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 *Martin v. Actavis, Inc.*, Case No. 15 C 4292)	)	

CASE MANAGEMENT ORDER NO. 166
(Memorandum Opinion and Order on Actavis, Inc.'s motion to exclude expert testimony and motions for summary judgment in *Martin v. Actavis, Inc.*, Case No. 15 C 4292)

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 or sell Androderm, one of the TRT products at issue in this litigation.[1] Plaintiff Brad Martin alleges that his use of Androderm from October 2012 to May 2013 caused him to suffer a myocardial infarction (heart attack) in May 2013. He asserts claims against Actavis under Minnesota law for design defect; failure to warn; negligence; breach of express warranty; breach of implied warranty of merchantability; negligent misrepresentation; fraudulent misrepresentation; redhibition; consumer protection (specifically, violation of the Minnesota False Statement in Advertising Act (MFSAA), MINN. STAT. § 325F.67, and the Minnesota

[1] As the Court discusses below, the parties dispute whether Actavis, Inc. is a mere holding company.

Deceptive Trade Practices Act (MDPTA), MINN. STAT. § 325D.44(13)); unjust enrichment; and punitive damages.

In 2018, based on proposals from Actavis and the Plaintiffs' Steering Committee, the Court selected Martin's case as the first Actavis bellwether trial case. Before trial, Actavis moved to exclude the testimony of several of Martin's expert witnesses under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Actavis also moved for summary judgment on the ground that Martin's failure to warn, design defect, and so-called "off-label promotion" claims are preempted by federal law. Finally, Actavis contended that all of Martin's claims fail under Minnesota law, which the parties agree applies. The motions were fully briefed in June 2018, but in July 2018, the Court terminated them as moot due to the execution of a Master Settlement Agreement covering cases involving Actavis. In August 2019, Martin informed the Court that he has elected not to settle his claims. Thus Actavis's *Daubert* and summary judgment motions are again before the Court.

For the following reasons, the Court denies Actavis's motion for summary judgment based on federal preemption; denies Actavis's motion to exclude Martin's expert testimony concerning general and specific causation; and terminates as moot Actavis's motion to exclude the expert testimony of Robert Johnson. The Court grants Actavis's motion for summary judgment on Martin's claims for breach of implied warranty of merchantability, negligent misrepresentation, unjust enrichment, redhibition, and violation of the MFSAA; reserves judgment on Actavis's motion for summary judgment on claims against Actavis, Inc.; and denies Actavis's motion in all other respects.

Background

The Court has ruled on motions raising similar issues in cases brought against AbbVie and Auxilium, other defendants in this MDL, concerning their TRT drugs AndroGel and Testim. *See In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, MDL No. 2545, 2018 WL 4030585 (N.D. Ill. Aug. 23, 2018) ("CMO 133"); *In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, MDL No. 2545, 2018 WL 4030586 (N.D. Ill. Aug. 23, 2018) ("CMO 132"); *In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, MDL No. 2545, 2017 WL 4772759 (N.D. Ill. Oct. 23, 2017) ("CMO 76"); *In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, MDL No. 2545, 2017 WL 1836443 (N.D. Ill. May 8, 2017) ("CMO 48"); *In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, MDL No. 2545, 2017 WL 1836435 (N.D. Ill. May 8, 2017) ("CMO 47"); *In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, MDL No. 2545, 2017 WL 1833173 (N.D. Ill. May 8, 2017) ("CMO 46"). The Court assumes familiarity with those orders but discusses them as necessary throughout this order. In addition, the Court takes the following factual background from Martin's and Actavis's briefs and exhibits. For summary judgment purposes, where facts are in dispute, the Court recounts them in the light most favorable to Martin, the non-moving party.

A. Hypogonadism

Male hypogonadism is an endocrine disorder characterized by abnormally low

levels of testosterone in the blood. "Classical" hypogonadism falls into two categories: "primary" and "secondary." Primary hypogonadism is the failure of testicles to produce adequate levels of testosterone, and it is caused by medical conditions such as Klinefelter syndrome and physical injuries to the testicles. Secondary hypogonadism results from a disorder of the pituitary gland or the hypothalamus. In adult males, hypogonadism may be accompanied by signs and symptoms including reduced libido, fatigue, infertility, depressed mood, and reduced muscle mass.

It is normal for testosterone levels to decline in men as they age. An age-related decline in testosterone is not "classical" hypogonadism and is generally not considered to be a medical condition that requires treatment. Like other plaintiffs in this proceeding, Martin contends that Actavis (along with other TRT manufacturers) created a fictitious condition called "age-related hypogonadism"—also referred to as "andropause" or "Low T"—and improperly marketed Androderm for the treatment of that supposed condition. Martin maintains that Androderm has never been proven safe or effective for that use. He also argues that Androderm does not provide significant relief for the symptoms of aging and that it increases the risk of cardiovascular injuries such as heart attacks.

B. Regulatory history of Androderm

The Food and Drug Administration (FDA) has approved numerous testosterone products to treat classical hypogonadism. In 1981, it issued a Class Labeling Guideline for androgens, a group of hormones that includes testosterone. *See* Expert Report of Dr. Peggy Pence ("Pence Report"), Ex. 2 to Martin Opp. to Actavis Mot. for Summ. J. Based on Federal Preemption ("Martin Preemption Opp."), ¶ 147. The Class Labeling Guideline was intended to promote consistency in labeling of drugs in the same class.

See id. ¶ 149. Among other things, it defined the FDA-approved uses for androgens. *See id.* ¶ 150.

Androderm is a testosterone transdermal system, meaning a patch that delivers testosterone to the body through the skin. The FDA approved Androderm in September 1995 for the treatment of male hypogonadism. The initial approval was for a 2.5 milligram strength. Between September 1995 and October 2011, the FDA approved supplemental new drug applications for Androderm in several different strengths. The FDA approved a new label in October 2011 to reflect the new strengths, but neither Martin nor Actavis contends that the label change is relevant to this case. In April 2012, the FDA approved a new label to account for the discontinuation of old strengths. Actavis says that between September 1995 and April 2012, the Androderm label followed the Class Labeling Guideline. Martin contends that during that time, the label "was not identical to the class labeling." Martin Resp. to Actavis Local Rule 56.1 Stat. ¶ 39. But he does not identify which portions of the Androderm label were different or explain why the differences are relevant. The Court, therefore, assumes that the differences, if any, are not material to this case.

The April 2012 label was in effect when Martin was prescribed and used Androderm. Actavis points out that the label referenced signs and symptoms of hypogonadism, as follows:

> Signs/symptoms associated with male hypogonadism include erectile dysfunction and decreased sexual desire, fatigue and loss of energy, mood depression, regression of secondary sexual characteristics, and osteoporosis.

See Actavis Mot. for Summ. J. Based on Federal Preemption ("Actavis Preemption Mot.") at 4 (quoting April 2012 Androderm Label, Ex. 9 to Actavis Mot. for Summ. J.

Based on State Law ("Actavis Mot. for Summ. J."), Full Prescribing Information § 12.1).

The FDA has, at various times, considered requiring TRT manufacturers and sellers, including Actavis, to warn about the risk of cardiovascular injuries that might accompany TRT use. The regulatory history is recounted in detail in the Court's prior orders. *See, e.g.*, CMO 76, 2017 WL 4772759, at *3-4; CMO 47, 2017 WL 18366435, at *1-4. In May 2015, the FDA required Actavis to add the following warning to the Warnings and Precautions section of the Full Prescribing Information in 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 continue to use ANDRODERM.

May 2015 Androderm Label, Ex. 10 to Actavis Mot. for Summ. J., Full Prescribing Information § 5.4; *see* Actavis Preemption Mot. at 4, 9. The FDA also required Actavis to add the following language to the Limitations of Use section of the Full Prescribing Information: "Safety and efficacy of ANDRODERM in men with 'age-related hypogonadism' (also referred to as 'late-onset hypogonadism') have not been established." May 2015 Androderm Label, Full Prescribing Information § 1; *see* Actavis Preemption Mot. at 9. The "Highlights of Prescribing Information" section of the May 2015 Androderm label cross-references the FDA-mandated changes. Martin contends that Actavis should have made similar changes to the Full Prescribing Information

before he was prescribed Androderm in October 2012.

C. Martin's use of Androderm

Martin was a Minnesota resident at all times relevant to this dispute. Before he began taking Androderm in October 2012, he suffered from various health problems. According to medical records from 2006, for example, Martin had hyperlipidemia (a high concentration of fats or lipids in the blood), hypercholesterolemia (high cholesterol), hypertension (high blood pressure), and elevated blood sugar. He took medications for some of these conditions, but the parties dispute the extent to which Martin managed them. Martin concedes that he is a former smoker and a recovering alcoholic. He also acknowledges that some of his close family members have had cardiovascular problems: his father had an angioplasty to clear clogged arteries in his heart; his mother had coronary artery bypass surgery; and one of his brothers had a stroke.

Martin testified during his deposition that beginning in 2011 or 2012, he felt "fatigued all the time." Dep. of Brad Martin ("Martin Dep."), Ex. 3 to Martin Summ. J. Opp., at 135:19-136:8. Martin's medical records indicate that he discussed the fatigue with his primary care physician, Dr. Stephen Firestone, during an annual physical in August 2012. *See* Martin St. Cloud VA Health System Records ("Martin Medical Records"), Ex. 2 to Martin Summ. J. Opp., at 000148-49. On October 15, 2012, Amy Hopkins—the nurse that worked with Dr. Firestone—spoke with Martin about his fatigue and a new medication he had started. *See id.* at 000141. According to Ms. Hopkins's notes in the records, Martin told her, "I don't feel like I should. I still have no energy, no motivation to do things. I don't feel depressed. I just feel fatigued all the time. I was wondering if it could be related to my testosterone level?" *Id.* Ms. Hopkins's notes also

state, in relevant part: "[V]eteran requesting testosterone level check. Plan: Will consult with PCP Firestone on above. Will return call to veteran with further orders or instructions." *Id.* at 000143.

On October 16, 2012, Ms. Hopkins wrote in Martin's medical records, "Consulted PCP Firestone. Chart reviewed. PCP orders: ok to check testosterone level, will supplement if necessary . . . . Veteran notified by phone . . . . Veteran is agreeable to have his testosterone level checked." *Id.* Martin had his testosterone level checked on October 19, 2012. The test showed that his level was in the "low end of [the] normal range." *Id.* at 000122. Ms. Hopkins reported the result to Martin and noted in his chart:

> Veteran reports "I have been doing some research on my own, trying to weigh the benefits versus risk of supplementing testosterone levels. All I really could find is the risk for prostate cancer, really."
>
> Today's lab results reviewed with veteran.
> Testosterone 345 10/19/2012
>
> Veteran inquires if Dr. Firestone would consider trialing supplementation, even though his result is low end of normal range. Verbalizes understanding of risks.
>
> . . . .
>
> Plan: Discussed with PCP Firestone. PCP orders: ok to trial low dose testosterone 2mg patch. Recheck level in 1-2 months.
>
> Veteran notified of above, and is agreeable with plan. Will schedule lab only appt in 1-2 months, to recheck testosterone level and effects.

Id.

Dr. Firestone prescribed Androderm to Martin on October 19, 2012, and Martin filled his first prescription that day. Approximately one month later, on November 15, 2012, Martin visited Ms. Hopkins for a follow-up appointment. According to the records of that visit, Martin "report[ed] compliance with testosterone patches," stated that his

"energy level [was] so much better," reported improvements in his libido, and "denie[d] any side effects or concerns with . . . use/application" of Androderm. *Id.* at 000121. Ms. Hopkins noted, "Therapeutic medication regimen, effective r/t management of testosterone level, libido and fatigue. Plan: Veteran would like to continue with testosterone patches at this time. Offers no further concerns or questions. . . . Will update PCP of above." *Id.* Martin refilled Androderm prescriptions in November 2012, December 2012, February 2013, and April 2013. On May 25, 2013, when Martin was 52 years old, he had a heart attack. It is undisputed that Dr. Firestone is deceased and has not given a deposition in this action.

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 Driveline Sys., LLC v. Arctic Cat, Inc.*, 936 F.3d 576, 579 (7th Cir. 2019). "The court does not assess the credibility of witnesses, choose between competing reasonable inferences, or balance the relative weight of conflicting evidence." *Driveline Sys.*, 936 F.3d at 579 (internal quotation marks omitted).

A. Preemption

Actavis contends that Martin's failure to warn, design defect, and so-called "off-label promotion" claims are preempted by federal law. As discussed below, the Court disagrees.

1. Failure to warn

Federal preemption "occurs when a state law is invalidated because it conflicts with a federal law." *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 390 (7th Cir. 2010). Courts have identified three forms of preemption: (1) express preemption, which occurs when Congress clearly declares its intent to preempt state law; (2) implied preemption, which occurs when the structure and purpose of federal law demonstrates Congress's intent to preempt state law; and (3) conflict preemption, which occurs when there is "an actual conflict between state and federal law such that it is impossible for a person to obey both." *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803, 811 (7th Cir. 2018) (internal quotation marks omitted); *see also Mason*, 596 F.3d at 390. Actavis relies on conflict preemption; it contends that Martin's failure to warn claims are preempted because it would be impossible to comply with both FDA labeling requirements and state-law duties on which the claims are premised.

The Supreme Court has held that state-law failure to warn claims concerning prescription drugs are preempted only where there is "clear evidence" that the FDA would have rejected the proposed label change. *Wyeth v. Levine*, 555 U.S. 555, 571-72 (2009); *see Dolin*, 901 F.3d at 812. The Court explained that typically, "a manufacturer may only change a drug label after the FDA approves a supplemental application." *Wyeth*, 555 U.S. at 568. But the FDA's "changes being effected" (CBE) regulation

makes an exception; it "permits a manufacturer to make certain changes to its label before receiving the agency's approval." *Id.* The CBE regulation, for example, allows a manufacturer to "add or strengthen a contraindication, warning, precaution, or adverse reaction" without waiting for the FDA to approve the change. *Id.* (citing 21 C.F.R. § 314.70(c)(6)(iii)(A)). This type of change must "reflect newly acquired information" and be supported by "reasonable evidence of a causal association with [the] drug." 21 C.F.R. § 314.70(c)(6)(iii)(A); 21 C.F.R. § 201.57(c)(6)(i).

Applying the standard set forth in *Wyeth* to failure to warn claims asserted previously in this MDL, this Court determined that the record lacked "clear evidence" that the FDA would have rejected efforts by AbbVie and Auxilium to add warnings about cardiovascular risk to their TRT drug labels. *See* CMO 76, 2017 WL 4772759, at *10-11; CMO 47, 2017 WL 1836435, at *7-11. Subsequently—and after Actavis's summary judgment and *Daubert* motions were fully briefed—the Supreme Court clarified the meaning of "clear evidence" under *Wyeth*. It held that "clear evidence" means "evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019). The Supreme Court also stated that "the only agency actions that can determine the answer to the pre-emption question . . . are agency actions taken pursuant to the FDA's congressionally delegated authority," such as "notice-and-comment rulemaking setting forth labeling standards" or "formally rejecting a warning label that would have been adequate under state law." *Id.* at 1679. And it held that the

question of preemption "is a legal one for the judge, not a jury," to decide. *Id.*

The regulatory history for Androderm is similar in all material respects to that of AbbVie and Auxilium's TRT drugs. Actavis advances several arguments that it contends support a different result in Martin's case, but none is persuasive.

a. Changes to the Highlights section of a label

First, Actavis argues that it would have been legally impossible to use the CBE process to make the label changes Martin contends were necessary: adding warnings, similar to those the FDA required in May 2015, concerning (1) increased cardiovascular risk and (2) lack of proven safety and efficacy for treating age-related hypogonadism. Actavis's theory is that if it had tried to add these warnings to the Full Prescribing Information, it would have had to add them to the Highlights section as well. But changes to the Highlights section, Actavis points out, cannot be made through the CBE process; rather, they require FDA pre-approval. *See* 21 C.F.R. § 314.70(b)(2)(v)(C) (with several exceptions that are inapplicable here, "any change to the information required by § 201.57(a) of this chapter"—*i.e.* the Highlights section—"require[es] supplement submission and approval prior to distribution of the product made using the change"). In other words, Actavis argues that "if a change to [the] Full Prescribing Information section requires a corresponding change to Highlights, the Full Prescribing Information section also cannot be changed independently." Actavis Preemption Mot. at 8. According to Actavis, this principle applies in Martin's case—even though Martin never alleged that Actavis should have made changes to the Highlights section—because the Highlights section cross-references the FDA-mandated changes to the Full Prescribing Information.

Actavis is correct that the Highlights section of the label and the Full Prescribing Information must contain many of the same categories of information, including "indications and usage," "dosage and administration," and "warnings and precautions." *Compare* 21 C.F.R. § 201.57(a)(6), (7), (10) *with id.* § 201.57(c)(2), (3), (6). But the Highlights section does not contain *all* of the information that appears in the Full Prescribing Information. *See id.* § 201.57(a)(1) (providing that the Highlights section must state, "These highlights do not include all the information needed to use [the drug] safely and effectively. See full prescribing information for [the drug]."); *see also id.* § 201.57(a)(6) (the Highlights section must reference "[*m]ajor* limitations of use" (emphasis added)); *id.* § 201.57(a)(10) (the Highlights section must provide "[a] concise *summary* of the *most clinically significant information* required under" the warnings and precautions section of the Full Prescribing Information, "including information that would affect decisions about whether to prescribe a drug . . . ." (emphasis added)). Actavis's argument thus appears to be that when changes to the Full Prescribing Information are so critical that they must also appear, in some form, in the Highlights section, the FDA prohibits manufacturers from using the CBE process to change the Full Prescribing Information.

Actavis cites no case law that supports its theory, and the Court concludes that it is misguided. Actavis, for example, does not cite any authority providing that the Highlights section and the Full Prescribing Information must be changed simultaneously. The relevant regulation, moreover, appears to contemplate a temporal gap between "major" label changes and corresponding updates to the Highlights section. *See* 21 C.F.R. § 201.57(a)(5) (Highlights section must contain a "list of the

section(s) of the full prescribing information . . . that contain(s) substantive labeling changes that *have been approved by* FDA or *authorized* under § 314.70(c)(6)" and must contain "the date . . . on which the change was incorporated in labeling" (emphasis added)). The Court thus sees no reason why a drug manufacturer could not first make a change to the Full Prescribing Information using the CBE process and later seek FDA approval to make a corresponding change to the Highlights section if the FDA determines that a corresponding change is required.

Actavis's theory is also problematic because it would severely limit the scope of the CBE process. The CBE provision at issue does reiterate that changes to the Highlights section cannot be made without FDA pre-approval. *See* 21 C.F.R. § 314.70(c)(6)(iii) (citing 21 C.F.R. § 314.70(b)(2)(v)(C)). But that same CBE provision expressly permits a manufacturer to change the label "to reflect newly acquired information . . . to accomplish" several purposes—including to "add or strengthen a contraindication, warning, precaution, or adverse reaction" for which there is reasonable evidence of a causal association, "add or strengthen a statement about drug abuse," "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," and "delete false, misleading, or unsupported indications for use or claims for effectiveness." 21 C.F.R. § 314.70(c)(6)(iii)(A)-(D).

These purposes directly implicate consumer safety. One could argue that almost any change made to accomplish these purposes concerns a "major" limitation of use or adds "information that would affect" a prescribing decision—and as noted, such a change must be referenced in the Highlights section. 21 C.F.R. §§ 201.57(a)(6),

(a)(10). Under Actavis's logic, a drug manufacturer would not be able to use the CBE process to make this kind of change. This would mean that the CBE process would be available only for minor label changes that are inconsequential for safety and efficacy. But the plain language of the CBE provision at issue suggests the opposite, not least because it permits a manufacturer to add or strengthen a contraindication or warning. *See* 21 C.F.R. § 314.70(c)(6)(iii)(A). The case law, too, indicates that the CBE process has broader applicability. In *Wyeth*, for example, the Supreme Court determined that "the CBE regulation permitted" a drug manufacturer to warn about "the risk of gangrene from IV-push injection" of the drug "before receiving the FDA's approval." 555 U.S. at 571. That warning was hardly inconsequential.

For these reasons, and absent controlling authority providing otherwise, the Court declines to adopt a statutory interpretation that would prevent drug manufacturers from making significant safety- and efficacy-related label changes using the CBE process. *See Gracia v. Sessions*, 873 F.3d 553, 557 (7th Cir. 2017) ("Canons of statutory construction discourage an interpretation that would render a statute meaningless . . . ."); *Scherr v. Marriott Int'l, Inc.*, 703 F.3d 1069, 1078 (7th Cir. 2013) (declining to "construe regulations in such a way as to render other provisions of the regulations meaningless or superfluous"). The Court concludes that Actavis's arguments concerning the Highlights section of the label do not support a finding of preemption.

b. Newly acquired information

Next, Actavis argues that Martin's claims are preempted because he has not identified "newly acquired information" discovered between April 2012, when the FDA

approved a new Androderm label, and October 2012, when he was first prescribed Androderm. *See* Actavis Preemption Mot. at 10 (quoting 21 C.F.R. § 314.70(c)(6)(iii)), 11 (emphasizing that according to Martin, (1) "information that should have prompted the MACE warning was known in 2007" and (2) the fact that safety and efficacy were not established for use in men with age-related hypogonadism was "known since [Androderm's] initial approval" in 1995).

Actavis's argument is unpersuasive because it assumes that the FDA's approval of the Androderm label in April 2012 constitutes "clear evidence" that it would have rejected an attempt by Actavis to add the relevant warnings between 1995 and October 2012 based on the information available during that time. For reasons the Court has articulated in previous decisions in this MDL, that assumption lacks merit. "[T]he FDA's initial approval of a drug," the Court has explained, "does not provide much, if any, evidence that the FDA would have rejected the warning the plaintiffs say should have been in place." CMO 47, 2017 WL 1836435, at *8 (quoting *Mason*, 596 F.3d at 391). "Nor does the fact that the FDA repeatedly approved labels that did not contain the warning." CMO 47, 2017 WL 1836435, at *8.

The Court also disagrees with Actavis's contention that it could not have used the CBE process to warn that safety and efficacy for treating age-related hypogonadism have not been established. According to Actavis, this information "does not fit within any of the categories for a CBE," such as adding or strengthening a warning or deleting misleading information about indications or efficacy. Actavis Preemption Mot. at 13-14; *see also id.* at 14 (emphasizing that the FDA-mandated language concerning this issue does not appear in the Warnings and Precaution section of the label). Actavis,

however, does not cite any authority providing that language must be in a certain section of the label to qualify as adding or strengthening a warning or precaution. Moreover, the safety and efficacy language at issue can fairly be characterized as an admonition to be cautious in prescribing or taking Androderm for age-related hypogonadism. The language, therefore, fits into at least one CBE category: adding or strengthening a warning or precaution. *See* 21 C.F.R. § 314.70(c)(6)(iii)(A). Like Actavis's arguments concerning the Highlights section, its arguments concerning newly acquired information do not support a finding of preemption.

c. Evidence of a causal association

Actavis also argues that it could not have unilaterally added a warning concerning increased cardiovascular risk because the warning, according to Actavis, is not supported by "reasonable evidence of a causal association with [the] drug." Actavis Preemption Mot. at 12 (quoting 21 C.F.R. § 314.70(c)(6)(iii)(A); 21 C.F.R. § 201.57(c)(6)(i)). Actavis contends that even in May 2015, the FDA "specifically disclaim[ed] 'reasonable evidence of a causal association' between major adverse cardiovascular events and Androderm" by stating in the mandated label change that "epidemiologic studies and randomized controlled trials have been *inconclusive* for determining the risk of major adverse cardiovascular events . . . ." Actavis Preemption Mot. at 12 (emphasis added) (quoting 21 C.F.R. § 201.57(c)(6)(i); May 2015 Androderm Label, Full Prescribing Information § 5.4). This argument, too, lacks merit. The FDA's statement that studies and trials have been "inconclusive for determining risk" does not equate to a conclusion that reasonable evidence of a causal association is lacking. Indeed, in the May 2015 label, the FDA recognized that there *is* evidence of an

association. *See* May 2015 Androderm Label, Full Prescribing Information § 5.4 ("Some studies, but not all, have reported an increased risk of MACE in association with use of testosterone replacement therapy in men."). Actavis's argument is also unconvincing because to add or strengthen a warning using the CBE process, "a causal relationship need not have been definitely established." 21 C.F.R. § 314.70(c)(6)(iii)(A); 21 C.F.R. § 201.57(c)(6)(i).

The Court's prior rulings on preemption in this MDL further undermine Actavis's argument. As one of the rulings provides, "the fact that the FDA was not affirmatively convinced of a causal link between" TRT use and cardiovascular risk "would not necessarily preclude [a drug manufacturer] from adding the warning on its own." CMO 47, 2017 WL 1836435, at *9 (internal quotation marks omitted). This is because on several occasions, "the FDA recognized the possibility of a link with" cardiovascular risk "even though it ultimately concluded that the available literature did not support an association." *Id.* (citing, *inter alia*, a 2010 FDA memorandum). Evidence that the FDA recognized a possible link "indicates a reasonable possibility" that if a TRT manufacturer had tried to add a cardiovascular risk warning, the FDA would have agreed there was "reasonable evidence" of an association. *Id.* By the same token, evidence that the FDA recognized a possible link reasonably indicated that the FDA would not have rejected a TRT manufacturer's request to add a cardiovascular risk warning. *See id.* Applying these principles, the FDA's reference to "inconclusive" risk information in the May 2015 label change does not demonstrate that clear evidence of an association was lacking. Nor does it constitute clear evidence that the FDA would have barred Actavis from adding a cardiovascular risk warning to the label before Martin

was prescribed Androderm. Martin's failure to warn claims, therefore, are not preempted.

The Supreme Court's decision in *Albrecht* only strengthens this conclusion. Namely, Actavis does not offer evidence that it "fully informed the FDA of the justifications for the warning[s]" that Martin contends were necessary. *Albrecht*, 139 S. Ct. at 1672 (emphasis added). It does not even offer evidence that it *partially* informed the FDA of those justifications. Likewise, Actavis does not offer evidence that the FDA "informed [it] that the FDA would not approve a change to [Androderm's] label to include" the warnings at issue, let alone that the FDA did so through an action it took pursuant to "congressionally delegated authority." *Id.* at 1672, 1679. Actavis cannot satisfy the "clear evidence" standard without this sort of proof. *See id.*

2. Design defect

Actavis also contends that Martin's design defect claims are preempted because they "would require a redesign of Androderm"—an action Actavis cannot take unilaterally. Actavis Preemption Mot. at 6; *see, e.g.*, *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 490 (2013) (holding that a design defect claim against a manufacturer of a generic drug was preempted because it was legally impossible for the manufacturer to change the drug's composition or warning label after the FDA had approved it); *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 298 (6th Cir. 2015) ("[Plaintiff's] post-approval design defect claim is clearly preempted by federal law" because "FDA regulations provide that once a drug, whether generic or brand-name, is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product'" without "prior FDA approval" (quoting 21

C.F.R. § 314.70(b)(2)(i))).

Actavis's argument is unavailing because Martin does "not allege that Actavis needed to change the design of Androderm." Martin Preemption Opp. at 1. Rather, Martin argues that Androderm is defectively designed for use in males with age-related hypogonadism, a use that the FDA has not approved. His theory is that the risks of using Androderm to treat age-related hypogonadism outweigh any benefits and that Actavis therefore "needed to stop marketing Androderm" for that use. *Id.* at 2-4. Under Minnesota law, Martin can prevail on a design defect claim without asserting that Androderm should have redesigned the drug. *See Kallio v. Ford Motor Co.*, 407 N.W.2d 92, 96-97 (Minn. 1987) ("Although normally evidence of a safer alternative design will be presented initially by the plaintiff, it is not necessarily required in all cases."). In ruling on the Auxilium defendants' motion for summary judgment in a previous bellwether case, the Court determined that because the plaintiff did "not seek to alter" the drug's design, his claim was "not precluded under *Bartlett* or *Yates*." CMO 76, 2017 WL 4772759, at *11. The same is true here.

3. Off-label promotion

Finally, Actavis contends that if Martin is asserting claims "based on" allegations that it promoted Androderm for off-label purposes, those claims are preempted. Actavis Preemption Mot. at 14. According to Actavis, such claims represent improper attempts to privately enforce Food, Drug, and Cosmetic Act (FDCA) regulations that prohibit drug manufacturers from engaging in off-label promotion. *See id.*; *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (holding that where state-law claims seek only to enforce FDA regulations, they are impliedly preempted). The Court

previously addressed a nearly identical argument in this MDL and ruled that where a plaintiff's "claims are grounded in traditional state law principles of liability such as negligence, failure to warn, strict product liability, and fraud that predate the relevant FDCA requirements," they are "not impliedly preempted by the FDCA or under *Buckman*." CMO 48, 2017 WL 1836443, at *7. The Court reasoned that the claims "do not depend on violations of requirements or prohibitions imposed by the FDCA." *Id.*

Martin's state-law tort claims fall into this category. For example, as the Court will discuss below, a jury reasonably could conclude, independently of the FDCA, that Actavis's conduct violated Minnesota law prohibiting fraudulent misrepresentation. Martin's case is therefore unlike several cases Actavis cites in support of its preemption argument, where courts determined that the claims were based "solely on illegal off-label promotion," *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1178 (C.D. Cal. 2013), or "would require reliance on the requirements of the FDCA." *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1219-20 (W.D. Okla. 2013). The claims that Actavis refers to as Martin's "off-label promotion" claims, which are more accurately characterized as state-law tort claims, are not preempted.

B. Expert testimony

Federal Rule of Evidence 702 and the principles set forth in *Daubert* govern the admissibility of expert testimony. Together, Rule 702 and the *Daubert* principles provide what is essentially a three-step analysis: for an expert's testimony to be admissible, (1) he or she must be qualified; (2) the reasoning or methodology underlying the testimony must be reliable; and (3) the testimony must be relevant, meaning likely to assist the trier of fact to understand the evidence or to determine a fact in issue. *See,*

e.g., *Gopalratnam v. Hewlett-Packard Co.*, 877 F.3d 771, 779 (7th Cir. 2017) (citing *Myers v. Ill. Cent. R.R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010)). *Daubert*'s "gatekeeping" requirement is meant to ensure that an expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). In exercising its gatekeeping role, a court should focus on the expert's "principles and methodology" rather than on his or her conclusions, *Daubert*, 509 U.S. at 595, or the "factual underpinnings" of those conclusions. *Walker v. Soo Line R.R. Co.*, 208 F.3d 581, 586 (7th Cir. 2000). That said, an opinion must be connected to the existing data by more than an expert's "*ipse dixit*." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). An opinion may be inadmissible if "there is simply too great an analytical gap between the data and the opinion proffered." *Id.* An opinion must also "fit the issue to which the expert is testifying and be tied to the facts of the case." *Owens v. Auxilium Pharm., Inc.*, 895 F.3d 971, 973 (7th Cir. 2018) (internal quotation marks omitted).

1. General causation

Actavis has moved to exclude the expert testimony of Drs. Burt Gerstman and Hossein Ardehali concerning general causation—that is, whether Androderm can cause the type of injury Martin alleges he suffered. It has also moved to exclude the expert testimony of Dr. Martin T. Wells. Dr. Wells is a biostatistician who offers opinions about the statistical power of studies concerning the connection between TRT and cardiovascular risk. For bellwether cases in which AbbVie was a defendant, all three experts offered reports at the summary judgment and *Daubert* phase nearly identical to the reports they offer here, and the Court determined that their testimony was

admissible. Specifically, the Court held that under Rule 702 and *Daubert*, Drs. Ardehali, Gerstman, and Wells are permitted to employ a methodology "that relies on the totality of the evidence, provided that the expert[s] consider[] the evidence carefully and explain[] how the weight of the various pieces of evidence led [them] to [their] conclusions." CMO 46, 2017 WL 1833173, at *9. The Court then determined that the experts had reliably applied this methodology because "they [had] carefully addressed the merits, flaws, and implications of both favorable and unfavorable studies." *Id.* at *13; *see also* CMO 133, 2018 WL 4030585, at *3-7. And the Court noted that "[a]t this stage, it is not the Court's role to choose between competing studies." CMO 46, 2017 WL 1833173, at *9; CMO 133, 2018 WL 4030585, at *3. In its prior opinions, the Court thoroughly addressed, in some shape or form, almost every argument that Actavis advances in moving to exclude the experts' general causation testimony here. And as the Court discusses below, to the extent Actavis makes new arguments, they affect the weight of the testimony, not its admissibility.

First, Actavis criticizes the experts' reliance on studies that report composite endpoints. An endpoint is an outcome or event, such as a stroke or heart attack, that is studied in clinical research. A composite endpoint combines "different individual endpoints for consideration as a single outcome." Actavis *Daubert* Mot. at 16. One example of a composite endpoint is "MACE," which stands for "major adverse cardiac events" and includes data concerning both heart attacks and strokes. *Id.* In reaching their conclusions that TRT can cause heart attacks, all three experts relied on studies that report MACE or a similar composite endpoint. Actavis argues that when studying composite endpoints, it is "good [statistical] practice" to also "report the component

endpoint results separately." *Id.* at 17. This is because component endpoints do not always move in the same direction; the result for one endpoint might show a statistically significant association while the result for another might not. All three experts, Actavis emphasizes, agree with this proposition as a general matter. *See id.* at 17-20. Yet the experts admit that in relying on studies that report MACE or a similar endpoint, they did not report component results separately. Actavis argues that by failing to do so, the experts concealed unfavorable evidence—*i.e.*, evidence that TRT use does not increase the risk of heart attack. *See id.* at 16-17 (contending that MACE and similar endpoints "obscure[] the *absence* of an increased risk of" heart attack).

The Court does not agree that the experts' failure to separately report component results renders their testimony unreliable and thus inadmissible. The experts testified during their depositions that it is not always prudent to separately report component results, and they explained why they did not do so here. *See* Dep. of Dr. Ardehali ("Ardehali Dep."), Ex. 11 to Martin *Daubert* Opp., at 194:4-10 (testifying that when a study's primary endpoint is a composite endpoint, "the study is not powered to look at each individual component," such that "if you are making conclusions based on those individual components, that conclusion is wrong"); Dep. of Dr. Gerstman ("Gerstman Dep."), Ex. 9 to Martin *Daubert* Opp., at 131:17-21 (testifying that there are "advantages and disadvantages in composite, and for the purposes of my meta-analysis here, there were [sic] insufficient number of cases in reported clinical trials, in my opinion, to justify individual endpoints"); Dep. of Dr. Wells ("Wells Dep."), Ex. 10 to Martin *Daubert* Opp., at 90:14-16, 98:20-21, 100:25-101:1, 103:12-20 (conceding that it would have been "good to look to do the stroke separately and the MI separately" and stating that he

should "maybe . . . do a supplementary report," but testifying that he "was trying to replicate what the FDA was doing," was "clear about what [he] used," and "think[s] the numbers were fair"). Actavis responds that each expert gave deposition testimony that, in its view, contradicts the testimony just cited. Actavis is free to address this point on cross-examination, but it is not an appropriate ground for excluding the experts' testimony.

Next, Actavis contends that Drs. Gerstman and Wells used unreliable methods in conducting Bayesian meta-analyses and, further, that the analyses do not fit the issues in the case. Actavis first faults the experts for allegedly failing to consider data quality, studies, and biases that allegedly weaken their conclusions concerning causal association. This argument is unpersuasive because the Court has already determined that in offering nearly identical opinions for other plaintiffs in this MDL, Drs. Gerstman and Wells carefully analyzed the available epidemiological data and explained why they drew different conclusions from data on which the TRT defendants rely. *See* CMO 46, 2017 WL 1833173, at *13. Actavis also complains that the experts failed to disclose that if they had conducted their analyses using heart attacks as the endpoint, the analyses would show a greater-than-fifty-percent probability that TRT use reduces the risk of heart attack. But as the deposition testimony makes clear, Actavis's argument concerns heart attack data reported in only one meta-analysis (Elliott, 2017). *See* Gerstman Dep. at 204:10-205:11; Wells Dep. at 181:16-182:22. The argument, therefore, loses sight of the fact that Drs. Gerstman and Wells based their opinions on the totality of the evidence, and contradicts the Court's prior determinations that these experts did not cherry-pick favorable evidence in reaching their conclusions. The

argument also recycles, to some extent, Actavis's criticism of the experts' reliance on composite endpoints, which the Court addressed above.

Actavis also contends that Dr. Gerstman's and Dr. Wells's Bayesian meta-analyses are flawed because both experts applied a method designed for "large sample-size data sets" to "small clinical trials with sparse event counts." Actavis *Daubert* Mot. at 22. Relatedly, according to Actavis, the experts did not test the viability of the method in sparse data sets or "consult[] the literature on the subject." *Id.* The Court is not persuaded that it should exclude Dr. Wells's testimony on this basis. He testified during his deposition that to determine whether this particular Bayesian method was appropriately applied, one must look at the "distribution of the log odds ratio," not the size of the data set. Wells Dep. at 189:25-192:16. According to Dr. Wells, the distribution in his data, represented in a histogram, "didn't look too bad." *Id.* at 190:16-17. Actavis responds that it has not been able to find Dr. Wells's histogram. Even if that is true, it affects only the weight of Dr. Wells's testimony; it is not an appropriate basis for exclusion. Separately, the Court is not persuaded that Dr. Gerstman's testimony is inadmissible because as far as the Court can tell, Dr. Gerstman never conceded that the data sets underlying his Bayesian meta-analysis were too small. Moreover, as Martin points out, Dr. Gerstman applied Bayesian meta-analysis to only some of the evidence he considered for this case. In offering his opinion on general causation, Dr. Gerstman also assessed an array of other evidence, including randomized controlled clinical trials, 18 observational studies, and principles of biochemistry and clinical pathology. Actavis can cross-examine Dr. Gerstman about purported flaws in his Bayesian methodology, but the Court denies the motion to

exclude it.

The following are Actavis's remaining criticisms of the experts' general causation testimony. Actavis contends that Drs. Gerstman and Ardehali improperly rely on evidence concerning estrogen to draw inferences about TRT. In addition, Actavis challenges Dr. Ardehali's and Dr. Gerstman's testimony that TRT can cause heart attacks by increasing hematocrit, platelet activity, and coronary artery plaque volume. Actavis also faults Drs. Ardehali and Gerstman for considering animal and *in vitro* studies in reaching their conclusions. Next, Actavis maintains that two observational studies on which the experts rely—Vigen (2013) and Finkle (2014)—are methodologically flawed and points out that the FDA concluded these studies had limitations. Finally, Actavis argues that the expert testimony concerning general causation does not fit the facts of Martin's case because Martin was 52 years old when he had the heart attack, yet the experts relied on studies concerning "older men." Actavis *Daubert* Mot. at 36. The Court has addressed the same arguments in prior orders in this MDL and has explained at length why they do not support exclusion of the testimony of Drs. Ardehali, Gerstman, and Wells. *See* CMO 133, 2018 WL 4030585, at *1-7; CMO 46, 2017 WL 1833173, at *9-14.

Actavis has not provided any evidence or argument that justifies different conclusions here. The argument that most fairly can be characterized as new concerns the Finkle study, which "identified and measured confounding variables"—meaning risk factors other than TRT use—"15 to 21 months before the non-fatal MIs ascertained in the study dataset." Actavis *Daubert* Reply at 7. Actavis points out that Dr. Ardehali relied on the Finkle study yet acknowledged that "risk factors can change substantially

within a year." *Id.* According to Actavis, neither AbbVie nor Auxilium raised this issue with the Court. Even if that is true, and even if Actavis has raised other "new" issues of a similar nature, this does not render the expert testimony inadmissible. This is because, as the Court has repeatedly ruled, Drs. Ardehali, Gerstman, and Wells did not rely solely on one study or one type of evidence in concluding that TRT use is associated with an increased cardiovascular risk. Instead, they considered the totality of the evidence; addressed limitations in the evidence they credited; and explained why the allegedly contrary evidence does not undermine their conclusions. It is for the jurors, not this Court, to weigh the "merits and demerits" of competing clinical studies and determine which studies they find more convincing. CMO 46, 2017 WL 1833173, at *11 (internal quotation marks omitted). The Court denies Actavis's motion to exclude the general causation testimony of Drs. Ardehali, Gerstman, and Wells.

2. Specific causation

Actavis has also moved to exclude the testimony of Dr. Ardehali concerning specific causation—that is, whether Androderm was a substantial factor in causing Martin's heart attack. Under Minnesota law, a "negligent act is a direct, or proximate, cause of harm if the act was a substantial factor in the harm's occurrence." *George v. Estate of Baker*, 724 N.W.2d 1, 10 (Minn. 2006); *see also Schanhaar v. EF Techs., Inc.*, No. 08-5382 ADM/LIB, 2010 WL 4056045, at *3 (D. Minn. Oct. 14, 2010) (applying substantial factor test to strict liability manufacturing defect claim). An act need not be the sole cause of an injury to be a substantial factor. *See Osborne v. Twin Town Bowl, Inc.*, 749 N.W.2d 367, 379 (Minn. 2008) (to satisfy proximate causation requirement, an act "need not be the sole proximate cause"); *McDermott v. Minneapolis, N. & S. Ry.*

Co., 283 N.W. 116, 117-18 (Minn. 1938) (similar). "But-for causation," however, is "necessary for substantial factor causation because if the harm would have occurred even without the negligent act, the act could not have been a substantial factor in bringing about the harm." *George*, 724 N.W.2d at 11. Dr. Ardehali opined "to a reasonable degree of medical certainty" that "but for" Martin's use of Androderm, "he would not have experienced" the heart attack. April 26, 2018 Supplemental Specific Causation Report ("Ardehali Supp. Specific Causation Report"), Ex. 4 to Martin *Daubert* Opp., at 15. He also opined that Androderm "was a substantial factor in causing" Martin's heart attack "because of its effects on coagulation under circumstances of a systemic chronic inflammatory disease." *Id.* at 14.

Like other experts who have offered specific causation opinions in this MDL, Dr. Ardehali reached his conclusion by conducting a differential etiology. *See* CMO 46, 2017 WL 1833173, at *5 (in a differential etiology, an expert "rules in all the potential causes of a patient's ailment and then by systematically ruling out causes that would not apply to the patient . . . arrives at what is the likely cause of the ailment" (quoting *Myers*, 629 F.3d at 644)). In asking the Court to exclude Dr. Ardehali's specific causation testimony, Actavis argues, first, that Dr. Ardehali lacked foundation to "rule in" Androderm as a cause of Martin's heart attack. But because the Court has determined that Martin's expert testimony concerning general causation is admissible, this argument falls flat. *See, e.g.*, CMO 132, 2018 WL 4030586, at *2 ("The Court has repeatedly held in this litigation that Dr. Ardehali's general causation opinion meets the *Daubert* standard and that he can rely on it to 'rule in' AndroGel.").

Next, Actavis argues that Dr. Ardehali did not reliably conduct a differential

etiology because he did not explain why Martin's pre-existing risk factors were not the sole cause of the heart attack. A review of Dr. Ardehali's specific causation report reveals the opposite. Dr. Ardehali considered Martin's pre-existing risk factors, including hypertension, hyperlipidemia, substance use, a body mass index reflecting that Martin is overweight, and a family history of cardiovascular problems. Dr. Ardehali explained that in his medical opinion, Martin's pre-existing risk factors made the dangerous effects of Androderm worse. *See* Ardehali Supp. Specific Causation Report at 14 ("[T]he adverse effects of testosterone therapy are significantly higher in Mr. Martin because of his preexisting comorbid conditions . . . . These risk factors increase the atherosclerotic burden and associated chronic inflammatory state on which testosterone acts to cause an acute coronary artery event."). Although the jury is free to disagree, this analysis provides a basis for Martin's contention that his risk factors were not the sole cause of his heart attack.

Other portions of Dr. Ardehali's opinion strengthen, but are not necessary to, this conclusion. Dr. Ardehali, for example, noted that in 2007, long before the heart attack and long before Martin began using Androderm, Martin was given a stress test "because he ha[d] some risk factors for coronary artery disease." *Id.* at 3. The test showed that Martin was "completely asymptomatic." *Id.* Additionally, Dr. Ardehali calculated Martin's Framingham coronary heart disease risk score at the time of his heart attack. *See id.* at 14. A Framingham risk score calculation accounts for pre-existing risk factors but not TRT use. *See id.* Dr. Ardehali interpreted Martin's score, 7.3 percent, as indicating that at the time of his heart attack, setting aside TRT use, Martin "was considered low risk for coronary heart disease over ten years." Martin

Daubert Opp. at 30. Actavis moves to strike Dr. Ardehali's testimony concerning the Framingham risk score because it appears only in his supplemental specific causation report, which he served after his deposition. But Actavis raised this argument for the first time on reply, so it is forfeited. *See* Actavis *Daubert* Reply at 9 n.2; *Campos v. Cook Cnty.*, 932 F.3d 972, 976 n.2 (7th Cir. 2019) ("Parties waive arguments which they develop for the first time in a reply brief."). Moreover, Actavis acknowledges that Dr. Ardehali mentioned the Framingham risk score during his deposition. Thus despite Actavis's protestations, it could have questioned Dr. Ardehali about the score at that time. Any late disclosure was harmless.

Finally, Actavis contends that Dr. Ardehali did not reliably conduct a differential etiology because despite describing in his general causation testimony various biological mechanisms through which TRTs can allegedly cause heart attacks, he failed to offer evidence that any such mechanisms were present in Martin. This argument is unpersuasive because Dr. Ardehali lacked control over this issue; he testified during his deposition that at the time of Martin's heart attack, no one measured the biomarkers for most of the mechanisms. *See* Ardehali Dep. at 272:19-274:24. A jury can consider the absence of such evidence in determining how much weight to assign to Dr. Ardehali's specific causation testimony, but the absence of evidence itself does not justify excluding the testimony. Relatedly, the Court acknowledges that there is evidence in Martin's medical records concerning one biological mechanism: hematocrit, which when elevated can lead to a higher incidence of clotting. The records show that Martin's hematocrit was not elevated when he had the heart attack. *See* Actavis *Daubert* Mot. at 40; Ardehali Dep. at 273:17-274:3. This evidence does not show that

Dr. Ardehali's specific causation testimony is unreliable, however, because according to Dr. Ardehali, TRT can increase the risk of clotting in other ways. *See, e.g.*, Ardehali General Causation Report, Ex. 3 to Martin *Daubert* Opp., § IX.5 (opining that TRT can increase estradiol and thromboxane A2 receptors, which in turn can increase the risk of clotting); CMO 46, 2017 WL 1833173, at *2 (discussing same). Dr. Ardehali stated that Martin had a "clot in his coronary vessel" at the time of his heart attack and opined that Androderm had "effects on coagulation under circumstances of [Martin's] systemic chronic inflammatory disease." Ardehali Supp. Specific Causation Report at 6, 14. Dr. Ardehali's general causation testimony, therefore, relates logically and directly to his specific causation testimony in Martin's case. The specific causation testimony, therefore, meets the reliability threshold.

For foregoing reasons, the Court concludes that Dr. Ardehali's specific causation testimony satisfies the standards of *Daubert*, Rule 702, and Minnesota law on causation. The Court, therefore, denies Actavis's motion to exclude it.

3. Actavis's financial condition

Actavis has moved to exclude the testimony of Robert Johnson concerning Actavis's financial condition. Because the parties have stipulated to Actavis's net worth, the Court terminates Actavis's motion as moot.

C. Actavis's motion for summary judgment on state law claims

Actavis has moved for summary judgment on all claims, arguing that Martin does not have sufficient evidence to support any of them. To start, Actavis argues that if the Court excludes Martin's expert testimony concerning general and specific causation, none of his claims can survive summary judgment. Because the Court has determined

that the expert testimony is admissible, this argument fails. The Court, therefore, addresses Actavis's remaining arguments.

1. Failure to warn

Martin alleges that Actavis failed to warn Androderm users about the increased risk of cardiovascular injury and that safety and efficacy of Androderm for use in men with age-related hypogonadism have not been established. It is unclear whether Martin is asserting a strict liability failure to warn claim, a negligent failure to warn claim, or both. *See* Compl., Count Two (appearing to assert only a strict liability failure to warn claim); Martin Summ. J. Opp. at 4 (referencing a negligent failure to warn claim). The distinction does not matter because under Minnesota law, "failure to warn claims based on negligence and on strict liability merge into a single cause of action." *Green Plains Otter Tail, LLC v. Pro-Envtl., Inc.*, 349 F. Supp. 3d 768, 773 (D. Minn. 2018) (citing *Bilotta v. Kelley Co.*, 346 N.W.2d 616, 623 (Minn. 1984)). A plaintiff asserting a failure to warn claim must show that (1) defendant "had a duty to warn"; (2) defendant "breached that duty by providing an inadequate warning (or no warning at all)"; and (3) defendant's "inadequate (or nonexistent) warning caused [plaintiff's] damages." *Green Plains*, 349 F. Supp. 3d at 778 (internal quotation marks omitted); *see also In re Levaquin Prods. Liab. Litig.*, 700 F.3d 1161, 1166 (8th Cir. 2012) (similar).

a. Duty to warn

Actavis first attacks Martin's evidence concerning the alleged duty to warn. For failure to warn claims, "a manufacturer's duty 'arises from the probability or foreseeability of injury to the plaintiff.'" *Montemayor v. Sebright Prods., Inc.*, 898 N.W.2d 623, 629 (Minn. 2017) (quoting *Domagala v. Rolland*, 805 N.W.2d 14, 26 (Minn.

2011)); *see Kruszka v. Novartis Pharm. Corp.*, 19 F. Supp. 3d 875, 894 (D. Minn. 2014), *as amended* (May 19, 2014) ("[G]enerally, a pharmaceuticals manufacturer has a duty to warn of known dangers associated with their product (or dangers of which they should have known)."). Under Minnesota law, "duty is generally a legal question for the court to decide." *Montemayor*, 898 N.W.2d at 629 (citing *Germann v. F.L. Smithe Mach. Co.*, 395 N.W.2d 922, 924 (Minn. 1986)). But "it is well established that foreseeability is a question for the jury 'if there is a specific factual dispute concerning a manufacturer's awareness of a risk.'" *Montemayor*, 898 N.W.2d at 629 (quoting *Huber v. Niagara Mach. & Tool Works*, 430 N.W.2d 465, 467 (Minn. 1988)); *see also Doe 169 v. Brandon*, 845 N.W.2d 174, 178 n.2 (Minn. 2014) ("[I]n close cases, foreseeability as it relates to duty is a jury question.").

To determine whether a risk is foreseeable, courts "look to the defendant's conduct and ask whether it was objectively reasonable to expect the specific danger causing the plaintiff's injury." *Montemayor*, 898 N.W.2d at 629 (quoting *Domagala*, 805 N.W.2d at 27). "If the connection between the danger and the alleged negligent act 'is too remote to impose liability as a matter of public policy, the courts then hold there is no duty.'" *Montemayor*, 898 N.W.2d at 629 (quoting *Domagala*, 805 N.W.2d at 27). The Minnesota Supreme Court has "held as a matter of law that an injury is not reasonably foreseeable when the 'undisputed facts, considered together,' established that the connection between the defendant's conduct and the plaintiff's injury was 'too attenuated.'" *Montemayor*, 898 N.W.2d at 629 (quoting *Doe 169*, 845 N.W.2d at 179). When "'reasonable persons might differ as to whether the evidence' establishes that the injury was foreseeable," however, Minnesota courts "have consistently submitted the

issue to the jury." *Montemayor*, 898 N.W.2d at 630 (quoting *Ill. Farmers Ins. Co. v. Tapemark Co.*, 273 N.W.2d 630, 636-37 (Minn. 1978)). Here, reasonable jurors could disagree concerning whether the increased risk of cardiovascular injury allegedly associated with Androderm use was foreseeable.

Martin's regulatory expert, Dr. Peggy Pence, testified during her deposition that Actavis should have added a cardiovascular risk warning to the Androderm label by 2007. *See* Dep. of Dr. Peggy Pence ("Pence Dep."), Ex. 11 to Actavis Mot. for Summ. J., at 189:20-193:10. She also testified that the warning should have been "very similar" to the one that now appears in the Warnings and Precautions section of the label, which the FDA required Actavis to add in May 2015. *See id.* at 190:13-15. Actavis maintains that because the May 2015 warning states that evidence concerning cardiovascular risk is "inconclusive," *see* May 2015 Androderm Label, Full Prescribing Information § 5.4, there is no "known danger" of cardiovascular risk associated with Androderm. Actavis Mot. for Summ. J. at 8-9. The absence of a "known danger," Actavis maintains, is further supported by the number of "MACE reports" it received between 2000 and October 2012: only two, by Actavis's count. *Id.* at 9 n.8. According to Actavis, it has no duty to warn of an unknown danger, and Martin's failure to warn claim must therefore be dismissed.

From the Court's perspective, the question whether the danger is "unknown" is nowhere near as clear as Actavis contends. Rather, as noted above, the foreseeability of the danger is a disputed factual issue that the jury must decide. The Court has already noted, for example, that despite stating that evidence concerning cardiovascular risk is "inconclusive," the May 2015 warning states that "[s]ome studies . . . *have*

reported an increased risk . . . ." May 2015 Androderm Label, Full Prescribing Information § 5.4 (emphasis added). It also states that "[p]atients should be informed of this possible risk . . . ." *Id.* A jury considering this language reasonably could determine that the risk of suffering a heart attack as a result of taking Androderm is not only foreseeable, but known. Moreover, Martin's experts, such as Drs. Ardehali, Gerstman, Pence, and Wells, offer testimony that a causal association between Androderm use and cardiovascular risk was well-supported by the regulatory and scientific evidence as early as 2007. And Actavis's contention that it received only two MACE reports in twelve years is a disputed fact. *See* Martin Resp. to Actavis Local Rule 56.1 Stat. ¶ 48. This evidence, too, could permit a jury to reject Actavis's argument that the risk of cardiovascular injury was "unknown." Likewise, it could permit a jury to conclude that the risk was known or foreseeable before Martin was prescribed Androderm. Accordingly, the Court cannot properly determine as a matter of law that Actavis lacked a duty to warn and will instead submit the issue of foreseeability to the jury. *See, e.g.*, *Montemayor*, 898 N.W.2d at 633.

Actavis also argues that because Minnesota law does not recognize failure to test as an independent cause of action, *see Huggins v. Stryker Corp.*, 932 F. Supp. 2d 972, 987 & n.15 (D. Minn. 2013), it had no duty to warn that Androderm's safety and efficacy in men with age-related hypogonadism have not been established. *See* Actavis Mot. for Summ. J. at 9. Actavis contends that if Martin is asserting an independent failure to warn claim based on this safety and efficacy language, the Court should dismiss that claim. Martin does not respond to this argument or verify whether he is asserting an independent failure to warn claim of this nature. Accordingly, the Court

understands Martin to be asserting only a failure to warn claim concerning increased cardiovascular risk—and for the reasons discussed in this opinion, the Court denies Actavis's motion for summary judgment on that claim. Furthermore, the claim can be supported with evidence that safety and efficacy of use in men with age-related hypogonadism have allegedly not been established.

b. Causation

Next, Actavis argues that Martin cannot establish that the alleged failure to warn of cardiovascular risk caused his injury. Minnesota courts apply the learned intermediary doctrine to failure to warn claims, which "provides that a drug 'manufacturer has no duty to warn the lay public regarding prescription drugs,' but rather must warn the prescribing physician." *In re Levaquin*, 700 F.3d at 1166 n.5 (quoting *Mulder v. Parke Davis & Co.*, 181 N.W.2d 882, 885 & n.1 (Minn. 1970)). Thus to prove causation, Martin must show that (1) Actavis failed to adequately warn his prescribing physician, Dr. Firestone, about cardiovascular risk associated with Androderm, and (2) Dr. Firestone would not have prescribed Androderm for Martin if Actavis had provided an adequate warning. *See, e.g.*, *In re Levaquin*, 700 F.3d at 1168-69.

Actavis contends that there is "no evidence" that Dr. Firestone read or relied on the Androderm label in prescribing the drug to Martin. Actavis Mot. for Summ. J. at 9-10. A reasonable jury, however, could conclude otherwise based on Martin's medical records. As recounted above, the records show that Martin communicated with Ms. Hopkins, a nurse that worked with Dr. Firestone, about TRT use. Specifically, the records show that in October 2012, Martin asked Ms. Hopkins whether his fatigue—a condition he had discussed with Dr. Firestone just months before—could be related to

his testosterone level. Ms. Hopkins noted that she would "consult" with Dr. Firestone, and Dr. Firestone subsequently authorized a test of Martin's testosterone level to determine if TRT was necessary. Martin Medical Records at 000143. In addition, Martin's medical records show that when Ms. Hopkins reported the test results to Martin, he mentioned research he had done concerning risks and benefits of TRT use. According to the medical records, Ms. Hopkins relayed this conversation to Dr. Firestone, who decided that it was "ok to trial low dose testosterone 2mg patch." *Id.* at 000122. Finally, the medical records show that approximately one month after Martin began taking Androderm, he told Ms. Hopkins that he was experiencing benefits without side effects. Ms. Hopkins wrote in Martin's chart that she would update Dr. Firestone. In the ensuing months, Martin refilled several Androderm prescriptions.

Although the medical records indicate that Martin did not communicate directly with Dr. Firestone about TRT use, they permit a reasonable inference that Dr. Firestone was actively involved in Martin's treatment with Androderm—particularly because Ms. Hopkins repeatedly noted that she kept Dr. Firestone, the ultimate decisionmaker, apprised of her conversations with Martin. Accordingly, a jury reasonably could conclude that Ms. Hopkins relayed Martin's concerns about TRT risks to Dr. Firestone and that Dr. Firestone consulted Androderm's label before making his prescribing decision. Likewise, a jury reasonably could conclude that Dr. Firestone allowed Martin to continue taking Androderm only after receiving Ms. Hopkins's report from the November 2012 follow-up visit: that Androderm was improving Martin's energy level and libido without causing negative symptoms.

Actavis also argues that the record contains "no evidence" that Dr. Firestone

would not have prescribed Androderm for Martin if had Actavis provided an adequate warning concerning increased cardiovascular risk. Actavis Mot. for Summ. J. at 10. Again, a reasonable jury could disagree based on the evidence, which permits an inference that Martin would not have wanted to take Androderm if he had known of the undisclosed cardiovascular risk, as well as an inference that Dr. Firestone, knowing Martin's wishes, would not have prescribed the drug. The evidence supporting these inferences includes Martin's medical records, which show that he researched TRT risks and benefits before Androderm was prescribed to him, and his deposition testimony that when he first receives a new drug, he "absolutely" reads the package insert (*i.e.*, the drug label). Martin Medical Records at 000122; Martin Dep. at 32:25-33:10. The inferences are also supported by a declaration that Martin submitted to supplement his deposition testimony. The declaration states, in relevant part, that (1) Dr. Firestone was Martin's primary care physician from approximately 2007 to 2014; (2) Dr. Firestone normally discussed the risks and benefits of any treatment with Martin; and (3) "[w]hen Dr. Firestone made a treatment recommendation and explained the risks and benefits to [Martin], he respected [Martin's] decision to use or not use a prescription medication." *See* Martin December 7, 2017 Declaration ("Martin Decl."), Ex. 7 to Martin Summ. J. Opp., ¶¶ 3-5. In addition, the declaration states that if Martin "had known, before first taking it, that Androderm is associated with causing myocardial infarctions, strokes, and death, [he] would not have used [it]." *Id.* ¶ 13.

Actavis moves to strike Martin's declaration under 28 U.S.C. § 1746 because, according to Actavis, it is undated. *See* 28 U.S.C. § 1746 (providing that a matter may be "supported, evidenced, established, or proved" by an unsworn declaration so long as

it is, among other things, signed and dated). The Court denies the motion to strike because Martin attached his declaration to his deposition errata, which is both signed and dated. *See* Martin Decl. at 5. Next, Actavis argues that if Martin is offering the declaration as evidence of Dr. Firestone's habit under Federal Rule of Evidence 406, it is inadmissible because Martin has not satisfied the rule's threshold requirements. Specifically, Actavis cites *Thompson v. Boggs*, 33 F.3d 847 (7th Cir. 1994), for the proposition that under Federal Rule of Evidence 406, habit can be established only through evidence of a specific practice that is so "frequent[]" and "uniform" that a fact-finder would conclude the practice is "semi-automatic in nature." *Id.* at 854 (internal quotation marks omitted).

The Court concludes that the statements in Martin's declaration concerning Dr. Firestone's practices are admissible under Rule 406. According to Martin, Dr. Firestone was his primary care provider for nearly seven years. Other evidence in the record shows that Martin suffered from numerous health problems for which he took medication. And as noted, Martin testified during his deposition that he generally reads the drug label for new medications. This evidence is sufficient to establish that Martin spoke with Dr. Firestone "frequently" about medications, including their risks and benefits, and that Dr. Firestone habitually deferred to Martin's decision whether to take a medication. *See Boggs*, 33 F.3d at 854. The fact that Martin may not have spoken directly to Dr. Firestone about Androderm's risks and benefits or the decision to take it does not alter the Court's conclusion. *See* Actavis Summ. J. Reply at 6. This is because, as already noted, the record permits an inference that Martin was communicating with Dr. Firestone through Ms. Hopkins.

2. Design defect

As with Martin's failure to warn claim, it is unclear whether Martin is asserting a design defect claim based on strict liability, negligence, or both. *See* Compl., Count One (appearing to assert only a strict liability design defect claim); Martin Summ. J. Opp. at 3-4 (arguing that he can prevail under both theories). Again, the distinction does not matter because "[w]here design defect cases are involved, Minnesota merges the theories of strict liability and negligence." *Green Plains*, 349 F. Supp. 3d at 773 (quoting *Piotrowski v. Southworth Prods. Corp.*, 15 F.3d 748, 751 (8th Cir. 1994)); *see also Bilotta*, 346 N.W.2d at 622-23. To prevail on a design defect claim under Minnesota law, a plaintiff must establish that the defendant's product "was in a defective condition unreasonably dangerous for its intended use." *Bilotta*, 346 N.W.2d at 623 n.3. Minnesota courts apply a "reasonable care balancing test" to determine whether a product is unreasonably dangerous. *Id.* at 622. The Minnesota Supreme Court has defined the test as follows:

> [A] manufacturer is obligated to exercise that degree of care in his plan or design so as to avoid any unreasonable risk of harm to anyone who is likely to be exposed to the danger when the product is used in the manner for which the product was intended, as well as an unintended yet reasonably foreseeable use.
>
> What constitutes "reasonable care" will, of course, vary with the surrounding circumstances and will involve "a balancing of the likelihood of harm, and the gravity of harm if it happens, against the burden of the precaution which would be effective to avoid the harm."

Id. at 621 (quoting *Holm v. Sponco*, 324 N.W.2d 207, 212 (Minn. 1982)). Factors a jury may consider in assessing a manufacturer's conduct include:

> (1) the usefulness and desirability of the product; (2) the availability of other and safer products to meet the same need; (3) the likelihood of injury and its probable seriousness; (4) the obviousness of the danger; (5)

> common knowledge and normal public expectation of the danger; (6) the avoidability of injury by care in use of the product (including the effects of instruction or warning); and (7) the ability to eliminate the danger without seriously impairing the usefulness of the product or making it unduly expensive.

Kociemba v. G.D. Searle & Co., 695 F. Supp. 432, 434 (D. Minn. 1988) (quoting *Krein v. Raudabough,* 406 N.W.2d 315, 318 (Minn. Ct. App. 1987)).

Evidence of a safer alternative design is not a required element of a design defect claim. *See Kallio*, 407 N.W.2d 92 at 96-97 & n.8; *Young v. Pollock Eng'g Grp., Inc.*, 428 F.3d 786, 789 (8th Cir. 2005); *Kruszka*, 19 F. Supp. 3d at 897. Minnesota courts, however, have stated that plaintiffs will rarely prevail without it. *See Kallio*, 407 N.W.2d at 96-97 & nn.6, 8 ("[A]s a practical matter, successful plaintiffs, almost without fail, introduce evidence of an alternative safer design," but "[c]onceivably, rare cases may exist where the product may be judged unreasonably dangerous because it should be removed from the market rather than be redesigned"); *Young*, 428 F.3d at 789 (same).

Actavis acknowledges that Martin does not need evidence of a safer alternative design to prevail on his design defect claim. But Actavis contends that under *Kallio*, Martin's only alternative is to argue that Androderm should be removed from the market entirely—and Martin does not make that argument. According to Actavis, therefore, the Court should grant summary judgment in its favor on Martin's design defect claim.

The Court is not persuaded that the "rare case[]" language in *Kallio* defines the only universe of design defect claims that are viable without proof of a feasible, safer alternative design. *Kallio*, 407 N.W.2d at 97 n.8. Indeed, the Minnesota Supreme Court has stated that "[w]hat constitutes 'reasonable care'" depends on the "surrounding

circumstances." *Bilotta*, 346 N.W.2d at 621 (quoting *Holm*, 324 N.W.2d at 212). "[T]he manufacturer's conduct in balancing its product's risk against its utility is the key element in determining liability," and a fact-finder can consider the seven factors referenced above in assessing this issue. *Kociemba*, 695 F. Supp. at 434 (citing *Bilotta*, 346 N.W.2d at 622).

Martin offers evidence and argument that is relevant to several of the factors outlined in *Kociemba*, such as Androderm's degree of utility and the seriousness of the harm it can cause. Indeed, as previously noted, Martin argues that Androderm is "defectively designed for use in men with age-related declines in their testosterone" because "there is no evidence that Androderm is effective" for that use. Martin Preemption Opp. at 2; *see* Martin Summ. J. Opp. at 3 (incorporating same by reference). He offers evidence in support of this argument, including the expert testimony of Dr. Ardehali. *See, e.g.*, Ardehali General Causation Report § VII.37 (opining that "the state of knowledge regarding either the safety or efficacy of testosterone product use in middle-aged and older men with declines in testosterone levels related to aging or the comorbidities of aging" was "deficient in 2012"). Martin also contends that Androderm can cause grave harm in men with age-related hypogonadism. He offers evidence and expert testimony in support of that proposition. *See, e.g.*, *id.* § II.B.3.t (opining based on the "totality of the evidence," including medical and scientific literature, that administering "exogenous testosterone to middle-aged and older men who are diagnosed with testosterone declines unrelated to classical hypogonadism is harmful" because it "increases the risk of coronary artery and cerebrovascular occlusive events (heart attack and stroke)").

Martin also offers evidence concerning the "likelihood" that Androderm can cause heart attacks and the "obviousness" of that risk. *Kociemba*, 695 F. Supp. at 434. As the Court has already discussed, a jury reasonably could credit the testimony of Martin's experts that Actavis knew or should have known of Androderm's cardiovascular risk by 2007. Relatedly, Dr. Pence has opined that notwithstanding this known or foreseeable risk, Actavis marketed Androderm for men with age-related hypogonadism. *See, e.g.*, Pence Report ¶¶ 405-44. Actavis denies that it did so, but reasonable minds could differ based on evidence including Dr. Pence's report, which Actavis has not moved to exclude, and internal Actavis documents concerning Androderm marketing strategy. *See, e.g.*, June 15, 2004 New Hire Presentation, Ex. 16 to Martin Summ. J. Opp., at 00294390 ("Androderm Strategy: Raise awareness of T-deficiency symptoms to drive prescribing."); *id.* at 00294393 ("Core selling message: Doctor, Androderm is an optimal therapeutic solution for your patients with testosterone deficiency. Androderm may help restore their T levels to normal and improve their sexual function, mood, and energy."). Finally, Martin has offered evidence concerning the "avoidability of injury," such as through "instruction or warning." *Kociemba*, 695 F. Supp. at 434. Dr. Pence, for example, opined that Actavis could and should have added a cardiovascular risk warning to Androderm's label before Martin was prescribed the drug, *see* Pence Report ¶¶ 445-50, and a jury reasonably could credit that opinion.

Taken together, the evidence allows an inference that Actavis failed to exercise "reasonable care" in balancing the likelihood and gravity of harm posed by Androderm "against the burden of" taking precautions that could prevent it. *Bilotta*, 346 N.W.2d at 621. A jury, therefore, reasonably could find in Martin's favor on his design defect claim,

and the Court denies Actavis's motion for summary judgment.

3. Negligence

Actavis contends that if Martin is asserting a negligence claim based only on an alleged failure to test Androderm's safety and efficacy, the Court should dismiss it because Minnesota law does not recognize negligent failure to test as an independent cause of action. *See* Actavis Mot. for Summ. J. at 11 (citing *Huggins*, 932 F. Supp. 2d at 987 n.15). Martin confirms that he is not asserting an independent failure to test claim, so this argument is moot. Next, Actavis argues that any negligence claims that "include allegations of 'negligent marketing,' 'off-label marketing,' and 'misbranding'" are preempted by federal law. Actavis Mot. for Summ. J. at 11. The Court has already rejected this argument.

Finally, in what appears to be an argument that Martin cannot prevail on a negligent marketing claim, Actavis maintains that there is "no evidence Dr. Firestone saw or relied on Androderm marketing or promotion materials." *Id.* Actavis also contends that even assuming the learned intermediary doctrine does not apply to a negligent marketing claim, Martin cannot prevail because the record lacks evidence that he saw or relied upon Androderm marketing or promotion materials. *Id.* According to Actavis, Martin testified during his deposition that he "recalled seeing only television ads for a gel testosterone product with a pump and an underarm deodorant-like product." *Id.* at n.11. Androderm is a patch and Actavis states that it "did not do television advertising for Androderm." *Id.* Martin does not dispute these representations of the factual record. His failure to do so, however, does not affect the Court's decision, because the Court understands Martin to be asserting a garden-variety negligence

claim, not a claim for negligent marketing. *See, e.g.*, Martin Summ. J. Opp. at 11 (arguing that the concept of failure to test "is addressed within the Negligence claim"); Compl., Count Three (asserting claim for "Negligence"). A negligence claim is broader than a negligent marketing claim and does not necessarily require proof of reliance on marketing materials. For all of these reasons, the Court denies Actavis's motion for summary judgment on Martin's negligence claim.

4. Express warranty

"An express warranty is created when '[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods . . . becomes part of the basis of the bargain' or '[a]ny description of the goods . . . is made part of the basis of the bargain.'" *In re Levaquin Prods. Liab. Litig.*, 752 F. Supp. 2d 1071, 1080 (D. Minn. 2010) (quoting MINN. STAT. § 336.2-313(1)(a), (b)). "To establish a warranty claim the plaintiff must basically prove: the existence of a warranty, a breach, and a causal link between the breach and the alleged harm." *In re Levaquin*, 752 F. Supp. 2d at 1080 (quoting *Peterson v. Bendix Home Sys., Inc.,* 318 N.W.2d 50, 52-53 (Minn. 1982)).

Actavis contends that the Court should grant summary judgment in its favor on this claim because, according to Actavis, there is no evidence that it made an affirmation of fact or promise to Dr. Firestone. This argument assumes that the learned intermediary doctrine applies to an express warranty claim under Minnesota law, but the cases on which Actavis relies do not clearly support this proposition. *See Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 789 (D. Minn. 2009) (indicating that an express warranty claim may be based on "representations . . . made *either* to [plaintiff] *or* his doctor" (emphasis added)); *Johnson v. Zimmer, Inc.*, No. Civ. 02-1328 JTNFLN, 2004

WL 742038, at *11 (D. Minn. Mar. 31, 2004) (evaluating breach of express warranty claim without reference to the learned intermediary doctrine).

Even assuming the learned intermediary doctrine applies, a jury reasonably could find in Martin's favor on this claim. For reasons already discussed, the evidence permits an inference that Dr. Firestone read and relied upon the Androderm label in prescribing the drug to Martin. At that time, the label stated that signs and symptoms "associated with male hypogonadism include . . . decreased sexual desire" and "fatigue and loss of energy . . . ." April 2012 Androderm Label, Full Prescribing Information § 12.1. Dr. Firestone initially prescribed Androderm because Martin was suffering from fatigue and his testosterone level was on the low end of normal. He allowed Martin to continue taking Androderm after Martin reported improvements in his energy level and libido without negative side effects. Furthermore, it is undisputed that at the time, the label did not include the warnings that the FDA required Actavis to add in 2015. Based on this evidence, a jury reasonably could conclude that the signs and symptoms language in the April 2012 label, combined with the lack of cardiovascular risk information, became part of the "basis of the bargain" in Dr. Firestone's decision to prescribe Androderm to Martin and continue authorizing refills. MINN. STAT. § 336.2-313(1)(a), (b).

A jury reasonably could find in Martin's favor, too, if the learned intermediary doctrine does not apply. As noted, Martin testified that when he receives a new drug, he "absolutely" reads the label. Martin Dep. at 32:25-33:10. Martin's medical records, moreover, reflect that he asked Ms. Hopkins whether his fatigue could be related to his testosterone level and that he researched TRT risks and benefits before Dr. Firestone

prescribed him Androderm. The records also reflect that Martin continued taking Androderm because it was improving his energy level and libido but causing no side effects. This evidence permits an inference that Martin read the information in the label concerning potential symptom relief and risks and that this information became part of the "basis of the bargain" in his decision take Androderm. MINN. STAT. § 336.2-313(1)(a), (b). For these reasons, the Court denies Actavis's motion for summary judgment on Martin's claim for breach of express warranty.

5. Implied warranty

Actavis contends that the Court should grant summary judgment in its favor on Martin's claim for breach of implied warranty of merchantability because under Minnesota law, "strict liability has effectively preempted implied warranty claims where," as here, "personal injury is involved." *Nimeth v. Prest Equip. Co.*, No. C1-93-685, 1993 WL 328767, at *1 (Minn. Ct. App. Aug. 31, 1993); *Westbrock v. Marshalltown Mfg. Co.*, 473 N.W.2d 352, 356 (Minn. Ct. App. 1991). Martin responds that the Court should not grant Actavis's motion because "a party can plead claims in the alternative, including in cases where the alternatives eventually merge or cannot both be granted." Martin Summ. J. Opp. at 12 (citing FED. R. CIV. P. 8(d)). Two cases in which district courts applied Minnesota law indicate that Actavis has the better of these arguments. *See, e.g.*, *Kruszka*, 19 F. Supp. 3d at 896 (dismissing plaintiffs' claims for breach of implied warranty as "subsumed by their strict liability claims"); *In re Levaquin*, 752 F. Supp. 2d at 1079 ("Plaintiffs' claims for breach of the implied warranty of merchantability" were "subsumed by their strict liability claims and warrant[ed] dismissal"). Because Martin has not cited any contrary case law, the Court grants Actavis's motion for summary

judgment on this claim.

6. Negligent misrepresentation and fraudulent misrepresentation

The Court grants Actavis's motion for summary judgment on Martin's negligent misrepresentation claim because Martin states that he will not pursue it. Martin, however, has not dropped his claim for fraudulent misrepresentation.[2] In Minnesota, a plaintiff must establish five elements to prevail on a fraudulent misrepresentation claim, including that (1) "there was a false representation by a party of a past or existing material fact susceptible of knowledge," and (2) "the representation caused the other party to act in reliance thereon." *Hoyt Props., Inc. v. Prod. Res. Grp., L.L.C.*, 736 N.W.2d 313, 318 (Minn. 2007) (internal quotation marks omitted).

The parties dispute whether the learned intermediary doctrine applies to a fraudulent misrepresentation claim. Citing only *Flynn v. American Home Products Corp.*, 627 N.W.2d 342 (Minn. Ct. App. 2001), Actavis maintains that it does. *Flynn* does not support this argument. The plaintiff in *Flynn* alleged that manufacturers of brand-name weight-loss drugs made misrepresentations to the FDA about the drugs' safety and efficacy, including by withholding known adverse event information. *See id.* at 345. The plaintiff's theory was that as a result of these misrepresentations, her doctor prescribed her a generic weight-loss drug without knowing its risks. *See id.* In determining that the district court properly granted summary judgment in favor of the manufacturers on plaintiff's fraudulent misrepresentation claim, the court stated that plaintiff had not "point[ed] to any affirmative misrepresentations made by

[2] In his complaint, Martin asserts a claim for fraud, not fraudulent misrepresentation. *See* Compl., Count Seven. But in the summary judgment briefing, both parties treat this claim as one for fraudulent misrepresentation. The Court, therefore, does the same.

[manufacturers]" that influenced her doctor's prescribing decision. *Id.* at 349-50. This is not the same as a determination that plaintiff needed such evidence to prevail on her claim. Indeed, the court did not even mention the learned intermediary doctrine. *See id.* The court went on to say that plaintiff's claim appeared to be one for "fraudulent misrepresentation based on the concealment of a material fact." *Id.* at 350. The court determined that plaintiff could not prevail on that claim, either, because she had not had any direct communications with the manufacturers. *See id.* (fraud for failure to disclose depends on duty to communicate the information allegedly withheld, and that duty does not extend to third parties). The court's analysis in *Flynn* does not close the door on fraudulent misrepresentation claims based on direct communications between drug manufacturers and patients.

In re Orthopedic Bone Screw Litigation, No. Civ. 3-96-1095RHKJMM, 1999 WL 628688 (D. Minn. Mar. 8, 1999), is no more helpful for Actavis. There, the court determined that the learned intermediary doctrine governed claims for fraudulent marketing and promotion and negligent misrepresentation. *See id.* at *14-15. In doing so, however, the court relied on principles that justify applying the doctrine to failure to warn claims—not to fraud claims. *See id.* Moreover, the case concerned a surgical device, and the court's analysis gives little indication that defendants marketed the device directly to consumers or intended for consumers to read the labeling. *See id.* In those circumstances, it makes more sense to require evidence of misrepresentations made to doctors than in the present situation, where manufacturers marketed both to doctors and consumers and intended for both populations to read the labeling. *See also* Martin Summ. J. Opp. at 12-13 (arguing that this case is distinguishable from *In re*

Orthopedic Bone Screw Litigation because "Actavis marketed directly to consumers").

The Court understands a fraudulent misrepresentation claim based on an affirmative representation to be viable under Minnesota law so long as the five elements set forth in *Hoyt* are satisfied, regardless of whether a doctor or a patient received the alleged misrepresentation. *Hoyt*, 736 N.W.2d at 318. Similarly, the Court understands a fraudulent misrepresentation claim based on concealment to be viable so long as there is a direct communication between the defendant and the plaintiff that is rendered misleading by the concealment. *See L&H Airco, Inc. v. Rapistan Corp.*, 446 N.W.2d 372, 380 (Minn. 1989) ("A duty to disclose facts" for purposes of a fraudulent concealment claim "may exist . . . when disclosure would be necessary to clarify information already disclosed, which would otherwise be misleading."); *Flynn*, 627 N.W.2d at 350 (plaintiff's fraudulent misrepresentation claim could not be based on defendant-manufacturers' communications with third party (the FDA) because "Minnesota common law . . . requires a stronger relationship and a direct communication"). Based on the same evidence that supports Martin's express warranty claim, a jury reasonably could conclude that Actavis is liable for fraudulent misrepresentations made both to Martin and to Dr. Firestone. Accordingly, the Court denies Actavis's motion for summary judgment on this claim.

7. Consumer protection, redhibition, and unjust enrichment

The Court grants Actavis's motion for summary judgment on Martin's unjust enrichment claim, which Martin states he does not intend to pursue. The Court also grants Actavis's motion for summary judgment on Martin's claims for redhibition and violation of the Minnesota False Statement in Advertising Act because Martin does not

respond to Actavis's argument that those claims are not viable. The Court, however, denies Actavis's motion for summary judgment on Martin's claim for violation of the Minnesota Deceptive Trade Practices Act, MINN. STAT. § 325D.44(13). Actavis argues that injunctive relief is the only remedy available under the MDTPA and that the Court should dismiss Martin's claim because he requests only damages, costs, and attorneys' fees. *See* Actavis Mot. for Summ. J. at 13-14 (citing *Dennis Simmons D.D.S., P.A. v. Modern Aero, Inc.*, 603 N.W.2d 336, 339 (Minn. Ct. App. 1999) (affirming dismissal of MDTPA claim because the Act "provides only injunctive relief" and "appellant pursued damages, not an injunction")). But as Martin points out, the Master Complaint in this MDL contains a request for injunctive relief. And in his short form complaint, Martin checked a box to incorporate by reference the Master Complaint's prayer for relief. Actavis's argument for summary judgment on the MDTPA claim, therefore, lacks merit.

8. Claims against Actavis, Inc.

Actavis moves for summary judgment on all claims against defendant Actavis, Inc. because, according to Actavis, that entity does not manufacture or sell Androderm. In support of this argument, Actavis cites Minnesota Statute § 544.41, which applies to "product liability action[s] based in whole or in part on strict liability in tort."[3] MINN. STAT. § 544.41, subdiv. 1. Section 544.41 provides that except in limited circumstances, a court must dismiss claims brought against a "defendant other than the manufacturer" so long as the manufacturer can be sued and can satisfy the judgment. *See id.* at subdiv. 1-3. In response, Martin points the Court to a motion for sanctions it filed in June 2018.

[3] Actavis actually cites Minnesota Statute § 544.4, *see* Actavis Mot. for Summ. J. at 15, but as far as the Court can tell, that statute does not exist.

In that motion, Martin asked the Court to deny Actavis's motion for summary judgment on claims against Actavis, Inc. as a sanction for Actavis's alleged refusal to produce a Rule 30(b)(6) witness concerning its corporate structure. According to Actavis, Martin's motion for sanctions is unwarranted because Martin did not properly notice the Rule 30(b)(6) deposition and because Actavis's discovery responses "explicitly state that Actavis, Inc., is a holding company that did not manufacture, market, or sell Androderm." Actavis June 13, 2018 Opp. to Mot. for Sanctions at 10.

Information concerning Actavis, Inc.'s corporate structure would guide the Court in deciding whether it must dismiss certain claims against it under Minnesota Statue § 544.41. But the Court terminated Martin's motion for sanctions as moot in November 2018 in light of the Master Settlement Agreement. The Court orders the parties to attempt to reach a stipulation that will resolve Actavis's motion for summary judgment on claims against Actavis, Inc. If the parties cannot do so, the Court will order Actavis to produce a 30(b)(6) witness who can provide relevant testimony. After the deposition is complete, the Court will order the parties to file simultaneous, five-page supplemental briefs on this portion of Actavis's motion for summary judgment.

9. Comparative fault

Minnesota law provides, in relevant part, that "[c]ontributory fault does not bar recovery in an action by any person . . . to recover damages for fault resulting . . . in injury to person . . . if the contributory fault was not greater than the fault of the person against whom recovery is sought." MINN. STAT. § 604.01. "[A]ny damages allowed," however, "must be diminished in proportion to the amount of fault attributable to the person recovering." *Id.* Actavis requests summary judgment on Martin's comparative

fault because, it argues, it presented "unopposed" expert testimony that Martin's fault, such as his failure to manage pre-existing medical conditions, "was a substantial factor in causing" his heart attack. Actavis Mot. for Summ. J. at 17.

The Court denies Actavis's motion. Martin's specific causation expert, Dr. Ardehali, has opined that Martin's pre-existing medical conditions were not the sole cause of his heart attack. The Court has ruled that his testimony is admissible, so the contrary opinion offered by Actavis's expert is not unopposed. Moreover, based on Dr. Ardehali's testimony, a jury reasonably could conclude that Martin's "contributory fault was not greater than the fault of" Actavis. MINN. STAT. § 604.01. In that circumstance, Minnesota law would not bar recovery. *See id.* The Court recognizes that Martin did not respond to Actavis's arguments concerning contributory fault. It concludes that Martin did not forfeit the issue, however, because he defended Actavis's *Daubert* challenge to Dr. Ardehali's specific causation testimony.

10. Punitive damages

a. Choice of law

Actavis asks the Court to strike Martin's request for punitive damages. It first argues that the laws of three states could potentially govern the request: Minnesota, where Martin has resided at all relevant times; New Jersey, where defendant Actavis Pharma, Inc., a seller of Androderm, is located; and Utah, where Actavis Utah, a manufacturer of Androderm, is located.[4] Actavis then maintains that under the laws of each state, Martin's request for punitive damages is barred—and that even if it is not, no reasonable jury could find in Martin's favor. In response, Martin contends that the

[4] As far as the Court can tell, Actavis Utah is not a defendant in this action.

punitive damages laws of Minnesota, New Jersey, and Utah vary in material ways and that a choice of law analysis is therefore required. He further contends that under Case Management Order Nos. 12 and 47 in this MDL, Minnesota's choice of law analysis should be employed. Finally, he argues that the analysis favors applying Minnesota law to his request for punitive damages. Actavis does not respond to Martin's choice of law analysis, nor does it conduct its own. Instead, it its reply, it doubles down on the position that punitive damages are unavailable no matter which state law applies. The Court concludes that by failing to address the choice of law issue, Actavis has forfeited any objection to employing Minnesota choice of law rules and applying Minnesota law to the question of punitive damages. But even if Actavis had not forfeited these objections, Martin's analysis is sound.

Specifically, under CMO 12, Martin's case "shall be treated as if originally filed in the federal district where the Plaintiff was a citizen at the time of the filing of his . . . first Complaint." CMO 12 § II.B.ii. For Martin, that district is Minnesota—and that means that Minnesota's choice of law rules apply. *See* CMO 47, 2017 WL 1836435, at *21 ("The Seventh Circuit has indicated that in 'foreign cases filed directly in a district court as a part of ongoing multidistrict litigation,' courts generally should treat the cases, for purposes of applicable choice of law rules, as originating outside the district and thus should apply the choice of law rules of the originating states." (quoting *Dobbs v. DePuy Orthopedics, Inc.*, 842 F.3d 1045, 1049 (7th Cir. 2016)). In Minnesota, a court engages in a choice of law analysis only if there is a substantive, outcome-determinative conflict between laws. *See, e.g.*, *Healey v. I-Flow, LLC*, 853 F. Supp. 2d 868, 874 (D. Minn. 2012) (citing *Jepson v. Gen. Cas. Co. of Wis.*, 513 N.W.2d 467, 469 (Minn. 1994);

Christian v. Birch, 763 N.W.2d 50, 55 (Minn. Ct. App. 2009)). Moreover, "[f]or a State's substantive law to be selected in a constitutionally permissible manner, that State must have a significant contact or significant aggregation of contacts, creating state interests, such that choice of its law is neither arbitrary nor fundamentally unfair." *Jepson*, 513 N.W.2d at 469 (quoting *Allstate Ins. Co. v. Hague*, 449 U.S. 302, 312-13 (1981)).

Martin identifies at least one substantive, outcome-determinative conflict: New Jersey's punitive damages statute is vulnerable to a preemption challenge, while Minnesota's is not. *See* Martin Summ. J. Opp. at 14, 20; *see also In re Levaquin Products Liability Litigation*, MDL No. 08-1943 (JRT), 2010 WL 7852346, at *6-7 (D. Minn. Nov. 9, 2010) (finding an "actual conflict" between Minnesota and New Jersey punitive damages laws on this basis). A choice of law analysis is therefore appropriate, *see Healey*, 853 F. Supp. 2d at 874, and five factors have potential relevance: "(1) predictability of result; (2) maintenance of interstate and international order; (3) simplification of the judicial task; (4) advancement of the forum's governmental interest; and (5) application of the better rule of law." *Jepson*, 513 N.W.2d at 470.[5]

[5] In *In re Levaquin*, the court noted that Minnesota's five-factor choice of law analysis applies to substantive but not procedural or remedial laws, and it interpreted Minnesota's punitive damages statute as remedial. 2010 WL 7852346, at *7-8. The question whether Minnesota's punitive damages statute is substantive or remedial appears to be unsettled, however. *See, e.g.*, *In re Mirapex Prods. Liab. Litig.*, Civil No. 07-MD-1836 (JMR/FLN), 2007 WL 9636345, at *2-3 (D. Minn. Nov. 27, 2007) (interpreting the statute as substantive and concluding that it must employ the five-factor choice of law test). The court declines to venture into this territory because it likely does not affect the result of Actavis's motion. *See In re Levaquin*, 2010 WL 7852346, at *7-10 (concluding that Minnesota Statute § 549.20 applies regardless of whether it is considered substantive or remedial); *see also id.* at *8 n.5 ("The substantive/remedial determination for a conflict of law analysis under Minnesota law is a different inquiry than that posed to courts determining whether to apply a federal or state law under the *Erie* doctrine.").

Martin states that in two recent MDL cases, district courts applying Minnesota choice of law rules focused on the "governmental interest" factor and determined that Minnesota law should govern Minnesota citizens' punitive damages claims. *See In re Levaquin*, 2010 WL 7852346, at *7-10 (applying the five-factor test for the sake of argument; noting that Minnesota places "unique emphasis on only the government interest of the forum state in a conflict of law analysis"; and concluding that Minnesota's "strong interest in preventing injury to its citizens" through enforcement of its punitive damages statute was paramount); *In re Mirapex*, 2007 WL 9636345, at *4 ("The [fourth] factor, advancement of the forum's governmental interest, generally weighs in favor of application of the state law in which the plaintiff lives and in which the injury occurred."). These cases persuade the Court that Minnesota law governs Martin's request for punitive damages. Moreover, because Martin is a citizen of Minnesota, his heart attack occurred there, and Actavis conducted business there, applying Minnesota law would not be arbitrary or unfair. *See Jepson*, 513 N.W.2d at 469.

b. Punitive damages standard

Minnesota's punitive damages statute permits an award of punitive damages in a civil action:

> only upon clear and convincing evidence that the acts of the defendant show deliberate disregard for the rights or safety of others. . . . A defendant has acted with deliberate disregard . . . if [it] has knowledge of facts or intentionally disregards facts that create a high probability of injury to the rights or safety of others and: (1) deliberately proceeds to act in conscious or intentional disregard of the high degree of probability of injury to the rights or safety of others; or (2) deliberately proceeds to act with indifference to the high probability of injury to the rights or safety of others.

MINN. STAT. § 549.20 at subdiv. 1. Notably, under Minnesota law, a plaintiff cannot request punitive damages "[u]pon commencement of a civil action" but "may make a

motion to amend the pleadings to claim punitive damages" after he has filed suit. MINN. STAT. § 549.191. A court "shall" grant the motion if it finds that plaintiff has offered "prima facie evidence in support of the motion." *Id.*

Actavis appears to argue that although Martin requested punitive damages when he commenced the action, Minnesota Statute § 549.191 invalidates that request. It also argues that Martin cannot obtain punitive damages because he did not move to amend his complaint to add a request for punitive damages. Martin responds that he has not had a chance to depose former Actavis employees whose testimony is relevant to punitive damages. He states that he will file a motion to amend under Minnesota Statute § 549.191 after he takes the depositions. The Court resolves this issue on a ground neither party raises: 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)), and in the Court's view, the requirements of Minnesota Statute § 549.191 are procedural.

The Court is aware that Minnesota courts sitting in diversity have often applied Minnesota Statute § 549.191 to claims for punitive damages. *See Selective Ins. Co. of S.C. v. Sela*, 353 F. Supp. 3d 847, 855-56 (D. Minn. 2018) (collecting cases). But some courts have recently called this practice into question because "[p]leading standards are generally viewed as procedural . . . ." *Id.* at 855, 859 (in a diversity action, federal pleading standards, not Minnesota Statute § 604.18, should govern insured's motion for leave to amend counterclaim to add claim for bad-faith denial of insurance benefits); *id.* at 855-56 & n.3 (suggesting in dicta that the requirements of Minnesota Statute § 549.191, which are similar in some respects to those of Minnesota Statute § 604.18,

should not apply in diversity actions); *see also In re McNeilus Mfg. Explosion Coordination Litig.*, No. 17-cv-5237-PJS-KMM, 2019 WL 2387110, at *2 n.2 (D. Minn. June 6, 2019) (Federal Rule of Civil Procedure 15, not Minnesota Statute § 549.191, applied to plaintiff's motion for leave to amend complaint to add request for punitive damages).

Although the law on this issue is uncertain, *see, e.g.*, *Rilley v. MoneyMutual, LLC*, No. 16-cv-4001 (DWF/LIB), 2018 WL 6920764, at *5, *7 (D. Minn. Dec. 13, 2018) (interpreting Minnesota Statute § 549.191 as "a substantive law defining a substantive right" for purposes of an *Erie* determination and concluding that it should govern plaintiff's motion for leave to amend complaint to add punitive damages), the Court respectfully concludes that the reasoning in *Sela* and *In re McNeilus* is more persuasive. Accordingly, federal pleading standards apply to Martin's punitive damages claim. Martin's request for punitive damages does not suffer from a procedural defect because nothing in the Federal Rules of Civil Procedure bars a plaintiff from requesting punitive damages in his initial complaint. *See, e.g.*, FED. R. CIV. P. 8(a)(3) ("A pleading that states a claim for relief must contain: . . . a demand for the relief sought, which may include relief in the alternative or different types of relief."); *Smith v. I-Flow Corp.*, 753 F. Supp. 2d 744, 749-50 (N.D. Ill. 2010) (determining that the allegations in plaintiffs' complaint "plausibly give rise to a viable claim for punitive damages" and therefore satisfy Rule 8(a)'s pleading requirements).

Even if Minnesota Statute § 549.191 applies, Martin could satisfy its requirements because the Court finds that a genuine dispute exists concerning whether Actavis acted with "deliberate disregard for the rights or safety of others." MINN. STAT. §

549.20 at subdiv. 1. If Martin moved to amend his complaint to request punitive damages, the Court would grant it based on the same evidence. Specifically, Martin has offered evidence supporting a reasonable inference that Actavis knew that Androderm increases cardiovascular risk but did not provide an adequate warning. In addition, Martin has offered evidence from which a jury reasonably could conclude that Actavis knew that Androderm has not been proven safe or effective for use in men with age-related hypogonadism yet marketed it for that purpose. A jury, therefore, reasonably could find that Actavis knew or disregarded information that "create[s] a high probability of injury" and acted in "conscious or intentional disregard of," or with "indifference to," that risk. *Id.*

In a final push for dismissal of Martin's punitive damages request, Actavis contends that Martin cannot show a "nexus" between the alleged misconduct and the "specific harm" he suffered, as required under *State Farm Mutual Auto Insurance Co. v. Campbell*, 538 U.S. 408, 422 (2003). This argument lacks merit because as noted, a jury reasonably could find based on the evidence that Actavis marketed Androderm for use in patients like Martin. Moreover, Martin claims that he suffered the exact injury for which Actavis allegedly failed to provide adequate warnings. The Court denies Actavis's motion to strike Martin's request for punitive damages.

Conclusion

For the foregoing reasons, the Court denies Actavis's Motion for Summary Judgment Based on Federal Preemption [dkt. no. 41]; denies Actavis's Motion to Exclude the Testimony of Martin's Experts Burt Gerstman, Ph.D., Martin. T. Wells, Ph.D., and Hossein Ardehali, M.D., and terminates as moot Actavis's Motion to Exclude

the Testimony of Martin's Expert Robert Johnson [dkt. no. 38]; and grants in part and denies in part Actavis's Motion for Summary Judgment [dkt. no. 32]. Specifically, the Court grants Actavis's Motion for Summary Judgment on Martin's claims for breach of implied warranty of merchantability, negligent misrepresentation, unjust enrichment, redhibition, and violation of the Minnesota False Statement in Advertising Act; denies Actavis's Motion for Summary Judgment on Martin's claims for failure to warn, design defect, negligence, breach of express warranty, fraudulent misrepresentation, and violation of the Minnesota Deceptive Trade Practices Act; denies Actavis's Motion for Summary Judgment based on comparative fault; denies Actavis's motion to strike Martin's request for punitive damages; and reserves judgment on Actavis's Motion for Summary Judgment on claims against Actavis, Inc.

MATTHEW F. KENNELLY
United States District Judge

Date: December 30, 2019