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

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	**Case No. 1:14-cv-1748** **MDL No. 2545** **Hon. Matthew F. Kennelly**
THIS DOCUMENT RELATES TO: Holtsclaw v. Auxilium Pharmaceuticals, LLC, Case No. 1:15-cv-3941	

DEFENDANT'S MOTION UNDER RULE 50(A) FOR JUDGMENT AS A MATTER OF LAW AND MEMORANDUM IN SUPPORT

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INTRODUCTION

Pursuant to Federal Rule of Civil Procedure 50(a), Defendant Auxilium Pharmaceuticals, LLC (f/k/a Auxilium Pharmaceuticals, Inc.) ("Auxilium") respectfully moves for judgment as a matter of law for the reasons set forth in this memorandum. After six days of trial, having called 11 witnesses (three live witnesses and eight video deposition designations) and introduced close to 100 exhibits, Plaintiff has failed to present evidence sufficient to permit a reasonable jury to find in his favor on any of his claims, or to award punitive damages. "Rule 50 requires a court to render judgment as a matter of law when a party has been fully heard on an issue, and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 135 (2000); Fed. R. Civ. P. 50(a)(1). "[T]he question is simply whether the evidence as a whole, when combined with all reasonable inferences permissibly drawn from that evidence, is sufficient to allow a reasonable jury to find in favor of the plaintiff." *Hall v. Forest River, Inc.*, 536 F.3d 615, 619 (7th Cir. 2008). "A mere scintilla of evidence … will not suffice" to prevent judgment as a matter of law. *Id.* (quotation marks omitted). Judgment as a matter of law is properly granted against a party that relies only on "sheer speculation and conjecture." *Garrett v. Barnes*, 961 F.2d 629, 632, 634 (7th Cir. 1992) (granting judgment as a matter of law, as "speculation cannot be the basis of a jury verdict").

Plaintiff has failed to show that Testim caused his heart attack. Plaintiff concedes—and his expert witnesses and all of Plaintiff's treating physicians agree—that he had multiple known risk factors for a heart attack. Plaintiff has offered no evidence to show that Testim, rather than a constellation of those undeniable risk factors, caused his heart attack on July 3, 2014. This deficiency in Plaintiff's evidence warrants judgment for Auxilium on all claims, but Plaintiff's evidence is also insufficient for claim-specific reasons. Plaintiff's failure to establish necessary elements of each of his claims requires entry of judgment as a matter of law for Auxilium.

ARGUMENT

I. PLAINTIFF FAILED TO PRESENT SUFFICIENT EVIDENCE THAT HE WOULD NOT HAVE HAD HIS HEART ATTACK BUT FOR TESTIM

Plaintiff cannot prevail on any of his claims because he failed to establish by a preponderance of the evidence that he would not have suffered his heart attack had he not taken Testim. Plaintiff had several known risk factors for a heart attack long before he began taking Testim, including high cholesterol, diabetes, obesity, and obstructive sleep apnea. *See* Tr. 281:4-6; 282:14-17; 283:11-13; 283:20-284:1 (Holtsclaw); 558:2-5 (Ardehali); *accord* Smith Dep. 55:18-56:20; McLaughlin Dep. 33:23-38:8. Plaintiff's expert witness, Dr. Hossein Ardehali, agreed that if a person with these risk factors had a heart attack and was not on other medications, he would tell the person that those risk factors caused the heart attack. Tr. 558:21-559:4. Plaintiff's treating cardiologist, Dr. Steven Smith, likewise testified that there was nothing unusual about Plaintiff's arteries, or the fact or nature of Plaintiff's heart attack, that would distinguish his illness from that of a typical patient with the same risk factors. Smith Dep. 59:20-61:1; 62:19-63:18; 68:22-69:24.

Plaintiff's sole evidence that Testim was a medical cause of his injury was select testimony of Dr. Ardehali, who testified that "but for his use of the testosterone product, [Plaintiff] would not have had a heart attack on July 3rd, 2014," and that "Plaintiff's use of the Testim product, the testosterone product, was a substantial factor in causing his heart attack." Tr. 508:3-12. Dr. Ardehali opined that all the other risk factors "push you to the edge, and it was Testim that was the last push, that pushed you over and caused your heart attack." Tr. 559:4-11. But Dr. Ardehali provided no opinion about the actual mechanism of Plaintiff's injury. Dr. Ardehali testified at length about five "biologically plausible" mechanisms for his theory that "testosterone can cause heart attacks in men." Tr. 351:18-437:20. But after giving six hours of

testimony and discussing no fewer than fifteen studies about these five possible mechanisms, Dr. Ardehali ultimately admitted that there is no actual evidence that any of these mechanisms caused Plaintiff's heart attack. *See* Tr. 525:9-21 (hematocrit); 525:22-24, 526:8-22 (estradiol); 536:16-537:1 (VCAM); 537:10-538:1 (reactive oxygen species); 536:4-7, 536:11-15 (thromboxane).

Based on Plaintiff's preexisting risk factors and the lack of evidence to support that Testim was a medical cause of his heart attack, no reasonable jury could conclude that Plaintiff would not have suffered his injury had he not taken Testim. Because Plaintiff's claims all require him to prove that Testim was a cause in fact of his injury, Plaintiff cannot prevail on any of his claims. The Court should therefore enter judgment as a matter of law for Auxilium.

II. PLAINTIFF FAILED TO ESTABLISH NECESSARY ELEMENTS OF HIS NEGLIGENCE AND STRICT LIABILITY CLAIMS

To prevail on his negligence and strict liability claims, Plaintiff must prove that Testim's label was inadequate and rendered Testim unreasonably dangerous, and that the inadequate labeling caused his heart attack. Plaintiff's evidence fails to satisfy any of these necessary elements, and so the Court should enter judgment for Auxilium on these claims.

A. Plaintiff Failed to Present Sufficient Evidence that Testim was Unreasonably Dangerous

Plaintiff's evidence fails to establish that Testim was unreasonably dangerous under Tennessee law. Tennessee law recognizes two tests for determining whether a product is unreasonably dangerous: first, the "consumer expectation test," which asks whether the product "is dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics," and second, the "prudent manufacturer test," which asks whether the product "because of its dangerous condition would not be put on the market by a reasonably prudent

manufacturer or seller, assuming that the manufacturer or seller knew of its dangerous condition." Tenn. Code Ann. § 29-28-102(8). But Tennessee courts have acknowledged that "the consumer expectation test will be inapplicable, by definition, to certain products about which an ordinary consumer can have no expectation." *Ray by Holman v. BIC Corp.*, 925 S.W.2d 527, 530 (Tenn. 1996). In such cases, the prudent manufacturer test will often be "the only appropriate means" to determine whether a product is unreasonably dangerous. *Id.* at 531; *accord Jackson v. Gen. Motors Corp.*, 60 S.W.3d 800, 806 (Tenn. 2001) (affirming *BIC* and agreeing that the consumer expectation test may be unsuited to cases involving highly complex products).

Pharmaceuticals are highly complex products. The ordinary consumer does not possess the medical or scientific knowledge required for a full understanding of their purposes, risks, or benefits. *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 397 (6th Cir. 2013) (applying Tennessee law). That is why the prudent manufacturer test, rather than the ordinary consumer test, is the appropriate test in this case. *Id.* Based on the record evidence, Plaintiff fails to satisfy that standard. "[E]xpert testimony about the prudence of the decision to market [Testim] would be essential." *King v. Danek Med., Inc.*, 37 S.W.3d 429, 436 (Tenn. Ct. App. 2000) (quoting *BIC*, 915 S.W.2d at 531); *see also, e.g.*, *Kibbler v. Richards Med. Co.*, No. 02A01-9110-cv-00214, 1992 WL 233027, at *3 (Tenn. Ct. App. Sept. 23, 1992) (directed verdict for defendant in a products liability case warranted in the absence of expert testimony that the medical device was defective or unreasonably dangerous). But Plaintiff has presented no evidence that a prudent manufacturer would not have "put [Testim] on the market" in light of the alleged cardiovascular risks. Tenn. Code Ann. § 29-28-102(8).

As Dr. Anthony DelConte, former Chief Medical Officer of Auxilium, testified, there were no "real" safety signals that would have warranted a change in Testim's label. DelConte Dep. 477:1-11. Dr. Peggy Pence, Plaintiff's sole "expert" on Auxilium's conduct, conceded that Testim's label was repeatedly approved by FDA, which had the power to require a labeling change, and chose not to do so while Plaintiff used Testim. Tr. 896:2-898:3. Dr. Pence conceded that Testim's label was adequate when Testim was approved in 2002, but opined that the label "became inadequate" in 2004, when it allegedly should have included information about increased risk of cardiovascular events for patients in populations other than those encompassed in the original indications, such as men with so-called "age-related hypogonadism" or overlapping cardiovascular risk factors. Tr. 884:1-18, 895:19-896:1; *see also* Tr. 779:17-780:2; 831:7-832:5. But Dr. Pence also acknowledged that FDA did not require such a label change until 2015—even in the face of all the studies and evidence on which Dr. Pence based her opinion that the label required supplementation. And while Plaintiff has argued that Auxilium bore the final responsibility for its product, Tr. 198:8-14; 646:19-25, the evidence reflects that the FDA on multiple occasions rejected proposals (including a proposal from Auxilium) that would have added cardiovascular risk warnings to Testim's label prior to the label change in 2015. Given this, Plaintiff's argument that Testim was unreasonably dangerous under the prudent manufacturer test cannot withstand scrutiny.

Even if, contrary to law, the consumer expectation test applied, Plaintiff has not presented sufficient evidence to satisfy it. That test "requires the consumer to establish what an ordinary consumer purchasing the product would expect." *BIC*, 925 S.W.2d at 531. A plaintiff "must present evidence that the ordinary consumer has an expectation regarding the safety of the product," *Jackson*, 60 S.W.3d at 804. Here, Plaintiff testified as to his own expectations about

Testim, Tr. 301:18-302:5, but he presented no evidence bearing on what the ordinary consumer would reasonably have expected from Testim, based on ordinary knowledge of the product's characteristics. *See Jackson*, 60 S.W.3d at 804.

B. Plaintiff Failed To Present Sufficient Evidence that Testim's Labeling Caused His Injury

The Court should enter a directed verdict on Plaintiff's strict liability and negligence claims for the independent reason that Plaintiff cannot establish by a preponderance of the evidence that Testim's labeling was the proximate cause of his heart attack.

Under the learned intermediary doctrine, Auxilium was entitled to rely on Dr. McLaughlin to convey Testim's risks and benefits to Plaintiff. *See Pittman v. Upjohn Co*., 890 S.W.2d 425, 428 (Tenn. 1994); *see also Nye v. Bayer Cropscience, Inc.*, 347 S.W. 3d 686, 701 (Tenn. 2011) ("[T]he learned intermediary doctrine is applicable in failure to warn suits where a physician is the intermediary between a defendant pharmaceutical … manufacturer and an injured patient."). Thus, Plaintiff must show that Auxilium failed to warn Dr. McLaughlin that Testim could increase cardiovascular risk for a patient like Mr. Holtsclaw, that Testim had not been proven safe and effective other than to treat "classic hypogonadism," and that Auxilium's failure to so warn Dr. McLaughlin was the proximate cause of Plaintiff's heart attack.

Plaintiff has not carried his burden. Plaintiff's evidence does not establish that the absence of a warning regarding cardiovascular risk from Testim's label was a substantial factor in Dr. McLaughlin's decision to prescribe the drug to Plaintiff. Dr. McLaughlin diagnosed Mr. Holtsclaw with hypogonadism and prescribed Testim to treat that condition. There is no indication that Dr. McLaughlin would have made a different decision had the label included a cardiovascular risk warning. Indeed, Dr. McLaughlin testified in 2017—two years after FDA required revisions to the label to warn of possible increased cardiovascular risk—that he

continues to prescribe Testim to men with hypogonadism. McLaughlin Dep. 27:17-19; *see also King*, 37 S.W.3d at 453 (proximate cause not shown where plaintiffs failed to establish that physicians' decisions were influenced by any representation or omission by defendants).

Moreover, Plaintiff actively participated in the decision to take Testim. He "decided he wanted to start it" after numerous discussions with Dr. McLaughlin about Testim's risks and benefits. McLaughlin Dep. 58:2-59:20. He "preferred" to use testosterone gel rather than injectable testosterone. McLaughlin Dep. 59:7-11. Plaintiff failed to offer evidence—other than conclusory, self-serving statements, Tr. 302:9-22—that advice about the possible cardiovascular risk would have altered his decision. Indeed, the evidence reflects that Plaintiff disregarded clear warnings of significant increased cardiovascular risk due to his untreated hyperlipidemia. Dr. McLaughlin repeatedly warned Plaintiff that he needed to take cholesterol-lowering medication, and that Plaintiff's failure to do so placed him at "an elevated risk of a heart attack." McLaughlin Dep. 112:12-114:12. Nevertheless, other than taking a few samples of Crestor, Plaintiff did not fill a prescription for a cholesterol-lowering medication until after his heart attack. Plaintiff offered no evidence to support the conclusion that he would have heeded advice from Dr. McLaughlin about the possible cardiovascular risks of taking Testim.

Plaintiff's own testimony further undermines any argument that Auxilium's failure to include a cardiovascular risk warning on the Testim label proximately caused Plaintiff's injury. Plaintiff admitted he never read the medication guide for Testim. Tr. 313:14 ("I didn't read none of it. I done told you that."). Thus, no additional warning could have altered Plaintiff's decision to take Testim. Indeed, the warning on the increased risk of prostate cancer included in the medication guide had no effect on Plaintiff's decision to take Testim, even though Plaintiff viewed that risk as material to his decision whether or not to use the product. Tr. 313:15-25.

Based on Plaintiff's own evidence, no reasonable jury could find that the absence of a cardiovascular risk warning on Testim's label in 2014 was a factor—let alone a substantial factor—in causing Plaintiff's heart attack. The Court should enter a directed verdict for Auxilium on Plaintiff's negligence and strict liability claims.

III. PLAINTIFF FAILED TO ESTABLISH NECESSARY ELEMENTS OF HIS MISREPRESENTATION CLAIM

To prevail on his intentional misrepresentation claim under Tennessee law, Plaintiff had to prove that Auxilium made a false representation regarding an existing or past material fact, that it made that representation knowingly or recklessly, and that Plaintiff relied on the representation and was injured as a result. *Davis v. McGuigan*, 325 S.W.3d 149, 154 (Tenn. 2010). Plaintiff failed to demonstrate that he or Dr. McLaughlin in fact relied on any intentional, material misrepresentation. Accordingly, the Court should enter judgment in Auxilium's favor.

Plaintiff's misrepresentation claim is premised on the notion that Auxilium improperly promoted Testim for off-label uses by misleading patients and physicians into believing that Testim was approved to treat low testosterone associated with conditions other than "classic hypogonadism," which Plaintiff contends was the exclusive approved use for Testim. *See, e.g.* Tr. 696:12-697:4. But Plaintiff offered no evidence that Auxilium ever stated that Testim had been approved for such purposes. The only evidence Plaintiff put forward was certain marketing materials that at most "implied" that Testim or testosterone could be used for purposes other than the approved use. Ex. 26; Tr. 799:25-800:2 (Pence) ("Q. What is being implied there? A. That testosterone can be used to treat diabetes or the signs and symptoms associated with diabetes."); *see also, e.g.*, Exs. 102, 866. Even assuming these "implications" amounted to misrepresentations of material fact, the trial record is devoid of evidence that any reliance on Auxilium's purported marketing for off-label uses caused Plaintiff's injury.

Plaintiff presented no evidence that Auxilium ever marketed Testim to Plaintiff or Dr. McLaughlin claiming that Testim treats anything other than hypogonadism. Plaintiff himself admitted that he never saw any marketing materials about Testim. Tr. 310:4-8. He explained, "Even if I had, I wouldn't have paid no attention to it." Tr. 310:6. Plaintiff's admission forecloses any argument that he relied on any misrepresentation by Auxilium regarding off-label uses of Testim, and requires judgment in Auxilium's favor.

Likewise, Plaintiff presented no evidence that Dr. McLaughlin—on whom Auxilium could rely as a learned intermediary to convey information about Testim for purposes of both the intentional misrepresentation claim, and the misrepresentation by concealment claim, *see infra* Part IV, as Plaintiff has framed those claims, *see, e.g.*, *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736, 743-45 (S.D.W. Va. 2014)—relied on any allegedly misleading advertisements about Testim. *See* Tr. 838:22-25 (Pence) ("Q. And you're not offering any opinions that any testosterone promotional material specifically affected Dr. McLaughlin's prescribing practices, right? A. That's correct."). The evidence Plaintiff has introduced regarding Auxilium's strategies for marketing to physicians, *see, e.g.*, Rosenberger Dep. 143:5-23, 144:2-4, 144:6-146:19, 148:8-10, 148:14-20, 307:3-8, 308:4-15; 309:9-310:1, 310:11-17, 313:1-10, 313:17-22, 315:4-17, 315:21-316:3; Hess Dep. 511:5-513:11, 528:4-535:2, 535:6-7, 535:9-20, or the number of times Testim sales representatives apparently contacted Dr. McLaughlin, *see, e.g.*, Sturgill Dep. 97:21-23, 98:1, 98:3-12, 98:14-99:5, 112:21-113:1, 113:11-13; Ex. 2033, is immaterial.

Even assuming reliance by Dr. McLaughlin is relevant, *cf. Walker v. Sunrise Pontiac-GMC Truck, Inc.*, 249 S.W.3d 301, 311 (Tenn. 2008) (misrepresentation claims require that "plaintiff reasonably relied on the misrepresented material fact"); *Coffey v. Foamex L.P.*, 2 F.3d 157, 161 (6th Cir. 1993) (quoting *Atkins v. Kirkpatrick*, 823 S.W.2d 547, 552 (Tenn. Ct. App.

1991)) (similar), Dr. McLaughlin testified that he did not recall hearing any of the purported misrepresentations that Plaintiff attributes to Auxilium. *See* McLaughlin Dep. 132:24-133:3 ("Q: Do you have an image in your mind [of the Testim representatives' brochure]? No? Okay. A: No, ma'am."); 133:5-12 ("Q. Do you remember hearing from Testim sales representatives anything about which types of patients would be appropriate patients to test their testosterone level to see if they might be hypogonadal or have hypogonadism? A. No, I don't."); 133:15-134:12 ("Q: Do you recall hearing from any Testim sales representatives that 50 percent of men with diabetes have low testosterone? A: No, I don't recall that."); 106:10-15 ("Q: You were never told by a manufacturer's representative that Testim can be used to treat erectile dysfunction or diabetes or opioid addiction, were you? A: No."); 106:17-22 (Q: You were never told by a manufacturer's representative that Testim was approved to treat sexual dysfunction or to improve lean body mass; is that right? A: No."). And while Dr. McLaughlin was familiar with the "ADAM Questionnaire," he stated, "[W]e don't use them." McLaughlin Dep. 135:5-16. Dr. McLaughlin further testified that he was "conservative" about adopting new medicines and consulted a variety of sources, including statements from medical organizations and current medical literature, to inform his decision about whether to use a new medication. McLaughlin Dep. 99:7-100:5, 101:17-102:19. Plaintiff's inability to identify substantial evidence of reliance on any purported misrepresentation dooms his claim.

IV. PLAINTIFF FAILED TO ESTABLISH NECESSARY ELEMENTS OF HIS CLAIM FOR CONCEALMENT

Tennessee law provides that "the tort of fraudulent concealment is committed when a party who has a duty to disclose a known fact or condition fails to do so, and another party reasonably relies upon the resulting misrepresentation, thereby suffering injury." *Chrisman v.*

Hill Home Dev., Inc., 978 S.W.2d 535, 538-39 (Tenn. 1998). Like his misrepresentation claim, Plaintiff's concealment claim fails at each step for lack of sufficient evidence.

A. Plaintiff Failed To Present Sufficient Evidence of Any Material Omission that Auxilium Had a Duty to Disclose

Plaintiff's concealment claim posits that Auxilium failed to disclose that Testim had not been proven safe and effective to treat "age-related or late-onset hypogonadism" or low testosterone associated with conditions other than "classic hypogonadism." *See, e.g.*, Tr. 194:9-17, 1044:21-45:2 (Pence) ("Q. And with respect to the safety and efficacy for use in diabetics, should Auxilium have warned the general medical community that safety and efficacy in diabetics had not been established? A. Absolutely, they should have. Q. And did they? A. They did not."); 1046:8-1047:14 (similar). But Tennessee law requires "something more than mere silence, or a mere failure to disclose known facts." *Leeper v. Cook*, 688 S.W.2d 94, 96 (Tenn. Ct. App. 1985). The defendant must have intended to mislead the plaintiff, or failed to disclose known facts that it had a duty to disclose. *Id.*

Plaintiff failed to offer substantial evidence either that Auxilium intended to mislead him, or that it concealed any information that it had a duty to disclose. Dr. Pence disavowed the notion that Auxilium ever failed to submit any required information to FDA, Tr. 841:11-13, hid information from the FDA with regard to its label, Tr. 841:13-25, or ever misrepresented any information or data related to Testim with FDA, Tr. 841:24-842:1. Dr. Pence admitted that FDA was aware of and analyzed all the relevant studies on which she based her opinion that the label should have included additional warnings. Tr. 898:19-899:2. At no time prior to Plaintiff's heart attack did any study or FDA itself recommend a change in the label. Indeed, while FDA opened a Tracked Safety Issue ("TSI") to review the cardiovascular risks of testosterone replacement therapy products in the wake of the early termination of the TOM trial, it closed the TSI

indicating "insufficient evidence of a cardiovascular risk associated with TRT to warrant regulatory action." *See* Tr. 925:25- 926:18, 927:1-3 (Pence). *Cf., e.g.*, Ex. 4303 (Institute of Medicine report analyzed existing literature but did not recommend a label change); Tr. 557:1-16 (Ardehali) (agreeing that FDA has never identified an actual risk of heart disease associated with testosterone use).

B. Plaintiff Failed To Show that He Relied on Any Misrepresentation by Concealment

Even if Plaintiff had identified a material omission, he failed to present sufficient evidence that he relied on and was injured by the resulting misrepresentation, as Tennessee law requires to establish the tort of fraudulent concealment. Plaintiff emphasized that he had "never seen" any advertising or promotional material about testosterone products, Tr. 310:4-8, and "never read" Testim's label or medication guide, Tr. 313:5-9, let alone acted in reliance on the impression that Testim had been proven safe and effective for particular off-label uses.

Plaintiff's denial that he read Testim's label dooms his concealment claim. Plaintiff suggests that Dr. McLaughlin relied on the misrepresentation resulting from Auxilium's purported omission of information from Testim's label. Tr. 212:22-213:4. But even if reliance by Dr. McLaughlin is relevant, *cf. Chrisman*, 978 S.W. 2d at 538-39 (action for fraudulent concealment lies where a party reasonably relies upon misrepresentation, thereby suffering injury), Plaintiff presented no evidence that Dr. McLaughlin would have acted differently had he been made aware that the product's "safety and efficacy" for treating "age-related hypogonadism" or anything other than "classic hypogonadism" had not been fully studied. There is no evidence that Dr. McLaughlin diagnosed Plaintiff with "age-related hypogonadism" or that he prescribed Testim to Plaintiff for an off-label use. Plaintiff had complained of chronic fatigue, which Dr. McLaughlin determined was consistent with his low testosterone level.

More important, Plaintiff presented no evidence that Dr. McLaughlin was misled into believing that Testim had been more widely tested, and that Plaintiff would not have taken Testim had Auxilium disclosed the extent of the clinical evidence. To the contrary, Dr. McLaughlin testified in 2017—two years after the information Plaintiff contends was wrongly omitted was added to the label—that he currently prescribes Testim to patients with hypogonadism. McLaughlin Dep. 27:17-19. That the new information has not altered his prescribing practices disproves Plaintiff's contention that its earlier "omission" caused his injury.

V. THE EVIDENCE ESTABLISHES THAT PLAINTIFF'S STATE LAW CLAIMS CHALLENGING THE ADEQUACY OF TESTIM'S LABELING ARE PREEMPTED BY FEDERAL LAW

Auxilium renews its argument, set forth in detail in its motion for summary judgment on preemption grounds, ECF No. 38, that federal law preempts Plaintiff's state law claims. State law claims based on alleged deficiencies in drug labeling are preempted if the manufacturer provides "clear evidence that the FDA would not have approved a change" to the label of a prescription drug. *Wyeth v. Levine*, 555 U.S. 555, 571 (2009). *See also In re Testosterone Replacement Therapy Prods. Liab. Litig.*, No. 14 C 1748, 2017 WL 1833173, at *7 (N.D. Ill. May 8, 2017).

The "clear evidence" standard is met here. Plaintiff's case in chief does not controvert the fact that FDA concluded on multiple occasions—before and after Plaintiff took Testim—that there was insufficient medical evidence supporting an association between testosterone therapy and an increased risk of adverse cardiovascular outcomes that would require a change to Testim's label. Exs. 3127, 3123. Moreover, the agency rejected specific proposals to add a cardiovascular risk warning to Testim's label, demonstrating that an attempt by Auxilium to add such a warning would have been futile. *See Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 873 (7th Cir. 2010) (FDA's refusal to require warning satisfies *Wyeth*'s "clear evidence"

standard). In June 2013, FDA rejected Auxilium's proposal to include a broad warning on Testim's label about the risk of "thrombosis and embolic events" that would have encompassed Plaintiffs' desired warning regarding cardiovascular risk, including heart attack. Exs. 3113, 3114, 3116. Furthermore, on July 16, 2014, just thirteen days after Plaintiff stopped using Testim, FDA denied a citizen petition to add a warning to the label of testosterone products (including Testim) advising of the increased risks of heart attacks and other cardiovascular dangers. Nothing indicates that FDA would have reached a different conclusion had Auxilium itself requested the change. *Cf. Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1102 (manufacturer requests for label changes receive no greater deference than citizen petitions).

VI. PLAINTIFF FAILED TO PRESENT SUFFICIENT EVIDENCE TO JUSTIFY AN AWARD OF PUNITIVE DAMAGES

Under Pennsylvania law, "[p]unitive damages may be awarded for conduct that is outrageous, because of the defendant's evil motive or his reckless indifference to the rights of others. As the name suggests, punitive damages are penal in nature and are proper only in cases where the defendant's actions are so outrageous as to demonstrate willful, wanton or reckless conduct." *Hutchison ex rel. Hutchison v. Luddy*, 870 A.2d 766, 770 (Pa. 2005) (internal quotation marks and citations omitted).

"Conduct is considered outrageous where a defendant's action shows either an evil motive or reckless indifference to the rights of others. Reckless indifference to the interests of others, or as it is sometimes referred to, wanton misconduct, means that the actor has intentionally done an act of an unreasonable character, in disregard of a risk known to him or so obvious that he must be taken to have been aware of it, and so great as to make it highly probable that harm would follow." *B.G. Balmer & Co., Inc. v. Frank Crystal & Co., Inc.*, 148 A.3d 454, 463 (Pa. Super. Ct. 2016) (citation omitted). "Thus, in Pennsylvania, a punitive damages claim

must be supported by evidence sufficient to establish that (1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in conscious disregard of that risk." *Hutchinson*, 870 A.2d at 772.

Plaintiff's evidence fails to satisfy this stringent standard. Plaintiff's own expert conceded that FDA has never stated that there is an actual risk of heart disease associated with testosterone use, and that Testim's current label says only that the evidence of a "possible" risk is "inconclusive." Tr. 557:1-16 (Ardehali). Dr. Ardehali acknowledged the existence of numerous peer-reviewed studies contradicting his opinions about the risks of testosterone products, Tr. 541-53, as well as the lack of consensus among the professional medical community and medical associations about whether testosterone replacement therapy can increase cardiovascular risk, Tr. 554:3-555:12; 556:22-25. This necessarily precludes a finding that Auxilium acted in disregard of a "known" or "obvious" risk, and forecloses an award of punitive damages.

At bottom, Plaintiff's claim for punitive damages rests on the bold and unsupported claim that Auxilium engaged in a "mass uncontrolled experiment." Tr. 194:18-20, 207:13-15, 219:15-17. But "speculation cannot be the basis of a jury verdict." *Garrett v. Barnes*, 961 F.2d 629, 634 (7th Cir. 1992). Plaintiff has presented no evidence of an opinion that Auxilium conducted a "mass uncontrolled experiment." Plaintiff's rhetoric is further belied by the evidence that Auxilium complied at every turn with FDA's directives, and that FDA did not see fit to require alterations to Testim's label until 2015. Because the record contains no evidence sufficient to establish that Auxilium engaged in wanton, willful, or reckless conduct, the Court should grant a directed verdict for Auxilium on Plaintiff's claim for punitive damages.

CONCLUSION

For all the foregoing reasons, the Court should enter judgment as a matter of law for Auxilium on all of Plaintiff's claims.

Respectfully submitted,

/s/ Andrew K. Solow

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CERTIFICATE OF SERVICE

I, Andrew K. Solow, hereby certify that on November 14, 2017, the foregoing **Motion Under Rule 50(a) for Judgment as a Matter of Law and Memorandum in Support** was filed via the Court's CM/ECF system, which will automatically serve and send notification of such filing to all registered attorneys of record.

Dated: November 14, 2017

/s/ Andrew K. Solow
Andrew K. Solow