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

In re Testosterone Replacement Therapy Products Liability Litigation	)	**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. 196
(Order on Plaintiffs' motion to exclude expert testimony, Defendants' motion to exclude expert testimony, and Defendants' 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 (venous thromboembolisms) 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 Androderm, one of the TRT products at issue in this litigation. Before the Court are the plaintiffs' motion to exclude expert testimony and Actavis's motions to exclude expert testimony and for summary judgment in *Davis v. Actavis, Inc.* Douglas Davis and his wife, Laura Davis, allege the Douglas's use of Androderm caused the stroke that he suffered in August 2015.

The plaintiffs have moved under Federal Rule of Evidence 702 to exclude the testimony of expert witness Dr. Alan Segal. Actavis has moved to exclude the testimony of the plaintiffs' causation witnesses, Dr. Hossein Ardehali and Dr. Ronald Ziman. Actavis also has moved for summary judgment on all of the plaintiffs' remaining

claims. For the following reasons, the Court denies both parties' motions to exclude. The Court grants summary judgment in favor of Actavis on the plaintiffs' express and implied breach of warranty, negligent misrepresentation, fraud, unjust enrichment, and consumer protection claims but otherwise denies Actavis's motion for summary judgment.

Background

The Court assumes familiarity with the background as set out in its prior case management orders and therefore discusses only those details relevant to the motions at issue. The facts are undisputed except where otherwise stated.

Douglas Davis first received testosterone replacement therapy in injectable form between 2013 and 2015. He stopped taking the testosterone injections in May 2015. Davis then began seeing a new physician, Dr. Frank Avey, who ordered a new round of testing of Davis's testosterone level. On July 17, 2015, Dr. Avey noted that the testing showed that Davis's testosterone level was low. Dr. Avey then prescribed him Androderm, which supplies testosterone via a patch placed on the skin. Davis began using the Androderm patches on July 22, 2015. Davis says that when he received his Androderm prescription, it came with prescribing information last updated in 2013; as a result, it did not include an FDA-mandated cardiovascular risk warning. As of the date Dr. Avey prescribed Androderm to Davis, the FDA recently had ordered Actavis to include a warning about the drug's cardiovascular risks including the risk of stroke. Actavis revised Androderm's package insert to include the warning in May 2015. The parties dispute whether Dr. Avey was aware of this warning when he prescribed Androderm to Davis in July 2015. On August 14, 2015, after approximately 23 days of

Androderm use, Davis suffered an ischemic stroke.

The plaintiffs filed suit in May 2017 asserting claims under Florida law for design defect, failure to warn, negligent misrepresentation, fraud, breach of implied and express warranty, redhibition, consumer protection, unjust enrichment, and punitive damages. Laura Davis asserted a claim for loss of consortium. In support of their claims, the plaintiffs rely on the testimony of medical experts Dr. Ardehali and Dr. Ziman that Androderm was a substantial cause of Davis's stroke. They also rely on the testimony of Dr. Joshua Sharlin, a regulatory expert, regarding Actavis's failure to respond to warning signs that Androderm was dangerous and its "off-label" marketing of Androderm. Dr. Sharlin's report states that the FDA approved Androderm only for treatment of "classical hypogonadism" but that Actavis marketed the drug as a blanket solution for low testosterone and certain associated symptoms regardless of the cause. *See* Sharlin Expert Rep. at 33–56. Actavis relies on testimony of its medical expert, Dr. Alan Segal, that the cause of Davis's stroke was unknown and that the stroke was not the result of his Androderm usage.

In April 2020, Actavis moved for summary judgment on the plaintiffs' failure to warn theory of liability. Actavis argued that it updated Androderm's label to include a stroke warning approximately two months before Dr. Avey prescribed Androderm to Davis and that it had no duty under Florida law to provide warnings in some manner apart from the product's FDA-approved package insert. The Court denied Actavis's motion, concluding that "[i]f 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 . . . 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." *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proc.*, No. 14 C 1748, 2020 WL 6487327, at *9 (N.D. Ill. Nov. 4, 2020) (hereinafter CMO 179).

Douglas Davis passed away on September 19, 2023. No motion for substitution of his estate or other appropriate representative has been filed as of the date this order is being entered.

Discussion

A. Admissibility of expert testimony

1. Dr. Ardehali's and Dr. Ziman's general causation opinions

The parties agree that Florida law governs the plaintiffs' claims. Under Florida law, a plaintiff must show that the defendant's conduct was "'a substantial factor in bringing about' the plaintiff's injury," although it need not be "the exclusive or even the primary cause." *Ruiz v. Tenet Hialeah Healthsystem, Inc.*, 260 So. 3d 977, 982 (Fla. 2018) (quoting *Gooding v. Univ. Hosp. Bldg.*, 445 So. 2d 1015, 1018 (Fla. 1984)). The plaintiffs' experts have provided both "general causation" and "specific causation" opinions. General causation concerns whether the product at issue had the capacity to cause the type of injury alleged, and specific causation deals with whether the product in fact caused the plaintiff's injury. *See C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 831 (7th Cir. 2015).

The Court has assessed the general causation opinions of Dr. Ardehali and Dr. Ziman in detail in other cases in this MDL and has admitted those opinions. *See In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proc.*, No. 14

C 1748, 2017 WL 1833173, at *2 (N.D. Ill. May 8, 2017) (hereinafter CMO 46); *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proc.*, No. 14 C 1748, 2018 WL 4030585 (N.D. Ill. Aug. 23, 2018); *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proc.*, 430 F. Supp. 3d 516, 533 (N.D. Ill. 2019). Actavis advances two reasons why the Court should not do so in this case. First, Actavis argues that this Court has mistakenly employed a "weight of the evidence" approach to expert testimony rather than the "scientific method standard" that Actavis says is required by Federal Rule of Evidence 702 and the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). In Actavis's view, the expert testimony at issue is inadmissible under the "scientific method standard" because the "plaintiffs' experts have no scientifically recognized data demonstrating a reliable association between TRT and ischemic stroke." Actavis Mot. to Exclude at 7. Second, Actavis contends that the experts' general causation testimony must be excluded because they have no data "demonstrating an ischemic stroke can be caused by 23 days [sic] use of Androderm." *Id.*

Rule 702 requires a court to evaluate "(1) the proffered expert's *qualifications*; (2) the *reliability* of the expert's methodology; and (3) the *relevance* of the expert's testimony." *Gopalratnam v. Hewlett-Packard Co.*, 877 F.3d 771, 779 (7th Cir. 2017). Actavis's argument focuses on the reliability of the experts' general causation opinions. To determine the reliability of expert testimony, Rule 702 directs courts to consider whether an expert's opinion is "based on sufficient facts or data," whether the opinion is "the product of reliable principles and methods," and whether that methodology has been "reliably applied . . . to the facts of the case." Fed. R. Evid. 702(b)–(d). The

Seventh Circuit has explained that "reliability is determined on a case-by-case basis." *C.W. ex rel. Wood*, 807 F.3d at 835. The Supreme Court has "provide[d] several guideposts for determining reliability" including "(1) whether the scientific theory has been or can be tested; (2) whether the theory has been subjected to peer-review and/or academic publication; (3) whether the theory has a known rate of error; and (4) whether the theory is generally accepted in the relevant scientific community." *Id.* But this list "is neither exhaustive nor mandatory." *Id.* Among other things, a district court may determine that an expert opinion is unreliable if there is "too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

Actavis repeatedly asserts that "Rule 702 and *Daubert* require that expert testimony be evaluated to make sure it is grounded in the procedures and methods of science," the Court should "apply the scientific method required by *Daubert* and Rule 702," and "[t]he general causation questions . . . should be evaluated using the scientific method." Actavis Mem. in Supp. of Summ. J. at 7, 11. Actavis contrasts its proposed "scientific method" standard with the Court's use of the phrase "totality of the evidence" in an earlier opinion in this MDL that denied a motion to exclude expert testimony proffered by the bellwether plaintiffs. CMO 46, 2017 WL 1833173, at *9. In that motion to exclude, defendant AbbVie argued that the opinions of the plaintiffs' general causation expert witnesses were unreliable because "they ha[d] not demonstrated that there [was] a statistically significant association between TRT and increased cardiovascular risk." *Id.* at *9. In response, the bellwether plaintiffs "disputed that a valid opinion regarding causation must involve a finding of a statistically significant

association in the epidemiological literature." *Id.* Instead, they argued that "an expert is permitted to form an opinion based on the 'totality of the evidence,' which may include analysis of randomized control trials, observational studies, meta-analyses, case reports, and animal and *in vitro* studies, as well as criteria such as the plausibility of proposed causal mechanisms, the magnitude of reported findings of associations, and results of studies in analogous circumstances." *Id.*

The Court agreed with the bellwether plaintiffs that "there is nothing inherently unreliable about a method that relies on the totality of the evidence, provided that the expert considers the evidence carefully and explains how the weight of the various pieces of evidence led him to his conclusion." *Id.* The Court therefore determined that the better approach was to avoid creating a bright-line rule and to instead examine the different bases for the experts' opinions to determine whether "the experts adequately explain why their view of the evidence supports a finding of causation." *Id.* at *11. The Court also noted that the evidence cited by the experts *did* include studies that demonstrated a statistically significant association between TRT medications and elevated cardiovascular risk. *Id.*

As best the Court can tell, Actavis uses the term "scientific method" to argue, like AbbVie, that the Court can admit general causation opinions only if they are based primarily (or perhaps exclusively) on studies that show a statistically significant association between Androderm and stroke under highly similar circumstances to those of the plaintiff. *See* Actavis Mem. in Supp. of Summ. J. at 11 (stating that the Court should "have either Dr. Ardehali or Dr. Ziman come forward with *data* (not opinion, not hypotheses) showing, or giving rise to a properly derived inference, that 23 days of use

can cause ischemic stroke in a person like Mr. Davis"). The Court disagrees with this categorical view for the reasons it has just summarized. Rather, "[t]he critical inquiry is whether there is a connection between the data employed and the opinion offered." *Manpower, Inc. v. Ins. Co. of Pa.*, 732 F.3d 796, 806 (7th Cir. 2013).

Dr. Ardehali and Dr. Ziman both rely on various studies that *have* reported a significant association between TRT medications and cardiovascular events, including the Basaria study, the Xu study, the Albert study, the Vigen study, and the Finkle study. In addition, both Dr. Ardehali and Dr. Ziman explain why other evidence supports their opinion that Androderm increases the risk of stroke. For example, although some studies did not show a significant increase in adverse cardiovascular events, they showed significant increases in hemoglobin, hematocrit, and plaque volume, which the experts explain are associated with increased risk of cardiovascular events.

As the Court has explained previously, "experts on both sides of this litigation have analyzed the existing epidemiological evidence in detail, criticizing the studies on which the other side relies, and drawing different conclusions from the literature." CMO 46, 2017 WL 1833173, at *11. The plaintiffs' experts have cited to numerous scientific studies, acknowledged the inconsistent outcomes of the studies, discussed the various limitations of the studies, and explained why they believe some results are more reliable than others. The Court concludes that Dr. Ardehali's and Dr. Ziman's methodology is sufficiently reliable to meet the demands of Rule 702. [T]he studies' "merits and demerits . . . can be explored at trial." *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 433 (7th Cir. 2013).

Actavis also argues that the experts' general causation opinions must be

excluded because no study has established that only 23 days' use of testosterone medication increases the risk of stroke. As an initial matter, the Court notes that Actavis's narrow focus on the specific number of days that Davis used Androderm suggests that the 23-day issue is more appropriately a question of specific rather than general causation. Experts' *general* causation reports can hardly be expected to discuss the precise circumstances of each potential plaintiff's injury. That would effectively erase the distinction between general and specific causation.

Regardless of whether the issue is viewed as one of specific or general causation, however, the Court agrees with the general premise that the plaintiffs' experts must provide evidence that short-term TRT usage can increase cardiovascular risks. The problem for Actavis is that the plaintiffs' experts have done so. The Basaria study, for example, observed an increased risk of cardiovascular events within six months of TRT usage. *See* Ardehali Gen. Causation Expert Rep. at 84–85; Ziman Gen. Causation Expert Rep. at 26. The Albert study reported that "a statistically significant increase in risk of [cardiovascular] events was found for men participating in trials of <1 year duration" and "[t]he authors concluded that [TRT] may be associated with increased CV events in those ≥ 65 years especially during the first year." Ardehali Gen. Causation Expert Rep. at 97 (internal quotations omitted). The Finkle study reported "an increased risk of acute myocardial infarction in [sic] 90-day period after filling a testosterone prescription versus the 1-year baseline before testosterone." *Id.* at 100; Ziman Gen. Causation Expert Rep. at 39 (additionally noting that "[a]lthough this study only examined non-fatal [myocardial infarction] in association with TRT, notable is the rapid period within which events occurred, i.e., 90 days. This is in keeping with the

rapid rheological effects of Testosterone on the blood as well as increases in estradiol, as seen in studies of women on hormones and the e Coronary Drug Project (CDP) 1970."). The Layton analysis "found that Testosterone injections were uniquely associated with short-term risk of acute cardio- and cerebrovascular events in older adult men shortly following TRT injection." Ziman Gen. Causation Expert Rep. at 40. The Etminan study reported "an association between [myocardial infarction] and first time TRT use," which the study authors defined as "the first 90 days of use." Ardehali Gen. Causation Expert Rep. at 101; Ziman Gen. Causation Expert Rep. at 39 (adding that "[t]he finding that risk of TRT increased at initiation [of treatment], is consistent with biological mechanisms that have been documented in association with sex hormone biological actions"). The Wallis study authors "reported that long-term exposure to TRT was associated with reduced risks of mortality while short duration of TRT was associated with increased risk of mortality and cardiovascular events." Ardehali Gen. Causation Expert Rep. at 102; Ziman Gen. Causation Expert Rep. at 47. Further, the Bachman study on testosterone's effect on hemoglobin and hematocrit reported significantly increased levels at "1 and 3 months." Ziman Gen. Causation Expert Rep. at 30–31. The Court concludes that the experts have sufficiently supported their opinions that even short-term TRT use can cause an increase in cardiovascular risk.

The Court denies Actavis's motion to exclude Dr. Ardehali's and Dr. Ziman's general causation opinions because they are sufficiently reliable to meet the requirements of Rule 702.

2. Dr. Ardehali's and Dr. Ziman's specific causation opinions

Actavis next argues that the Court should exclude Dr. Ardehali's and Dr. Ziman's

specific causation opinions that Androderm was a substantial cause of Davis's stroke because they cannot "rule in" Androderm as a potential cause. In addition, Actavis criticizes Dr. Ziman for failing to "rule out" a carotid artery dissection and migraines as alternative causes of Davis's stroke.

Actavis argues that the experts cannot "rule in" Androderm as a risk factor for Davis's stroke because his treating physicians at the hospital did not administer any tests to measure the levels various biological mechanisms via which Androderm might cause stroke. Although such evidence might make the experts' opinions more convincing, its absence does not render them unreliable or otherwise inadmissible. Both experts have adequately explained, in both their general and specific causation reports, why they hold the opinion that Androderm increased Davis's risk for stroke after reviewing his medical history, records, and the various tests and imaging scans administered after his stroke. They noted that Davis generally had a below-average risk of stroke based on factors such as his age, race, blood pressure, cholesterol, diabetic status, and smoking history. Despite this low risk, he experienced an "acute thrombotic episode in his right internal carotid artery and the M2 branch of the right middle cerebral artery 23 days after starting Androderm." Ardehali Specific Causation Expert Rep. at 8; Ziman Specific Causation Expert Rep. at 37–38. Both experts have opined that "testosterone supplementation with Androderm . . . magnified and promoted [Davis's] hypercoagulable, inflammatory, and prothrombotic state," creating the conditions necessary for thrombosis to occur and to cause his stroke. Ziman Specific Causation Expert Rep. at 39; Ardehali Specific Causation Expert Rep. at 9–10.

To the extent that Actavis argues that the experts' specific causation opinions

should be excluded on the ground that they do not adequately explain how Davis's 23-day usage of Androderm led to his stroke, the Court declines to exclude the opinions on this basis. There is no indication that the experts were unaware of or ignored this timeframe when forming their opinion. To the contrary, both reports specifically mention the 23-day timeframe. *See* Ardehali Specific Causation Expert Rep. at 9; Ziman Specific Causation Expert Rep. at 23. In addition, both experts addressed why they believed that Androderm—rather than the testosterone injections that Davis had been previously prescribed—was a substantial cause of Davis's stroke. *See* Ardehali Specific Causation Expert Rep. at 9 (explaining that Davis's "use of testosterone cypionate [injections] ended approximately three months prior to his stroke, which means many of the clotting-cascade factors would have returned to baseline" and that "the [injection] method of delivery—as opposed to Androderm's transdermal delivery—affects the clotting cascade differently"); Ziman Specific Causation Expert Rep. at 22 (explaining that the testosterone injections could be ruled out as a cause of Davis's stroke because his "his last shot was approximately 2.5–3 months prior to his stroke" and his testosterone levels before he began Androderm "did not reflect any Depo-testosterone supplementation"). Contrary to Actavis's contention, the Court does not see any inconsistency in the experts' explanations; both opine that the effects of the shots would not have lasted three months after Davis's last injection. The Court therefore sees no viable basis to exclude the opinions on these grounds.

Actavis argues that Dr. Ziman's opinion suffers from additional flaws because he failed to properly rule out a carotid artery dissection and migraines as possible alternative causes of Davis's stroke. Courts may consider "[w]hether the expert has

adequately accounted for obvious alternative explanations" when determining the reliability of an expert's methodology. *Schultz*, 721 F.3d at 434 (quoting Fed. R. Evid. 702 advisory committee's note to 2000 amendment). This does not mean, however, that an expert's opinion must "rule out every alternative cause" to be admissible. *Id.* Rather, "objections that . . . experts failed to consider facts (or that they placed too great an emphasis on certain facts over others) 'generally go to the weight of the expert's opinion, not its admissibility.'" *Africano v. Atrium Med. Corp.*, 561 F. Supp. 3d 772, 778 (N.D. Ill. 2021) (quoting *Jordan v. Dominick's Finer Foods*, 115 F. Supp. 3d 950, 963 (N.D. Ill. 2015)); *see also Burton v. Am. Cyanamid*, 362 F. Supp. 3d 588, 601 (E.D. Wis. 2019) ("That [an expert] did not consider and exclude *all* possible factors . . . goes to the weight and not the admissibility of his testimony.").

With respect to the carotid artery dissection issue, Dr. Ziman considered this in both his initial report and in a supplement in response to Actavis's expert's testimony suggesting carotid artery dissection as a possible cause. In both reports, Dr. Ziman concluded that carotid artery dissection was unlikely to be the cause of Davis's stroke. Although Actavis is correct that Dr. Ziman's supplemental report includes a more expansive discussion of why he believes Davis's stroke was not caused by a carotid artery dissection, the Court sees no reason to exclude his opinion on this basis. Experts are permitted (and often required) to make timely supplements to their initial reports. *See* Fed. R. Civ P. 26(e)(2). Actavis also argues that Dr. Ziman cannot rule out carotid artery dissection because "an MRA with fat suppressed images is the preferred study for diagnosis of arterial dissection, and [Dr. Ziman] cannot say that such an MRA was performed on Mr. Davis." Actavis Mot. to Exclude at 26. Again, however,

"[t]he critical inquiry is whether there is a connection between the data employed and the opinion offered." *Manpower, Inc.*, 732 F.3d at 806. An expert's opinion is not unreliable simply because some other piece of evidence, if it were to exist, might disprove the opinion. In this case, Dr. Ziman relied on the various x-ray, MRI, MRA, and CT imaging scans that were available to him. Actavis is welcome to press at trial its theory that the evidence Dr. Ziman considered does not remove doubt that a carotid artery dissection occurred, but that is an argument for the jury, not a basis to exclude his opinion.

Finally, the Court declines to exclude Dr. Ziman's opinion based on his alleged failure to rule out migraines as a potential cause of Davis's stroke. The record is inconsistent regarding whether Davis in fact suffered from migraines, and Dr. Ziman's supplemental report adequately explains why he does not believe that Davis had a history of migraines that needed to be considered in his analysis. Actavis may present evidence to the contrary and use that to impeach Dr. Ziman, but the Court concludes that Davis's potential migraine history does not render Dr. Ziman's methodology unreliable. *See Africano*, 561 F. Supp. at 778 ("[O]bjections that . . . experts failed to consider facts (or that they placed too great an emphasis on certain facts over others) 'generally go to the weight of the expert's opinion, not its admissibility.'" (quoting *Jordan*, 115 F. Supp. 3d at 963)).

In sum, the Court concludes that Dr. Ardehali's and Dr. Ziman's specific causation opinions meet the requirements of Rule 702. The weight to be given to those opinions is appropriately a matter for consideration by the jury. The flaws that Actavis highlights are more properly addressed through the "traditional and appropriate means

of attacking shaky but admissible evidence": "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof." *Schultz*, 721 F.3d at 431 (quoting *Daubert*, 509 U.S. at 596).

3. Dr. Segal's specific causation opinion

The plaintiffs have moved to exclude three elements of Dr. Segal's testimony: (1) "the etiology of Mr. Davis' stroke is unknown or 'cryptogenic'"; (2) "a carotid artery dissection is possibly an alternate explanation for Mr. Davis' stroke"; and (3) "Mr. Davis was receiving less testosterone because the Androderm patch loosened when he worked out."

The plaintiffs first argue that the Court should exclude Dr. Segal's testimony that the cause of Davis's stroke is "unknown" or "cryptogenic." They argue at length that Dr. Segal misuses the so-called "TOAST" classification system to support his causal opinion. The parties agree that "TOAST" is a system for categorization of subtypes of ischemic strokes derived from the Trial of Org 10172 in Acute Stroke Treatment (TOAST) study. There are five subtypes: "1) large-artery atherosclerosis, 2) cardioembolism, 3) small-artery occlusion (lacune), 4) stroke of other determined etiology, and 5) stroke of undetermined etiology." Pls.' Mot. to Exclude at 4. Dr. Segal's report states that Davis's stroke belongs in the fifth category. The plaintiffs argue that Dr. Segal should not be allowed to opine that, merely because Davis's stroke falls into the unknown TOAST category, Androderm cannot have caused his stroke.

The Court does not read Dr. Segal's report as improperly relying on TOAST labels to arrive at his conclusions regarding the potential causes of Davis's stroke. It is true that Dr. Segal states in his report that he believes Davis's stroke was "cryptogenic"

(i.e., of unknown origin) based on TOAST criteria. But Dr. Segal arrived at his conclusions regarding the various possible causes of the stroke by reviewing Davis's pre-stroke medical history, the various imaging scans taken at the time of and after the stroke, and his post-stroke medical history. Dr. Segal explains why, in his opinion, the information in these records does not permit him (or any other expert) to identify the cause of Davis's stroke. Dr. Segal then explains why he believes that Dr. Ardehali's and Dr. Ziman's contrary conclusions rely on erroneous assumptions. Although the experts' conclusions differ, the records that Dr. Segal relies on are quite similar to those that Dr. Ardehali and Dr. Ziman have used to support their own specific causation opinions. Dr. Segal, like Dr. Ardehali and Dr. Ziman, has the qualifications and experience necessary to examine those medical records and explain what they reveal regarding the possible causes of Davis's stroke. The Court therefore declines to exclude his opinion that the cause of Davis's stroke is unknown.

The plaintiffs next argue that Dr. Segal's suggestion that "it is possible that Mr. Davis had a carotid dissection" is inadmissible because he opines only that it was "possible" rather than "probable." Pls.' Mot. to Exclude at 7. But unlike the plaintiffs' experts, who seek to show that Androderm was a substantial cause of Davis's stroke, the reliability of Dr. Segal's opinion does not depend on his ability to identify a "probable" cause. Rather, Dr. Segal appropriately challenges the plaintiffs' experts' opinions by identifying possible alternative causes. *See Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 808 (3d Cir. 1997) ("In attacking the differential diagnosis performed by the plaintiff's expert, the defendant may point to a plausible cause of the plaintiff's illness other than the defendant's actions."). Given that the plaintiffs' experts cite the

fact that Davis was at a low risk of stroke to support their conclusion that Androderm caused his stroke, Dr. Segal is entitled to point out that a carotid artery dissection "would also be a compelling mechanism by which an otherwise healthy vessel as large as the carotid would suddenly occlude." Segal Expert Rep. at 4. The claimed lack of support for this in Davis's medical records is a matter for cross-examination and argument, not a basis to exclude Dr. Segal's opinion.

Moreover, Dr. Segal formed his opinion in essentially the same manner as Dr. Ziman did in concluding that a carotid artery dissection was *not* a likely cause: by reviewing the various MRI, MRA, and CT imaging scans taken after Davis's stroke. *See id.* at 2–4. Dr. Segal specifically explained that "the length of the occlusion is consistent with a dissection" and that the carotid dissection diagnosis "could have been missed since dissections are not early recognized when there is a total arterial blockage." *Id.* The Court concludes that Dr. Segal's testimony that a carotid artery dissection is a possible alternative cause of Davis's stroke is sufficiently reliable to meet the requirements of Rule 702.

Lastly, the plaintiffs argue that the Court should exclude Dr. Segal's testimony that Davis's "serum testosterone level from an ill-adhering patch was likely lower than that achieved by injections he had received during the two years prior." Segal Expert Rep. at 4. But there is evidence in the record that Davis complained to Dr. Avey about the Androderm patches falling off, and the Court sees no reason why Dr. Segal should not be able to consider the "ill-adhering" nature of the patch and the possibility that this decreased Davis's testosterone dosage. The Court declines to exclude this component of Dr. Segal's testimony.

B. Summary judgment on the plaintiffs' failure to warn theory

The Court next turns to Actavis's motion for summary judgment. Summary judgment is appropriate only if "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). In considering a motion for summary judgment, the Court must "construe all facts and inferences in favor of the nonmoving party." *Love v. JP Cullen & Sons, Inc.*, 779 F.3d 697, 701 (7th Cir. 2015). Actavis argues that it is entitled to summary judgment on all the plaintiffs' claims premised on a failure to warn theory for three reasons. First, Actavis contends that Davis has failed to show that its alleged failure to warn proximately caused Davis's stroke. Second, it argues that Davis has not shown that Actavis violated a duty to warn under Florida law. Third, it asserts that Florida's "government rules" statute provides a defense to the plaintiffs' claims.

1. Proximate cause

To prevail on a failure to warn claim under Florida law, a plaintiff must show that "the inadequacy of the warning proximately caused his injury." *Hoffmann-La Roche Inc. v. Mason*, 27 So. 3d 75, 77 (Fla. Dist. Ct. App. 2009). Florida follows the "learned intermediary" rule, under which the duty to warn of a drug's dangerous side effects is "directed to the physician rather than the patient." *Felix v. Hoffman-LaRoche, Inc.*, 540 So. 2d 102, 104 (Fla. 1989). "The learned intermediary rule provides that the failure of the manufacturer to provide the physician with an adequate warning of the risks associated with a prescription product is not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warning should have communicated." *Christopher v. Cutter Lab'ys*, 53 F.3d 1184, 1192

(11th Cir. 1995) (applying Florida law).

Actavis argues that Dr. Avey was independently aware that Androderm carried a risk of stroke when he prescribed the drug to Davis. Some portions of Dr. Avey's deposition testimony arguably support Actavis's position. But Dr. Avey also repeatedly testified during his deposition that he was not sure when he became aware of the possible stroke risks associated with TRT products and that it could have been *after* he prescribed Androderm to Davis. For example:

> Q: And at the time you prescribed Androderm to Mr. Davis, you were aware of a possible risk of stroke associated with testosterone use, correct?
> A: I don't recall if I was aware at the time I prescribed or sometime around that time.
> Q: At some point you became aware of a possible risk, correct?
> A: Yes.
> Q: But you can't say you were aware at the time you prescribed it to Mr. Davis?
> A: No, I'm not certain.

Pls.' Mot. to Exclude, Ex. G (Avey Dep.) at 39:22–40:11 (objection omitted).[1]

> Q: So at some point in and around March 2015 you became aware of the class labeling changes warning of a possible increased risk of heart attacks and strokes associated with testosterone use?
> A: At some point after that. I can't tell you when exactly.
> Q: Why would it have been after that?
> A: Well, I'm sure I wasn't on the cutting edge of reading the journal the day it arrived on my desk and see the reports, you know. Could have been some point after that. Within a few months, within a year, I don't know.
> [. . .]
> Q: But your testimony is that it may have been as much as a year later before you became aware of the possible risk of stroke associated with testosterone replacement therapy products?
> A: My testimony is I don't recall exactly when. It was sometime within the next few months or year.
> Q: So it could have been up to a year later?
> A: It could have been.

[1] During the deposition, both parties' counsel objected to some of the following questions, but they did not articulate any basis for the objections. Before the Court, neither party has suggested that this testimony by Dr. Avey would be inadmissible.

Id. at 41:16–42:22 (objection omitted).

> Q: Is it likely that this October 2015 or shortly before is when you learned about the association between Androderm and the stroke risk? Is that likely what prompts your instruction now to stay off testosterone?
> A: It's quite possible.

Id. at 106:25–107:5 (objection omitted). Moreover, even the portion of Dr. Avey's testimony that Actavis argues shows that he had independent knowledge of Androderm's risks is subject to interpretation. Actavis emphasizes the following exchange:

> Q: So you were aware of a possible risk of stroke at the time that you prescribed Androderm to Mr. Davis, fair?
> A: No. I was aware of a controversy in the literature. [. . .] A controversy means it's controversial, we don't know if there's a risk of stroke. That's what the literature supported at the time.
> Q: Meaning the risk was possible?
> A: And also not possible, correct.
> Q: Okay. But you were familiar with studies that indicated there was a possible risk, correct?
> A: Yes.
> Q: At the time you prescribed Androderm to Mr. Davis?
> A: Yes.

Id. at 46:10–47:5 (objection omitted). As noted above, other portions of Dr. Avey's testimony conflict with this statement. But, even if taken at face value, the fact that Dr. Avey had some knowledge of studies on the link between TRT medications and stroke does not mean that he had the same degree of knowledge that an adequate warning from Androderm would have provided. Arguably, Dr. Avey is precisely the audience that could have benefited from a label warning, because it might have alerted him that the risk had been substantiated more than he previously believed.

In addition, Davis testified during his deposition that he did not believe that Dr. Avey warned him about a risk of stroke. Given that Dr. Avey testified that he began to

inform patients of that risk after he learned about the updated stroke warning, his alleged failure to counsel Davis could support a reasonable inference that Dr. Avey was not aware of the risk when he prescribed Androderm to Davis in July 2015. In sum, there is a genuine factual dispute whether Dr. Avey had independent knowledge of the risk that an adequate warning would have communicated.

Actavis also argues that it is entitled to summary judgment because there is no evidence that Dr. Avey would not have prescribed Androderm to Davis if he had been adequately warned. Specifically, Actavis points to Dr. Avey's deposition testimony that he was not sure whether he would have prescribed Androderm to Davis if he had been fully informed of the risks.

The Court disagrees with Actavis's assumption that the only manner in which a plaintiff can show that a defendant's failure to warn proximately caused the plaintiff's injury is through the physician's testimony that, but for the failure to warn, the physician would not have prescribed the drug. Under the learned intermediary rule, the drug manufacturer has a duty to warn to the physician, not the patient, about a drug's risk. *Felix*, 540 So. 2d at 104. As a result, Florida courts have held that plaintiffs cannot show proximate cause in cases where there was no evidence that a different warning would have changed the physician's behavior. *See Mason*, 27 So. 3d at 77; *Felix*, 540 So. 2d at 105.

In this case, however, Dr. Avey did not testify that an adequate warning would have had *no* effect on his interactions with Davis. To the contrary, he testified that he would have liked to have been warned regarding the association between Androderm and stroke; he would have considered that warning in deciding whether to prescribe the

drug to Davis; he could not say whether he would or would not have prescribed the drug to Davis; he generally became "more likely to discuss cardiovascular risks" with patients after he learned of these risks; and he would have "discussed it with [Davis] before making a decision." Pls.' Mot. to Exclude, Ex. G (Avey Dep.) at 119:21–120:5; 138:4–139:5. Further, Davis testified during his deposition and stated in an affidavit that, had Dr. Avey informed him of the stroke risk associated with Androderm, he would not have used Androderm. *See* Pls.' Mot. to Exclude, Ex. G (Davis Dep.) at 133:3–22. A reasonable jury therefore could conclude that a different warning may have led Dr. Avey to act differently, either by declining to prescribe Androderm or by giving Davis a stronger admonition that would have led Davis to pass on the medication.

Actavis argues that "Florida proximate cause law focuses on the learned intermediary's prescribing decision, not patient choice." Actavis Reply in Supp. of Summ. J. at 7. The Court recognizes that some federal courts applying Florida law have stated that "to satisfy the causation requirement in a medical device failure-to-warn claim, 'a plaintiff must show that her treating physician would not have used the product had adequate warnings been provided.'" *Salinero v. Johnson & Johnson*, 995 F.3d 959, 964–65 (11th Cir. 2021) (quoting *Eghnayem v. Bos. Sci. Corp.*, 873 F.3d 1304, 1321 (11th Cir. 2017)). But these cases did not rule out liability under the circumstances presented here, where evidence supports the conclusion that Dr. Avey would have materially altered his behavior in response to a different warning, even if there is no *conclusive* evidence that he would have declined to prescribe Androderm to Davis. The Eleventh Circuit in *Eghnayem*, for example, held that the plaintiff provided sufficient evidence that the defendant's failure to warn proximately caused her injuries based on

her doctor's testimony that "he would have liked to know the risk [of the medical device at issue]" and "that had he known he would have had concerns about [ ] using [the device] in a patient and *would have discussed those concerns with [the plaintiff]*." *Eghnayem*, 873 F.3d at 1323 (internal quotation marks omitted) (emphasis added). In addition, Actavis does not cite to, and the Court is not aware of, any case in which a Florida court has rejected this theory of proximate cause. The Court therefore concludes that Actavis is not entitled to summary judgment on this basis.

2. Lack of duty

Actavis next argues that it had no duty to warn Dr. Avey, for three reasons. First, Actavis asserts that Dr. Avey already had the same knowledge that an adequate warning would have provided. As the Court has just explained, however, there is a genuine factual dispute regarding what Dr. Avey knew at the time he prescribed Androderm to Davis.

Second, Actavis argues that it had no duty to warn Dr. Avey because there is only a "possible" risk of stroke associated with Androderm rather than a "known" risk of stroke. Actavis Mem. in Supp. of Summ. J. at 8. Actavis provides no support for its assertion that Florida law treats warnings that discuss "known" versus "possible" risks differently, apart from a single citation to a footnote in a federal district court case that does not concern the issue. *See id.* (citing *Pringle v. Johnson & Johnson*, No. 13-81022-CIV, 2019 WL 6723822, at *3 n.4 (S.D. Fla. Dec. 11, 2019)). But even if such a distinction exists under Florida law, Actavis would not be entitled to summary judgment on this basis. As the Court has discussed with respect to the parties' motions to exclude, whether Androderm in fact increases the risk of stroke is one of the most hotly

contested issues in this case. That is a question for the jury, not one for the Court to resolve at the summary judgment stage.

Third, Actavis argues that "there is no duty under Florida law for prescription drug manufacturers 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 Mem. in Supp. of Summ. J. at 9. As Actavis acknowledges, however, the Court previously denied its earlier motion for summary judgment on this exact issue. *See* CMO 179, 2020 WL 6487327, at *1. Actavis did not move for reconsideration, and the Court denied Actavis's motion for certification of an interlocutory appeal of that decision. *See* ECF No. 69, *Davis v. Actavis, Inc.*, No. 17 C 3775 (N.D. Ill. Apr. 1, 2021). Actavis provides no reason why the Court should revisit its earlier ruling other than pointing to a Pennsylvania decision, *Zitney v. Wyeth*, 2020 PA Super 278, 243 A.3d 241 (Pa. Super. Ct. 2020). But even if the Court were inclined to revisit its decision on this basis, nothing in *Zitney* persuades the Court to change course. That case is quite similar to *Sherman v. Pfizer, Inc.*, 8 Wash. App. 2d 686, 440 P.3d 1016 (2019), which the Court considered and declined to follow in its earlier order. In both cases, the plaintiffs alleged that a generic metoclopramide manufacturer had a duty to warn physicians with "Dear Doctor" letter in addition to the warnings provided in the drug's package insert. In both cases, the courts rejected the plaintiffs' arguments. But the Court has already explained why it "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." CMO 179, 2020 WL 6487327, at *7. Namely, "there was no allegation . . . that the wrong package insert accompanied the plaintiff's

prescription"; "the defendant was a generic drug manufacturer"; and "the similarities that Actavis identifies between Washington and Florida law are not, on their own, strong indicators that the Florida Supreme Court would follow *Sherman*." *Id.*

All of these reasons apply with equal force to *Zitney*. The plaintiffs in *Zitney* "conceded that [the manufacturer] fulfilled their duty to provide content-appropriate warning labels in their metoclopramide package"; the defendants were generic drug manufacturers; and Actavis bases its argument on alleged similarities between Pennsylvania and Florida law. *Zitney*, 2020 PA Super 278, ¶ 22, 243 A.3d at 246. Moreover, the Court notes that *Zitney* lacks any meaningful analysis of the relevant tort law concepts at play. That is understandable given that the Pennsylvania court expressly noted that the plaintiffs failed to develop their argument for a "heightened" duty to warn. *See id.* ¶ 20, 243 A.3d at 246 ("Appellants baldly assert, without citation to any authority, that the learned intermediary doctrine imposes upon Appellees a duty to warn [a physician] individually through a [Dear Doctor] letter of the risks posed by [the plaintiff's drug use].").

The Court declines to grant summary judgment for Actavis on the ground that it did not owe Dr. Avey a duty to warn.

3. Government rules defense

Actavis's final argument for summary judgment on the plaintiffs' failure to warn claims is that these claims are barred by Florida's "government rules defense." Section 768.1256 of the Florida Statutes establishes a "rebuttable presumption that [a] product is not defective or unreasonably dangerous and the manufacturer or seller is not liable if, at the time the specific unit of the product was sold or delivered to the initial

purchaser or user, the aspect of the product that allegedly caused the harm . . . [c]omplied with federal or state codes, statutes, rules, regulations, or standards relevant to the event causing the death or injury." Actavis argues that it is entitled to this defense because Androderm, including its label and warnings, was FDA-approved at the time Dr. Avey prescribed it to Davis.

But even assuming that Actavis is entitled to the government rules defense, that does not mean it is entitled to immunity from liability. Rather, the statute expressly establishes a *rebuttable* presumption that Androderm was not defective. *See Guenther v. Novartis Pharm. Corp.*, No. 8-CV-456, 2013 WL 1498162, at *3 (M.D. Fla. Apr. 9, 2013) ("Assuming *arguendo* that this Florida statutory presumption would . . . apply . . . the presumption is by its terms rebuttable."); *Rydzewski v. DePuy Orthopaedics, Inc.*, No. 11-80007-CIV, 2012 WL 7997961, at *2 (S.D. Fla. Aug. 14, 2012) (same); *In re Fosamax Products Liability Litig.,* 742 F. Supp. 2d 460, 473 (S.D.N.Y. 2010) (same). As discussed, Davis has produced evidence that would permit a reasonable jury to conclude that Androderm increases the risk of stroke, that Actavis failed to warn Dr. Avey about this risk, and that this failure caused Davis's stroke. This is sufficient to rebut the presumption. Actavis is therefore not entitled to summary judgment on this basis.

C. Remaining state law claims

Actavis has also moved for summary judgment on the plaintiffs' remaining state law claims. It first argues that it is entitled to summary judgment because these claims merely repackage the plaintiffs' failure to warn theory. Because the Court has concluded that Actavis is not entitled to summary judgment on the failure to warn claim,

Actavis is not entitled to summary judgment on the remaining state law claims on this basis. Actavis argues in the alternative that even if the plaintiffs have non-failure-to-warn theories to support their remaining state law claims, these claims fail for various other reasons. The Court addresses these contentions below.

1. Strict liability design defect

Actavis argues that it is entitled to summary judgment because plaintiffs have not presented expert testimony that Androderm had a design defect apart from the allegedly defective warning. In Androderm's view, a plaintiff must present expert testimony that "a change in the design of Androderm would have prevented Mr. Davis's stroke." Actavis Mem. in Supp. of Summ. J. at 15. The Court interprets Actavis's argument as invoking the "reasonable alternative design" requirement of the "risk utility" test found in the Third Restatement of Torts. Jurisdictions that apply this rule require plaintiffs to establish that "the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller." Restatement (Third) of Torts: Prod. Liab. § 2(b) (1998).

The Florida Supreme Court, however, has held that plaintiffs do not need to show proof of a reasonable alternative design to prevail on design defect claims. In *Aubin v. Union Carbide Corp.*, 177 So. 3d 489, 510 (Fla. 2015), the Florida Supreme Court discussed the competing tests for design defect claims at length and concluded that "in approaching design defect claims, we adhere to the consumer expectations test, as set forth in the Second Restatement, and reject the categorical adoption of the Third Restatement and its reasonable alternative design requirement." The court explained that "[u]nder the consumer expectations test, a product is considered to be defective

'where the product is, at the time it leaves the seller's hands, in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him.'" *Id.* at 513 (quoting Restatement (Second) of Torts § 402A, cmt. g. (1965)). Although a plaintiff *may* provide evidence of a reasonable alternative design to support his claim, such evidence is not required to prevail. *Id.* at 511.

The touchstone under Florida law is thus what a reasonable consumer would expect. Actavis does not cite to any post-*Aubin* case that requires a plaintiff to have expert testimony in order to prevail under the consumer expectations test. At any rate, the plaintiffs' regulatory expert, Dr. Sharlin, has opined at length that Actavis aggressively marketed Androderm "off-label" (i.e., without FDA approval and in contravention of FDA regulations) for certain groups of men with "Low T" without first studying the risks and benefits of TRT medication in those populations. A reasonable jury could conclude that this constitutes "a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him." *Id.* at 513 (quoting Restatement (Second) § 402A, cmt. g). At the very least, Actavis has not explained in its motion for summary judgment why plaintiffs cannot prevail on such a theory.

Actavis also states, in a footnote, that the consumer expectations test should not apply in "prescription medical products cases." Actavis Reply in Supp. of Summ. J. at 12 n.3. But, again, Actavis does not cite to any post-*Aubin* cases to support this argument or explain why it believes the consumer expectations test should not apply to cases involving prescription medical products. The Court therefore declines to stray from the Florida Supreme Court's clear statement that courts should apply the "consumer expectations test, as set forth in the Second Restatement, and reject the

categorical adoption of the Third Restatement and its reasonable alternative design requirement." *Aubin*, 177 So. 3d at 510. In conclusion, Actavis has not shown that it is entitled to judgment as a matter of law on the plaintiffs' design defect claim.

2. Implied and express warranty claims

Actavis argues that "under Florida law, privity of contract is required for a plaintiff to proceed on an implied or express warranty claim." Actavis Mem. in Supp. of Summ. J. at 16. Because Davis did not purchase Androderm directly from Actavis, it argues that the privity requirement defeats the plaintiffs' implied and express warranty claims.

Under Florida law, "[p]rivity is required in order to recover damages from the seller of a product for breach of express or implied warranties." *Douse v. Bos. Sci. Corp.*, 314 F. Supp. 3d 1251, 1261 (M.D. Fla. 2018) (quoting *Intergraph Corp. v. Stearman*, 555 So. 2d 1282, 1283 (Fla. Dist. Ct. App. 1990); *see also Elizabeth N. v. Riverside Grp., Inc.*, 585 So. 2d 376, 378 (Fla. Dist. Ct. App. 1991)). There are some limited circumstances in which Florida courts have relaxed the privity requirement. For example, courts have permitted claims for breach of express and implied warranty to proceed where the manufacturer was not the ultimate seller but nevertheless made "direct representations" about the product in order to "induce" the purchaser. *See Cedars of Lebanon Hosp. Corp. v. Eur. X-Ray Distribs. of Am., Inc.*, 444 So. 2d 1068, 1072 (Fla. Dist. Ct. App. 1984).

The plaintiffs argue that this exception should apply here given Actavis's marketing to medical providers and directly to patients. But the plaintiffs have not offered evidence that either Dr. Avey or Davis received or relied on any advertisements or promotions directly from Actavis regarding Androderm. Neither Dr. Avey nor Davis

testified to seeing any Androderm marketing or advertisements. Moreover, the plaintiffs do not cite to any concrete evidence to show that Androderm sales representatives contacted either Dr. Avey or Davis. Although the plaintiffs insist that Dr. Avey recalled various "marketing messages" associated with TRT products, that is insufficient given that Androderm was not the only TRT product on the market at the time promoted via such techniques. The plaintiffs therefore have not pointed to evidence that would warrant an exception from the general privity rule. *See id.* at 1072 n.4 ("We wish to emphasize that we are focusing on the direct contacts between the manufacturer and the ultimate purchaser/consumer in finding that privity exists in this case. Had there been no direct contact between the two parties, appellee's contention that there was no privity, and thus no liability for breach of warranties, would be correct."). This lack of evidence differentiates this case from other cases in this MDL in which the Court has permitted breach of warranty claims to proceed. *See In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proc.*, No. 14 C 1748, 2017 WL 1836443, at *9 (N.D. Ill. May 8, 2017) (hereinafter CMO 48) (denying summary judgment on breach of warranty claims where defendant's "advertising prompted [the plaintiff] . . . to ask his doctor to prescribe AndroGel" and where plaintiffs "provided evidence of specific affirmations that [defendant's] representatives made to plaintiffs' prescribing physicians, including that AndroGel was a safe, effective treatment for age-related hypogonadism"). As a result, Actavis is entitled to summary judgment on the plaintiffs' implied and express warranty claims.

3. Negligent misrepresentation and fraud

Actavis argues that Florida law requires plaintiffs to show that Dr. Avey relied on

Actavis's false statements to prevail on either a negligent misrepresentation or a fraud claim; the plaintiffs do not dispute this requirement. To the extent that plaintiffs intend to pursue a negligent misrepresentation or fraud theory that is not based on Actavis's failure to warn about the risk of stroke, the Court interprets the plaintiffs' argument to again be based on Actavis's off-label marketing of Androderm as a sweeping solution for "Low T." As just discussed, however, plaintiffs have not provided evidence that Dr. Avey relied on Actavis's off-label marketing in deciding to prescribe Androderm to Davis. Actavis is therefore entitled to summary judgment on the plaintiffs' negligent misrepresentation and fraud claims.

4. Consumer protection

Actavis argues that it is entitled to summary judgment on the plaintiffs' consumer protection claim under the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, because that statute does not provide plaintiffs with a cause of action for personal injury claims. Actavis is correct that the Act does not apply to "[a] claim for personal injury or death or a claim for damage to property other than the property that is the subject of the consumer transaction." Fla. Stat. § 501.212(3). The Court notes that it has permitted a plaintiff to proceed under an analogous Utah statute where the plaintiff argued that he sought only "to recover economic losses, such as the costs of purchasing [the defendant's product]." CMO 48, 2017 WL 1836443, at *10. The plaintiffs in this case, however, have not advanced that argument. Rather, they suggest that the mere fact that they have requested restitution, disgorgement, and other equitable relief is sufficient to save their claim. Because the plaintiffs do not explain why they are entitled to relief under the Act and how that theory of recovery is distinct from

their personal injury claims, the Court grants Actavis's motion for summary judgment on the plaintiffs' consumer protection claim.

5. Unjust enrichment

The plaintiffs stated in their response to Actavis's motion for summary judgment that they do not intend to pursue an unjust enrichment claim. The Court therefore grants summary judgment for Actavis on this claim.

6. Loss of consortium

Actavis argues that it is entitled to summary judgment on Laura Davis's loss of consortium claim on the sole ground that it is derivative of other claims on which the plaintiffs cannot prevail. Because the Court has concluded that several of the plaintiffs' claims survive summary judgment, it declines to grant Actavis's motion for summary judgment on the loss of consortium claim.

7. Punitive damages

Lastly, Actavis asserts that it is entitled to summary judgment with respect to the plaintiffs' request for punitive damages. Actavis states that "three states' laws potentially could govern Plaintiffs' punitive damage request" given that Davis's injury occurred in Florida; Actavis Pharma, which sold Androderm, is headquartered in New Jersey; and Actavis Laboratories UT, which manufactured and applied for FDA approval for Androderm, is located in Utah. Actavis Mem. in Supp. of Summ. J. at 19. Actavis nevertheless does not address the underlying choice-of-law issue because it argues that punitive damages are barred in all three states. First, it argues that Florida bars a plaintiff from seeking punitive damages unless the plaintiff first makes a specific motion for such damages and the court finds that the plaintiff has made a prima facie case for

punitive damages. *See* Fla. Stat. § 768.72. Second, it argues that New Jersey and Utah both have statutes that bar punitive damages for alleged injuries resulting from FDA-approved drugs. *See* N.J. Stat. § 2A:58C-5(c); Utah Code § 78B-8-203.

In response, the plaintiffs also forego a choice-of-law analysis. Rather, they state (without support) that "Florida law is the most likely law to be applied since Mr. Davis lived in Florida at the time of prescription and injury (and still today), was prescribed in Florida and was injured in Florida." Pls.' Opp. to Mot. for Summ. J. at 16. They argue that the Florida bar on punitive damages that Actavis relies upon is inapplicable in federal court because it conflicts with federal procedural rules. They do not respond to Actavis's argument that punitive damages are unavailable under New Jersey and Utah law.

Courts need not conduct a choice-of-law analysis if there is no real conflict between different states' laws on a specific issue. *See In re Air Crash Disaster*, 644 F.2d 594, 605 n.2 (7th Cir. 1981). Under such circumstances, Actavis's argument that the Court can grant summary judgment without addressing the choice-of-law question would be more persuasive. But the Court concludes that a conflict exists here.

To begin, the Court agrees with the plaintiffs that the Florida pleading requirements cited by Actavis conflict with federal procedural requirements and therefore do not apply in federal court. Under the *Erie* doctrine, a federal court sitting in diversity applies "federal procedural law." *Gasperini v. Ctr. for Humanities, Inc.*, 518 U.S. 415, 427 (1996) (citing *Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938)). Section 768.72 "prohibits the inclusion of a request for punitive damages in any pleading without leave of court." *Cohen v. Off. Depot, Inc.*, 184 F.3d 1292, 1298 (11th Cir. 1999),

vacated in part on other grounds, 204 F.3d 1069 (11th Cir. 2000). In contrast, Federal Rule of Civil Procedure 8(a) requires a plaintiff to plead "a short and plain statement of the claim showing that the pleader is entitled to relief" and "a demand for the relief sought[.]"

When federal and state pleading requirements conflict, a federal court "evaluate[s] the state-law claims . . . under the federal pleading standard" so long as the federal rule is valid and constitutional. *Windy City Metal Fabricators & Supply, Inc. v. CIT Tech. Fin. Servs., Inc.*, 536 F.3d 663, 672 (7th Cir. 2008). The Seventh Circuit has held that "[p]rescribing the specificity with which a claim must be pleaded relates solely to the practice and procedure of a court and clearly falls within the scope of the Rules Enabling Act" and that there is "no basis for concluding that the regulation of pleading requirement in federal court is beyond the limits of federal constitutional authority." *Id.* Applying this same analytical framework to section 768.72, the Eleventh Circuit held that "the pleading requirements of Florida Statutes § 768.72 are inapplicable in federal diversity cases" because "the pleading component of § 768.72 . . . conflict[s] with Rule 8(a)(3)." *See Cohen*, 184 F.3d at 1299. The Court agrees and concludes that section 768.72 does not bar the plaintiffs' punitive damages claim.

Turning to New Jersey law, this Court previously concluded in a different case in this MDL that New Jersey law bars punitive damages for alleged injuries caused by drugs that are FDA-approved. *See In re Testosterone Replacement Therapy Prod. Liab. Litig.*, No. 14 C 1748, 2023 WL 1808409, at *6 (N.D. Ill. Feb. 7, 2023). Plaintiffs do not advance any argument for why the Court should reach a different outcome here. Nor do plaintiffs respond to Actavis's argument that Utah's statute is "substantively

identical" to New Jersey's. Actavis Mem. in Supp. of Summ. J. at 20. This is sufficient for the Court to conclude that a conflict exists and a choice-of-law analysis is necessary.

Given that neither party has briefed the choice-of-law issue, the Court declines to decide at this stage whether Florida, New Jersey, or Utah law applies with respect to punitive damages. The plaintiffs' complaint alleges that the Middle District of Florida is the appropriate venue for remand and trial. Because this means that Florida choice-of-law rules govern,[2] the Court will defer the choice-of-law analysis regarding punitive damages for the Middle District of Florida court to decide on remand.

Conclusion

For the foregoing reasons, the Court denies the plaintiffs' motion to exclude [dkt. 134] and Actavis's motion to exclude [dkt. 128] The Court grants Actavis's motion for summary judgment [dkt. 131] on the plaintiffs' claims for express and implied breach of warranty, negligent misrepresentation, fraud, consumer protection, and unjust enrichment. The Court denies the motion for summary judgment on plaintiffs' claims for failure to warn, strict liability design defect, loss of consortium, and punitive damages. The question of the availability of punitive damages is left for determination by the court in the Middle District of Florida following transfer.

Date: November 1, 2023

MATTHEW F. KENNELLY
United States District Judge

[2] "A federal court sitting in diversity jurisdiction typically applies the choice-of-law rules of the state in which it sits." *Dobbs v. DePuy Orthopedics, Inc.*, 842 F.3d 1045, 1048 (7th Cir. 2016). There is an exception to this rule for "foreign cases filed directly in a district court as a part of ongoing multidistrict litigation." *Id.* at 1049. Under these circumstances, the MDL transferee court generally should treat the case "as having originated outside of that district" and apply the choice-of-law rules of the appropriate venue absent the MDL proceedings. *Id.*