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

In re Testosterone Replacement Therapy Products Liability Litigation Coordinated Pretrial Proceedings	)	**Case No. 14 C 1748** **MDL No. 2545**
(This document applies to *Davis v. Actavis, Inc.*, Case No. 17 C 3775)	)	

CASE MANAGEMENT ORDER NO. 179
(Memorandum Opinion and Order on Actavis, Inc.'s motion for summary judgment in *Davis v. Actavis, Inc.*, Case No. 17 C 3775)

MATTHEW F. KENNELLY, District Judge:

Plaintiffs in this multidistrict litigation (MDL) proceeding allege that they suffered either arterial cardiovascular injuries or injuries related to blood clots in the veins as a result of taking prescription testosterone replacement therapy (TRT) drugs. Defendants Actavis, Inc., Actavis Pharma, Inc., and Actavis Laboratories UT, Inc. (collectively, Actavis) manufacture or sell Androderm, one of the TRT products at issue in this litigation. Plaintiff Douglas L. Davis alleges that his use of Androderm in July and August 2015 caused him to suffer a stroke in August 2015. He asserts claims against Actavis under Florida law for design defect; failure to warn; negligence; negligent misrepresentation; breach of implied warranty of merchantability; breach of express warranty; fraud; redhibition; consumer protection; unjust enrichment; and punitive damages. Plaintiff Laura C. Davis asserts a claim against Actavis under Florida law for loss of consortium.[1]

[1] In this opinion, the Court refers to plaintiffs collectively as Davis.

In July 2018, a Master Settlement Agreement was executed covering cases involving Actavis. In August 2019, Davis informed the Court that he elected not to settle his claims. Actavis now moves for summary judgment on a single legal issue: whether a duty exists under Florida law for a prescription drug manufacturer to provide warnings in some manner apart from the product's FDA-approved package insert. According to Actavis, there is no such duty, leaving Davis without any viable claim. For the following reasons, the Court denies Actavis's motion for summary judgment.

Background

A. Androderm

Androderm is a testosterone transdermal system, meaning a patch that delivers testosterone to the body through the skin. The Food and Drug Administration (FDA) approved Androderm in September 1995. The uses for which the FDA approved the drug are not relevant for present purposes. In 2015, the FDA ordered Actavis to include the following language in the Warning and Precautions section of the Androderm label:

> **5.4 Cardiovascular Risk**
>
> Long term clinical safety trials have not been conducted to assess the cardiovascular outcomes of testosterone replacement therapy in men. To date, epidemiologic studies and randomized controlled trials have been inconclusive for determining the risk of major adverse cardiovascular events (MACE) such as non-fatal myocardial infarction, non-fatal stroke, and cardiovascular death, with the use of testosterone compared to non-use. Some studies, but not all, have reported an increased risk of MACE in association with use of testosterone replacement therapy in men. Patients should be informed of this possible risk when deciding whether to use or to continue to use ANDRODERM.

Actavis Mot. for Summ J., Ex. 4 (Androderm Label Rev. 5/2015) [35-4] § 5.4; Actavis L.R. 56.1 Resp. [52] ¶ 6. The FDA ordered other TRT manufacturers to include the same language in the Warning and Precautions section of their TRT product labels. In

May 2015, the FDA approved a new Androderm label that incorporated the required language.

B. Davis's Androderm prescription

Dr. J. Frank Avey prescribed Androderm for Davis on July 22, 2015. Davis filled the prescription that same day. Davis contends (and Actavis disputes) that he used one Androderm patch per day for the next 23 days. On August 14, 2015, Davis had a stroke and was transported to a hospital.

Davis states that when he received his Androderm prescription, it came with prescribing information last updated in 2013. In other words, Davis contends he received an outdated version of the Androderm label that did not include the FDA-mandated cardiovascular risk language. In support, Davis offers a photograph of the label he contends he received. *See* Davis Opp. to Mot. for Summ. J., Ex. 22 (Androderm Label Rev. 11/2013) [47-8].

Actavis admits only that the photograph depicts "a copy of the Androderm Full Prescribing Information and Patient Information, revised in 2013", which did not contain the FDA-mandated cardiovascular risk language. Actavis L.R. 56.1 Resp. ¶¶ 37-38. Actavis maintains that there is no admissible evidence that the photograph portrays the copy of the Androderm label Davis received. According to Davis, Dr. Avey testified that it is unlikely he saw the May 2015 cardiovascular risk language before he made his prescribing decision. Actavis disputes Davis's characterization of the testimony.

C. Davis's theory of recovery

This Court has ruled on motions for summary judgment in several cases that were selected as bellwether trial cases in this MDL. *See In re Testosterone*

Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings, 430 F. Supp. 3d 516, 523 (N.D. Ill. 2019) (*CMO 166*) (collecting cases). The plaintiffs in those cases argued (among other things) that before 2015—when the defendants added the FDA-mandated cardiovascular risk language to their TRT product labels—the labels failed to adequately warn that TRT use increases the risk of cardiovascular injury. The plaintiffs also argued that the defendants knew or should have known about the increased risk well before 2015. Davis's case is different. As noted above, Dr. Avey prescribed Androderm for Davis about two months after Actavis updated the label to include the FDA-mandated cardiovascular risk language. Davis contends that the Androderm he received did not include the new label and that Dr. Avey did not see the new label before prescribing Androderm for him. Davis seeks to hold Actavis liable for failing to adequately communicate the label change to physicians.

Davis first gave notice of this theory in a joint status report filed in November 2019. The Court has permitted Actavis to file a motion for summary judgment limited to one issue: whether a drug manufacturer has a duty under Florida law to provide warnings in some manner apart from the product's FDA-approved package insert. *See* Actavis Mem. in Supp. of Mot. for Summ. J. (Actavis Br.) [34] at 1; Actavis Reply in Supp. of Mot. for Summ. J. (Actavis Reply) [51] at 3. Actavis maintains that Florida law imposes no such duty.

Discussion

Summary judgment is appropriate if the moving party "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). There is a genuine issue of material fact, and

summary judgment is precluded, "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). When ruling on a motion for summary judgment, a court views the record in the light most favorable to the non-moving party and draws all reasonable inferences in that party's favor. *Id.* at 255; *see also, e.g.*, *Driveline Sys., LLC v. Arctic Cat, Inc.*, 936 F.3d 576, 579 (7th Cir. 2019).

A. Florida law on failure to warn

Addressing the legal question presented here requires an understanding of Florida tort law and the learned intermediary doctrine. Under Florida law, the manufacturer of a defective product may be held liable under theories of negligence and strict liability. *See Small v. Amgen, Inc.*, 134 F. Supp. 3d 1358, 1366 (M.D. Fla. 2015), *aff'd*, 723 F. App'x 722 (11th Cir. 2018). "[A] product may be defective by virtue of . . . an inadequate warning." *Ferayorni v. Hyundai Motor Co.*, 711 So. 2d 1167, 1170 (Fla. Dist. Ct. App. 1998). To prevail on a claim of failure to warn based on either negligence or strict liability, a plaintiff must show that "the warning label was inadequate," "the inadequacy of the warning proximately caused his injury," and "he suffered an injury from using" the defendant's product. *Hoffmann-La Roche Inc. v. Mason*, 27 So. 3d 75, 77 (Fla. Dist. Ct. App. 2009).

Florida has adopted the doctrine of strict liability set forth in the Restatement (Second) of Torts § 402A. *See West v. Caterpillar Tractor Co.*, 336 So. 2d 80, 87 (Fla. 1976). Section 402A provides that a manufacturer who "sells any product in a defective condition unreasonably dangerous to the user . . . is subject to liability for physical harm thereby caused to the ultimate user" if (1) "the seller is engaged in the business of

selling such a product" and (2) "it is expected to and does reach the user . . . without substantial change in the condition in which it is sold." Restatement (Second) of Torts § 402A. The rule applies even if "the seller has exercised all possible care in the preparation and sale of his product." *Id.*

Comment k to Section 402A addresses "[u]navoidably unsafe products", including prescription drugs. Restatement (Second) of Torts § 402A, cmt. k. In relevant part, it provides that "[s]uch a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous." *Id.* Accordingly, the manufacturer of an unavoidably unsafe product that was properly prepared and accompanied by adequate directions and warnings will not be strictly liable "for unfortunate consequences attending [its] use . . . ." *Id.* Florida courts have rejected a "blanket approach" that applies comment k to all prescription drugs and instead have held "that comment k is an affirmative defense to a strict liability claim." *Adams v. G.D. Searle & Co.*, 576 So. 2d 728, 733 (Fla. Dist. Ct. App. 1991). To be protected under comment k, a manufacturer must show that the product "is as safe as current testing and research permits" and that its benefits "outweigh its known risks as of the date the product is distributed." *Id.* at 732-33.

Where, as here, the manufacturer's product is a prescription drug, "the duty to warn is directed to physicians rather than patients under the 'learned intermediary' doctrine." *Mason*, 27 So. 3d at 77 (quoting *Felix v. Hoffmann-LaRoche, Inc.*, 540 So. 2d 102, 104 (Fla. 1989)). In *Buckner v. Allergan Pharmaceuticals, Inc.*, 400 So. 2d 820 (Fla. Dist. Ct. App. 1981), the court explained that a physician acts as a learned intermediary between the manufacturer and the patient because, "[a]s a medical

expert," he or she can make an informed prescribing decision that "weigh[s] the benefits of any medication against its potential dangers" for the individual patient. *Id.* at 822 (quoting *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974)). So long as "the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved," a manufacturer "may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient." *Buckner,* 400 So. 2d at 823 (quoting *Terhune v. A.H. Robins Co.*, 90 Wash. 2d 9, 14, 577 P.2d 975, 978 (1978)). "Thus, the duty of a drug manufacturer to warn of the dangers involved in the use of a drug is satisfied if it gives an adequate warning to the physician who prescribes the drug." *Mason*, 27 So. 3d at 77 (citing *Buckner,* 400 So. 2d at 823). "This reasoning applies" even in a strict liability action governed by comment k of Section 402A. *Buckner*, 400 So. 2d at 823.

In determining whether a warning is adequate, the "crucial question is whether" it was "adequate to warn a physician of the possibility that [the drug] might be causing the condition experienced by [the plaintiff]." *Upjohn Co. v. MacMurdo*, 562 So. 2d 680, 683 (Fla. 1990). "While in many instances the adequacy of warnings concerning drugs is a question of fact," Florida courts have held "that it can become a question of law where the warning is accurate, clear, and unambiguous." *Felix*, 540 So. 2d at 105.

B. Scope of a drug manufacturer's duty to warn

As a federal court sitting in diversity and applying Florida law, this Court must make its best prediction of how the Florida Supreme Court would decide the legal issue Actavis has presented. *See, e.g.*, *Nationwide Agribusiness Ins. Co. v. Dugan*, 810 F.3d

446, 450 (7th Cir. 2015). If the Florida Supreme Court has not ruled on the issue, decisions of Florida's appellate courts "control, unless there are persuasive indications that the [Florida] Supreme Court would decide the issue differently." *Id.* "In the absence of any [Florida] authority on the question, decisions from other jurisdictions may prove instructive." *Pippen v. NBCUniversal Media, LLC*, 734 F.3d 610, 615 (7th Cir. 2013).

The Florida Supreme Court has not ruled on the issue presented here. Suggesting otherwise, Actavis highlights the court's statement in *E.R. Squibb & Sons, Inc. v. Farnes*, 697 So. 2d 825 (Fla. 1997), that "[p]harmaceutical manufacturers discharge their duty to warn the learned intermediary by way of a package insert which accompanies each vial of vaccine." *Id.* at 827 (quoting the trial court's order that granted the defendant's motion for a new trial). The court also stated that "[w]hether the physician in fact reads the warning, or passes its contents along to the recipient of the drug is irrelevant." *Id.* (quoting same). But the quoted passages must be considered in context. The plaintiff in *E.R. Squibb* did not allege that he received the wrong package insert or that his physician was unaware of the relevant warning. *See id.* at 826-28. Nor did he contend that the defendant's duty to warn extended beyond placing the warning in the drug's package insert. *See id.* The court in *E.R. Squibb* addressed only whether (1) the warning language itself was adequate as a matter of law and (2) the allegedly inadequate warning was the proximate cause of the plaintiff's injury. *See id*. Accordingly, the quoted language does not resolve whether a drug manufacturer's duty to warn is as limited as Actavis contends. Other cases from the Florida Supreme Court are inapposite for substantially similar reasons. *See Upjohn*, 562 So. 2d at 683

(addressing adequacy of the warning language); *Felix*, 540 So. 2d at 104-05 (addressing adequacy of the warning language and whether the allegedly inadequate warning was the proximate cause of the plaintiff's injury).

Likewise, decisions by Florida appellate courts shed little light on the question presented. Actavis highlights the court's holding in *Buckner* that even if a manufacturer "knew or should have known that the medical profession was not warning patients of potential side effects," it had no duty to warn patients about side effects; the manufacturer's duty to warn runs only to the doctor. *Id.* at 823-24; *see* Actavis Br. at 6. The holding, however, was rooted in the principle that a "*doctor's* duty to warn patients of possible side effects is not absolute" and that a doctor exercises medical judgment in determining what risks to disclose to patients. *Buckner*, 400 So. 2d at 823-24 (emphasis added). Like the Florida Supreme Court cases discussed above, *Buckner* provides little assistance here because it did not address whether a manufacturer has a duty to warn a physician in some manner apart from the package insert. *Pysz v. Henry's Drug Store*, 457 So. 2d 561 (Fla. Dist. Ct. App. 1984), and *Arnold v. Novartis Pharm. Corp.*, 28 F. Supp. 3d 1268 (M.D. Fla. 2014), cited by Actavis, also address entirely different questions. *See Pysz*, 457 So. 2d at 562 (affirming dismissal of a failure to warn claim against a pharmacist who filled the plaintiff's prescription); *Arnold*, 28 F. Supp. 3d at 1270-71 (applying Florida law) (excluding evidence regarding the plaintiff's theory that the drug manufacturer had a duty to warn a dentist who did not prescribe the drug but allegedly could have mitigated the plaintiff's injury).

Davis's reliance on *Brown v. Glade & Grove Supply, Inc.*, 647 So. 2d 1033, 1035 (Fla. Dist. Ct. App. 1994) and *MacMurdo v. Upjohn Co.*, 444 So. 2d 449, 450-51 (Fla.

Dist. Ct. App. 1984), is equally misplaced. In *Brown*, where the court stated that a warning may be defective "as a result of its location and the manner in which the warning is conveyed", the allegedly defective product was a tractor. *See Brown*, 647 So. 2d at 1035. Therefore, the principles underlying comment k and the learned intermediary doctrine were not in play. In *MacMurdo*, the court stated that "it is for the jury to determine if a particular warning is adequate under the circumstances." *MacMurdo*, 444 So. 2d at 450-51. The issue in *MacMurdo*, however, was the adequacy of the warning language and there was no indication that the physician (or the plaintiff) lacked access to it. *See id.*[2] The same is true of *Cornelius v. Cain*, No. CACE 01-020213(02), 2004 WL 48102 (Fla. Cir. Ct. Jan. 5, 2004), which the Court located in its independent research. *See id.* at *4 ("Because the FDA-approved package insert for OxyContin contained accurate, clear, and unambiguous warnings, [the defendant drug manufacturer] satisfied its duty to warn under Florida law."). Finally, *Mason* addressed only whether the plaintiff established "that the allegedly deficient warning was the proximate cause of his injury." *Mason*, 27 So. 3d at 76.

Two federal cases applying Florida law come closer to addressing the issue that Actavis presents but ultimately miss the mark. *See Metz v. Wyeth, LLC*, 872 F. Supp. 2d 1335 (M.D. Fla. 2012), *aff'd*, 525 F. App'x 893 (11th Cir. 2013); *Guarino v. Wyeth, LLC*, 719 F.3d 1245 (11th Cir. 2013). *Metz* and *Guarino* concerned injuries allegedly resulting from use of the prescription drug metoclopramide. *See Metz*, 872 F. Supp. 2d at 1337; *Guarino*, 719 F.3d at 1247. The plaintiffs in both cases asserted negligence

[2] Moreover, the Florida Supreme Court later disapproved *MacMurdo* and held that the adequacy of a warning can become a matter of law where the warning is "accurate, clear, and unambiguous." *Felix*, 540 So. 2d at 105.

claims against manufacturers of generic metoclopramide, advancing a theory similar to Davis's: they contended that the generic manufacturers "fail[ed] to take additional steps to warn doctors and/or consumers of information already appearing in, or recently added to," the drug label. *Metz*, 872 F. Supp. 2d at 1340; *see also Guarino*, 719 F.3d at 1248 (similar).

In *Guarino*, the court held that the plaintiff's claim was preempted under federal law because, as the Supreme Court explained in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), federal law "demand[s] that generic drug labels be the same at all times as the corresponding brand-name drug labels." *Mensing*, 564 U.S. at 618 (holding that state-law failure to warn claims against generic drug manufacturers were preempted because it would be impossible for the manufacturers "to comply with both their state-law duty to change the label and their federal-law duty to keep the label the same"); *see Guarino*, 719 F.3d at 1248-49. The court in *Guarino* observed that if a generic drug manufacturer sent physicians additional communications about the drug's warning label, it would be suggesting—contrary to the "duty of sameness" described in *Mensing*—that there is a therapeutic difference between the generic and brand-name versions of the drug. *Id.* at 1249 (quoting *Mensing*, 564 U.S. at 616). Accordingly, the court determined that the plaintiff's failure to communicate claim was preempted. *Guarino*, 719 F.3d at 1250. In *Metz*, by contrast, the court stated that "it is arguable that claims based on [the generic manufacturer's] failure to more effectively communicate the warnings contained in the FDA approved label survive preemption under *Mensing*." *Metz*, 872 F. Supp. 2d at 1343.

Both courts then determined that even if the failure to communicate claims were

not preempted, they failed on the merits because of Florida's learned intermediary doctrine. In *Guarino*, the court observed that there was no dispute that the warning language was clear and unambiguous and was provided in the drug label. *Guarino*, 719 F.3d at 1250. Therefore, the court concluded that the generic manufacturer "satisfied its duty to provide [the plaintiff's] physician—the learned intermediary—with information regarding" the relevant risk. *Id*. In *Metz*, the court similarly determined that the warning—which was "accurate, clear, and unambiguous" and "available both in the package insert" and on the FDA website—"satisfied [the generic manufacturer's] duty to provide Plaintiff's treating physician with adequate information about the risks associated with metoclopramide use." *Metz*, 872 F. Supp. 2d at 1344-45.

Actavis argues that the decisions on the merits in *Metz* and *Guarino* support its argument that under Florida law, a prescription drug manufacturer has no duty "to provide warnings in any manner apart from, or in addition to, the FDA-approved package insert that accompanies the drug to the pharmacy." Actavis Br. at 1; *see also* Actavis Reply at 11. Davis responds that *Metz* and *Guarino* are inapplicable because the defendants in those cases, unlike Actavis here, were generic drug manufacturers subject to the preemption principles explained in *Mensing*.

The Court recognizes that in *Metz* and *Guarino*, the courts determined that even if the plaintiffs' failure to communicate claims were not preempted, they failed under Florida law. *See* Actavis Reply at 11 (arguing that the courts in *Metz* and *Guarino* construed Florida law to "address[] the very theory [Davis is] trying to pursue now"). Nonetheless, the Court agrees with Davis that because the decisions in *Metz* and *Guarino* were so heavily grounded in preemption principles, they provide little support

for Actavis's position. The discussion of the duty to warn was somewhat abbreviated in both cases, and it is difficult for this Court to determine whether the analysis would have been the same for a brand-name manufacturer. The Court also notes that in a case cited by neither side, a Florida circuit court dismissed a plaintiff's claims against a generic metoclopramide manufacturer, including a failure to communicate claim, as preempted or barred by Florida's learned intermediary doctrine. *See Dietrich v. Wyeth, Inc.*, 502009CA021586XXXXMB, 2012 WL 12314992, at *2 (Fla. Cir. Ct. Nov. 26, 2012) (citing *Metz* and *Guarino* with approval). The district court of appeal affirmed, but only on the ground that the claims were preempted. *See Dietrich v. Actavis, Inc.*, 138 So. 3d 1163, 1163 (Fla. Dist. Ct. App. 2014). The appellate court's approach in *Dietrich* bolsters this Court's conclusion that *Metz* and *Guarino* do not reliably signal whether a Florida court would endorse the narrow definition of the duty to warn that Actavis presses.

Due to the absence of Florida authority on the question presented, the Court turns to other jurisdictions for guidance. Actavis points to *Sherman v. Pfizer, Inc.*, 8 Wash. App. 2d 686, 440 P.3d 1016 (2019), *review denied sub nom. Sherman v. Pliva, Inc.*, 194 Wash. 2d 1015, 452 P.3d 1241 (2019), another case in which a plaintiff alleged that a generic metoclopramide manufacturer failed to communicate strengthened warnings "to the physician community in ways other than in the package insert," such as through Dear Doctor letters. *Sherman*, 8 Wash. App. 2d at 699-701, 440 P.3d at 1023-1024. The court did not address preemption and determined that under the Washington Product Liability Act (WPLA)—which "closely mirrors" section 402A—a prescription drug manufacturer has no duty to "provide additional warnings

beyond those that are provided with the product." *Id.* at 701-02, 440 P.3d at 1024-25 (internal quotation marks omitted); *see also id.* (noting that the WPLA requires warnings to be "provided with products"; comment k to Section 402A similarly states that unavoidably safe products must be "accompanied by proper directions and warning"; and warnings for prescription drugs are found in package inserts) (internal quotation marks omitted). Actavis contends that a Florida court would reach the same conclusion because both jurisdictions follow comment k of Section 402A and provide the same rationale for applying the learned intermediary doctrine. *Compare id.* at 696, 440 P.3d at 1022 ("[I]f the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise . . . informed judgment . . . in the best interest of the patient." (quoting *Terhune*, 90 Wash. 2d at 14, 577 P.2d at 978)) *with Buckner*, 400 So. 2d at 823 (quoting same from *Terhune*).

The Court is not persuaded that the Florida Supreme Court would rely on *Sherman* to hold that a drug manufacturer has no duty to provide warnings in any manner other than the FDA-approved package insert. First, as Davis notes, there was no allegation in *Sherman* that the wrong package insert accompanied the plaintiff's prescription. Although Florida law is clear that a manufacturer's duty to warn runs to the physician, a patient's receipt of the wrong package insert arguably has relevance to the scope of the manufacturer's duty, given comment k's requirement that unavoidably safe products be "*accompanied by* proper directions and warning." Restatement (Second) of Torts § 402A, cmt. k (emphasis added). Actavis, moreover, provides no support for its

contention that it lacks control over whether a patient receives the appropriate package insert. *See* Actavis Reply at 12. Accordingly, that argument does not support a finding that Florida courts would adopt Actavis's position on the scope of its duty to warn.

Second, the court agrees with Davis that *Sherman* has little applicability here because the defendant was a generic drug manufacturer. True, the court in *Sherman* did not address preemption. *See Sherman*, 8 Wash. App. 2d at 690 n.1, 440 P.3d at 1019 n.1. But in holding that "a drug manufacturer's duty to warn is limited to providing a package insert that accompanies the product," the court relied on *Metz* and *Guarino*. *See Sherman*, 8 Wash. App. 2d at 702, 440 P.3d at 1025. As already explained, *Metz* and *Guarino* are uninformative on the scope of a brand-name manufacturer's duty to warn because they are colored by preemption principles applicable only to generic manufacturers. Because *Sherman* relies on *Metz* and *Guarino*, it suffers from the same flaw. Finally, although Washington courts follow comment k and offer the same reasoning as Florida courts for applying the learned intermediary doctrine, the same can be said of other states where courts have indicated that a drug manufacturer's duty to warn is broader than Actavis argues it is. The Court discusses some of those cases below. In short, the similarities Actavis identifies between Washington and Florida law are not, on their own, strong indicators that the Florida Supreme Court would follow *Sherman*.

Davis cites several cases for the proposition that a drug manufacturer has a duty to warn physicians not only through the package insert but also through other means. The court first disposes of the cases it finds uninformative. One is *Tatum v. Schering Corp.*, 795 F.2d 925 (11th Cir. 1986), where the Eleventh Circuit, applying Alabama law,

noted that "[t]here is evidence that [the brand-name drug manufacturer's] method of calling attention to a change in warning . . . is inconsistent with the practice of other drug manufacturers." *Id.* at 928. Neither the district court nor the Eleventh Circuit considered how that evidence affected the plaintiff's failure to warn claim, *see id.*, so the Court does not factor *Tatum* into its analysis.

Davis also cites *In re Zyprexa Products Liability Litigation*, 489 F. Supp. 2d 230 (E.D.N.Y. 2007), arguing that the court held that "even after Dear Doctor letters [about a label change] were sent", "a jury could still find the mode of warning was insufficient." Davis Opp. to Mot. for Summ. J. (Davis Opp.) [43] at 10. That is not exactly what the court said. In the cited passage, the court was discussing the "latest date beyond which it was unreasonable" for a doctor to be unaware of a label change. *See In re Zyprexa*, 489 F. Supp. 2d at 245. The court determined that although it would be reasonable to conclude that the so-called "cutoff" date was when the manufacturer sent the Dear Doctor letters, the cutoff date ultimately was for the jury to decide. *Id.* The court reached that conclusion because the plaintiff had offered evidence that the defendant's sales personnel misrepresented safety information in communications with doctors during the relevant time. *Id.* It is unclear whether the court was discussing the duty to warn (as opposed to the independent issue of proximate cause), and it is also unclear what state's law the court was applying. Therefore, *In re Zyprexa* is not useful for present purposes.

Finally, *Shipley v. Forest Laboratories, Inc.*, No. 1:06-cv-00048-TC, 2015 WL 4199739 (D. Utah July 13, 2015) (applying Utah law), has little persuasive value because the issue there was whether the manufacturer should have notified physicians

of an upcoming label change—not whether it had a duty to communicate a published recent label change to physicians. *See id.* at *13-14. Similarly, *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978 (8th Cir. 1969) (applying South Dakota law), does not sway the Court in either direction because it was not a case where the defendant allegedly failed to communicate a warning that it had recently been required to add to package inserts. *See id.* at 985-88, 991-92. Rather, it appears that the defendant first warned of the relevant risk by sending Dear Doctor letters, and the plaintiff argued that the defendant should have instructed its sales representatives to warn physicians about the risk before the Dear Doctor letters were sent. *See id.*

Davis's citation to *In re Levaquin Products Liability Litigation*, 700 F.3d 1161 (8th Cir. 2012), is more helpful. In *Levaquin*, where Minnesota law applied, a brand-name drug manufacturer added warning language to the label in 2001. The plaintiff alleged that the manufacturer negligently failed to "take adequate steps to alert doctors to the information in the 2001 warning." *Id.* at 1164, 1165. The court observed that there is disagreement among states "about whether simply changing the package insert warnings insulates a drug manufacturer from failure-to-warn liability" and that Minnesota courts have not decided the issue. *Id.* at 1167. The court stated that "[m]any courts . . . have held a properly worded package insert is a sufficient warning as a matter of law, at least when it is combined with an entry in the PDR [Physician' Desk Reference]." *Id.* (citing cases applying Kentucky, Maryland, Tennessee, and District of Columbia law).[3] By contrast, the court noted that in *Sterling*, it concluded that "when the dangers of the

[3] The PDR is "a common medical publication that contains label information about numerous drugs." *Id.* at 1164.

prolonged use of [a] drug . . . became reasonably apparent, it was not unreasonable to find that the [manufacturer] should have employed all its usual means of communication, including [sales representatives], to warn the prescribing physicians of these dangers." *Id.* at 1167 (quoting *Sterling*, 408 F.2d at 992). The court determined that it need not decide the scope of the duty to warn as a matter of law "because, on the narrow facts of th[e] case," the jury was not unreasonable in finding that the defendant "had reason to know it needed to do more to inform physicians of the 2001 warning, such as sending 'Dear Doctor' letters or directing sales representatives to warn physicians directly." *Levaquin*, 700 F.3d at 1167.

The decision in *Levaquin* supports Davis's position that there may be circumstances where a drug manufacturer's duty to warn extends beyond placing the warning in the package insert. Actavis asks the Court to disregard *Levaquin*, but its arguments are unpersuasive. First, Actavis contends that there is no evidence here that it should have known it needed to take extra steps to communicate the May 2015 label change. The premise of Actavis's motion, however, was that the Court should decide the scope of its duty to warn as a matter of law and ignore the factual record. For present purposes, therefore, the relevant principle from *Levaquin* is that a drug manufacturer does not necessarily discharge its duty to warn by placing the warning in the package insert—not whether the circumstances underlying that conclusion are identical to those in this case. Second, Actavis contends that there was unquestionably a risk associated with the product in *Levaquin*, whereas the Androderm cardiovascular risk language states only that the risk information is "inconclusive." Actavis Reply at 10. Actavis has pressed several variations of this argument in this litigation, each time

without success. As the Court has explained, the reference to inconclusive risk information does not compel acceptance of Actavis's position that there is no causal association between Androderm use and increased cardiovascular risk. *See, e.g.*, *CMO 166*, 430 F. Supp. 3d at 539.

Levaquin is directly relevant to the scope of a drug manufacturer's duty to warn, and there is no indication that the court's decision turned on a feature of Minnesota law that Florida law lacks. Like Florida, Minnesota applies the learned intermediary doctrine because "the physician, as the prescriber of a drug, is in the best position to give a highly individualized warning to a patient based on the physician's knowledge of the patient and the inherent risks of the drug." *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1305 (D. Minn. 1988); *see Mulder v. Parke Davis & Co.*, 288 Minn. 332, 335 & n.1, 181 N.W.2d 882, 885 & n.1 (1970) (confirming that Minnesota applies the learned intermediary doctrine). Unlike Florida, Minnesota merges strict liability and negligence for design defect claims and has not expressly adopted comment k. *See Kociemba v. G.D. Searle & Co.*, 695 F. Supp. 432, 434 (D. Minn. 1988). For design defect cases, however, the Minnesota Supreme Court has adopted a "negligence-like 'reasonable care' standard" that "implicitly acknowledges" the policy considerations reflected in comment k. *Id.* Relevant here, Minnesota's standard attempts to encourage development of prescription drugs by limiting a manufacturer's liability to circumstances where it "fails to adequately warn the user of the reasonable dangers inherent in the product." *Id.* Florida law similarly shields a drug manufacturer from liability where the product's instructions and warnings "fully apprise the physician of the proper procedures for use and the dangers involved." *Buckner,* 400 So. 2d at 823

(quoting *Terhune,* 90 Wash. 2d at 14, 577 P.2d at 978). Considering Florida's expectation that a manufacturer will "fully apprise" a physician of a drug's risks, the Court concludes that the Florida Supreme Court likely would recognize—as did the court in *Levaquin*—that there may be circumstances where fully apprising physicians of risk information requires more than placing a warning in the package insert.

The Florida Supreme Court's decision in *Aubin v. Union Carbide Corp.*, 177 So. 3d 489 (Fla. 2015), provides additional support for this conclusion. There, the court discussed a learned intermediary defense available to suppliers of hazardous non-medical goods. *See id.* at 515 ("The Second and Third Restatements both recognize that a manufacturer may be able to rely on an intermediary to relay warnings to the end user . . . ."). The court stated that if a manufacturer fails to "adequately convey the danger to the intermediary *or take steps to ensure that the intermediary would adequately warn the end user*, a manufacturer may not be reasonable in relying on an intermediary to pass along such a crucial warning to the end user." *Id.* (emphasis added). "The reasonableness of a manufacturer's reliance on an intermediary to convey the warnings to the end user," moreover, is "impacted by the dangerousness of the product." *Id.*

The learned intermediary defense discussed in *Aubin* is distinct from the learned intermediary doctrine applicable to claims involving prescription drugs. But there is no question that prescription drugs can be very dangerous and that physicians can best serve as learned intermediaries when they are fully aware of those dangers. If the Florida Supreme Court were asked whether a prescription drug manufacturer's duty to warn is invariably limited to providing a warning via the package insert, there is reason

to believe it would draw an analogy to the learned intermediary principles discussed in *Aubin* and answer in the negative—at least in the situation where, as in this case, regulatory authorities have recently mandated a change in the package insert's warnings.

The Court's independent research revealed another case that is on point: *Baker v. St. Agnes Hospital*, 70 A.D.2d 400, 421 N.Y.S.2d 81 (App. Div. 1979). There, a New York appellate court held that a drug manufacturer must not only "keep abreast of knowledge of its products" but also "take such steps as are reasonably necessary to bring that knowledge to the attention of the medical profession." *Id.* at 406, 421 N.Y.S.2d at 85. The court added, "[t]he greater the potential hazard of the drug, the more extensive must be the manufacturer's efforts to make that hazard known to the medical profession." *Id.* at 406, 421 N.Y.S.2d at 85-86. The court's analysis was guided by the principle, encompassed in comment k, that a drug manufacturer may avoid liability where its product is "pure and accompanied by adequate warnings." *Id.* at 405, 421 N.Y.S.2d at 85. The court also recognized that physicians rely on drug manufacturers' representations about their products. *Id.*

In *Baker*, the drug's package insert carried the relevant warning but the plaintiff's physician testified that he did not see it before he made his prescribing decision. *Id.* at 402, 406, 421 N.Y.S.2d at 83-84, 86. Noting that the drug posed "extremely grave" dangers and that there are well-known methods for apprising doctors of a drug's risks—including updating the PDR and sending Dear Doctor letters—the court declined to hold as a matter of law that the defendant's "decision to limit its warning to its package inserts was reasonable and therefore sufficient." *Id.* at 407, 421 N.Y.S.2d at 86; *see*

also id. at 406, 421 N.Y.S.2d at 85 ("[N]o matter how detailed and accurate, an uncommunicated warning is no warning at all."). *Baker* is still good law. *See, e.g.*, *Trisvan v. Heyman*, 305 F. Supp. 3d 381, 400-02 & n.16 (E.D.N.Y. 2018) (where the relevant warning was available on the FDA website at the time of the prescribing decision, dismissing a failure to warn claim without prejudice to amend with "non-conclusory allegations as to why [the plaintiff] believes Defendants failed to provide warnings to his physicians") (citing *Baker*, 700 A.D.2d at 407, 421 N.Y.S.2d at 86).

As with *Levaquin*, there is no indication that the court's decision in *Baker* was rooted in a unique feature of New York law. Like Florida, New York considers a product to be defective if it lacks an adequate warning. *See Trisvan*, 305 F. Supp. 3d at 399. To prevail on a failure to warn claim, a New York plaintiff, like a Florida plaintiff, must show that the warning was inadequate and that the failure to provide an adequate warning was the proximate cause of his injuries. *See id.*; *Mason*, 27 So. 3d at 77. Drug manufacturers can raise comment k as a defense in New York, and New York follows the learned intermediary doctrine because a physician's role is to assess a drug's risks and benefits and make an informed decision based on a patient's individual circumstances. *See Abrams v. Bute*, 138 A.D.3d 179, 186-87, 27 N.Y.S.3d 58, 64-65 (App. Div. 2016). New York courts, like Florida's, expect drug manufacturers to make physicians fully aware of a drug's risks. *See, e.g.*, *id.* at 186, 27 N.Y.S.3d at 65 ("The manufacturer's duty is to warn of all potential dangers in its prescription drugs that it knew, or, in the exercise of reasonable care, should have known to exist." (internal quotation marks omitted)). Finally, the courts in *Baker* and *Aubin* both supported the principle that the more dangerous a product, the more vigilant the manufacturer must be

in ensuring that the end-user receives a warning. *See Baker*, 70 A.D.2d at 406, 421 N.Y.S.2d at 85-86; *Aubin*, 177 So. 3d at 515. This Court predicts that if it considered the question posed here, the Florida Supreme Court would share the *Baker* court's view on the scope of a drug manufacturer's duty to warn.

For the foregoing reasons, the Court disagrees with Actavis that under Florida law, a prescription drug manufacturer has no duty to provide warnings in a manner apart from the FDA-approved package insert. In reaching this result, the Court recognizes that it must take care not to expand Florida law "beyond the boundaries established" in the state's jurisprudence. *King v. Damiron Corp.*, 113 F.3d 93, 97 (7th Cir. 1997) (internal quotation marks omitted); AbbVie Reply at 7 (quoting same). Florida courts have not addressed the question Actavis presents, and there is ample support for the conclusion that Florida courts would reject Actavis's narrow interpretation of the duty to warn. Therefore, the Court denies Actavis's motion for summary judgment.[4]

Conclusion

For the foregoing reasons, the Court denies Actavis's motion for summary judgment [dkt. no. 33]. The case is set for a telephone status hearing on November 23, 2020 at 9:30 a.m. to discuss further proceedings in this matter, using call-in number 888-684-8852, access code 746-1053. Counsel are directed to confer and are to file a joint status report on November 18, 2020 with an agreed-upon proposal for pretrial case management or, if they cannot agree, alternative proposals with a justification for each.

MATTHEW F. KENNELLY
United States District Judge

Date: November 4, 2020

[4] Given this conclusion, is unnecessary for the Court to address Actavis's argument that it had no special relationship with Dr. Avey that created an expanded duty to warn.