IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

In re Testosterone Replacement	**)**	
Therapy Products Liability Litigation	**)**	**No. 14 C 1748**
Coordinated Pretrial Proceedings	**)**	**MDL No. 2545**

MEMORANDUM OPINION AND ORDER

This multidistrict litigation proceeding (MDL) involves lawsuits by over 2,500 plaintiffs who allege that they have suffered injuries caused by defendants' testosterone replacement therapy (TRT) drugs. The Judicial Panel on Multidistrict Litigation consolidated the cases before this Court for pretrial proceedings. Eight defendants—Actavis, Inc., Actavis Pharma, Inc., Actavis Laboratories UT, Inc., Watson, Laboratories, Inc. (the Actavis defendants); Pfizer Inc. and Pharmacia & Upjohn Company, LLC (the Pfizer defendants); and Auxilium Pharmaceuticals, Inc.—have moved to dismiss the state law claims against them, or for judgment on the pleadings, concerning their generic TRT drugs, arguing that the claims are preempted by federal law. In their response, plaintiffs represent that they have voluntarily dismissed all claims against the Actavis defendants involving generic products. Thus the only claims still at issue are those concerning the generic TRT drugs of the Pfizer Defendants and Auxilium. Plaintiffs deny that these claims, as alleged, are preempted, but in the alternative, they request discovery to establish that their claims survive preemption. For the reasons stated below, the Court grants defendants' motion to dismiss and denies plaintiffs' request for discovery.

Background

The Food, Drug, and Cosmetic Act (FDCA) requires drug manufacturers to gain

approval from the United States Food and Drug Administration (FDA) before introducing a drug into interstate commerce. 21 U.S.C. § 355(a). To obtain FDA approval for a new drug, a manufacturer must submit a New Drug Application (NDA), a comprehensive submission that must include, for example, detailed information about the drug's composition and full reports of investigations into the drug's safety and effectiveness. *See id.* § 355(b)(1). In addition, NDA applicants must submit "the labeling proposed to be used for [the] drug," § 355(b)(1)(F), and they are "responsible for the accuracy and adequacy of [the] label" they submit. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574 (2011) (citing 21 U.S.C. §§ 355(b)(1), (d)). Manufacturers of generic drugs, however, need not submit such comprehensive applications. Rather, the FDA will approve a generic drug pursuant to an abbreviated new drug application (ANDA) upon a showing that the generic drug is equivalent to a previously approved "reference listed drug" (RLD). *See* 21 U.S.C. § 355(j)(2)(A). The labeling proposed in the ANDA must also be "the same as the labeling approved" for the generic drug's RLD. *Id.* § 355(j)(2)(A)(v).

An RLD is a previously approved drug "identified by FDA as the drug product upon which an applicant relies in seeking approval of its [ANDA]." 21 C.F.R. § 314.3(b). The FDA designates a "single [RLD] as the standard to which all generic versions must be shown to be bioequivalent" in order to "avoid possible significant variations among generic drugs and their brand name counterpart." FDA, *Drugs@FDA Glossary of Terms*, http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm (last visited Nov. 9, 2015). Usually, the RLD will be a non-generic, branded drug that was approved pursuant to an NDA. But in certain circumstances—for example, if the original NDA drug has been discontinued—the drug designated as the RLD may simply be "the market

leader as determined by FDA on the basis of commercial data." Final Rule, Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,958 (Apr. 28, 1992). It is possible, therefore, for a generic drug approved pursuant to an ANDA to become the RLD upon which future ANDA applicants rely in seeking FDA approval.

For purposes of this motion, the Court accepts as true the facts plaintiffs have alleged jointly in their master complaint. The Court also takes judicial notice of the following publicly available facts with which both parties agree. The Pfizer defendants' and Auxilium's generic TRT drugs (Depo-Testosterone and Testopel, respectively) were approved through the ANDA process. Though they are "generic" in the sense that neither was the pioneer drug, both drugs are marketed and sold under their branded names. In addition, FDA has designated both drugs as RLDs: Depo-Testosterone for other testosterone cypionate TRTs, and Testopel for other testosterone pellet TRTs. In their response to defendants' motion to dismiss, plaintiffs state that every claim against the Actavis defendants involving a generic TRT product has been voluntarily dismissed, and defendants clarify in their reply that their motion does not seek dismissal of any claims involving products approved pursuant to an NDA, such as the Actavis defendants' drug Androderm. Thus the only claims before the Court on this motion are those involving the ANDA RLDs of the Pfizer defendants and Auxilium (the ANDA defendants).

The FDA has approved TRT products for the treatment of hypogonadism, the diminished functional activity of the gonads, which may involve the severely diminished production or nonproduction of testosterone. According to plaintiffs, however, defendants in this MDL have marketed their TRT drugs (including Depo-Testosterone and Testopel) for treatment of a condition referred to as "Low T," which is not a form of

classical hypogonadism and for which, plaintiffs allege, TRT drugs confer little or no benefit. In addition, they allege that the drugs cause serious cardiovascular problems, for which defendants failed to provide adequate warnings and which resulted in injuries to plaintiffs.

Plaintiffs' master complaint asserts ten primary state law claims for relief against all defendants: strict liability claims based on design defect and failure to warn, negligence, negligent misrepresentation, breach of implied warranty of merchantability, breach of express warranty, fraud, redhibition, consumer protection, and unjust enrichment. In addition to those primary claims, the complaint also asserts "claims"[1] for wrongful death, survival, loss of consortium, and punitive damages.

The ANDA defendants have filed a motion to dismiss all claims and for judgment on the pleadings pursuant to Federal Rules of Civil Procedure 12(b)(6) and 12(c), arguing that plaintiffs' state-law claims are preempted under the impossibility preemption doctrine, as articulated in *Mensing* and *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

Discussion

A Court applies the same standard of review to motions under Federal Rules of Civil Procedure 12(b)(6) and 12(c), "accept[ing] all well-pleaded allegations in the complaint as true and draw[ing] all reasonable inferences in favor of the plaintiff." *Rutledge v. City of Chicago*, No. 13 C 870, 2013 WL 6645510, at *1 (N.D. Ill. Dec. 17, 2013) (citing *Fail-Safe, LLC v. A.O. Smith Corp.*, 674 F.3d 889, 892 (7th Cir. 2012)). The

[1] The latter three counts are not actually independent tort claims.

Court also takes judicial notice of matters of public record. *Young-Smith v. Holt*, 575 F. App'x 680, 682 (7th Cir. 2014). In this case, the relevant facts are not in dispute, as the Court is presented with the primarily legal question of whether federal law preempts the state-law claims plaintiffs have asserted. If the Court concludes at this stage that the claims are preempted, dismissal is appropriate. *See In re Darvocet, Darvon, & Propoxyphene Products Liab. Litig.*, 756 F.3d 917, 922 (6th Cir. 2014) (affirming district court's grant of motions to dismiss or for judgment on pleadings where federal law preempted plaintiffs' state-law claims).

A. Preemption

Through their briefing, the parties have distilled the preemption issue down to a single question: whether federal law permits the ANDA defendants to unilaterally make changes to their TRT drugs' warning labels.[2] The ANDA defendants argue that it does not. As a result, they argue that they could escape state-law liability, under the failure-to-warn claims plaintiffs have asserted, only by strengthening their warning labels in violation of federal law or by leaving the marketplace altogether. State-law claims that place defendants in such a position are preempted. *Mensing*, 131 S. Ct. at 2578 (finding impossibility preemption of state-law failure-to-warn claims where defendant was

[2] In addition to raising this preemption question, defendants' motion to dismiss also attacks the adequacy of plaintiffs' allegations that defendants promoted their TRT drugs "off label," as well as the adequacy of plaintiffs' pleadings in support of their design defect claim, and argues that plaintiff's claims for fraud on the FDA are also preempted. In their response, plaintiffs clarify that they are not relying on defendants' off-label promotion to save their claims from preemption and that they are not asserting a "fraud on the FDA" claim separate from their failure-to-warn claims. Defendants' arguments on those points are thus irrelevant for purposes of deciding this motion. The Court also need not address the sufficiency of plaintiffs' design defect allegations because it concludes that all of plaintiffs' claims against the ANDA defendants (including those based on design defect) are preempted.

prohibited from changing warning labels independently of FDA); *Bartlett*, 133 S. Ct. at 2470 (rejecting theory that defendant's option to pull drug from the market saved plaintiff's claims from preemption). Similarly, because federal law prohibits the ANDA defendants from redesigning their generic drugs (and because, they argue, doing so would be physically impossible), they would be able to escape liability from plaintiffs' design-defect claims only by changing their warning labels or exiting the market. Thus the ANDA defendants contend that plaintiffs' design-defect claims are also preempted under *Bartlett*, 133 S. Ct. at 2470 (finding state-law design-defect claims preempted where "federal law and basic chemistry" prevented defendant from redesigning drug and where defendant could not independently change drug's warning label under federal law).

Plaintiffs do not contend that the ANDA defendants are able to redesign or alter the composition of their ANDA drugs. They do, however, dispute the ANDA defendants' contention that they cannot unilaterally change their drugs' warnings. Plaintiffs argue that because the ANDA defendants may strengthen their warnings, and because all of plaintiffs' claims "flow, to some extent" from the ANDA defendants' alleged failure to provide adequate warnings, Pls.' Resp. at 17, the ANDA defendants had a permissible avenue under federal law to escape state-law liability on each of plaintiffs' claims. Thus they argue that under *Wyeth v. Levine*, 555 U.S. 555 (2009), all of their claims survive preemption. *See id.* at 573 (state-law failure-to-warn claims not preempted where defendant permitted to unilaterally change drug's warning label).

The Court agrees with the parties' respective statements of preemption law. Plaintiffs do not deny that the ANDA defendants are unable to redesign their drugs under

federal law, and they admit that all of their claims are premised on an alleged failure to warn. Thus the ANDA defendants are correct that under *Bartlett* and *Mensing*, if federal law prohibits them from unilaterally changing their warning labels, all of plaintiffs' claims against them are preempted. Similarly, plaintiffs are correct that under *Wyeth*, plaintiffs' claims survive if federal law allows a path for the ANDA defendants to change their labels independently. The Court thus turns to the pivotal question of whether any such path exists.

In *Wyeth*, the Supreme Court ruled that state-law failure-to-warn claims brought against the manufacturer of a brand-name NDA drug were not preempted because federal law permitted the manufacturer to modify the drug's warning label to escape state-law liability. Though changing a drug's label usually requires FDA approval of a supplemental drug application, the Court identified an FDA regulation—the "changes being effected" (CBE) regulation—which permitted manufacturers to change their drugs' labels without waiting for FDA's approval to do so. *Id.* at 568. The CBE regulation allows manufacturers to change their drug labels "to 'add or strengthen a contraindication, warning, precaution, or adverse reaction' or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product.'" *Id.* (quoting 21 C.F.R. §§ 314.70(c)(6)(iii)(A), (C)). Because the manufacturer in *Wyeth* could have taken advantage of the CBE process to improve its drug's warning, it could comply with both federal and state law, and thus plaintiff's state-law failure-to-warn claims were not preempted. *Id.* at 573.

Two years after *Wyeth*, the Supreme Court confronted a similar set of facts in *Mensing*, a case in which manufacturers faced state-law claims based on their alleged

failure to provide adequate warning labels for their drug. *Mensing*, 131 S. Ct. at 2572. Unlike in *Wyeth*, however, *Mensing* involved a generic drug, which FDA had approved pursuant to an ANDA. *Id.* at 2575. The Court ruled that federal law did not allow generic manufacturers to use the CBE process or any other process to change their labels unilaterally. *Id.* at 2575–76. Thus because it was "not lawful under federal law for the [m]anufacturers to do what state law required of them," the state-law claims against them were preempted. *Id.* at 2577.

On its face, the CBE regulation itself does not distinguish between generic and branded (or ANDA and NDA) drug manufacturers in allowing unilateral changes to strengthen drug labels. *See* 21 C.F.R. § 314.70(c)(6) (referring only to "the holder of an approved application"). But other FDA regulations, as well as the FDCA, require ANDA applicants to "ensur[e] that [the drug's] warning label is the same as the brand name's." *Mensing*, 131 S. Ct. at 2574 (citing 21 U.S.C. §§ 355(j)(2)(A)(v), (4)(G); 21 C.F.R. §§ 314.94(a)(8), 314.127(a)(7)). The FDA, as *amicus curiae* in *Mensing*, interpreted its regulations as requiring a generic drug's label to remain identical to that of the RLD on which the ANDA was based even *after* the application has been approved. *Id.* at 2574–75 (describing the FDA's position that generic drug manufacturers have an "ongoing federal duty of 'sameness'"). Thus, to maintain consistency with regulations requiring the "sameness" of generic labels, the FDA interpreted the CBE regulation as allowing changes to generic drug labels "only when a generic drug manufacturer changes its label to match an updated brand-name label or to follow the FDA's instructions." *Id.* at 2575. The Supreme Court deferred to the agency's interpretation and concluded that the CBE

process did not allow the ANDA manufacturers to make unilateral label changes.[3] *Id.* at 2575–76. The plaintiffs' state-law claims were therefore preempted.

Under a straightforward application of *Mensing*, the state-law claims against the ANDA holders in this case would also appear to be preempted. Plaintiffs argue, however, that this case differs from *Mensing.* They contend that unlike the generic drugs at issue there, the FDA has designated the ANDA defendants' drugs as RLDs. According to plaintiffs, this designation permits the ANDA defendants to use the CBE process to change their labels unilaterally, thus permitting them to comply with both federal and state law.

In deferring to the FDA's position that generic manufacturers could not make unilateral labeling changes through the CBE process without violating federal law, the Court in *Mensing* cited the federal statutory and regulatory provisions that "require[d] a generic drug's label to match its brand-name counterpart's." *Id.* at 2575. But, as plaintiffs explain, those provisions do not actually use the terms "generic" or "brand-name." Instead, they only require the ANDA drug's label to be the same as the *RLD* upon which its application is based. *See, e.g.*, 21 U.S.C. § 355(j)(4)(G) (labeling proposed for ANDA must be "same as the labeling approved for the [RLD]"); 21 C.F.R. §§ 314.94(a)(8)(iii) (requiring ANDA to include statement that "applicant's proposed labeling . . . is the same as the labeling of the [RLD]"), 314.150(b)(10) (FDA may notify applicant of proposal to withdrawal approval of ANDA if ANDA drug's labeling "is no

[3] The Court also rejected the possibility that manufacturers could escape state-law liability by sending additional warnings via "Dear Doctor" letters, deferring to FDA's position that such letters qualify as "labeling" and so must be consistent with the labeling FDA had already approved. *Id.* at 2576.

longer consistent with that for the [RLD] referred to in the ANDA). Thus, plaintiffs contend, when an ANDA has been designated as an RLD, the manufacturer can make unilateral changes to the ANDA's label while still maintaining its sameness with the RLD's labeling, because the ANDA itself *is* the RLD. *See* Pls.' Resp. at 2 ("Where a particular generic *is* the reference listed drug, unilateral changes to the label will not result in a discrepancy between the label for that particular generic and the label for the listed drug."). The RLD holder, they argue, is "free [under federal law] to make such changes as it believes are necessary," *id.*, and thus under *Wyeth*, state-law claims against that RLD holder are not preempted.

Every federal court to consider plaintiffs' argument has rejected it. *See, e.g.*, *Darvocet*, 756 F.3d at 934 ("[M]erely becoming an RLD holder does not empower a generic manufacturer to independently change the drug's warning label. Every federal court to consider this issue has held that FDA's designation of a generic manufacturer's drug as the RLD does not subject an ANDA product to NDA, or brand-name, status or requirements.").[4] According to plaintiffs, these courts have been "led astray" by the "lack of precision in the language" of the majority's opinion in *Mensing*. Pls.' Resp. at 13. For

[4] *See also* Hogue v. Pfizer, Inc., No. 2:10-CV-805, 2012 WL 11944897, at *4 (S.D. Ohio Sept. 27, 2012) ("[T]he RLD designation does nothing to alter an ANDA holder's duties concerning labeling changes."); *Cooper v. Wyeth, Inc.*, No. CIV. A. 09-929-JJB, 2012 WL 733846, at *9 (M.D. La. Mar. 6, 2012) ("[The defendant] does not hold NDA status by virtue of becoming an RLD and thus does not bear the burden of its brand name counterpart."); *Morris v. Wyeth, Inc.*, No. CIV. A. 09-0854, 2012 WL 601455, at *6 (W.D. La. Feb. 23, 2012) ("The generic manufacturer with a drug classified as an RLD does not . . . incur the responsibility of unilaterally updating the product's warning label."), *aff'd sub nom. Morris v. PLIVA, Inc.*, 713 F.3d 774 (5th Cir. 2013); *Moore v. Mylan Inc.*, 840 F. Supp. 2d 1337, 1348 (N.D. Ga. 2012) ("FDA's designation of [the ANDA drug] as an RLD would not have permitted [the manufacturer] to use the CBE process to change the label . . . .").

example, the Court in *Mensing* refers to "brand-name drugs" where the relevant statutes and regulations refer to RLDs. Such "emendation[s] [were] harmless on the facts of *Mensing*, because the brand-name drug was the [RLD]." *Id.* But partly as a result of the Court's language, plaintiffs argue, other courts have mistakenly read *Mensing* broadly to prohibit all generic manufacturers (including RLD holders) from using the CBE process despite the lack of support for such a position in either the FDCA or FDA regulations. Plaintiffs urge this Court to reject the approach of these other federal courts and to instead follow a Pennsylvania appellate court in ruling that ANDA RLD holders may use the CBE process to change their labels unilaterally. *See In re Reglan / Metoclopramide Litig.*, 2013 PA Super 215, 74 A.3d 221, 227 (2013). According to plaintiffs, in reaching the conclusion that state-law failure-to-warn claims against ANDA RLD holders are not preempted, the court in *Reglan* avoided the errors of other courts by looking carefully at both the applicable FDA regulations and the Court's opinion in *Mensing*.

In *Reglan*, the court concluded that the defendant RLD holder had failed to establish with "the requisite certainty" that modifying its label was impossible. *Id.* The court noted that none of the generic manufacturers in *Mensing* were RLD holders, *id.* at 226, and—operating without "the benefit of the FDA's interpretation of its own regulations"—it found no indication in the FDA's regulations that "only brand-name manufacturers that obtained NDA approval, rather than RLDs generally, can utilize the [CBE] process." *Id.* at 227. In reaching its conclusion, the court reasoned that if the CBE process were only available to NDA RLD holders, FDA would have no reason to designate a successor RLD once the original RLD withdraws its drug. *Id.* In such situations, ANDA applicants could continue to show in their applications that their drugs

were equivalent to the original NDA RLD. *Id.* But, the court suggested, a successor RLD is necessary to "bear . . . responsibility for the content of the label [and] the continued safety and efficacy of the drug." *Id.* When an ANDA drug is designated as the RLD, the court concluded, the manufacturer must be able to use the CBE process to exercise this responsibility.

As defendants point out, however, the interpretation of FDA regulations offered by the court in *Reglan* is unpersuasive in light of FDA's own interpretation of the same regulations. As the Sixth Circuit concluded in *Darvocet*, FDA "made clear" in a guidance issued in 2013 that the CBE process is not available to ANDA RLD holders. 756 F.3d at 933. A footnote in that guidance, relied upon by the court in *Darvocet*, provided:

> Under existing FDA regulations, ANDA holders cannot make labeling changes through the formal supplement process under 21 CFR 314.70 in all circumstances in which NDA holders can because an ANDA's labeling must be the same as the NDA RLD's labeling (with some exceptions, as described in 21 CFR 314.94(a)(8)(iv)). Accordingly the [CBE] supplement process under 21 CFR 314.70(c) is not expressly available to ANDA holders except to match the RLD labeling or to respond to FDA's specific request to submit a labeling change under this provision.

FDA, Center for Drug Evaluation and Research, *Guidance for Industry: Safety Labeling Changes—Implementation of Section 505(o)(4) of the FD & C Act*, at 7 n.10 (July 2013), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM250783.pdf (last visited Nov. 9, 2015). Plaintiffs argue that the Sixth Circuit misinterpreted the guidance as providing that ANDA RLDs can never use the CBE process to make unilateral labeling changes. This interpretation, plaintiffs contend, ignores an important qualifying phrase: the provision says only that ANDA holders are unable to make labeling changes "in all circumstances in which NDA holders can." Plaintiffs argue that FDA included that qualification to allow for the circumstance in

which ANDA holders *can* make labeling changes: namely, when the ANDA holder is also the RLD holder. As defendants argue, this is a strained reading. Under a straightforward reading of the provision, the sentence following the "in all circumstances" qualification provides the express circumstances under which ANDA holders can use the CBE process to make label changes. They can do so (1) to match the RLD labeling or (2) to respond to FDA's request to submit a labeling change. Under neither circumstance would the ANDA RLD holder be making a unilateral labeling change.

A later interpretation from the FDA reinforces the Sixth Circuit's interpretation of the FDA guidance in *Darvocet*. In November 2013, the FDA issued an analysis of a proposed rule that would allow ANDA holder to make unilateral changes to their labels. In its analysis, the FDA expressly discussed the options available to ANDA RLD holders who believe their drugs' labeling should be changed: "Currently, these ANDA holders must contact FDA if they believe that new safety information should be added to their product labeling unless a labeling change already has been requested by FDA." FDA, *Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products: Preliminary Regulatory Impact Analysis*, at 9, *available at* http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM375128.pdf (last visited Nov. 9, 2015). According to FDA, therefore, ANDA RLD holders have no more authority than other ANDA holders to change their labeling unilaterally through the CBE process.

With the benefit of FDA's interpretation of its own regulations, which the court in *Reglan* lacked, this Court agrees with the Sixth Circuit in *Darvocet* and all the other federal courts to address this issue in concluding that RLD ANDA holders are prohibited

under federal law from unilaterally changing their drugs' warning labels. As defendants note in response to the court's question in *Reglan* about the purpose of designating a successor RLD if the ANDA RLD holder could not use the CBE process: "Future ANDA applicants must have a drug against which to compare their active ingredient, route of administration, dosage form, strength, and bioequivalence, and to match their current labeling . . . ." Defs.' Reply Br. at 8 (citing 21 U.S.C. § 355(j)(2)(A)(i)–(v)). In other words, a successor RLD designation ensures that future ANDA applicants will be able to base their applications on a non-obsolete drug; FDA need not alter the ANDA RLD holder's labeling rights or duties to serve this purpose.

Because, as every other federal court has concluded, the ANDA defendants are prohibited from unilaterally altering their warning labels under federal law, plaintiffs' state-law claims that depend on those defendants' failure to do so are preempted. *See Mensing*, 131 S. Ct. at 2578; *Bartlett*, 133 S. Ct. at 2470. As Plaintiffs concede, all of their claims against the ANDA defendants (including their design defect claims) "flow, to some extent" from the ANDA defendants' alleged failure to alter their drugs' warning labels, Pls.' Resp. at 17, and thus all of plaintiffs' claims against those defendants are preempted.

B. Discovery

Plaintiffs request discovery, prior to a ruling on this motion, in the hope that they might find evidence that the ANDA defendants actually made unilateral changes to their RLDs' labels. Plaintiffs state they are aware of at least two instances where the previous RLD holder for Depo-Testosterone made such changes to the Depo-Testosterone label. As plaintiffs concede, however, the preemption issue is "primarily a legal question." Pls.'

Resp. at 21. "The 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 discovery request in deciding *Mensing* preemption motion). The Court has concluded as a matter of law that federal law prohibits the ANDA defendants from unilaterally changing their drugs' warning labels. Additional facts about whether the ANDA defendants have attempted to make such unilateral changes would not alter that legal conclusion.

In addition, plaintiffs request discovery regarding the possibility that the ANDA defendants knew or should have known of the need to change their labels before the enactment of laws in 1984 (the so-called Hatch-Waxman Amendments) that established the requirement that an ANDA drug's label be identical to the drug listed in its application. Defendants respond that plaintiffs' complaint does not contain any allegations that the ANDA defendants knew or should have known of the need to change their labels prior to 1984. For this reason, the Court denies plaintiffs' request for discovery. If plaintiffs believe they can, consistent with their obligations under Federal Rule of Civil Procedure 11, make allegations about what the ANDA defendants knew or should have known prior to the Hatch-Waxman Amendments, plaintiffs may seek leave to amend their master complaint to do so.

Conclusion

For the reasons stated above, the Court grants defendants' motion to dismiss [dkt. no. 770] with regard to all claims involving defendants' drugs that were approved pursuant to abbreviated new drug applications and denies plaintiffs' request for discovery

related to the preemption issue.

MATTHEW F. KENNELLY
United States District Judge

Date: November 9, 2015