

The majority of jurisdictions will only find the clear evidence standard satisfied in scenarios where FDA had previously rejected the exact label modification in question.<sup>53</sup> For example, in *Schedin v. Ortho-McNeil-Janssen Pharm., Inc.*, plaintiff alleged that defendant failed to warn of brand name drug Levaquin's tendon rupture risks.<sup>54</sup> Defendant pointed to correspondence from FDA that rejected the connection between tendon rupture and Levaquin as clear evidence that the warning change would have been rejected by FDA.<sup>55</sup> The court disagreed, stating that "to trigger preemption, a brand name manufacturer . . . likely must proffer evidence of the FDA's rejection of an actual label change."<sup>56</sup>

Similarly, *Gaeta v. Perrigo Pharm. Co.* involved allegations that an ibuprofen-containing product had adequate warnings of the dangers of concomitant use of the ibuprofen-containing product with other hepatotoxic products.<sup>57</sup> Defendants pointed to several instances where FDA had rejected ibuprofen-specific hepatotoxicity warnings.<sup>58</sup> The Court of Appeals disagreed, stating that FDA must have rejected a label change *specifically* warning of the risk of hepatotoxicity due to concomitant use of ibuprofen and other drugs known to be hepatotoxic.<sup>59</sup>

The Pennsylvania Superior Court has since adopted a similar line of reasoning in *Gurley v. Janssen Pharm. Inc.*<sup>60</sup> *Gurley* involved allegations that the defendant had failed to warn of the increased risk of birth defects associated with use of Topamax during pregnancy, including the risk of cleft lip.<sup>61</sup> Defendants argued for preemption, pointing to previously rejected changes by FDA to the patient package insert (PPI).<sup>62</sup> These changes would have warned of dangers associated with genitalia malformation and other birth defects in infants.<sup>63</sup> Defendants claimed that this was

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<sup>51</sup> See discussion *infra* Part II.B.

<sup>52</sup> See discussion *infra* Part II.B.

<sup>53</sup> Thomas V. Ayala & M. Elizabeth Graham, *Overcome the Clear Evidence Defense*, TRIAL, July 2016, at 34-35.

<sup>54</sup> *Schedin v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F. Supp. 2d 1125, 1129 (D. Minn. 2011), *aff'd in part, rev'd on other grounds, In re Levaquin Prod. Liab. Litig.*, 700 F.3d 1161 (8th Cir. 2012).

<sup>55</sup> *Id.* at 1132-33.

<sup>56</sup> *Id.* at 1132; see also *Schilf v. Eli Lilly & Co.*, No. CIV 07-4015, 2010 WL 3909909, at \*4 (D.S.D. Sept. 30, 2010) (finding that email from FDA "indicating that Lilly should not change the Cymbalta label until it is finally approved by the FDA is not 'clear evidence' that the FDA would have rejected attempts by Lilly to 'get the word out' in other ways").

<sup>57</sup> *Gaeta v. Perrigo Pharm. Co.*, 630 F.3d 1225, 1235-37 (9th Cir. 2011), *cert. granted, judgment vacated sub nom.*, *L. Perrigo Co. v. Gaeta*, 565 U.S. 973 (2011).

<sup>58</sup> *Id.* at 1236-37.

<sup>59</sup> *Id.* at 1237.

<sup>60</sup> *Gurley v. Janssen Pharm., Inc.*, 113 A.3d 283, 291-92 (Pa. Super. Ct. 2015).

<sup>61</sup> *Id.* at 286-87.

<sup>62</sup> *Id.* at 291.

<sup>63</sup> *Id.* at 292.

clear evidence that FDA “would have also rejected a proposed change to the Topamax label to warn that the drug caused oral clefts in humans.”<sup>64</sup> The court rejected this argument, noting that FDA’s rejection of a warning related to genitalia malformation did not demonstrate that FDA would have rejected a different warning relating to cleft lip/palate.<sup>65</sup> Most other state and federal courts continue to rule along similar lines.<sup>66</sup>

It is important to note that a minority of jurisdictions have found that FDA’s consideration and rejection of the precise label change is not critical to a preemption defense, so long as the defendant has proffered overwhelming, alternative evidence that the label change would not have been approved.<sup>67</sup> For example, the recent case of *Seufert v. Merck Sharp & Dohme Corp.* involved allegations that the defendant had failed to warn of increased risk of pancreatic cancer from use of its incretin mimetics, Onglyza and Kombiglyze.<sup>68</sup> The defendants argued that the claims were barred by conflict preemption, pointing, as clear evidence, to several comprehensive studies conducted by FDA concluding that there was no causal link between incretin mimetics and pancreatic cancer.<sup>69</sup> The California district court agreed with defendants, noting that FDA’s “repeated review of pancreatic safety, coupled with its consistent conclusion that product labeling adequately reflected the state of scientific data,” proves that if the manufacturer had asked for additional warnings of pancreatic cancer on Onglyza and Kombiglyze, FDA would have denied their request.<sup>70</sup>

Similarly, in *Dobbs v. Wyeth Pharm.*, an Oklahoma federal district court determined that while the manufacturer of the anti-depressant, Effexor, had made no attempts to add additional warnings of increased suicide risk in adults, the defendant had proffered clear evidence that a label change relating to that specific risk would have been rejected.<sup>71</sup> Factors that weighed heavily in the court’s analysis included FDA’s rejection of multiple citizen petitions requesting enhanced suicidality warnings for adult patients with similar anti-depressants.<sup>72</sup> The court also noted as dispositive

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<sup>64</sup>*Id.* at 291.

<sup>65</sup>*Id.* at 291–92.

<sup>66</sup>*See, e.g., In re Tylenol (Acetaminophen) Mktg.*, 144 F. Supp. 3d 699, 727 (E.D. Pa. 2015) (“The Supreme Court opined in dicta that a failure-to-warn claim may be preempted if a drug manufacturer submitted a CBE change and the FDA rejected it.”); *Rheinfrank v. Abbott Labs., Inc.*, 119 F. Supp. 3d 749, 770 (S.D. Ohio 2015) (ruling that FDA’s denial of two label update requests subsequent to plaintiff ingesting anti-seizure drug Depakote constituted clear evidence that FDA would have denied a proposed labeling change if confronted with a request during the time of injury), *reconsideration denied*, 137 F. Supp. 3d 1035 (S.D. Ohio 2015), and *aff’d*, No. 16-3347, 2017 WL 680349 (6th Cir. Feb. 21, 2017); *Wolfe v. McNeil–Lofton v. McNeil Consumer & Specialty Pharm.*, 682 F. Supp. 2d 662, 678 (N.D. Tex. 2010) (noting that plaintiffs’ claims that were “broader [than] the symptoms of SJS and TEN,” and thus previously denied citizen petition requesting same was not sufficient to satisfy clear evidence standard); *Forst v. SmithKline Beecham Co.*, 639 F. Supp. 2d 948, 953–54 (E.D. Wis. 2009) (finding that FDA’s approval of alternative use of drug but failure to mandate stronger warnings not clear evidence that FDA would have rejected proposed label change).

<sup>67</sup>Diane E. Lifton, *Dobbs v. Wyeth: Are We There Yet, And At What Cost?*, LAW360 (Nov. 2015), <https://www.law360.com/articles/393532/dobbs-v-wyeth-are-we-there-yet-and-at-what-cost> [<https://perma.cc/89EX-E2PM>].

<sup>68</sup>*Seufert v. Merck Sharp & Dohme Co.*, 187 F. Supp. 3d 1163, 1165–66 (S.D. Cal. 2016).

<sup>69</sup>*Id.* at 1166.

<sup>70</sup>*Id.* at 1180–81.

<sup>71</sup>*Dobbs v. Wyeth Pharm.*, 797 F. Supp. 2d 1264, 1280 (W.D. Okla. 2011).

<sup>72</sup>*Id.* at 1277, 1279.

scientific studies conducted by FDA concluding that anti-depressants caused no increased risk in suicide.<sup>73</sup> Additionally, the court noted as critical to their analysis that FDA had repeatedly denied the manufacturer's requests to add a suicidality warning for use of Effexor with children.<sup>74</sup>

*b. Citizen Petition Requesting Change*

As explained in the previous subsection, as a precondition to *Levine* preemption, most courts require a showing that the proposed labeling change was previously considered and rejected by FDA.<sup>75</sup> Amongst the majority, however, significant debate persists relating to scenarios where it was a third party, such as a citizen petition, which has requested the labeling change.<sup>76</sup> Defendants have argued that it is immaterial who submits a request for a labeling change.<sup>77</sup> Defendants contend that if it can be shown that FDA considered, and then denied a labeling change reflecting the exact risk under question, it is clear evidence that FDA would have rejected a labeling change request by the manufacturer.<sup>78</sup> In turn, plaintiffs have argued that there is a fundamental difference between FDA refusing to mandate a label change pursuant to a citizen petition and prohibiting a label change pursuant to a manufacturer's request.<sup>79</sup> The former is given less consideration by FDA, being granted less than 20 percent of the time.<sup>80</sup> The latter is given heavy consideration, and is routinely permitted.<sup>81</sup>

In the initial wake of *Levine*, most courts required a showing that the manufacturer itself, as opposed to any third party, had proposed the labeling change. For example, in *Schedin v. Ortho-McNeil-Janssen Pharm., Inc.*, discussed in the previous section, defendant also argued that a denied citizen petition satisfied the clear evidence standard of *Levine*.<sup>82</sup> The court disagreed, noting that a label change proposed by a citizen petition did not constitute clear evidence that FDA would have rejected a label

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<sup>73</sup> *Id.* at 1278.

<sup>74</sup> *Id.* at 1276.

<sup>75</sup> See discussion *supra* Part II.A.

<sup>76</sup> Erin Bosman, Julie Park & Austin Marsh, *Federal Preemption Claims: Clear Evidence and an Unclear Standard*, CLASS DISMISSED: CLASS ACTION AND PROD. INSIGHTS FOR YOUR BUS. (Mar. 30, 2016), <http://classdismissed.mofo.com/product-liability/federal-preemption-claims-clear-evidence-unclear-standard/> [<https://perma.cc/T3NC-T9DJ>].

<sup>77</sup> Michelle Yeary, *More Clear Evidence of Conflict Preemption*, DRUG & DEVICE L. (March 22, 2016), <https://www.druganddevicelawblog.com/2016/03/more-clear-evidence-of-conflict.html> [<https://perma.cc/9LG8-8KSZ>].

<sup>78</sup> *Id.*

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

<sup>80</sup> See Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 CARDOZO L. REV. 249, 282 (2012) (concluding that "the FDA has granted 19 percent of citizen petitions and has denied 81 percent. It finds that generics' petitions are more successful, with 28% granted and 72% denied, as compared to brands' petitions, of which 19 percent are granted and 81 percent denied.").

<sup>81</sup> Courts have noted that it is one thing to require a manufacturer to change the label, and whole other thing to allow it, in response to a request by a manufacturer. See *Dorsett v. Sandoz, Inc.*, 699 F. Supp. 2d 1142, 1157 (C.D. Cal. 2010) (stating that rejections of a citizen petition "constituted determinations that the warnings should not be *mandated*; they were not determinations that manufacturers could not choose to add warnings that they believed were scientifically substantiated.").

<sup>82</sup> *Schedin v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F. Supp. 2d 1125, 1133 (D. Minn. 2011), *aff'd in part, rev'd in part sub nom. In re Levaquin Prod. Liab. Litig.*, 700 F.3d 1161 (8th Cir. 2012).

change by manufacturer.<sup>83</sup> Similarly, in *Baumgardner v. Wyeth Pharm.*, defendants urged for preemption on the basis that FDA had considered and rejected several citizen petitions requesting labels containing more robust suicide warnings for the anti-depressant, Effexor.<sup>84</sup> Relying heavily upon the Supreme Court's proclamation that "the manufacturer bears responsibility for the content of its label at all times," the court concluded that a denied citizen petition simply does not demonstrate that if the label was proposed by the manufacturer, it would have been denied.<sup>85</sup>

Other jurisdictions have refused to categorically declare citizen petitions as irrelevant to their consideration of whether the defendant has satisfied the clear evidence standard.<sup>86</sup> These courts have instead chosen to focus on the precise language of the petition and FDA response.<sup>87</sup> For example, *Reckis v. Johnson & Johnson*, involved allegations that the manufacturer of Children's Motrin had failed to adequately warn of potentially life-threatening skin conditions including redness, rash, or blisters that may lead to Stevens-Johnson Syndrome (STS) or Toxic Epidermal Necrolysis (TEN).<sup>88</sup> The defendant argued for preemption, pointing to a denied citizen petition proposing similar labels.<sup>89</sup> The court concluded that while FDA had previously rejected the petition's request for explicit references to STS/TEN, it was less clear that FDA had taken a position against inclusion of "life-threatening" language.<sup>90</sup> The court thus found that any allegations related to the presence of STS/TEN on the label were preempted, but that reference to "life-threatening" conditions was not.<sup>91</sup>

Still other jurisdictions have considered previously denied citizen petitions as relevant to a determination of the clear evidence standard, but only where the denial has occurred subsequent to plaintiff's ingestion of the drug in question.<sup>92</sup> For example,

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<sup>83</sup> *Id.* at 1133 ("That the FDA did not require a label change . . . in the face of a Citizen's Petition, not supported by the manufacturer does not constitute clear evidence that the FDA would have rejected a label change proposed by [defendant].") (emphasis omitted). See also *Reckis v. Johnson & Johnson*, 28 N.E.3d 445, 459 (2015), *cert. denied*, 136 S. Ct. 896 (2016) (stating that FDA's rejection of a citizen petition "would not answer whether the FDA would have rejected the warning had it been sought by the defendants themselves").

<sup>84</sup> *Baumgardner v. Wyeth Pharm.*, No. 06-2519, 2010 WL 3431671, at \*1 (E.D. Pa. Aug. 31, 2010).

<sup>85</sup> *Id.* at \*1 ("None of this evidence proves that the FDA would have rejected relevant warnings had Wyeth, the manufacturer, proposed them. In attempting to, in effect, shift the responsibility for its labeling decisions onto the FDA, Wyeth has lost sight of the Supreme Court's statement that 'the manufacturer bears responsibility for the content of its label at all times.'").

<sup>86</sup> Rachel B. Weil, *Silence Would Have Been Golden: Unnecessary Illogical Preemption Decision in Motrin SJS/TENS Summary Judgment Victory*, DRUG & DEVICE L. (March 25, 2016), <https://www.druganddevicelawblog.com/2016/03/silence-would-have-been-golden.html> [<https://perma.cc/PDD9-GVHE>].

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

<sup>88</sup> *Reckis v. Johnson & Johnson*, 28 N.E.3d 445, 449 (Mass. 2015).

<sup>89</sup> *Id.* at 452.

<sup>90</sup> *Id.* at 459.

<sup>91</sup> *Id.*; see also *In re Testosterone Replacement Therapy Prods. Liab. Litig.* Coordinated Pretrial Proceedings, 2017 U.S. Dist. LEXIS 69402, \*999 (N.D. Ill. May 8, 2017) (ruling that the precise response to the citizen petition is critical in an analysis of whether FDA would have rejected a similar label change requested by the manufacturer). *But see* *Cerveney v. Aventis, Inc.*, 855 F.3d 1091, 1104 (10th Cir. 2017) (rejecting the premise that a citizen petition could never, on its own, support a showing of clear evidence).

<sup>92</sup> Gallagher, *supra* note 48, at 466.

in *Mason v. SmithKline Beecham Corp.*, the court was faced with allegations that the anti-depressant, Paxil, contained inadequate warnings regarding suicide.<sup>93</sup> The defendant urged for application of federal preemption, pointing to several citizen petitions requesting a label change reflecting those risks.<sup>94</sup> The Seventh Circuit implicitly conceded that a citizen petition could be helpful to the clear evidence analysis.<sup>95</sup> However, the court ultimately rejected defendant's preemption arguments, holding that the suicide at issue occurred many years after the citizen petitions were rejected, and that "[t]his temporal gap is especially important in the analysis of prescription drugs because it constantly evolves as new data emerges."<sup>96</sup> Many other courts have ruled along very similar lines.<sup>97</sup>

### *c. Clear Evidence Question for Judge or Jury*

Most recently, debate has emerged regarding whether the clear evidence standard is a question of law for a judge or question fact for the jury.<sup>98</sup> Since *Levine*, almost every federal court in the country has either explicitly stated or implicitly accepted that the clear evidence analysis presents a pure legal question of law, appropriate for consideration by a judge.<sup>99</sup> However, in March 2017, the Third Circuit in *In re Fosamax* issued an opinion that seemingly disregarded the clear federal precedent.<sup>100</sup>

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<sup>93</sup> *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 389 (7th Cir. 2010).

<sup>94</sup> *Id.* at 393, 394.

<sup>95</sup> *Id.* at 393.

<sup>96</sup> *Id.* at 395, 396.

<sup>97</sup> See, e.g., *Koho v. Forest Labs., Inc.*, 17 F. Supp. 3d 1109, 1117 (W.D. Wash. 2014) (citing *Mason* for support that the passage of time defeats the argument that rejection of citizen petition constitutes "clear evidence" under *Wyeth*); *Hunt v. McNeil Consumer Healthcare*, 6 F. Supp. 3d 694, 701 (E.D. La. 2014) (finding that "the FDA's response in 2006 to the Citizen Petition is not clear evidence the agency would have rejected in 2010 the stronger warnings plaintiff proposes"); *Dorsett v. Sandoz, Inc.*, 699 F. Supp. 2d 1142, 1157 (C.D. Cal. 2010) (concluding that FDA's rejection of a citizen petition in the 1990s was not clear evidence that FDA would have rejected the change request in 2004). *But cf.* *Cerveney v. Aventis, Inc.*, 855 F.3d 1091, 1099 (10th Cir. 2017) (finding that a denied citizen's petition requesting warnings of birth defects over fifteen years after the plaintiff had ingested the drug standing alone, is clear evidence that FDA would not have permitted the label change); *Rheinfrank v. Abbott Labs., Inc.*, 119 F. Supp. 3d 749, 766 (S.D. Ohio 2015) (finding that the clear evidence standard satisfied where a label change was sought be denied in the years following plaintiff's injury); *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig.*, 852 F.3d 268, 284 (3d Cir. 2017) (citing, with approval, the aforementioned cases, in finding that a citizen petition denial which occurred twenty years after the ingestion of a drug could constitute clear evidence that FDA would have denied the request at time of ingestion).

<sup>98</sup> See Michelle Yeary, *Third Circuit Reinterprets Wyeth v. Levine for the Worse and Finds Preemption Jury Question*, DRUG & DEVICE L. (March 28, 2017), <https://www.druganddeviceblog.com/2017/03/third-circuit-reinterprets-wyeth-v-levine-for-the-worse-and-finds-preemption-is-a-jury-question.html> [<https://perma.cc/BHA3-MXA6>].

<sup>99</sup> See, e.g., *In re Incretin-Based Therapies Prods. Liab. Litig.*, 142 F. Supp. 3d 1108, 1114 (S.D. Cal. 2015) ("preemption presents purely a question of law appropriate for resolution by summary judgment"); *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, 142 F. Supp. 3d 747, 755 (N.D. Ill. 2015) ("preemption decision is not evidence-based but is rather a question of law"); *Garza v. Wyeth LLC*, No. 2:12-CV-198, 2015 WL 364286, at \*4 (S.D. Tex. Jan. 27, 2015) (denying request for discovery and stating that the "preemption decision is not evidence-based but is rather a question of law"); *Dobbs v. Wyeth Pharm.*, 797 F. Supp. 2d 1264, 1267 (W.D. Okla. 2011) ("Where, as here, the moving party asserts entitlement to judgment because a claim is preempted by federal law, the motion presents only a legal question for the court; if the court concludes that a state law claim is preempted, summary judgment is proper as to that claim.").

<sup>100</sup> *In re Fosamax*, 852 F.3d at 288.

*In re Fosamax* involved allegations that Fosamax, a drug used to treat osteoporosis, provided inadequate warnings concerning the increased risk of femur fractures.<sup>101</sup> The New Jersey district court held that the failure to warn claims were preempted, on the grounds that FDA's previous denial of the manufacturer's request to add the risk satisfied the clear evidence standard.<sup>102</sup> In a 3-0 decision, the Third Circuit reversed, finding that the determination of what FDA would have done under the given circumstances was ultimately a question of fact to be determined by a jury.<sup>103</sup> Interestingly, the court noted the abundance of federal case law which opposed their position, but concluded that the issue had "not been thoroughly analyzed."<sup>104</sup> While the precise implications of *In re Fosamax* are not yet known, the decision highlights the inconsistent judicial approaches involving brand name preemption of failure to warn claims. The decision also adds credence to those who argue that Supreme Court elucidation of *Levine* is long overdue.

### III. BRAND NAME DRUGS – DESIGN DEFECT

As discussed, *Bartlett* and *Mensing* established a clear preemptive landscape for generic drugs with regards to both failure to warn and design defect claims.<sup>105</sup> All claims against generic manufacturers are now preempted except in narrow circumstances.<sup>106</sup> In turn, *Wyeth* attempted to establish the preemptive landscape of failure to warn claims against brand name drugs.<sup>107</sup> However, to date, no Supreme Court decisions have dealt with design defect claims relating to a brand name drugs.<sup>108</sup> Defending against these claims, manufacturers have increasingly argued that, like the manufacturer of the generic drug in *Bartlett*, brand name drugs are barred from unilaterally altering the composition of the drug.<sup>109</sup> Therefore, these defendants contend, all design defect claims made against them should be preempted.<sup>110</sup> In turn, plaintiffs have put forth a number of legal theories in support of their contention that these claims should not be preempted.<sup>111</sup>

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<sup>101</sup>*Id.* at 271.

<sup>102</sup>*Id.*

<sup>103</sup>*Id.* at 293.

<sup>104</sup>*Id.* at 287.

<sup>105</sup>See discussion *supra* Part I.A–B.

<sup>106</sup>See discussion *supra* Part I.C.

<sup>107</sup>See discussion *supra* Part II.

<sup>108</sup>Stikeleather, *supra* note 11, at 53.

<sup>109</sup>Defendants usually begin their analysis with the quote from *Mutual Pharmaceuticals Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013) which states, "[o]nce a drug—whether generic or brand name—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'"

<sup>110</sup>See *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 296 (6th Cir. 2015); *Brazil v. Janssen Research & Dev. LLC*, No. 4:15-CV-0204-HLM, 2016 WL 4844442, at \*14 (N.D. Ga. Mar. 24, 2016).

<sup>111</sup>See discussion *infra* Part III.A–C.

a. “Pre-Approval” Design Defect Preemption Avoidance

In the initial wake of *Bartlett*, plaintiffs were successful in sidestepping preemption by arguing that brand name design defect claims, and the associated duties to design the safest product, should be assessed *prior* to FDA approval as opposed to *after* FDA approval.<sup>112</sup> Therefore, these plaintiffs posit, defendant’s state law duties to design a reasonably safe drug are not barred by content changes restrictions of the FDCA.<sup>113</sup> In 2014, the Wisconsin federal court in *Estate of Cassel v. Alza Corp.* became the first court, post-*Mensing*, to issue a decision accepting this line of reasoning.<sup>114</sup>

In *Cassel*, defendants argued that design defect claims relating to brand name transdermal fentanyl patch were preempted because they were restricted from making unilateral changes to the biochemistry of the drug.<sup>115</sup> The court rejected this argument, reasoning that the argument would only have merit “if defendants’ tort lies solely in failing to redesign the patch *after* FDA approval.”<sup>116</sup> Instead, the court determined that the defendants “had a duty to employ an alternative design . . . *before* FDA approval.”<sup>117</sup> The court thus rejected the defendant’s preemption argument.<sup>118</sup>

A New York district court in *Sullivan v. Aventis, Inc.* relied heavily upon *Cassel* in rejecting defendant’s arguments for preemption.<sup>119</sup> *Sullivan* involved allegations that the fertility drug, Clomid, had been the cause of plaintiff’s birth defects.<sup>120</sup> Plaintiff claimed, in part, that the drug was defectively designed under New York state law.<sup>121</sup> In turn, the defendants argued that the plaintiff’s claims were preempted under the logic propounded by the Supreme Court in *Bartlett*.<sup>122</sup> The New York district court disagreed with defendants, distinguishing the facts in *Bartlett*, with the facts underlying *Sullivan*.<sup>123</sup> The court stressed that *Bartlett* involved claims against a generic drug, which necessarily always involved allegations that the generic manufacturer should have taken additional steps to modify a drug’s bio-chemistry *post*-approval.<sup>124</sup> However, the court noted *Sullivan* involved a brand name drug, and that there exists “no federal law that restricts a brand- name drug manufacturer from designing a reasonably safe product *prior* to FDA approval.”<sup>125</sup>

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<sup>112</sup>Eric Alexander, *The Saga of Preemption Prescription Drug Design Defect Claims*, DRUG & DEVICE L. (January 1, 2016), <https://www.druganddevicelawblog.com/2016/01/the-saga-of-preempting-prescription.html> [<https://perma.cc/PED9-9X9T>].

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

<sup>114</sup>*Estate of Cassel v. Alza Corp.*, No. 12-CV-771-WMC, 2014 WL 856023, at \*5 (W.D. Wis. Mar. 5, 2014).

<sup>115</sup>*Id.* at \*4.

<sup>116</sup>*Id.* at \*5.

<sup>117</sup>*Id.*

<sup>118</sup>*Id.* at \*6.

<sup>119</sup>*Sullivan v. Aventis, Inc.*, No. 14-CV-2939-NSR, 2015 WL 4879112 (S.D.N.Y. Aug. 13, 2015).

<sup>120</sup>*Id.* at \*1.

<sup>121</sup>*Id.*

<sup>122</sup>*Id.* at \*4.

<sup>123</sup>*Id.* at \*4–6.

<sup>124</sup>*Id.*

<sup>125</sup>*Id.* at \*6.



Contrastingly, a number of prominent federal courts have recently found that *Bartlett*-style preemption *should* apply in the brand name design defect context.<sup>126</sup> In December 2015, the Sixth Circuit in *Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, became the first Court of Appeals to explicitly weigh in on the issue.<sup>127</sup> *Yates* involved a woman who suffered a severe stroke only a week after beginning the brand name, birth control patch, Ortho-Evra.<sup>128</sup> Plaintiff argued that the defendants breached their duty to make their medication reasonably safe before seeking FDA approval.<sup>129</sup> The Sixth Circuit disagreed, stating that pre-approval, design defect claims are “too attenuated” to constitute a legally cognizable duty.<sup>130</sup> The court further held that adoption of plaintiff’s theory would force them to “speculate” that “FDA would have approved the alternate design,” that plaintiff “would have selected this method of birth control,” and that “this alternate design would not have caused [plaintiff] to suffer a stroke.”<sup>131</sup> This, the court stated, was “several steps too far.”<sup>132</sup> The court further noted that holding brand name manufacturers liable in pre-approval would be analogous to the “stop selling” rationale, a theory explicitly considered and rejected in *Bartlett*.<sup>133</sup>

Many other courts have since adopted the reasoning laid out in *Yates*.<sup>134</sup> For example, *Utts v. Bristol-Myers Squibb Co.*, involved allegations that the brand name anticoagulant, Eliquis, caused severe internal bleeding.<sup>135</sup> In dispensing plaintiff’s pre-approval rationale, the court noted that adoption of plaintiff’s theory would force the court to “speculate that had the defendants designed Eliquis differently, FDA would have approved the alternate design; that Mr. Utts would have been prescribed this alternately designed Eliquis; and that this alternate design would not have caused Mr. Utts to suffer severe internal bleeding.”<sup>136</sup> Similarly, in *Brazil v. Janssen Research & Development LLC*,<sup>137</sup> a federal district court in Georgia dispensed of the pre-approval theory, noting that “[t]his original design theory of liability makes little sense in the face of the Supreme Court’s precedents. The Supreme Court has repeatedly

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<sup>126</sup>See Bosman, *supra* note 8.

<sup>127</sup>*Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281 (6th Cir. 2015).

<sup>128</sup>*Id.* at 286.

<sup>129</sup>*Id.* at 299.

<sup>130</sup>*Id.*

<sup>131</sup>*Id.*

<sup>132</sup>*Id.*

<sup>133</sup>*Id.* at 300. *Yates*’s pre-approval claim fails for another reason. In *Bartlett*, the Supreme Court held that “[t]he [First Circuit] Court of Appeals’ solution—that [the manufacturer] should simply have pulled [the drug] from the market in order to comply with both state and federal law—is no solution.” *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470 (2013). This “stop-selling” rationale is “incompatible with . . . preemption jurisprudence,” which “presume[s] that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability.” *Id.* At 2477.

<sup>134</sup>See Stephen McConnell, *SDNY Applies Preemption in Favor of Branded Drug*, DRUG & DEVICE L. (Jan. 4, 2017), <https://www.druganddevicelawblog.com/2017/01/sdny-applies-preemption-in-favor-of-branded-drug.html> [<https://perma.cc/DAX5-HMYS>].

<sup>135</sup>*Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 172 (S.D.N.Y. 2016).

<sup>136</sup>*Id.* at 186.

<sup>137</sup>*Brazil v. Janssen Research & Dev. LLC*, 196 F. Supp. 3d 1351, 1364 (N.D. Ga. 2016).

characterized the state tort law at issue in this case as a duty to make changes or as a remedial effort.”<sup>138</sup>

Despite the directive set by the Sixth Circuit in *Yates*, several courts continue to accept plaintiffs’ pre-approval rationale.<sup>139</sup> For example, a Louisiana district court in *Guidry v. Janssen Pharmaceuticals, Inc.* recently refused to preempt design defect claims involving Invokana, a brand name drug used to treat diabetes.<sup>140</sup> The court swiftly dispensed of defendant’s arguments that pre-approval duties were analogous to the “stop-selling” rationale considered and rejected in *Bartlett*.<sup>141</sup> The court stated, “[t]he raison d’être of products liability litigation is to penalize manufacturers who design unreasonably dangerous products *in hopes that they never start selling them*. State products liability law functions as a compliment to federal drug regulations to keep unreasonably dangerous drugs off the market.”<sup>142</sup> More recently, the court in *Young v. Bristol-Myers Squibb Co.* decided against preemption along similar lines, stressing that “*Yates* misstates the ‘stop selling’ rationale explained in *Bartlett* . . . The preapproval theory does not argue that a manufacturer should have stopped acting, just that it should have acted *differently*.”<sup>143</sup>

### b. Stronger Warnings as Design Defect Preemption Avoidance

In those jurisdictions that are unreceptive to the pre-approval theory, plaintiffs have, in a last-ditch effort to salvage their brand name design defect claims, utilized innovative, but ultimately hollow legal theories. As discussed previously, the state design defect law under consideration in *Bartlett* analyzed the drug’s design *and* warnings.<sup>144</sup> The court determined that because the generic manufacturer was precluded from unilaterally altering the design *and* the warnings, the design defect claim against it failed.<sup>145</sup> Plaintiff attorneys are now attempting to avoid preemption

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<sup>138</sup>*Id.*; see also *Fleming v. Janssen Pharm., Inc.*, 186 F. Supp. 3d 826, 833 (W.D. Tenn. 2016) (dismissing the pre-approval reasoning, noting that *Yates* had held that the pre-approval theories were “‘too attenuated’ and ‘speculat[ive]’ because it requires several assumptions as to FDA approval and a patient’s selection of and medical reaction to the alternative design”); *Rheinfrank v. Abbott Labs., Inc.*, 137 F. Supp. 3d 1035, 1040–1041 (S.D. Ohio 2015) (refusing to even address the pre-approval issue, even though the plaintiff had couched her claims in duties in pre-approval).

<sup>139</sup>See Pamela C. Maloney, *Claims That Invokana Maker Should Have Adopted Alternative Design Before Seeking FDA Approval Not Preempted*, HEALTH L. DAILY (Sept. 1, 2016), <https://irus.wolterskluwer.com/news/health-law-daily/claims-that-invokana-maker-should-have-adopted-alternative-design-before-seeking-fda-approval-not-preempted/31840/> [<https://perma.cc/A272-VKNC>].

<sup>140</sup>*Guidry v. Janssen Pharm., Inc.*, 206 F. Supp. 3d 1187 (E.D. La. 2016).

<sup>141</sup>*Id.* at 1208.

<sup>142</sup>*Id.*; see also *In re Xarelto (Rivaroxaban) Prods. Liab. Litig.*, 2017 U.S. Dist. LEXIS 56629, at \*9–10 (E.D. La. Apr. 12, 2017) (finding that *Guidry* was directly on point to the facts involving a brand name manufacturer, and thus all design defect claims made against the manufacturer survived preemption).

<sup>143</sup>*Young v. Bristol-Myers Squibb Co.*, No. 4:16-CV-00108-DMB-JMV, 2017 WL 706320, at \*8 (N.D. Miss. Feb. 22, 2017). In this case, Mississippi became the most recent jurisdiction to adopt the pre-approval rationale laid out by *Cassel* and its progeny. *Id.* The court also disagreed with the “attenuation” issue expounded by *Yates*, simply stating that it finds the court in *Guidry*’s analysis on the issue “largely persuasive.” *Id.*

<sup>144</sup>*Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470 (2013).

<sup>145</sup>*Id.* at 2480; see *Guenther v. Novartis Pharm. Corp.*, No. 6:08-CV-456-Orl-31DAB, 2013 WL 4648449, at \*5 (M.D. Fla. Aug. 29, 2013) (“[A] review of the opinion demonstrates that the FDCA’s prohibition on label alterations by generic drug manufacturers was as central to the decision in that case as it was in *PLIVA*.”).

on its brand name design defect claims by pointing to the strong similarities between New Hampshire's design defect test and their own state specific test.<sup>146</sup> These plaintiffs argue that because their brand name design defect claim includes an analysis of the drug's warnings, a court cannot categorically preempt claims made in design defect.<sup>147</sup> Rather, a court should engage in the *Levine*, clear-evidence standard within the design defect analysis itself.<sup>148</sup>

For example, in March 2016, a Georgia District Court in *Brazil v. Janssen Research & Development LLC* agreed with plaintiff's arguments that its design defect claims against the manufacturer of the brand name product Invokana were not preempted because, like New Hampshire, "a design defect claim under Georgia law . . . allows a drug manufacturer . . . to fulfill its legal duty by improving the warnings attached to the product."<sup>149</sup> Similarly, the court in *Sullivan v. Aventis, Inc.*, discussed above, also held that another way brand name drug manufacturers can avoid design defect liability is to strengthen a drug's warning label.<sup>150</sup> The court therefore held that the design defect claims were not barred by impossibility preemption under *Bartlett*.<sup>151</sup> However, it should be noted that other courts, including the Sixth Circuit Court in *Yates*, have issued opinions that directly conflict with this rationale.<sup>152</sup>

Ultimately, however, the usefulness of this theory is questionable. Even the jurisdictions that have been amenable to the theory have ruled that "[a]ny claim by plaintiff that defendants should change the formulation . . . [of the drug] . . . is preempted by FDA regulations.<sup>153</sup> In other words, courts amenable to the theory simply leave plaintiffs with a hollowed, design defect claim that, for all intents and

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<sup>146</sup>See *Brazil v. Janssen Research & Dev. LLC*, No. 4:15-CV-0204-HLM, 2016 WL 4844442, at \*14–16 (N.D. Ga. Mar. 24, 2016); *Sullivan v. Aventis, Inc.*, No. 14-CV-2939-NSR, 2015 WL 4879112, at \*4–5 (S.D.N.Y. Aug. 13, 2015); Pl.'s Opp'n to Def.'s Mot. to Dismiss Compl. Under F.R.C.P. 12(b)(2) and 12(b)(6), *Allen v. Janssen Pharm. Inc.*, No. 3:15-cv-01195, 2016 WL 491709 (S.D. Ill. 2016); *Young v. Bristol-Myers Squibb Co.*, No. 4:16-CV-00108-DMB-JMV, 2017 WL 706320, at \*5–6 (N.D. Miss. Feb. 22, 2017).

<sup>147</sup>See *Brazil*, 2016 WL 4844442, at \*15–17; *Sullivan*, 2015 WL 4879112, at \*6; Pl.'s Opp'n to Def.'s Mot. to Dismiss Compl. Under F.R.C.P. 12(b)(2) and 12(b)(6), *Allen*, 2016 WL 491709; *Young*, 2017 WL 706320, at \*5–6.

<sup>148</sup>See *Brazil*, 2016 WL 4844442, at \*15–16; *Sullivan*, 2015 WL 4879112, at \*6; Pl.'s Opp'n to Def.'s Mot. to Dismiss Compl. Under F.R.C.P. 12(b)(2) and 12(b)(6), *Allen*, 2016 WL 491709; *Young*, 2017 WL 706320, at \*5–8.

<sup>149</sup>*Brazil*, 2016 WL 4844442, at \*15. However, the court ultimately found the failure to warn claims against Jansen preempted, without engaging in the *Levine* clear-evidence analysis, because Jansen was not the NDA holder of the drug, and thus unable to make unilateral changes to the label under the CBE procedures. *Id.* For this same reason, it is curious as to why it did not preempt the plaintiff's design defect claims, as the court essentially reduced them to failure to warn claims. See *id.* at \*16.

<sup>150</sup>*Sullivan*, 2015 WL 4879112, at \*6.

<sup>151</sup>*Id.*; see also Pl.'s Opp'n to Def.'s Mot. to Dismiss Compl. under F.R.C.P. 12(b)(2) and 12(b)(6), *Allen*, 2016 WL 491709 ("Lastly, even if impossibility preemption was a viable defense, Defendants' argument still fails because . . . [t]he Supreme Court expressly found the FDCA does not prevent a brand name drug manufacturer from changing its warning label.").

<sup>152</sup>See *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 298–300 (6th Cir. 2015). (noting that the state design defect claims under question could be cured with a more robust label, but then bizarrely ruling for preemption without addressing the plausibility of a post-approval labeling change); see also *Fleming v. Janssen Pharm., Inc.*, 186 F. Supp. 3d 826, 833–34 (W.D. Tenn. 2016) (noting the curious logic of *Yates*, and the alternate route presented by *Brazil* in this regard, but ultimately ruling that "unlike in *Brazil* in the Northern District of Georgia, *Yates* is controlling authority in the instant case.").

<sup>153</sup>*Brazil*, 2016 WL 4844442, at \*7.

purposes, resembles a failure to warn claim.<sup>154</sup> In all cases, plaintiffs are barred from claiming that defendants should have altered the biochemistry of the drug.<sup>155</sup> For this reason, the theory will likely prove to be an impractical legal weapon for plaintiffs.

#### IV. OTC DRUGS AND PREEMPTION

Plaintiffs who wish to bring claims against brand name or generic manufacturers for defects in over-the-counter (OTC) drugs face additional hurdles.<sup>156</sup> For example, defendants have increasingly argued that the “savings clause” contained within the OTC regime does not save claims made against OTC drugs from implied conflict preemption principles.<sup>157</sup> Second, defense-oriented commentators have recently suggested that the CBE change restrictions should not apply to OTC drugs.<sup>158</sup> These entities posit that the OTC regime itself contains its own, more restrictive label change requirements that prevent manufacturers from ever making unilateral changes to their labels.<sup>159</sup>

##### a. *The Savings Clause*

Recently, significant litigation has focused on the interpretation of the OTC statute, 28 U.S.C. § 379r, which contains within it an express preemption clause as well as a savings clause.<sup>160</sup> The preemption clause, section 379r(a), states that state tort law claims which demand warnings or changes in an OTC drug “that is different from or in addition to, or that is otherwise not identical with federal requirements” are preempted.<sup>161</sup> In turn, the saving clause, section 379r(e), states “[n]othing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.”<sup>162</sup> Plaintiff attorneys have increasingly posited that the OTC savings clause saves claims against all preemption, including *Bartlett*-style implied conflict preemption.<sup>163</sup> In turn, defense attorneys have stressed that the savings clause contained within the OTC statute, by its plain language, does not preclude implied conflict preemption.<sup>164</sup>

Plaintiff attorneys seeking to avoid preemption were initially successful at focusing on the intent of Congress and positing that the mere existence of a statutory savings clause conveys Congress’ overarching intent to preserve all claims

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<sup>154</sup>*See id.*

<sup>155</sup>*See id.*

<sup>156</sup>Alan Klien, Sharon L. Caffrey & Fletcher W. Moore, *Federal Preemption for Generic OTC Drugs?*, LAW360 (November 8, 2011), <https://www.law360.com/articles/282937/federal-preemption-for-generic-otc-drugs>.

<sup>157</sup>*See* discussion *infra* Part IV.A.

<sup>158</sup>*See* discussion *infra* Part IV.B.

<sup>159</sup>*See* discussion *infra* Part IV.B.

<sup>160</sup>21 U.S.C. § 379r (2012).

<sup>161</sup>*Id.* § 379r(a).

<sup>162</sup>*Id.* § 379r(e).

<sup>163</sup>*See* discussion *infra* Part V.A.

<sup>164</sup>*See* discussion *infra* Part V.A.

against OTC manufacturers.<sup>165</sup> For example, *Hunt v. McNeil Consumer Healthcare*, involved allegations that Children’s Motrin was defectively designed and contained inadequate warnings relating to SJS/TEN, a potentially fatal skin condition.<sup>166</sup> The Louisiana district court ultimately ruled that claims made against the manufacturer were precluded from *Bartlett*-type impossibility preemption through the OTC drug’s savings clause.<sup>167</sup> The court stressed that:

Congress’ intent to preserve state-law product liability actions with respect to non-prescription drugs could not be more clear. This conclusion is underscored by the axiom that courts should assume Congress did not intend to displace state law, especially when Congress legislates in a field traditionally regulated by the states such as health and safety.<sup>168</sup>

Nine months later, a Pennsylvania district court in *Brown v. Johnson & Johnson*,<sup>169</sup> faced with similar claims involving Motrin, cited to *Hunt* for support that federal law did not preempt the design defect claims against manufacturers of OTC products.<sup>170</sup>

More recently, however, courts have begun siding with defendants’ arguments that the savings clause contained in section 379r(e) is limited to express preemption.<sup>171</sup> For example, *Reckis v. Johnson & Johnson* involved allegations that the manufacturer of ibuprofen provided inadequate warnings regarding a life-threatening skin disorder resulting from its product.<sup>172</sup> The court rejected the plaintiff’s arguments against implied preemption, concluding that the savings clause contained in section 379r(e), “does not extend beyond the provisions of section 379(r), and in particular does not preclude ‘the ordinary working of conflict pre-emption principles.’”<sup>173</sup> The court thus rejected plaintiff’s arguments and found that *Bartlett*-type style preemption was applicable.<sup>174</sup> One year later, in *Batoh v. McNeil-PPC, Inc.*,<sup>175</sup> a federal district court cited to *Reckis* in rejecting plaintiff’s urging for a narrow reading of the “savings clause”, finding instead that “the statute at issue . . . does not foreclose the possibility that conflict preemption may arise from other sources of federal law.”<sup>176</sup>

<sup>165</sup>See Rachel B. Weil, *J&J Files Cert Petition in Massachusetts Supreme Court’s Unsupportable Rejection of Preemption Defense in Reckis TEN/Children’s Motrin Case*, DRUG & DEVICE L. (Nov. 20, 2015), <https://www.druganddevicelawblog.com/2015/11/j-j-files-cert-petition-in.html>.

<sup>166</sup>*Hunt v. McNeil Consumer Healthcare*, 6 F. Supp. 3d 694, 697 (E.D. La. 2014).

<sup>167</sup>*Id.* at 704.

<sup>168</sup>*Id.*

<sup>169</sup>*Brown v. Johnson & Johnson*, 64 F. Supp. 3d 717 (E.D. Pa. 2014)

<sup>170</sup>*Id.* at 720

<sup>171</sup>Weil, *supra* note 86.

<sup>172</sup>*Reckis v. Johnson & Johnson*, 28 N.E.3d 445 (Mass. 2015), *cert. denied*, 136 S. Ct. 896 (2016).

<sup>173</sup>*Id.* at 454.

<sup>174</sup>*Id.*

<sup>175</sup>*Batoh v. McNeil-PPC, Inc.*, 167 F. Supp. 3d 296, 316 (D. Conn. 2016).

<sup>176</sup>*Id.* at 316 n.15. These entities have cited to Supreme Court decisions that have stood for the proposition that that the limiting language contained in savings provisions such as § 379r(e) must be construed as not applying to implied preemption. *See, e.g.*, *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000) (finding that “savings” provision does “not bar the ordinary working of conflict preemption principles.”); *Buckman v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 352 (2001); (“[N]either an express preemption provision nor a saving clause bars the ordinary working of conflict preemption principles”); *Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1, 8–9 (Cal. 2004).

b. “Sameness” for Monographs

A less prominent, although equally fascinating debate, has centered on the labeling and design change obligations for monographs. As previously articulated, the reason claims against generic drugs have been implicitly preempted is because, under the CBE regulations, a manufacturer cannot make a unilateral change to the design or label of the drug.<sup>177</sup> The reason claims against brand name manufacturers have been allowed to proceed is because a manufacturer can make unilateral changes to a drug’s label.<sup>178</sup>

Defendants who make brand name OTC products have increasingly claimed that the CBE change restrictions simply do not apply in the context of OTC drugs.<sup>179</sup> Seeking to avoid the plaintiff-friendly clear evidence standard of *Levine*, these defendants posit that the regulatory regime governing OTC drugs should apply instead.<sup>180</sup> These defendants further argue that the regulatory regime governing OTC drugs, like the CBE regulation for prescription generics, restrict them from making unilateral changes to the drug’s label or design.<sup>181</sup>

The few courts that have addressed preemption in the OTC context have found that the CBE regulations apply to OTC drugs. For example, in *Batoh v. McNeil-PPC, Inc.*, the court rejected defendant’s arguments that the CBE regulations applied only in the context of prescription drugs, stating, “nowhere does the CBE regulation suggest that it applies only to prescription drugs. To the contrary, the regulation addresses changes to ‘approved [drug] applications,’ which are applicable to OTC drugs as well as prescription drugs.”<sup>182</sup> And while defense-oriented commentators have suggested that the OTC regulations do not allow for unilateral changes in a OTC drug’s labels, to date, there has not been a federal court that has affirmed this position.<sup>183</sup>

## V. POLITICAL CHANGES – LOOKING AHEAD

Federal preemption in pharmaceutical litigation has traditionally been a distinctly partisan issue, with Republicans far more likely than Democrats to favor a broad

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<sup>177</sup> See discussion *supra* Part I.A.

<sup>178</sup> See discussion *supra* Part I.A.

<sup>179</sup> See, e.g., Brief in Support of Petitioner for Writ of Certiorari, *McNeil-PPC, Inc. v. Hutto*, 2012 WL 3756878 (U.S.) (2012) (No. 12-122) (“The CBE regulation on which *Wyeth* relied to find that compliance with state law was possible applies only to *prescription* drugs.”).

<sup>180</sup> *Id.*

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

<sup>182</sup> *Batoh v. McNeil-PPC, Inc.*, 167 F. Supp. 3d 296, 317 (D. Conn. 2016); see also *Hutto v. McNeil-PPC, Inc.*, 79 So. 3d 1199 (La. Ct. App. 2011), *appeal denied*, 86 So. 3d 628 (La. 2012) (failing to address the unique labeling requirements of OTC drugs, and instead, engaging in a *Levine*-type clear evidence standard); *Reckis v. Johnson & Johnson*, 28 N.E.3d 445, 457 (Mass. 2015) (noting the disagreement in the drug industry of whether CBE applies to OTC drugs, but concluding that since the defendant had relied on *Levine* in his brief, the court was going to presume that it does); *Newman v. McNeil Consumer Healthcare*, No. 10–CV–01541, 2012 WL 39793 (N.D. Ill. Jan. 9, 2012) (applying the CBE regulation to failure-to-warn claims against an OTC drug).

<sup>183</sup> See James Beck, *Implied Preemption and Monograph Drugs*, DRUG & DEVICE L. (Dec. 12, 2016), <https://www.druganddeviceblog.com/2016/12/implied-preemption-and-monograph-drugs.html>; David B. Sudzus, B. Todd Vinson & Russell J. Chibe, *Supreme Court Decision Opens Door for Possible Implied Conflict Preemption of Over-the-Counter Drugs*, LEXOLOGY (May 2, 2012), <http://www.lexology.com/library/detail.aspx?g=3e3730c0-c5da-47d9-a2cd-c0227578d443>.

preemptive regime.<sup>184</sup> Therefore, recent political developments, including the 2016 election of Donald Trump<sup>185</sup> and the reclamation of the congressional majority by the GOP,<sup>186</sup> will inevitably have a significant impact upon the preemption landscape. While these forces are unlikely to overturn the decisions of *Bartlett* and *Mensing*, they will undoubtedly work to stymie any regulatory or legislative changes intended to undo the impact of those decisions. Also significant is the recent appointment of Neil Gorsuch to the Supreme Court.<sup>187</sup> Gorsuch's unique jurisprudential philosophy is sure to have influence on any preemption issue which makes its way before the court.

*a. CBE-0 Proposal is Dead*

As an initial matter, it is important to note that legislative efforts to undo the broad preemptive regime of generic drugs are likely dead.<sup>188</sup> Since their inception, the decisions of *Mensing* and *Bartlett* have attracted significant criticism, with commentators and plaintiffs' attorneys arguing that federal preemption of state law tort suits has had a negative impact on pharmaceutical safety.<sup>189</sup> These entities contend that immunity has eliminated incentive for manufacturers of generic drugs to engage in thorough premarket studies and to vigorously pursue reports of post-market risks.<sup>190</sup> Additionally, they posit that immunity leaves consumers gravely injured by generic drugs with no avenue of redress.<sup>191</sup>

In response to the criticism, in 2013 FDA issued a proposed change to the CBE procedure.<sup>192</sup> This change would permit a manufacturer of a generic drug to

<sup>184</sup>See Samuel Raymond, *Judicial Politics and Medical Device Preemption After Riegel*, 5 NYU J.L. & LIBERTY 745, 780 (2010). Relatedly, another hot-button field worth paying attention to for the near future is 3D printing. See, e.g., Jasper L. Tran, *3D-Printed Food*, 17 MINN. J.L. SCI. & TECH. 855, 857–60 (2016); Jasper L. Tran, *Press Clause and 3D Printing*, 14 NW. J. TECH. & INTELL. PROP. 75, 78 (2016); Jasper L. Tran, *To Bioprint or Not to Bioprint*, 17 N.C. J.L. & TECH. 123, 133–35 (2015); Jasper L. Tran, *The Law and 3D Printing*, 31 J. MARSHALL J. INFO. TECH. & PRIVACY L. 505, 505–08 (2015).

<sup>185</sup>Shortly after being sworn in, President Donald Trump proclaimed that he intends “to bring down drug prices.” Bill Berkrot & Lewis Krauskopf, *Trump Vows to Bring Down Drug Prices, Doesn't Say How*, CNBC (Dec. 7, 2016), <http://www.cnn.com/2016/12/07/reuters-america-update-4-trump-vows-to-bring-down-drug-prices-doesnt-say-how.html>.

<sup>186</sup>Karoun Demirjian, *Republicans Keep Control of Congress After Decisive Senate Wins in Missouri, Pennsylvania, Indiana, Wisconsin and N.C.*, WASH. POST (Nov. 9, 2016), [https://www.washingtonpost.com/news/powerpost/wp/2016/11/08/senate-house-majorities-hang-in-the-balance-on-electionday/?utm\\_term=.1d22052f7596](https://www.washingtonpost.com/news/powerpost/wp/2016/11/08/senate-house-majorities-hang-in-the-balance-on-electionday/?utm_term=.1d22052f7596).

<sup>187</sup>Carl Hulse, *In Neil Gorsuch's Confirmations, Parsing the Meaning of 'Yes,'* N.Y. TIMES (Feb. 11, 2017), [https://www.nytimes.com/2017/02/11/us/politics/neil-gorsuch-supreme-court-confirmation.html?\\_r=0](https://www.nytimes.com/2017/02/11/us/politics/neil-gorsuch-supreme-court-confirmation.html?_r=0).

<sup>188</sup>James Beck, *How Might a Trump Administration Affect Our Sandbox?*, DRUG & DEVICE L. (Nov. 14, 2016), <https://www.druganddevicelawblog.com/2016/11/how-might-a-trump-administration-affect-our-sandbox.html>.

<sup>189</sup>Tyler W. Olson, *The Supreme Court's Overreaching Preemption Interpretation and Its Consequences: Granting Generic Drug Manufacturers Legal Immunity Through "The Duty of Sameness" in Mutual Pharmaceutical Co. v. Bartlett and PLIVA v. Mensing*, 12 IND. HEALTH L. REV. 769, 807 (2015).

<sup>190</sup>*Id.*

<sup>191</sup>See Samantha Koopman, *Hidden Risks of Taking Generic Drugs over Brand Name: The Impact of Drug Labeling Regulations on Injured Consumers and the Pharmaceutical Industry*, 34 J. NAT'L ASS'N ADMIN. L. JUDICIARY 112, 114 (2014); Jordan A. Marzocco, *A Dose of Reality: The Deadly Truth About Federal Preemption of Generic Drug Manufacturer Liability*, 24 WIDENER L.J. 355, 380 (2015).

<sup>192</sup>Food & Drug Admin., *Examining Concerns Regarding FDA's Proposed Changes to Generic Drug Labeling*, FDA NEWS AND EVENTS, Apr. 4, 2014 <https://www.fda.gov/NewsEvents/Testimony/>

unilaterally update its label, thus making it possible for generic drug manufactures to comply with both state failure to warn standards and federal law.<sup>193</sup> As such, federal preemption principles would no longer bar suits against generic drugs.<sup>194</sup>

The recent election of Donald Trump, the confirmation of Tom Price as Secretary of Health and Human Services, and the Republican Party's grasp over both houses of Congress indicate the proposed rule change is likely dead.<sup>195</sup> Commentators have even suggested that these forces may encourage the replacement of CBE-0 with the alternative Expedited Agency Review (EAR) proposal, which would work to undo the plaintiff-friendly decision in *Levine* and expand the bounds of preemption.<sup>196</sup> Essentially, the EAR proposal would make FDA the initial and final arbiter of label changes for both NDA and ANDA holders.<sup>197</sup> This would effectively undermine the assumption underlying *Levine* that claims against brand name manufacturers are not preempted because the manufacturer can unilaterally update its labels to comply with state tort law.<sup>198</sup> Given the likely death of the CBE-0 proposal, it is likely that plaintiffs' attorneys will continue to bring claims against brand name drugs with increased regularity.

### *b. Clear Evidence Revisited*

As articulated in Part II, courts have increasingly grappled with the clear evidence standard laid out in *Levine*.<sup>199</sup> Given the inconsistencies that have resulted from the confusion, the Supreme Court may choose to revisit the clear evidence standard in the near future.<sup>200</sup> It is important to note that litigants have previously attempted, but failed, to have the standard clarified by the Supreme Court.<sup>201</sup> In *Reckis v. Johnson & Johnson*, the Massachusetts Supreme Court found that defendant failed to proffer clear evidence that FDA would have denied a warning change, despite the existence of previously denied citizen petition requesting it.<sup>202</sup> In their Petition for a Writ of Certiorari, defendants urged the Court to revisit the holding in *Levine*, citing to inconsistencies among the lower courts, and a federal court decision that had

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ucm389606.html [https://wayback.archive-it.org/7993/20170111165008/http://www.fda.gov/NewsEvents/Testimony/ucm389606.htm]

<sup>193</sup>See Marcia Boumil, *FDA Approval of Drugs and Devices: Preemption of State Laws for "Parallel" Tort Claims*, 18 J. HEALTH CARE L. & POL'Y 1, 29 (2015).

<sup>194</sup>*Id.*

<sup>195</sup>James Beck, *Stick a Fork in It – FDA Anti-Generic Preemption Proposal Postponed Until After the Presidential Election*, DRUG & DEVICE L. (May 25, 2016), <https://www.druganddevicelawblog.com/2016/05/stick-a-fork-in-it-fda-anti-generic-drug-preemption-proposal-postponed-until-after-the-presidential-election.html>.

<sup>196</sup>James Beck, *The FDA gets an EARful on Label Changes*, DRUG & DEVICE L. (Apr. 21, 2015) <https://www.druganddevicelawblog.com/2015/04/the-fda-gets-earful-on-label-changes.html>.

<sup>197</sup>ANTHONY H. NGUYEN, WOLTERS KLUWER, AN IMPOSSIBLE COURSE: NAVIGATING THE GENERIC DRUG LABEL DELAY (2016), [health.wolterskluwerlb.com/wp-content/uploads/.../Generic-drug-label\\_09\\_2016.pdf](http://health.wolterskluwerlb.com/wp-content/uploads/.../Generic-drug-label_09_2016.pdf).

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

<sup>199</sup>See discussion *supra* Part II.

<sup>200</sup>Erika Lietzan & Sarah E. Pitlyk, *Thoughts on Preemption in the Wake of the Levine Decision*, 13 J. HEALTH CARE L. & POL'Y 225, 255 (2010).

<sup>201</sup>*Reckis v. Johnson & Johnson*, 28 N.E.3d 445 (Mass. 2015).

<sup>202</sup>*Id.* at 458.



previously found FDA's rejection of a citizen petition with the exact drug and warning in issue as satisfying *Levine's* clear evidence standard.<sup>203</sup> Several other advocacy groups filed amicus briefs in the matter on behalf of defendants.<sup>204</sup> However, notably absent in these briefs was any articulation of a true and clear circuit split on the relevant issues.<sup>205</sup>

Political developments suggest that the clear circuit split and a high-court elucidation of *Levine's* clear evidence standard may occur in the near future. Donald Trump is expected to appoint the greatest share of federal judges than any president in forty years.<sup>206</sup> Experts project that nominations will come from the conservative pool of justices and will be swiftly confirmed by the Republican majority senate.<sup>207</sup> Given that preemption is a demonstrably partisan issue, with conservative judges far more likely to rule in favor of preemption than liberal judges, it is probable that several of these judges will take a more defendant-friendly approach to the clear evidence standard.<sup>208</sup> These rulings would inevitably clash with the traditionally plaintiff-friendly decisions following *Levine*, thus potentially establishing Circuit splits on many key issues. It is also possible that these judges may go further, and take an alternative approach to the more established interpretations of *Levine*.<sup>209</sup> For example, defense-oriented legal scholars have, on occasion, suggested that *Levine's* use of "clear evidence" language was not intended to establish a standard of proof that exceeds "beyond the preponderance of the evidence."<sup>210</sup> Rather, these scholars contend that "clear evidence" simply means that "the defendant asserting preemption has the burden of going forward with evidence showing the conflict the defendant claims to exist."<sup>211</sup>

### *c. Pre-approval & OTC Elucidated*

As discussed in Part III, plaintiffs have continued to evade preemption on their brand name design defect claims through utilization of the pre-approval theory.<sup>212</sup> This theory has proven especially successful in district courts within the Fifth Circuit even in the face of the Sixth Circuit Court of Appeals ruling in *Yates*, which rejected the

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<sup>203</sup> *Id.*

<sup>204</sup> See Weil, *supra* note 165 (stating that a host of advocacy groups, including PLAC, the Chamber of Commerce of the United States, the Washington Legal Foundation, the Biotechnology Industry Organization, the Consumer Healthcare Products Association, and the Pharmaceutical Research and Manufacturers of America have filed *amicus curiae* briefs).

<sup>205</sup> See *Reckis*, 28 N.E.3d at 445.

<sup>206</sup> There are currently 123 federal court vacancies, 19 from the Courts of Appeals.

<sup>207</sup> Philip Ruck & Robert Barnes, *Trump to Inherit More than 100 Court Vacancies, Plans to Reshape Judiciary*, WASH. POST, [https://www.washingtonpost.com/politics/trump-to-inherit-more-than-100-court-vacancies-plans-to-reshape-judiciary/2016/12/25/d190dd18-c928-11e6-85b5-76616a33048d\\_story.html?utm\\_term=.19e7d6f3ce1c](https://www.washingtonpost.com/politics/trump-to-inherit-more-than-100-court-vacancies-plans-to-reshape-judiciary/2016/12/25/d190dd18-c928-11e6-85b5-76616a33048d_story.html?utm_term=.19e7d6f3ce1c).

<sup>208</sup> See, e.g., Jeffrey Toobin, *How Obama Transformed the Federal Judiciary*, NEW YORKER MAG. (Oct. 27, 2014), <http://www.newyorker.com/magazine/2014/10/27/obama-brief>. See generally CASS R. SUNSTEIN ET. AL., ARE JUDGES POLITICAL? 17-21 (2006).

<sup>209</sup> Wheeler, *supra* note 48, at 329.

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

<sup>211</sup> *Id.*; see also Yeary, *supra* note 98.

<sup>212</sup> See discussion *infra* Part III.A.

theory.<sup>213</sup> As plaintiffs increasingly attempt to bring claims within the Fifth Circuit and other plaintiff-friendly jurisdictions, the pre-approval issue will inevitably be presented to another Court of Appeals.<sup>214</sup> And should the Fifth, or any other Circuit, take a position contrary to the Sixth Circuit's reasoning in *Yates*, the issue would finally be ripe for Supreme Court review.<sup>215</sup> Indeed, the Supreme Court has never addressed design defect claims within the brand name context.<sup>216</sup> A circuit split on the pre-approval issue may provide the Court the perfect opportunity to do so.

Contrastingly, Supreme Court elucidation of the unique issues related to preemption OTC drug claims in the near future is unlikely.<sup>217</sup> For one thing, the Supreme Court has twice rejected petitions for certiorari in cases where OTC issues featured prominently.<sup>218</sup> For example, in *Reckis v. Johnson & Johnson*, the Supreme Court rejected defendants' pleas to clarify the precise preemptive scope of the savings clause.<sup>219</sup> Similarly, in *Hutto v. McNeil-PPC, Inc.*, the Supreme Court refused to review a case that involved the application of CBE procedures to OTC drugs, despite several amicus briefs that urged that Supreme Court clarification was necessary.<sup>220</sup> While there is significant confusion amongst the lower courts regarding OTC preemption, it appears that, at least for the time being, these issues will continue to go unresolved.

#### *d. Neil Gorsuch's Impact*

Recently confirmed Supreme Court Justice Neil Gorsuch will be a major variable in the event that any of the aforementioned brand name, implied preemption issues make their way before the Court.<sup>221</sup> This is especially significant given that both *Mensing* and *Bartlett* were 5-4 decisions, with conservatives in the majority on both occasions.<sup>222</sup> While it is notoriously difficult to predict how the Supreme Court or any particular justice will rule in any given case, a careful analysis of Justice Gorsuch's previous cases reveals a judicial philosophy which may be more amenable to anti-preemption arguments than that of his conservative colleagues or predecessor. Indeed, over the past ten years, conservative justices on the Supreme Court have taken a pro-

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<sup>213</sup>See discussion *infra* Part III.A.

<sup>214</sup>See generally, Eric Alexander, *The Saga of Preempting Prescription Design Defect Claims*, DRUG & DEVICE L. (Jan. 1, 2016), <https://www.druganddevicelawblog.com/2016/01/the-saga-of-preempting-prescription.html>.

<sup>215</sup>*Id.*

<sup>216</sup>As discussed in Parts I and II, *Mensing* involved the preemption of failure to warn claims in the generic context, *Bartlett* involved preemption of failure to warn in the generic context, and *Levin* involved preemption in the brand name context. However, the Supreme Court has not addressed design defect claims in the brand name context.

<sup>217</sup>See generally James Beck, *Implied Preemption and Monograph Drugs*, DRUG & DEVICE L. (Dec. 12, 2016), <https://www.druganddevicelawblog.com/2016/12/implicit-preemption-and-monograph-drugs.html>.

<sup>218</sup>Gallagher, *supra* note 48, at 480.

<sup>219</sup>*Reckis v. Johnson & Johnson*, 28 N.E.3d 445 (Mass. 2015).

<sup>220</sup>Brief in Support of Petitioner for Writ of Certiorari, *McNeil-PPC, Inc. v. Hutto*, 2012 WL 3756878 (U.S.) (2012) (No. 12-122).

<sup>221</sup>James Beck, *Gorsuch Looks Pretty Good on Preemption*, DRUG & DEVICE L. (Feb. 6, 2017), <https://www.druganddevicelawblog.com/2017/02/gorsuch-looks-pretty-good-on-preemption.html>.

<sup>222</sup>*Id.*

implied preemption position that departs significantly from traditional conservative notions of federalism and separation of powers.<sup>223</sup> In contrast, Neil Gorsuch's jurisprudence reveals consistent support for principles of federalism, separation of powers and the reigning in of judicial overreach.

For example, in *Cook v. Rockwell Int'l Corp.* Gorsuch, writing for the Tenth Circuit, dismissed defendant's claims after engaging in a thorough exposition of the tenets underlying federalism.<sup>224</sup> In his opinion, Gorsuch emphasized the strong "presumption against preemption," especially in cases where "the area of law in question is one of traditional state regulation like public health and safety."<sup>225</sup> A commentator has recently suggested that Gorsuch's inclination towards "protecting the sovereign regulatory spheres of the states" is also evident in his opposition to current Dormant Commerce Clause jurisprudence.<sup>226</sup> Similarly, Gorsuch's highly textualist approach to statutory construction also suggests that he may be amenable to anti-preemption arguments that make their way before the court.<sup>227</sup> Indeed, many prominent textualists have previously found that "[w]here Congress has failed to endorse preemption with explicit and clear language, judicial supplementation to interpret the enactments of Congress takes the courts improperly into the legislative realm, rendering them a kind of 'superlegislature.'"<sup>228</sup>

## CONCLUSION

A careful examination of the federal case law indicates an absence of a clear method of application of federal preemption principles with respect to brand name drugs. While the Supreme Court has issued some guidance in regard to brand name, failure to warn claims, it has ultimately proven to be vague, unhelpful and yielding conflicting results in the courts. Additionally, the Supreme Court has issued zero guidance with regards to brand name, design defect claims. This void in high-court precedent has led to divergent and conflicting lower court decisions, convoluted legal analysis and exasperated plaintiff and defense bars. Despite some of the confusion, political developments suggest that high-court elucidation of some of the most muddled areas of brand name preemption is on the horizon. However, until that time, litigants will continue to utilize the legal strategies discussed herein with varying degrees of success.

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<sup>223</sup>Elizabeth M. LaFayette, *Always Ask for A Brand Name Drug: Trying to Untangle the Holding in PLIVA v. Mensing*, 115 W. VA. L. REV. 457, 472 (2012).

<sup>224</sup>*Cook v. Rockwell Int'l Corp.*, 790 F.3d 1088, 1094 (10th Cir. 2015).

<sup>225</sup>*Id.*

<sup>226</sup>Eric Wolff, *Justice Gorsuch and Product Liability Litigation*, LAW360 (Feb. 8, 2017), <https://www.law360.com/articles/889480/justice-gorsuch-and-product-liability-litigation>.

<sup>227</sup>*Id.*

<sup>228</sup>Robert S. Peck, *A Separation-of-Powers Defense of the "Presumption Against Preemption,"* 84 TUL. L. REV. 1185, 1200 (2010).