

# Taking the “Product” Out of Product Liability: Litigation Risks and Business Implications of Innovator and Co-Promoter Liability

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**P**LAINTIFF files a lawsuit claiming that her use of a prescription medication caused her to sustain injuries. Brand Pharmaceuticals did not manufacture the drug and therefore cannot be liable to Plaintiff, right? Not necessarily. Two emerging theories of liability, so-called “innovator liability” and “co-promoter liability,”

aim to hold a non-manufacturer responsible for injuries caused by another company’s pharmaceutical product. Under innovator liability, a pharmaceutical manufacturer may be liable for injuries caused by a competitor’s generic version of its brand drug based on its supposed responsibility for the drug’s

prescribing information. Under co-promoter liability, a company that contracts to market another manufacturer's pharmaceutical product may be liable based solely on its marketing activities. This article explores the theories underlying these novel sources of liability and proposes business strategies to consider that could help mitigate these emerging risks.

## I. Traditional Tort Doctrine Limits Product Liability to the Manufacturer of the Product.

By asserting innovator and co-promoter liability, plaintiffs are attempting to circumvent well-established tort law principles. It is axiomatic that “[a] fundamental principle of traditional products liability law is that the plaintiff must prove that the defendant supplied the product which caused the injury.”<sup>1</sup> A plaintiff suing for alleged injuries from a pharmaceutical product (or medical device) must identify the actual defendant that manufactured the product she alleges injured her.<sup>2</sup>

<sup>1</sup> *In re Aredia & Zometa Products Liab. Litig.* (McDaniel), No. 3-06-MD-1760, 2010 WL 5136142, at \*2 (M.D. Tenn. Dec 7, 2010); see also *In re Darvocet, Darvon & Propoxyphene Products Liab. Litig.*, 856 F. Supp.2d 904, 908 (E.D. Ky. 2012) (“[I]t is well-settled law that a ‘threshold requirement of any products-liability claim is that the plaintiff assert that the defendant’s product caused the plaintiff’s injury.’ (quoting *Smith v. Wyeth*, 657 F.3d 420, 423 (6th Cir. 2011) and citing cases applying Georgia, Indiana, Louisiana, Minnesota, Mississippi, New Jersey, New York, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee and Texas law)), *aff’d*, 756 F.3d 917 (6th Cir. 2014).

<sup>2</sup> See, e.g., *Patterson v. Novartis Pharm. Corp.*, 451 Fed. App’x 495, 497 (6th Cir. 2011) (the

When advancing theories of innovator and co-promoter liability, plaintiffs target defendants they acknowledge played no role in manufacturing or supplying the drug that allegedly caused their injury. These theories require courts to suspend traditional tort law doctrines of causation and duty and have, for that reason, largely been rejected. However, as discussed below, a handful of jurisdictions have viewed these theories more favorably.

## II. Innovator Liability Against Brand Manufacturers for Generic Drugs

### A. Background: Hatch-Waxman Act, *Wyeth v. Levine*, and *PLIVA v. Mensing*

The roots of innovator liability can be found in the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the “Hatch-Waxman Act.”<sup>3</sup> Designed to facilitate the entrance of generic drugs into the pharmaceuticals market, the Hatch-Waxman Act relaxed the requirements for U.S. Food and Drug Administration (FDA)

mere possibility that the plaintiff received (and allegedly was injured by) a defendant manufacturer’s drug does not “satisfy the pleading standards set forth in *Twombly* and *Iqbal*”); *Adams v. I-Flow Corp.*, No. CV09-09550 R SSX, 2010 WL 1339948, at \*3 (C.D. Cal. Mar. 30, 2010) (“Specifically, in an action such as this, a plaintiff must allege the identity of the particular defendant who manufactured the pain pump and the particular defendant who manufactured the anesthetic that allegedly injured plaintiff.”).

<sup>3</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355(j) and 35 U.S.C. §§ 156, 271(e)).

approval for those drugs. Instead of having to leap the same clinical hurdles as the original drug sponsor, generic manufacturers need only demonstrate that their product is “the same as” an existing brand drug, meaning that it is bioequivalent to its brand counterpart and has the same active ingredient(s), route of administration, dosage form, and strength.<sup>4</sup> Other than routine information reflecting the different manufacturer or distributor, the generic drug also must have “the same” prescribing information, *i.e.* label, as the brand drug (*i.e.*, the reference listed drug) on which its approval was based.<sup>5</sup>

This requirement of “sameness” is key to two recent U.S. Supreme Court decisions addressing federal preemption that appear to have reinvigorated innovator liability arguments. In *Wyeth v. Levine*, the Court held that FDA’s approval of a brand drug’s prescribing information did not preempt state-law failure-to-warn claims because the brand manufacturer had discretion under FDA’s “changes being effected” (CBE) regulation to unilaterally strengthen a drug warning.<sup>6</sup> Two years later, however, the Court held in *PLIVA, Inc. v. Mensing*, that failure to warn claims against generic manufacturers were preempted because – due to the Hatch-Waxman Act’s sameness requirement – generic manufacturers cannot use the CBE process to unilaterally change their labels.<sup>7</sup>

<sup>4</sup> See 21 U.S.C. § 355(j)(2)(A) (West) (describing the information required for abbreviated new drug applications (ANDAs)).

<sup>5</sup> *Id.*

<sup>6</sup> See 555 U.S. 555, 558-559 (2009).

<sup>7</sup> 131 S. Ct. 2567, 2572, 2575 (2011) (citing 21 U.S.C. § 355(j)(4)(G); 21 CFR §§ 314.94(a)(8)(iii), 314.150(b)(10)). In *Mutual*

In the post-Hatch-Waxman age, approximately 80% of prescriptions are filled with generic pharmaceuticals.<sup>8</sup> After *Mensing*, failure-to-warn claims involving a generic pharmaceutical should be preempted, arguably denying consumers of such products an effective remedy if they believe they were injured by the drug.<sup>9</sup> Enter innovator liability.

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*Pharmaceutical Company v. Bartlett*, the Court further held that design defect claims against generic drug manufacturers also are preempted because of the manufacturer’s inability under federal law to unilaterally alter either the generic drug’s composition or its labeling. 133 S. Ct. 2466, 2476-2477, 2479 (2013); see also Tony M. Diab, *Too Good To Last? Will the FDA’S Proposed Rule Put an End to Generic Drug Preemption Under Mensing and Bartlett?*, 83 DEF. COUNS. J. 28 (2015).

<sup>8</sup> See 78 Fed. Reg. 67985, 67988 (proposed Nov. 13, 2013).

<sup>9</sup> The one success that some plaintiffs have had in circumventing *Mensing* preemption is the claim that a generic manufacturer failed to timely update its drug’s label to match a change implemented by the brand manufacturer. See, e.g., *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 584 (6th Cir. 2013) (finding claims against generic manufacturer not preempted, because “not only could PLIVA have independently updated its labeling to match that of the branded manufacturer through the CBE process, see *Mensing*, 131 S.Ct. at 2575, but it had a federal duty to do so, 21 C.F.R. § 314.150(b)(10).”); see also *In re Fosamax Products Liab. Litig.*, 965 F. Supp.2d 413, 417 (S.D.N.Y. 2013) (citing *Fulgenzi* and collecting cases reaching “the same conclusion”); but see *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) (“a claim that PLIVA breached a federal labeling obligation sounds exclusively in federal (not state) law, and is preempted”); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1098 (8th Cir. 2013) (finding “no causal link” between generic manufacturer’s failure to update and plaintiff’s injury when prescribing physician solely relied on brand drug’s labeling).

## B. Judicial Response to Innovator Liability

Innovator liability first arose in a California case in 2008, in which an appellate court allowed a generic consumer's misrepresentation claims against the brand manufacturer to survive on the grounds that it was foreseeable that the prescribing doctor would see and rely on the brand manufacturer's prescribing information.<sup>10</sup> A federal court in Vermont later followed suit.<sup>11</sup>

However, the vast majority of courts faced with claims based on innovator liability have rejected the theory.<sup>12</sup> In fact,

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<sup>10</sup> *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89, 105 (Cal. App. 2008) (finding it “highly likely that a prescription for [brand drug] written in reliance on [brand’s] product information will be filled with [a generic version]” and also “eminently foreseeable that a physician might prescribe [the generic] in reliance on [brand manufacturer’s] representations” about its own drug).

<sup>11</sup> *Kellogg v. Wyeth*, 762 F. Supp.2d 694, 705 (D. Vt. 2010) (noting that “doctors routinely rely on information provided by the brand name manufacturers of drugs, in particular on the [Physician’s Desk Reference]” which “includes label information for brand name drugs, not the generic equivalents”).

<sup>12</sup> See *In re Darvocet, Darvon, & Propoxyphene Products Liab. Litig.*, 756 F.3d 917, 938-939 (6th Cir. 2014) (noting that “an overwhelming majority of courts ... have rejected ‘the contention that a name brand manufacturer’s statements regarding its drug can serve as the basis for liability for injuries caused by another manufacturer’s drug’” and finding that the 22 states at issue “would not recognize Plaintiff’s misrepresentation claims under their respective state laws” (quoting *Foster v. Am. Home Products Corp.*, 29 F.3d 165, 170 (4th Cir. 1994)); see also *id.* at 938 (noting “at least fifty-five decisions from twenty-two states” rejecting innovator liability).

“[e]very circuit court of appeals that has addressed the issue is in accord.”<sup>13</sup> In July 2014, the Supreme Court of Iowa also rejected plaintiff’s attempt to hold a brand manufacturer liable for injuries allegedly caused by a generic version of the drug.<sup>14</sup>

Following *Mensing*, the innovator liability theory was at least somewhat revived by a handful of courts concerned about *Mensing’s* seeming elimination of a remedy for consumers of generic drugs. Most recently, the Supreme Court of Alabama held that a brand drug manufacturer “may be held liable for fraud or misrepresentation ... based on statements it made in connection with the manufacture of a brand-name prescription drug, by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company.”<sup>15</sup> The court recognized that

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<sup>13</sup> *Id.* at 939. The 4th, 5th, 6th, 8th, 10th, and 11th Circuits have rejected innovator liability, while the others have not yet addressed it. See *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1282 (10th Cir. 2013) (Oklahoma law); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1252-1253 (11th Cir. 2013) (Florida law); *Bell*, 716 F.3d at 1093 (Arkansas law); *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 183 (5th Cir. 2012) (Louisiana law), *cert. denied*, 134 S.Ct. 57 (2013); *Smith v. Wyeth, Inc.*, 657 F.3d 420, 424 (6th Cir. 2011) (Kentucky law); *Foster*, 29 F.3d at 168 (Maryland law).

<sup>14</sup> *Huck v. Wyeth*, 859 N.W. 2d 353, 369-370 (Iowa 2014) (noting an “overwhelming national consensus” and “declin[ing] to change Iowa law to impose a new duty on manufacturers to those who never used their products and were instead harmed by use of a competitor’s product”).

<sup>15</sup> *Wyeth v. Weeks*, No. 1101397, \_\_\_ So. 3d \_\_\_, 2014 WL 4055813, at \*21-22 (Ala. Aug. 15, 2014) (noting that the generic manufacturer had to copy the brand manufacturer’s label “verbatim”). *Weeks* was subsequently overturned by statute for claims filed after May 1,

federal courts predicting Alabama law had previously rejected innovator liability, but distinguished those cases as no longer correct post-*Mensing*.<sup>16</sup> Two additional courts reached the same conclusion under other states' laws, although one was effectively overruled by a subsequent ruling.<sup>17</sup>

### C. The Key Areas of Dispute

Although the courts considering innovator liability have addressed the laws of dozens of states, their reasoning usually boils down to their views on three basic principles.

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2015. See 2015 AL S.B. 80 (signed May 1, 2015) (requiring the plaintiff in a product liability suit to “prove . . . that the defendant designed, manufactured, sold, or leased the particular product the use of which is alleged to have caused the injury on which the claim is based, and not a similar or equivalent product”); see also Bryan Koenig, *Ala. Undoes Brand Drug Liability for Generic Injury*, LAW360, May 1, 2015, available at <http://www.law360.com/articles/650264/ala-undoes-brand-drug-liability-for-generic-injury> (last accessed May 19, 2015).

<sup>16</sup> *Weeks*, 2014 WL 4055813. at \*10, \*11-13.

<sup>17</sup> See *Dolin v. SmithKline Beecham Corp.*, No. 12 C 6403, 2014 WL 804458, at \*9 (N.D. Ill. Feb. 28, 2014) (innovator manufacturer can be liable under both negligence and misrepresentation theories under Illinois law because it alone was responsible for the warning label and design); *Chatman v. Pfizer*, 960 F. Supp.2d 641, 651 (S.D. Miss. 2013) (misrepresentation claims allowed against brand manufacturer under Mississippi law, despite “near universal rejection [of innovator liability] by other district courts”); but see *Lashley v. Pfizer*, 750 F.3d 470, 476 (5th Cir. 2014) (finding claims against brand manufacturers “foreclosed” under Mississippi law, which shields defendants “from liability for products they did not create”; presumptively overruling *Chatman*).

### I. Are All Product-Based Injury Claims Product Liability Claims?

The majority of courts rejecting the theory hold that where the alleged cause of the injury is a product, the resulting claim necessarily sounds in product liability, no matter how the plaintiff seeks to characterize it.<sup>18</sup> Plaintiffs cannot pin liability on a non-manufacturer of a brand drug through semantic wordplay seeking to separate the product from the alleged injury.

A minority of courts, however, views matters differently. For example, the *Weeks* court stated that Alabama’s product liability doctrine “did not subsume a common-law negligence or wantonness claim” or a claim for “fraudulent suppression,” and therefore plaintiff’s claims against the brand manufacturer would not be “governed by the principles” of Alabama product liability law.<sup>19</sup> These minority

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<sup>18</sup> See, e.g., *Huck*, 850 N.W. 2d at 373 (“Huck cannot evade the proof requirements of Iowa products liability law merely by labeling her claim as a common law negligent failure-to-warn theory. Her claims arise from injuries from her use of a product—PLIVA’s generic metoclopramide.”); see also *Foster*, 29 F.3d at 168 (holding that, “[a]lthough actions for negligent misrepresentation arise in many contexts other than products liability,” plaintiffs were seeking to recover for injuries caused by a product, and such a claim requires “that a defendant be shown to have manufactured the product that caused an injury prior to being held liable for such injury”).

<sup>19</sup> 2014 WL 4055813, at \*3; see also *id.* at \*4 (“This is not a claim that the drug ingested by Danny was defective; instead, it is a claim that Wyeth fraudulently misrepresented or suppressed information about the manner in which (i.e., the duration) the drug was to be taken.”); *Dolin*, 2014 WL 804458, at \*4 (“Nothing in

courts often treat a drug's prescribing information as somehow independent from the drug in question. The *Weeks* court, for example, reasoned that, "[b]ecause a warning label is not a part of the manufacturing process, . . . the fact that a brand-name manufacturer did not produce the version of the drug ingested by the plaintiff" did not "bar[ ] the plaintiff's tort action when the plaintiff is arguing that he or she was injured by a failure to warn."<sup>20</sup> Therefore (the argument goes), brand manufacturers are not liable because of their products, but because of their (allegedly false or inadequate) representations about their own drugs which "would necessarily be repeated in the generic labeling, foreseeably causing harm to a patient who ingested the generic product."<sup>21</sup>

This logic is most certainly wrong and misunderstands the fundamental nature of pharmaceutical products. Comment k to the Restatement (Second) of Torts recognizes that prescription pharmaceuticals are

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Illinois common law compels a court to construe Plaintiff's common law negligence claims as product liability claims . . ."; *Kellogg*, 762 F. Supp.2d at 704 ("Vermont has not eliminated common law actions for negligence or fraud merely because they involve products."); *Chatman*, 960 F. Supp.2d at 652 (finding brand manufacturers "not manufacturers" for purposes of plaintiff's misrepresentation claims and therefore Mississippi's product liability statute did not apply).

<sup>20</sup> 2014 WL 4055813, at \*16.

<sup>21</sup> *Id.* at \*17; see also *Dolin*, 2014 WL 804458, at \*8 (noting that brand manufacturer GSK's alleged negligence, regarding its design and warning label, "is extrinsic to the Paxil manufacturing process, and, if true, it could proximately cause injury to consumers of all versions of paroxetine, including the generic version that Mr. Dolin ingested").

unavoidably unsafe products, and thus they are neither defective nor "unreasonably dangerous" so long as they are "properly prepared, and accompanied by proper directions and warning."<sup>22</sup> In other words, a drug's warning cannot be separated from the product itself; it is an inherent part of the pharmaceutical product, *i.e.*, the means by which these otherwise unavoidably unsafe products are rendered non-defective. Nonetheless, in the minority jurisdictions, a plaintiff's artful pleading is sufficient.

## 2. Does a Brand Manufacturer Owe A Duty to the Consumer of a Generic Drug?

Even if claim(s) involving products do not have to be governed by products liability principles, most courts still recognize that a brand manufacturer owes no duty to consumers of generic drugs because it has no nexus with such consumers and no control over the products to which they are exposed. The Fourth Circuit found "no legal precedent for using a name brand manufacturer's statements about its own product as a basis for liability for injuries caused by other manufacturers' products, over whose production the name brand manufacturer had no control."<sup>23</sup> The Tenth Circuit rejected innovator liability based on negligent design because "[t]he brand-name manu-

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<sup>22</sup> RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

<sup>23</sup> *Foster*, 29 F.3d at 170-171; see also *Huck*, 850 N.W. 2d at 378 ("[I]liability generally follows control" in torts, but "[a] brand manufacturer cannot ensure that a generic manufacturer complies with federal law").

facturers do not have any relationship with the [plaintiffs].”<sup>24</sup>

The minority courts have attempted to skirt these basic principles through the concept of “foreseeability,” *i.e.*, brand manufacturers can foresee that their inadequate warning will harm users of the generic equivalent to their products.<sup>25</sup> But, as the Fourth Circuit held in *Foster*, the traditional tort law concept of duty still trumps an expanded notion of foreseeability. To impose a duty to consumers of another manufacturer’s products “would be to stretch the concept of foreseeability too far.”<sup>26</sup>

### 3. Do Public Policy Considerations Support Innovator Liability?

To the majority courts, public policy concerns “weigh against holding name-brand competitors liable for injuries caused by their generic competitor’s drug.”<sup>27</sup> As the *Foster* court explained, imposing innovator liability “would be especially unfair” when “the generic manufacturer reaps the benefits of the name brand manufacturer’s statements by

copying its labels and riding on the coattails of its advertising.”<sup>28</sup>

By contrast, the outlier courts have argued that the brand manufacturer has “been compensated for taking responsibility for [the generic drug’s] design and warning label with an extended period of government-impacted monopoly privileges in connection with the sale of its [brand drug].”<sup>29</sup> Moreover, these courts point to the brand manufacturer’s alleged moral culpability, which makes it “not fundamentally unfair” to hold them liable.<sup>30</sup>

But, as the *Huck* court cautioned, to make brand manufacturers liable to consumers of generic drugs “would alter the relationship between generic and brand manufacturers” created by Congressional legislation and “discourage investments necessary to develop new, beneficial drugs

<sup>24</sup> *Shrock*, 727 F.3d at 1282.

<sup>25</sup> See, e.g., *Kellogg*, 762 F. Supp.2d at 708-709 (finding it “reasonably foreseeable” a physician will rely on a brand manufacturer’s representations about its drug when prescribing that drug for a patient, “regardless of whether the pharmacist fills the prescription with a generic form of the drug”); *Weeks*, 2014 WL 4055813 at \*17 (“an omission or defect in the labeling for the brand-name drug would necessarily be repeated in the generic labeling, foreseeably causing harm to a patient who ingested the generic product.”).

<sup>26</sup> *Foster*, 29 F.3d as 171.

<sup>27</sup> *Schrock*, 727 F.3d at 1285.

<sup>28</sup> 29 F.3d at 170 (noting that brand manufacturers alone “undertake the expense of developing pioneer drugs, performing the studies necessary to obtain premarketing approval, and formulating labeling information”); see also *Huck*, 850 N.W. 2d at 378-379 (noting that brand manufacturers, “who incurred the costs to develop [brand drug], do not profit from PLIVA’s sale of the competing generic formulation” and have no control over PLIVA).

<sup>29</sup> *Dolin*, 2014 WL 804458, at \*6. The Hatch-Waxman Act did create a post-approval exclusivity period for brand drugs separate from (though not necessarily in addition to) the patent term as a trade-off for generic drugs’ easier entry into the market. See 21 C.F.R. § 314.108; available at <http://www.fda.gov/drugs/developmentapprovalprocess/ucm079031.htm> (last accessed May 19, 2015).

<sup>30</sup> *Weeks*, 2014 WL 4055813, at \*23; see also *Conte*, 168 Cal. App. 4th at 106 (“if Wyeth misrepresented the risks of taking its medication, any moral culpability it might bear for that misrepresentation is not lessened if the person who is harmed by his or her reliance on it happened to ingest the generic version as a result, rather than Wyeth’s Reglan brand.”).

by increasing the downside risks.”<sup>31</sup> The court, consistent with the majority, was “unwilling to make brand manufacturers the de facto insurers for competing generic manufacturers.”<sup>32</sup>

#### D. FDA’s Proposed Regulatory Solution

Responding to concerns raised by the plaintiffs’ bar and consumer groups following *Mensing*, FDA recently proposed new regulations that would, for the first time, allow generic manufacturers to use the CBE process to unilaterally update labeling.<sup>33</sup> This regulation likely would reopen generic manufacturers to failure-to-warn litigation and might ease the pressure for courts to adopt innovator liability.<sup>34</sup>

<sup>31</sup> 850 N.W.2d at 377.

<sup>32</sup> *Id.* at 380.

<sup>33</sup> 78 Fed. Reg. 67985 (proposed Nov. 13, 2013); *see id.* at 67988 (citing as reasons for the regulation (a) the “tension” now between the requirement that generic drugs have the same labeling as the reference listed drug and the need for the ANDA holder “to be able to independently update its labeling as part of its independent responsibility to ensure that the labeling is accurate and up-to-date,” (b) the need to incentivize generic companies to be pharmacovigilant, especially since data supporting labeling changes may become available after generics enter the market, and (c) the fact that, after *Mensing* and *Levine*, “access to the courts is dependent on whether an individual is dispensed a brand name or generic drug”).

<sup>34</sup> However, the proposed regulation also could change the generics industry model by effectively requiring generics to engage in brand-level pharmacovigilance and post-market trials, increasing costs and putting some manufacturers out of business – thereby betraying the purpose of the Hatch-Waxman Act. *See* Comments re: 78 Fed. Reg. 67985 at 19-22, Generic Pharmaceutical Association (Mar. 13, 2014)

FDA initially scheduled publication of the final rule for December 2014, but later pushed the date back to late September 2015.<sup>35</sup> In February 2015, FDA opened a new period of public comment on the proposal, to run through April 27, 2015, and set a full-day hearing for March 27, 2015.<sup>36</sup> GPhA reportedly has vowed to litigate if the rule is finalized in its present form, contending that it is beyond FDA’s authority to alter Congress’ “sameness” requirements reflected in Hatch-Wax-

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(“GPhA cmt.”). The rule also would undermine the Hatch-Waxman “sameness” requirement by allowing generic labeling to differ, at least temporarily, from that of the reference listed drug or brand drug, causing “unnecessary confusion” when multiple versions of safety warnings for the same products are allowed to exist simultaneously on the market. Comments re: 78 Fed. Reg. 67985 at 2, Pharmaceutical Research and Manufacturers of America (Mar. 11, 2014) (“PhRMA cmt.”); *see also* GPhA cmt. at 5-9. In addition, by requiring the generic manufacturer to send proposed label changes to the brand manufacturer at the same time they are submitted to FDA, the regulation theoretically could subject the brand manufacturer to litigation over labeling decisions made by competing generics manufacturers for their own drugs. *See* PhRMA cmt. at 11; 78 Fed. Reg. 67985, 67991.

<sup>35</sup> *See* <https://federalregister.gov/a/2013-26799> (last accessed May 15, 2015); *see also* Jeff Overley, *FDA Pushes Back Rule on Generic Drug Warning Labels*, LAW360, Nov. 18, 2014, available at <http://www.law360.com/articles/597192/fda-pushes-back-rule-on-generic-drug-warning-labels> (last accessed May 19, 2015) (noting FDA had received “a great deal of public input” and was “reviewing and considering all of the comment received”).

<sup>36</sup> *See* Jeff Overley, *FDA Eyes Alternatives To Generic-Drug Label Plan*, LAW360, Feb. 17, 2015, available at <http://www.law360.com/articles/622113/fda-eyes-alternatives-to-generic-drug-label-plan> (last accessed May 19, 2015).

man.<sup>37</sup> Whether or not a final rule is eventually promulgated that effectively vitiates *Mensing*, innovator liability remains for now a possibly potent risk for brand manufacturers in those courts that have accepted the theory (and potentially in other as-yet undecided courts in the future).

### III. Co-Promoter Liability

Co-promoter liability is another emergent theory that targets a defendant that did not manufacture, distribute, or sell the product allegedly causing the plaintiff's injury. A "co-promoter" contracts with the drug's manufacturer to promote the drug when the manufacturer, for whatever reason, does not have the necessary marketing apparatus. For example, a foreign manufacturer seeking to sell its drug in the United States may seek the assistance of an American marketer with a well-established network of sales representatives. The manufacturer and the co-promoter enter into a contractual relationship whereby the co-promoter agrees to disseminate information about the drug to prescribing physicians and other health care organizations.

The theory behind co-promoter liability is that co-promoters are "essential to the marketing, selling, and distribution" of the drug and, along with the manufacturer, are "in the best position to give doctors and patients the information they need to make informed decisions."<sup>38</sup> Courts have

had less opportunity to consider co-promoter liability than innovator liability, but a recent case in the U.S. District Court for the Western District of Louisiana could change that. In multi-district litigation, a federal jury handed down a \$9 billion punitive damages award, initially upheld by the MDL court, against both Takeda, the Japanese manufacturer of the prescription diabetes drug Actos, and Eli Lilly, the U.S. promoter of the drug, for failing to warn about the risk of bladder cancer.<sup>39</sup> The court later reduced the punitive damages award based on due process concerns, resulting in a total damages award of \$36.8 million, but not before the shock of the initial 10-figure award had reverberated throughout the pharmaceutical industry and the plaintiffs' bar.<sup>40</sup> The Fifth Circuit recently dismissed an appeal after Takeda announced a pending \$2.4 billion settlement of most Actos suits.<sup>41</sup>

In upholding the judgment against the co-promoter, the district court pointed to the fact that Lilly was Takeda's sole marketing arm in the US and "the sole provider of marketing information to physicians in the United States about

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at \*13, \*49 (W.D. La. Sept. 2, 2014) (emphasis removed).

<sup>39</sup> See *id.* at \*52.

<sup>40</sup> See Sindhu Sundar, *\$9B Takeda, Eli Lilly Actos Damages Slashed To \$37M*, LAW360, Oct. 27, 2014, available at <http://www.law360.com/articles/590855/-9b-takeda-eli-lilly-actos-damages-slashed-to-37m> (last accessed May 19, 2015).

<sup>41</sup> See Joe Van Acker, *Takeda's 2.4B Actos Deal Ends 5th Cir. Appeal*, LAW360, May 5, 2015, available at [http://www.law360.com/productliability/articles/651842?nl\\_pk=41e64eef-b648-46c6-9489-9093ee9e273a&utm\\_source=newsletter&utm\\_medium=email&utm\\_campaign=productliability](http://www.law360.com/productliability/articles/651842?nl_pk=41e64eef-b648-46c6-9489-9093ee9e273a&utm_source=newsletter&utm_medium=email&utm_campaign=productliability) (last accessed May 22, 2015).

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<sup>37</sup> See Jeff Overley, *Generics Lobby Threatens Suit Over FDA Warning Labels Plan*, LAW360 Sept. 23, 2014, available at <http://www.law360.com/articles/579957/generics-lobby-threatens-suit-over-fda-warning-labels-plan> (last accessed May 19, 2015).

<sup>38</sup> *In re Actos (Pioglitazone) Products Liab. Litig.*, No. 6:11-MD-2299, 2014 WL 4364832,

Actos;” that Lilly “detailed” plaintiff’s physicians “multiple times” before they prescribed her the drug; and that Lilly’s role was “active,” not passive, *i.e.*, Lilly did more than merely pass on Takeda’s information about the drug. Lilly was involved in “developing the strategy for responding to the FDA’s requests” and communicated with Takeda Japan about Actos at “the highest executive levels.”<sup>42</sup> The court concluded that Lilly was not “a simple marketer” of Actos, just “taking orders from Takeda and carrying them out,” but instead was actively involved in regulatory activities for the drug.<sup>43</sup>

Lilly argued that any claims against it were preempted because, following the rationale of *Mensing*, it could not unilaterally change the Actos label.<sup>44</sup> The court rejected this defense, concluding that because Lilly is not a generic drug company, “the underlying rationale at

play” in *Mensing* does not apply.<sup>45</sup> Judge Doherty rejected the argument that a co-promoter is limited to sharing with prescribing doctors only the information contained in the NDA holder’s label, noting that, in practice, sales pitches and marketing efforts were “not limited to the label, *per se*” but instead merely had to contain information that was “consistent with the label.”<sup>46</sup> To the court, this provided enough room for the possibility that Lilly *could have* provided a stronger warning to physicians than that contained in the Actos label: “Lilly has not identified any statutory provision, regulation, or rule, nor any controlling applicable jurisprudence compelling this Court to conclude that Lilly could not *vary its marketing literature in any way, whatsoever*, from the languaging of the insert label.”<sup>47</sup>

The co-promotor liability theory has not been endorsed as yet by any other court, and there are a handful of cases in which it has correctly been rejected.<sup>48</sup> Claims against co-promoters should be rejected because, as with innovator liability, co-promoters do not manufacture, sell,

<sup>42</sup> *In re Actos*, 2014 WL 4364832, at \*12-\*13.

<sup>43</sup> *Id.* at \*19. The court also highlighted plaintiff’s argument that Lilly was aware of suspicions of a connection between Actos and bladder cancer as early as 1999 (per a slide deck acknowledging it as a “significant adverse event”) but provided no warnings in its marketing or in discussing Actos with physicians and instead agreed to withhold information about bladder cancer from distributors and doctors. *Id.* at \*12-\*13.

<sup>44</sup> Indeed, FDA regulations do not even address co-promoters, let alone authorize them to change label warnings. The only regulation that applies to any type of “nonapplicant,” *i.e.*, an entity other than the sponsor of the New Drug Application, applies to “manufacturer[s], packer[s], or distributor[s],” not co-promoters. See 21 C.F.R. § 314.80(c)(1)(iii) (requiring manufacturers, packers, and distributors whose name appears on a drug label to submit adverse event reports to either FDA or to the applicant).

<sup>45</sup> 2014 WL 4364832 at \*17.

<sup>46</sup> *Id.* at \*18.

<sup>47</sup> *Id.* at \*17.

<sup>48</sup> See, e.g., *Lopienski v. Centocor, Inc.*, 2008 WL 2565065, at \*4 (D. N.J. Jun. 25, 2008) (“OMP did not design, research, develop, formulate, manufacture, package, distribute or sell Remicade. Accordingly, the Court finds that this alleged nexus between OMP and Centocor does not show that OMP is either a ‘seller’ or ‘manufacturer’ of Remicade, and therefore, OMP is not a proper defendant under the NJPLA or NJCFA.”); *Yurcic v. Purdue Pharma, L.P.*, 343 F. Supp.2d 386, 397 (M.D. Pa. 2004) (co-promoter not a “seller” for breach of warranty purposes).

or distribute the product in question. Also, despite the *Actos* court's quick dismissal of the argument, *Mensing* should be instructive. A co-promoter has no more ability to independently control a drug's labeling than does a generic drug manufacturer.<sup>49</sup>

In several OxyContin cases, however, the co-promoter, Abbott, was granted summary judgment not because the court found plaintiffs' co-promotion theory of liability non-viable, but because Abbott's co-promotion efforts could not be tied to the decisions of plaintiffs' prescribing physicians in those particular cases.<sup>50</sup> These cases leave the door open for recognition of

the theory in the right fact setting.<sup>51</sup> Given the potentially large payday as evidenced by the *Actos* jury's initial award, it is likely that other plaintiffs will attempt to follow the *Actos* model to hold co-promoters responsible for injuries allegedly caused by drugs they did not manufacture, sell, or distribute.

#### IV. Potential Business Strategies to Mitigate Risk

Given the emergence of these outlier theories of liability, it may be prudent for both manufacturers and co-promoters of brand pharmaceutical products to factor these litigation risks into their business strategies. There are a number of potential strategies that might be considered.

##### A. Business Strategies Addressing the Risk of Innovator Liability

When a New Drug Application is past patent and no longer factors into the company's business plans, a company may wish to divest the NDA in order to limit potential innovator liability. Under 21 C.F.R. § 314.72, a new drug applicant can transfer ownership of its application, at which point the new owner assumes regulatory responsibilities for the drug.<sup>52</sup>

<sup>49</sup> See *In re Fosamax (Alendronate Sodium) Products Liab. Litig.* (No. II), No. MDL 2243 JAP-LHG, 2012 WL 181411, at \*4 (D .N.J. Jan. 17, 2012) (holding state law claims against promoter/distributor of drug preempted under *Mensing* because "a contractual relationship between Watson and Merck cannot change the fact that Watson is not the NDA holder. Consequently, Watson has no power to unilaterally change Fosamax labeling"). The *Actos* court failed to recognize the central importance to the Supreme Court's preemption analysis of the availability *vel non* of the CBE regulation. The First Circuit recently confirmed that even claims against brand manufacturers are preempted under *Mensing* where the CBE regulation does not apply. See *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, No. 14-1290, \_\_\_ F.3d \_\_\_, 2015 WL 727970, at \*9 (1st Cir. Feb. 20, 2015) (finding claims preempted under *Mensing* when brand drug manufacturer could not have used CBE process to change label in way sought by plaintiff and therefore could not independently make the desired changes).

<sup>50</sup> See, e.g., *Koenig v. Purdue Pharma Co.*, 435 F. Supp.2d 551, 554 (N.D. Tex. 2006); *Timmons v. Purdue Pharma Co.*, No. 8:04-CV-1479-T-26MAP, 2006 WL 263602, at \*5 & n.9 (M.D. Fla. Feb. 2, 2006); *Foister v. Purdue Pharma, L.P.*, 295 F. Supp.2d 693, 709 (E.D. Ky. 2003); *Ewing v. Purdue Pharma, L.P.*, No. 2:02CV00150, 2003 WL 1883475, at \*2 (W.D. Va. Apr. 10, 2003).

<sup>51</sup> *But see Timmons*, 2006 WL 263602, at \*4 ("because Abbott played no part in the package insert in OxyContin, Abbott was not capable of misrepresenting or making omissions regarding the medication") (comment dismissing fraud and misrepresentation claim, without further explanation).

<sup>52</sup> See 21 C.F.R. § 314.72(a) (when an applicant transfers ownership of an NDA, the former owner must inform the FDA that it has transferred "all rights to the application" and

Because the innovator then no longer has any authority over the drug label, the theory underpinning innovator liability would no longer obtain.<sup>53</sup>

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the new owner must submit a letter stating its “commitment to agreements, promises, and conditions made by the former owner and contained in the application”); *see also* 21 C.F.R. § 314.70 (all supplements and other changes to an approved application, including labeling, must be made by “the applicant”, *i.e.*, “the [current] holder of an approved application”).

<sup>53</sup> *See In re Darvocet*, 756 F. 3d at 940 (“After the divestiture, Lilly had no more power to change the label than did [generic manufacturer] Mylan” and thus the district court rightly dismissed claims against Lilly). Plaintiffs had argued that Lilly could be held liable for post-divestiture injuries because, even after divestiture in early 2002, Lilly continued manufacturing drugs for the new NDA holder under a supply agreement. *In re Darvocet, Darvon & Propoxyphene Products Liab. Litig.*, No. 2:11-MD-2226-DCR, 2012 WL 767595, at \*6 (E.D. Ky. Mar. 7, 2012), *aff’d*, 756 F.3d 917 (6th Cir. 2014). The Eastern District of Kentucky rejected this argument, holding that “any state failure-to-warn claims [against Lilly] would be preempted by federal law because, as the plaintiffs concede, ‘Lilly had no power to change the labels for generic drugs, or for brand-name drugs that were made and sold by others.’” *Id.* at \*7; *In re Darvocet*, 756 F.3d at 940 (“a supply agreement” did not make “a brand manufacturer responsible as a generic manufacturer based on powers it held as a brand manufacturer”); *Hamilton v. AstraZeneca, et al.*, Minute Order, No. 37-2013-00070440-CU-MM-CTL (Cal. Super. Ct. Feb. 18, 2015) (sustaining demurrer to plaintiff’s complaint because defendant Novartis “owed Plaintiffs no duty as a matter of law” for claims arising six years after Novartis’s divestiture of the drug in question); *Conte*, 168 Cal. App. 4th at 95 n.1, 107 (“it appears Wyeth no longer has primary responsibility for Reglan-related claims arising after March 31, 2002” (when it divested its NDA)). Note that a brand manufacturer who divests the NDA could still potentially be liable on an innovator theory for pre-divestiture label warnings.

Short of divestiture, a brand manufacturer could also formally withdraw an NDA under FDA regulations if it no longer intends to market and sell the drug.<sup>54</sup> If FDA determines that the drug was voluntarily withdrawn from sale for reasons other than effectiveness or safety, the drug will be “delisted” as a “Discontinued Drug Product.”<sup>55</sup> Although the regulatory impact of this action is less clear, the withdrawal of an NDA appears to vest all future responsibility for generic versions’ labeling changes with FDA.<sup>56</sup> Note that *informally* removing a drug from the marketplace without adhering to the procedure laid out in

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<sup>54</sup> *See* 21 C.F.R. § 314.150(c) (FDA will withdraw approval of an application at the applicant’s request if the drug is no longer being marketed for reasons other than safety or efficacy).

<sup>55</sup> *See, e.g.*, 75 Fed. Reg. 48351 (Aug. 10, 2010) (After NDA holder notifies FDA that it is no longer marketing a drug, the drug will be moved to the “Discontinued Drug Product List” section of the Orange Book” which includes, “among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.”).

<sup>56</sup> *See id.* (“If FDA determines that labeling for this drug product should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.”); *see also Mensing*, 131 S. Ct. at 2593 (dissent) (“But brand-name manufacturers often leave the market once generic versions are available, meaning that there will be no manufacturer subject to failure-to-warn liability.”); Victor E. Schwartz et al., *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, 1846 (2013) (when FDA moves a drug to the Discontinued Drug Product List, “the FDA takes the central role of determining when a labeling change is needed and advises ANDA applicants accordingly” (citing 75 Fed. Reg. at 48,352)).

the regulations does not alter the manufacturer's regulatory responsibilities and therefore does not affect the threat of innovator liability.<sup>57</sup>

If business interests weigh against divesting or formally withdrawing an NDA, brand manufacturers might consider other steps to minimize their risk, such as aggressively engaging in pharmaco-vigilance in cooperation with generic manufacturers. While this would provide brand manufacturers with more safety data that might inform future labeling changes, it arguably also would put brand manufacturers in the role of policing generic manufacturers' conduct, raising many of the same concerns that have been voiced about the FDA's proposed new generics labeling rule. In addition, there may be practical impediments to obtaining meaningful and complete safety data from generic manufacturers.

## B. Business Strategies Addressing the Risk of Co-promoter Liability

A co-promoter can minimize its liability risk by taking care that the co-promotion agreement clearly defines the limits of its power and responsibilities with respect to the promoted drug and by bargaining for the strongest possible indemnity agreement from the product's manufacturer.

Under the *Actos* court's reasoning, a co-promoter's litigation risk will turn in significant part on the extent to which it involves itself in labeling, safety, or

regulatory decisionmaking over a drug. For example, a co-promoter whose only role is to use promotional materials developed and/or approved by the innovator will have a strong argument that it is "a simple marketer" that just "tak[es] orders from [the innovator] and carr[ies] them out."<sup>58</sup> On the other hand, a co-promoter that has the ability to review and comment on the drug approval application or regulatory communications and to attend and participate in FDA meetings would have a more difficult argument.<sup>59</sup> Accordingly, a co-promoter must think carefully before seeking or accepting such rights or responsibilities. A co-promoter should only agree to a more active role when there are identifiable business reasons for doing so.

A co-promoter should also negotiate an indemnification agreement that accounts for the arguments raised against Lilly in the *Actos* litigation. A co-promoter should not settle for boilerplate language that generally indemnifies it for liability absent evidence of its own wrongful conduct. Rather, the indemnification provision should explicitly address potential co-promoter liability arising both for the specific responsibilities the co-promoter is assuming under the contract and from responsibilities that the co-promoter is not assuming. Depending on the parties' broader business interests, the specific indemnities offered for different alleged conduct might be different. By clearly defining these indemnifications, however, the co-promoter (and the manufacturer) will have a better understanding of

<sup>57</sup> See 78 Fed. Reg. 67985, 67993 ("It should be noted that if an NDA holder has discontinued marketing a drug product, but approval of the NDA has not been withdrawn under § 314.150, the NDA holder still must comply with applicable statutory and regulatory requirements.").

<sup>58</sup> *In re Actos*, 2014 WL 4364832, at \*19.

<sup>59</sup> See *id.* at \*19 (highlighting the fact that Takeda and Lilly "exchanged information and communicated" during the regulatory history of *Actos*).

their potential legal liabilities and can avoid contractual disputes in the unfortunate event that products liability litigation occurs.<sup>60</sup>

Beyond securing a suitably-tailored indemnity, co-promoters may consider such steps as providing clear, written instructions to their sales representatives to only use and discuss information prepared by the manufacturer and (notwithstanding the *Actos* court) that is contained in the prescribing information for the drug, and to clearly document that all of the marketing materials used come directly from – or at least have the final approval of – the drug’s manufacturer.

## V. Conclusion

Innovator liability and co-promoter liability both seek to hold liable a company that did not manufacture, distribute, or sell the product that allegedly caused the plaintiff’s injuries. While neither theory has garnered majority support as yet, proponents of each have established important beachheads that present substantial litigation risks to pharmaceutical companies. These emerging theories of liability should be factored into future business planning.

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<sup>60</sup> Although the exact terms of Takeda and Lilly’s contract have not been made public, it is notable that Takeda has reserved the right to dispute Lilly’s claim, based on an indemnification agreement in the contract, that Takeda agreed to indemnify Lilly for losses in Actos litigation. See Lance Duroni, *Takeda Won’t Commit to Cover Eli Lilly for \$9B Verdict*, LAW 360, Apr. 24, 2014, available at <http://www.law360.com/articles/531635/takeda-won-t-commit-to-cover-eli-lilly-for-9b-verdict>.