UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	**CASE NO. 1:14-CV-01748** **MDL 2545** **JUDGE MATTHEW F. KENNELLY** **This Document Relates to:** ***Konrad* v. *AbbVie Inc.*,** **Case No. 1:15-cv-00966**

DEFENDANTS' MOTION FOR JUDGMENT AS A MATTER OF LAW PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 50(A), AND MEMORANDUM IN SUPPORT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES & RULES

Defendants AbbVie Inc. and Abbott Laboratories (collectively "AbbVie") respectfully move for judgment as a matter of law under Rule 50(a) of the Federal Rules of Civil Procedure. As set forth below, the evidence presented during Plaintiff Konrad's case was insufficient to allow a reasonable jury to find in his favor on any of his claims.

LEGAL STANDARD

"If a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue, the court may . . . grant a motion for judgment as a matter of law." Fed. R. Civ. P. 50(a). To avoid the entry of a judgment as a matter of law, there must be "'substantial affirmative evidence'" that would support a jury verdict in the non-movant's favor. *See, e.g., Florek* v. *Vill. of Mundelein, Ill.*, 649 F.3d 594, 601 (7th Cir. 2011) (quoting *Heft* v. *Moore*, 351 F.3d 278, 284 (7th Cir. 2003)). As set forth below, Plaintiff failed to present substantial affirmative evidence that would allow a reasonable jury to conclude that he met the elements of any of his claims.

A. PLAINTIFF FAILED TO PRESENT SUBSTANTIAL EVIDENCE THAT ANY ADDITIONAL WARNING WOULD HAVE PREVENTED HIS HEART ATTACK

Plaintiff's negligence and strict liability claims are predicated on a failure-to-warn theory. That theory required him to prove that: "(1) the warnings at issue were defective; (2) the defective warning made the product unreasonably dangerous; and (3) the inadequate labeling proximately caused the claimed injury." *Moore* v. *C.R. Bard, Inc.*, 217 F. Supp. 3d 990, 995 (E.D. Tenn. 2016); *Barnes* v. *Kerr Corp.*, 418 F.3d 583, 590 (6th Cir. 2005).

1. Plaintiff Did Not Overcome The Statutory Presumption That AndroGel Is Not "Unreasonably Dangerous"

All of Plaintiff's claims are governed by the Tennessee Products Liability Act ("TPLA"). *See, e.g.*, T.C.A. § 29-28-102(6); *Strayhorn* v. *Wyeth Pharm., Inc.*, 737 F.3d 378, 401 (6th Cir.

2013) (TPLA governs "regardless of the legal theory advanced"); *Privette* v. *CSX Transp., Inc.*, 79 F. App'x 879, 890 (6th Cir. 2003) (TPLA "exclusive and preemptive"). With respect to his failure-to-warn claim, the TPLA requires Plaintiff to prove that AndroGel was "defective" or "unreasonably dangerous." *See* T.C.A. § 29-28-105(a).

Plaintiff did not attempt to prove that AndroGel was "defective," which would have required evidence or testimony that AndroGel was "unsafe for normal or anticipatable handling and consumption." T.C.A. § 29-28-102(2). Plaintiff chose not to pursue a "defect" theory at trial—he presented no evidence or testimony that AndroGel was unsafe for normal consumption. Instead, Plaintiff's failure-to-warn claim rests solely on his contention that AndroGel was "unreasonably dangerous." The TPLA defines a product as "unreasonably dangerous" if it (A) 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," or (B) "would not be put on the market by a reasonably prudent manufacturer or seller." T.C.A. § 29-28-102(8); *Moore*, 217 F. Supp. at 994. The determination of whether a product is "unreasonably dangerous" must consider customary manufacturing practices "by other manufacturers … of similar products." T.C.A. § 29-28-105(b).

The TPLA establishes a rebuttable presumption that a product is ***not*** unreasonably dangerous if the manufacturer complied with applicable regulations. *See* T.C.A. § 29-28-104(a); *Frausto* v. *Cooper Tire & Rubber Co.*, 2014 WL 581724, at *2 (M.D. Tenn. Feb. 13, 2014). That presumption "was designed to give refuge to the manufacturer who is operating in good faith and [in] compliance of what the law requires him to do." *Flax* v. *DaimlerChrysler Corp.*, 272 S.W.3d 521, 536 (Tenn. 2008) (citation and internal quotation marks omitted).

Here, AbbVie is entitled to the presumption because it complied with all applicable FDA regulations: the FDA approved AndroGel as safe and effective (Tr. 713:11–21; 715:2–6); the

FDA approved the AndroGel labeling at issue (Tr. 715:2–6; 880:19–21); and the FDA reviewed and approved AbbVie's advertisements for AndroGel (*see, e.g.*, Tr. 809:25–811:7; 865:13–16; 867:11–13; 869:2–10; 889:22–890:1). This evidence is not contested. Dr. Kessler declined to opine that any of AbbVie's conduct violated FDA regulations, and no other qualified expert testified otherwise. (Tr. 798:15–23; 799:12–20). AbbVie is thus entitled to the presumption that AndroGel is not unreasonably dangerous. *See, e.g.*, *Goins* v. *Clorox Co.*, 926 F.2d 559, 562 (6th Cir. 1991) (finding manufacturers entitled to rebuttable presumption where there was uncontroverted testimony that, *inter alia*, "the warning . . . had been approved by the EPA, and was in full compliance with all applicable federal standards"); *Gentry* v. *Hershey Co.*, 687 F. Supp. 2d 711, 718 (M.D. Tenn. 2010) (finding presumption applicable where there was "no evidence that Hershey failed to comply with" regulations).

Plaintiff failed to rebut the TPLA's presumption. Plaintiff testified to his own expectations, but presented no evidence or testimony regarding "ordinary" consumer expectations based on common knowledge, nor any evidence or testimony asserting that a prudent manufacturer would not have "put [AndroGel] on the market," nor that AbbVie's manufacturing or labeling for AndroGel differed from those of any other TRT manufacturer. Dr. Ardehali admitted that his opinions about the adequacy of the AndroGel labeling warning are directly at odds with the FDA's. (Tr. 1484:13–22 ("I disagree with the FDA.").) And although Dr. Kessler opined that a prudent manufacturer would not have *marketed* AndroGel as AbbVie did (Tr. 740:20–741:3; 745:25–746:9; 790:21–24), he offered no opinion whatsoever that the FDA-approved warnings in the AndroGel labeling were inadequate. Dr. Pence admitted that the AndroGel label contained warnings about heart attacks. (Tr. 2442:15–2444:2.) Moreover, the uncontroverted evidence demonstrates that AndroGel had essentially the same labeling and chemical composition as the entire class of TRT drugs. (Tr. 721:8–14; 722:16–21; 756:16–22.)

Judgment as a matter of law is accordingly warranted on Plaintiff's strict liability and negligence claims. *See, e.g.*, *Johnson* v. *Volvo Truck Corp.*, 2010 WL 55317, at *6 (E.D. Tenn. Jan. 4, 2010) (granting summary judgment and finding no expert "can confirm that a specific defect or unreasonably dangerous condition existed"); *Kibbler* v. *Richards Med. Co.*, 1992 WL 233027, at *3 (Tenn. Ct. App. Sept. 23, 1992) ("In light of the absence of expert testimony that the product was either defective or unreasonably dangerous, the trial court properly directed a verdict for defendant.").

2. Plaintiff Failed to Present Substantial Evidence That Any Lack of Warning Caused His Heart Attack

Even if Plaintiff had demonstrated that AndroGel's labeling rendered it "unreasonably dangerous," he failed to present substantial evidence that any additional warning would have prevented his heart attack.

Tennessee recognizes the "independent knowledge" defense, which provides that a plaintiff cannot prevail on a failure-to-warn theory if his physician was independently aware of the risk at issue, irrespective of whether the defendant warned of it. *See, e.g.*, *Harden* v. *Danek Med., Inc.*, 985 S.W.2d 449, 451 (Tenn. Ct. App. 1998) (observing that failure to warn claim pertains to risks "not otherwise known to the physician" and that "the learned intermediary doctrine may shield a manufacturer from liability when the physician was independently aware of the risks"); *Collins* v. *Danek Med., Inc.*, 1999 WL 644813, at *9 (W.D. Tenn. Mar. 23, 1999) ("[T]he product manufacturer will not be liable if the plaintiff's physician independently knew of the risks . . . . [here] it is clear that Dr. Wood was independently aware[.]"); *King* v. *Danek Med., Inc.*, 37 S.W.3d 429, 453 (Tenn. Ct. App. 2000) ("[Plaintiffs] failed to establish that the defendants' alleged failure to warn was the proximate cause . . . . [Their] physicians were well experienced in the use of internal fixation devices . . . . [and] relied upon their own knowledge

and judgment."); *Ball* v. *Mallinkrodt Chem. Works*, 381 S.W.2d 563, 568 (Tenn. Ct. App. 1964) (affirming refusal to submit failure-to-warn claim to jury because the doctor was aware of the product's toxicity and had relied on his own experience in choosing to use it).

Here, Dr. Overby admits that when he prescribed AndroGel for Plaintiff, he already was aware of possible cardiovascular concerns associated with AndroGel. He testified that at the time of Plaintiff's prescription, it was "routine" for him to monitor patients' blood counts for increased risk for serum viscosity, and he explained why: "***And the reason that I do that, though, is myocardial infarction, stroke***. ***Even at that time, raising the red blood cell mass was known to be a risk with testosterone therapy.***" (Overby 175:1–10.) Consistent with that, Dr. Overby testified that even "back then" it was his "typical practice" to "check the complete blood count to make sure [the patients] were not having an increase [in] red blood cell mass" when he was measuring testosterone levels. (*Id.* 96:10–19.)

Furthermore, no reasonable jury could find that Dr. Overby was unaware of TRT's possible cardiovascular risk at the time of Plaintiff's prescription given that Dr. Overby admits he may have even discussed such risks with Plaintiff at the time—something that would have been *impossible* if Dr. Overby had been unaware of the alleged risk at issue. When asked to confirm that he "could not have" had such a discussion with Plaintiff in 2010, Dr. Overby responded: "We could have had the discussion . . . . [A]t that point for sure, I was discussing the risk of increased hematopoiesis and release of red blood cells . . . . So indirectly ***there would be always the risk for heart attack <u>even before the FDA warning</u>*** of that . . . ***that's something we were always following***." (*Id.* 138:18–139:17 (emphases added); *id.* 197:8–17 (providing substantially the same answer to the same question); *see also id.* 1626:22–24 (Plaintiff acknowledging that he and Dr. Overby may have discussed risks).)

Under the "independent knowledge" doctrine, Dr. Overby's admissions that he was aware of "myocardial infarction" risks and elevated red blood cell counts associated with TRT "[e]ven at that time" of Plaintiff's prescription are fatal to Plaintiff's failure-to-warn claim.[1] *See Harden*, 985 S.W.2d at 451; *Collins*, 1999 WL 644813, at *9; *King*, 37 S.W.3d at 453; *Ball*, 381 S.W.2d at 568.

Plaintiff's admissions likewise make clear that he would not have read (and therefore could not have heeded) any additional warning of risk in the AndroGel labeling. He testified that although he received the AndroGel labeling, he did not read it (Tr. 1592:22–1593:3; 1623:9–22 (Q: "Did you read the label, Mr. Konrad?" . . . . A: "I did not read the entire label document." Q: "You didn't read any of the label, did you?" A: "Not that I can recall." Q: "So no matter what the label said, you wouldn't have seen it, right?" A: "I saw it. ***I didn't read it***.") (emphasis added).) He stated it was not his "practice" to "read the risks information in the label or the brochure of the medications [he was] taking," and he instead "go[es] to the doctor" for that information. (*See* Tr. 1626:13–18.) He also admitted that he took AndroGel despite it warning of an increased risk of prostate cancer, even though he has a history of prostate cancer in his family and his father passed away from the disease. (Tr. 1624:11–1625:5; 1639:18–20.)[2]

[1] Moreover, that Dr. Overby prescribed Plaintiff AndroGel despite its stated prostate cancer risk and with the knowledge of Plaintiff's family history of prostate cancer further demonstrates that he would not have declined to prescribe AndroGel for Plaintiff had it included language regarding uncertain cardiovascular risk. (*See* Tr. 1639:25–1640:2.) To this day, even after the label now warns of a possible cardiovascular risk, Dr. Overby continues to prescribe TRTs for his patients. (Overby 113:9–12; 125:11–14.) He essentially admitted that from his standpoint, the new warning makes little difference in his prescribing assessments. (*Id.* 131:7–20 ("It is not necessarily that I am fearful of using the prescription. I've always screened the patient appropriately.").)

[2] Plaintiff's "failure to test" theory is subsumed under his warning claim, which fails for the reasons discussed above. *Rodriguez* v. *Stryker Corp.*, 2011 WL 31462, at *9 (M.D. Tenn. Jan. 5, 2011) ("[T]here is no broadly recognized 'duty to test' in Tennessee."), *aff'd*, 680 F.3d 568, 574 (6th Cir. 2012) ("This argument collapses into the failure-to-warn claim.").

B. PLAINTIFF FAILED TO PRESENT SUBSTANTIAL EVIDENCE THAT ABBVIE MADE A FALSE STATEMENT OF MATERIAL FACT, OR THAT ANY SUCH STATEMENT CAUSED HIS HEART ATTACK

1. No False Statement

Plaintiff's misrepresentation concerning a product claim and intentional misrepresentation claim require Plaintiff to prove, among other things, that AbbVie made a false statement of material fact. *See, e.g.*, *Ford Motor Co.* v. *Lonon*, 398 S.W.2d 240, 247 (1966) (citing Restatement (2d) of Torts § 402B, Cmt. (g)), *abrogated on other grounds*, 821 S.W.2d 925 (Tenn. 1991); T.P.I.-Civil 10.18, Cmt.; *Hodge* v. *Craig*, 382 S.W.3d 325, 343 (Tenn. 2012); *Walker* v. *Sunrise Pontiac-GMC Truck, Inc.*, 249 S.W.3d 301, 311 (Tenn. 2008); *Kelly* v. *Nordyne, Inc.*, 2008 WL 11342578, at *5 (E.D. Tenn. Sept. 8, 2008).

Throughout the entirety of his direct and cross examinations, Dr. Kessler did not identify any false statement of material fact in AbbVie's advertising. This is a dispositive failure of proof. *See, e.g.*, *In re Fosamax Prod. Liab. Litig.*, 924 F. Supp. 2d 477, 489 (S.D.N.Y. 2013) ("Plaintiff has failed to show that Merck's statement that Fosamax is 'safe and effective for the treatment of osteoporosis and Paget's disease' is false.").

To be sure, Dr. Kessler opined "[t]hat it would be false or misleading to market and promote AndroGel for these non-approved indications because it would ***imply*** that safety and efficacy were established," and that "the marketing for symptoms . . . was false and misleading because it ***implies*** that the drug is safe and effective for those uses." (Tr. 766:8–11; 791:8–12) (emphases added). An implication, however, does not satisfy the requirement of a false representation. *See, e.g.*, *Ritter* v. *Custom Chemicides, Inc.*, 912 S.W.2d 128, 131 (Tenn. 1995) ("There is no . . . assertion that information supplied was false . . . . Advertisements and even direct statements that the product was 'effective' does not constitute proof that the defendant supplied false information."); *Mutuelle Generale Francaise Vie* v. *Life Assur. Co. of*

Pennsylvania, 688 F. Supp. 386, 395 (N.D. Ill. 1988) (in context of fraud claim, observing that plaintiff "provided no case support for such 'implicit' representations being actionable in tort"); *Hollymatic Corp.* v. *Holly Sys., Inc.*, 620 F. Supp. 1366, 1370 (N.D. Ill. 1985) ("[W]e hold that the threshold for bringing a fraud action under the scheme or device exception is not met where the claimant alleges no more than an implied promise or representation as the predicate for fraud."); *Yanase* v. *Auto. Club of So. Cal.*, 260 Cal. Rptr. 513, 516 (Cal. Ct. App. 1989) (in evaluating a negligent misrepresentation tort requiring a "positive assertion," court found "the doctrine does not apply to implied representations").[3] Because AbbVie never stated, in any of its advertisements, that AndroGel had been approved as safe and effective for age-related hypogonadism, symptoms of aging, and/or andropause—and because Plaintiff failed to identify any such statements—AbbVie did not make any false representations.

Even if an implication were actionable in a misrepresentation tort, Dr. Kessler admitted that the "Low T" and "low testosterone" language in the brochure that Plaintiff received was not misleading or problematic (Tr. 883:8–13); that the description of the AndroGel indication in the brochure Plaintiff received was not misleading or problematic (Tr. 881:2–10); that the descriptions of symptoms that Dr. Kessler calls "implied benefits" in the "Shadow" ad that Plaintiff saw were also found in the FDA-approved labeling and Medication Guide (Tr. 814:14–815:6; 816:15–817:16; 880:18–21); and that the FDA-approved Medication Guide also stated that "AndroGel is used to treat adults who have low or no testosterone" (Tr. 877:2–6).

[3] This distinction has been routinely recognized in the context of statutes requiring a "false statement." *See, e.g.*, *United States* v. *Miller*, 734 F.3d 530, 543 (6th Cir. 2013) (in prosecution requiring "false statement" to bank, court observed that statute "'does not generally cover misleading statements'" nor "implied representations"); *United States* v. *Krilich*, 159 F.3d 1020, 1029 (7th Cir. 1998) (observing that under the Supreme Court precedent, "a misleading implication differs from a false statement," and finding that defendant did not benefit from principle because case involved "literally false statements").

Dr. Kessler further admitted that the FDA reviewed ads that said "some men have low testosterone" (Tr. 811:8–23); ads referring to "Low T" (Tr. 865:21–866:22); and ads containing language regarding symptoms (Tr. 865:21–866:22 (FDA reviewed ad that said "losing energy," "moody," and "all the symptoms," yet only provided unrelated comments).) Dr. Kessler further admitted that overall, the FDA reviewed and never criticized AbbVie's branded ads (*see, e.g.*, 890:7–12; 897:4–9); the FDA never commenced an enforcement action against AbbVie with respect to ads (Tr. 900:3–17); and the FDA never sent AbbVie a warning letter with respect to unbranded ads (Tr. 893:4–7; *see also* 828:23–829:2 (Kessler acknowledging the "low T shadow ad" was "well known to the FDA")).

2. No Reliance on Any Misrepresentation

Had Plaintiff identified a false representation of a material fact, he would still need to demonstrate that he justifiably relied on the representation and that such reliance caused his heart attack. *See* Tr. 154:8–25; 155:11–156:1; T.P.I.-Civil 8.36, 10.18; *Ford Motor*, 398 S.W.2d at 250; *Holt* v. *Am. Progressive Life Ins. Co.*, 731 S.W.2d 923, 927 (Tenn. Ct. App. 1987) (damage must result "from a justifiable reliance"); *Sec. Fed. Sav. & Loan Ass'n of Nashville* v. *Riviera, Ltd.*, 856 S.W.2d 709, 712–13 (Tenn. Ct. App. 1992) (finding reliance was not reasonable where individual relied on representations regarding property value even though he was well informed, sophisticated, and "actually warned"). He did not do so.

For his part, Mr. Konrad admits that he did not ask his doctor about AndroGel specifically and indeed, that he never knew anything about or even heard of AndroGel before it was prescribed for him. (Tr. 1616:7–13.) Mr. Konrad has thus necessarily conceded that he did not rely on any company representations about AndroGel whatsoever. With respect to unbranded materials, Mr. Konrad admits that he has no memory of ever filling out an ADAM questionnaire (Tr. 1616:14–1619:19), and that he has never visited the isitlowt.com website (Tr.

1619:20–23). Mr. Konrad does claim that he was influenced by an unbranded "shadow ad," but as discussed above, his expert conceded that the "Low T" language and supposed "implied benefits" were included in materials reviewed and approved by the FDA, and thus they were neither false nor misleading. *Supra* pp. 8–9. Mr. Konrad admits that he relied on his physician—not AbbVie advertisements—to start taking AndroGel. (Tr. 1602:25–1603:4 (Q: "And you trusted Dr. Overby?" A: "Yes, I did." Q: "[Y]ou trusted him to weigh the risks and benefits of medications before prescribing them to you, right?" A: "Yes."); 1587:25–1588:16 ("[Dr. Overby] recommended that we take a blood test and to test my testosterone level . . . . I believe [he performed] a CT scan and a vein scan, kind of like an echocardiogram, but also did like an ultrasound . . . . [He later] told me that I had low T, and he gave me a prescription for AndroGel."); Tr. 1589:2–6 ("He said that I had low testosterone reading . . . . He gave me the pamphlet.").) Finally, Plaintiff does not recall Dr. Overby ever telling him that he had age-related hypogonadism, which further undermines any claim that he relied on purported representations regarding age-related hypogonadism. (Tr. 1622:25–1623:8; *see also* Overby Tr. 172:8–19 (Dr. Overby diagnosed Plaintiff with secondary hypogonadism); *id.* 172:20–173:1 (Dr. Overby testifying he believed Plaintiff's secondary hypogonadism was manifestation of metabolic syndrome).)

Plaintiff also failed to present substantial evidence that Dr. Overby relied on any misrepresentation made by AbbVie. Quite the opposite, Dr. Overby's admissions make clear that he made an independent medical judgment and was not swayed by any marketing materials, branded or unbranded:

- He testified that an AndroGel sales representative visited his office every other month at the time of Plaintiff's prescription, and yet he does not recall "anything" about their presentations. (Overby 117:14–18.)

- He is unfamiliar with any AndroGel marketing campaign. (*Id.* 120:12–16; 120:24–121:2 ("I don't watch TV . . . I don't see the commercials.").)
- He did not receive "questionnaires" in 2010. (*Id.* 122:18–123:6.)
- He already had ample experience prescribing TRTs. (*Id.* 85:22–86:2 (Q. "How often did you prescribe testosterone replacement therapy, to the best of your recollection?" A. "I wouldn't say daily, but I would say three or four times a week."); 86:4–10 (Q. "How long have you been prescribing [TRT]?" "A. For 16 years, since 2000 . . . since 1997, as a resident.").)
- He relied on his own independent judgment and experience to prescribe AndroGel for Plaintiff, after a thorough workup. (*See id.* 103:4–9 (Q. "[Y]ou would use [prescribing data] in counseling your patients as to . . . the risks and benefits of the drug?" A. "In addition to my experience clinically, yes."); 131:20–24 ("As far as Mr. Konrad is concerned, ***I don't think you could have a more clear workup*** as he had had . . . as far as screening in the workup.") (emphasis added); 136:20–137:4 (Q. "Prior to prescribing AndroGel, you performed what you determined were the appropriate blood tests first. Correct?" A. "Correct." Q. "And was it your medical opinion at the time that Mr. Konrad's testosterone was in a range where you felt it was proper to prescribe AndroGel?" A. "Yes."); 156:20–157:1 (Q. "Have you ever made . . . a decision to prescribe a medication based entirely on the recommendations of a pharmaceutical representative or information that you obtained from a pharmaceutical company?" A. "No."); 168:17–169:24 (Q. "[D]id you make a professional judgment at that time about whether or not it was a good treatment option for him to go on AndroGel?" A. "I did.").)
- He felt more comfortable prescribing AndroGel to Plaintiff than he did to most patients, even today. (*Id.* 173:2–174:5.)

- Dr. Overby admitted that he was not motivated by any misconception about age-related hypogonadism by stating that he understood patients should not necessarily be treated for age-related declines in testosterone. (*Id.* 91:1–4 ("And you do have to counsel the patient. You are going to expect some change with age, and you don't necessarily need to treat something that is just a number."); *see also id.* 199:21–200:4 (expressing understanding that patients should not be treated with testosterone just because they are getting older).)

Plaintiff failed to present substantial evidence of reliance, and accordingly AbbVie is entitled to judgment as a matter of law on Plaintiff's misrepresentation claims. *See, e.g.*, *In re Neurontin Mktg., Sales Practices & Prod. Liab. Litig.*, 618 F. Supp. 2d 96, 112 (D. Mass. 2009) (dismissing "all fraud claims alleging affirmative misrepresentations or a suppression of information as part of a national marketing campaign because there is no allegation of reliance on specific statements or misrepresentations").

3. No Fraudulent Concealment

Plaintiff also cannot prevail under a misrepresentation theory framed as fraudulent concealment. First, AbbVie maintains that Plaintiff should not be able to proceed under three separate, duplicative misrepresentation claims, all of which are subsumed under the TPLA.[4] Second, even considering the concealment claim in isolation, under Tennessee law "[t]he duty to

[4] The TPLA is the exclusive remedy for products liability claims in Tennessee, and accordingly, Plaintiff only has a single cause of action under that statute. *See, e.g.*, *Strayhorn*, 737 F.3d at 401; *Privette*, 79 F. App'x at 890; *Meadow* v. *Nibco, Inc.*, 2016 WL 2986350, at *1–2 (M.D. Tenn. May 24, 2016) (dismissing "various theories" and requiring "single TPLA claim"); *Adkins* v. *Nestle Purina PetCare Co.*, 973 F. Supp. 2d 905, 918 (N.D. Ill. 2013) (dismissing common law product liability claims because the TPLA "is the exclusive avenue" under Tennessee law); *Rural Developments, LLC* v. *Tucker*, 2009 WL 112541, at *9 (Tenn. Ct. App. Jan. 14, 2009) (holding that two causes of action based on "the same lynchpin theory of liability" were "duplicitous" [sic] and affirming dismissal of one) (citing 61A Am. Jur. 2d Pleading § 53); *Daly* v. *Wacker-Chemie AG*, 2014 WL 3810595, at *11 (E.D. Tenn. Aug. 1, 2014) (dismissing "duplicative" fraudulent concealment claim based on "the same facts" underlying misrepresentation claim). AbbVie respectfully submits that it would be erroneous and prejudicial to ask the jurors to decide three separate claims for misrepresentation, all of which are subsumed by the TPLA.

disclose arises in three distinct circumstances: (1) where there is a previous definite fiduciary relation between the parties, (2) where it appears one or each of the parties to the contract expressly reposes a trust and confidence in the other, and (3) where the contract or transaction is intrinsically fiduciary and calls for perfect good faith." *Shah* v. *Racetrac Petroleum Co.*, 338 F.3d 557, 571 (6th Cir. 2003) (quoting *Domestic Sewing Mach. Co.* v. *Jackson*, 83 Tenn. 418, 425 (1885) (internal quotation marks omitted); *Huddleston* v. *Harper*, 2015 WL 3964791, at *4–5 (Tenn. Ct. App. June 30, 2015).

None of those three enumerated circumstances are presented: there is no fiduciary, contractual, nor confidential relationship between AbbVie and Plaintiff. Thus, as a matter of law, the fraudulent concealment claim is not viable. *See, e.g.*, *Mills* v. *Bluecross Blueshield of Tennessee*, 2017 WL 78488, at *5 (E.D. Tenn. Jan. 9, 2017) (no viable fraudulent concealment claim where none of three enumerated scenarios present); *Morgan* v. *Brush Wellman, Inc.*, 165 F. Supp. 2d 704, 721–22 (E.D. Tenn. 2001) (holding in context of product liability case that plaintiffs could not pursue fraudulent concealment claim against chemical manufacturer because none of the *Domestic Sewing* circumstances applied); *McConkey* v. *McGhan Med. Corp.*, 144 F. Supp. 2d 958, 965–66 (E.D. Tenn. 2000) (in product liability action brought by patients against implant manufacturer, finding fraudulent concealment claim not viable based on absence of fiduciary or contractual relationship).[5]

If the theory were viable, Plaintiff would still have to demonstrate that AbbVie actively concealed a material fact and did so with the intention of deceiving Plaintiff. *See* Tr. 156:8–21;

[5] Some courts have predicted that the Tennessee Supreme Court would expand fraudulent concealment claims to the product liability context. *See, e.g.*, *Smith* v. *Pfizer Inc.*, 688 F. Supp. 2d 735, 753 (M.D. Tenn. 2010). By contrast, when the Sixth Circuit evaluated whether to expand fraudulent concealment beyond the three circumstances set forth in *Domestic Sewing*, it declined: "Despite a few outliers, federal courts considering fraudulent concealment under Tennessee law have made clear that *Domestic Sewing* is the governing law . . . . We decline to anticipate that the Tennessee Supreme Court would extend the *Simmons* and *Lonning* cases to the context of a franchise dispute." *Shah*, 338 F.3d at 571–72, n.9.

Leeper v. *Cook*, 688 S.W.2d 94, 96 (Tenn. Ct. App. 1985) ("[T]here must be something more than mere silence, or a mere failure to disclose known facts. There must be a concealment, and the silence must amount to fraud.") (quoting *Patten* v. *Standard Oil Co.*, 165 Tenn. 438, 443, 55 S.W.2d 759 (Tenn. 1933)). Plaintiff did not present substantial affirmative evidence of active concealment of information with an intent to deceive. Dr. Kessler specifically testified that he was *not* opining on AbbVie's subjective intent, and Plaintiff failed to present any qualified testimony that would satisfy the intent requirement. (Tr. 801:8–12.).

The fraudulent concealment claim also fails for the same reliance and causation issues discussed with respect to Plaintiff's other misrepresentation theories. *See Bearden* v. *Honeywell Int'l, Inc.*, 2010 WL 1223936, at *5 (M.D. Tenn. Mar. 24, 2010) (dismissing fraudulent concealment claim where plaintiff failed to point to particular facts indicating he read and relied upon materials with purported omissions).

C. PLAINTIFF FAILED TO PRESENT SUBSTANTIAL EVIDENCE THAT PLAINTIFF WOULD NOT HAVE HAD A HEART ATTACK BUT-FOR ANDROGEL

Under the TPLA, an "essential element" of all of Plaintiff's claims is that AndroGel was a but-for and proximate cause of his heart attack. T.C.A. § 29-28-105(a); *Sanford* v. *L'Oreal USA S/D, Inc.*, 2017 WL 2376922, at *2 (M.D. Tenn. June 1, 2017); *Strayhorn*, 737 F.3d at 401; *Sigler* v. *Am. Honda Motor Co.*, 532 F.3d 469, 483 (6th Cir. 2008); Tr. 156:23–157:1; *Moore*, 217 F. Supp. 3d at 994–95.

Plaintiff's specific causation expert, Dr. Cuculich, failed to opine that Plaintiff's heart attack would not have occurred but-for his use of AndroGel. *Cf.* Tr. 165:2–3.[6] Indeed, Plaintiff

[6] Dr. Cuculich instead opined about whether AndroGel was a "substantial factor" in bringing about Plaintiff's heart attack, which only goes toward the legal cause element: "AbbVie's product or conduct was a legal cause of Mr. Konrad's heart attack if it was a substantial factor in bringing about the heart attack and the heart attack could have been reasonably foreseen or anticipated by a person of ordinary

failed to present any expert testimony whatsoever asserting that AndroGel was the but-for cause of his heart attack. Plaintiff has accordingly failed to prove the essential element that "without [AndroGel], his heart attack ***would not have occurred***." Tr. 157:2–5 (emphasis added)); T.P.I.-Civil 3.21; *Hale* v. *Ostrow*, 166 S.W.3d 713, 718 (Tenn. 2005) ("[W]e must ask whether the plaintiff's injury would have happened '**but for**' the defendants' act."). Dr. Cuculich also admits that a critical aspect of his opinion—the size of Plaintiff's plaque—is an assumption that he made. (Tr. 1782:10–14; *see also Harrison* v. *Addington*, 955 N.E.2d 700 (Ill. App. Ct. 2011) (mere "speculation" or "conjecture" cannot create a fact issue).) Finally, Dr. Cuculich admits that based on Plaintiff's prescription supply, it would have been physically impossible for Plaintiff to have taken the full prescribed dose of AndroGel consistently for the entire six-week period he claims to have used it. (Tr. 1800:13–1802:17; *see also* Tr. 1627:4–22 (Plaintiff failing to explain same issue).) That is a dispositive admission because Plaintiff presented no evidence whatsoever that AndroGel can cause heart attacks in patients who, like Plaintiff, used AndroGel intermittently.

Plaintiff's general causation expert, Dr. Ardehali, admits that there is no clinical or epidemiological study demonstrating an increased risk of cardiovascular events for men under 60 (Tr. 1543:19–1544:4); that, in fact, the only study that specifically looked at people under 55 found no statistically significant association (Tr. 1543:12–21); and that there is no study examining a two-month duration of testosterone use (Tr. 1551:15–18).

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intelligence and care." Tr. 157:8–12; T.P.I.-Civil 3.22; *McClenahan* v. *Cooley*, 806 S.W.2d 767, 775 (Tenn. 1991).

D. PLAINTIFF FAILED TO PRESENT SUBSTANTIAL EVIDENCE IN SUPPORT OF COMPENSATORY OR PUNITIVE DAMAGES

1. Compensatory Damages

Plaintiff has the burden of proving compensatory damages. *Cone* v. *Hankook Tire Co., Ltd.*, 2017 WL 401795, at *2 (W.D. Tenn. Jan. 25, 2017) (citing *Inman* v. *Union Planters Nat'l Bank*, 634 S.W.2d 270, 272 (Tenn. Ct. App. 1982)). Tennessee courts require an ***expert opinion*** that the amount of claimed medical expenses is "reasonable and necessary." *Stricklan* v. *Patterson*, 2008 WL 4791485, at *4 (Tenn. Ct. App. Nov. 4, 2008) ("An injured plaintiff can recover for reasonable and necessary medical expenses associated with the treatment of the injury. However, in order to recover for these expenses, expert opinion must be offered regarding the reasonableness and necessity of the physician's services and charges."); *Borner* v. *Autry*, 284 S.W.3d 216, 218 (Tenn. 2009) ("In all but the most obvious and routine cases, plaintiffs must present competent expert testimony to meet this burden of proof.").

Although Dr. Cuculich testified that he believed Plaintiff's "treatment" was reasonable and necessary (Tr. 1666:21–1667:1), Plaintiff presented no expert testimony that the ***amount*** of his medical ***expenses*** was reasonable and necessary, and accordingly he has failed to satisfy his burden of proof. *See, e.g.*, *Stricklan*, 2008 WL 4791485, at *4 ("[T]o recover for these expenses, expert opinion must be offered regarding the reasonableness and necessity of the physician's services ***and charges***"); *Jackson* v. *Sunkenberg*, 2000 WL 66045, at *2 (Tenn. Ct. App. Jan. 27, 2000) ("plaintiff must present expert medical testimony regarding the ***reasonableness and necessity of those charges***") (emphases added). Even where the necessity of treatment is not disputed, that does not entitle a plaintiff to unlimited medical expenses; instead, he must provide expert testimony that the particular expenses he seeks were reasonable. *See, e.g.*, *Stricklan*, 2008 WL 4791485 at *4 (upholding award where expert "went through the bills … and discussed in

detail the expenses"). Because Plaintiff failed to offer expert testimony justifying the specific expenses for which he seeks reimbursement, he has failed to meet his burden of proof that those charges were "reasonable and necessary."[7]

2. Punitive Damages

Under Illinois law, punitive damages may be awarded only for conduct "committed with fraud, actual malice, deliberate violence or oppression, or when the defendant acts willfully, or with such gross negligence as to indicate a wanton disregard of the rights of others." *See Loitz* v. *Remington Arms Co.*, 563 N.E.2d 397, 402 (Ill. 1990) (citation omitted); *Home Sav. & Loan Ass'n of Joliet* v. *Schneider*, 483 N.E.2d 1225, 1228 (Ill. 1985) (punitive damages allowed only "where the fraud is gross, or the case presents other extraordinary or exceptional circumstances clearly showing malice and willfulness.").[8] The conduct must involve "some element of outrage similar to that usually found in crime," which is to say conduct done "with an evil motive" or "with reckless indifference to the rights of others." *Loitz*, 563 N.E.2d at 402. Where the evidence establishes only "garden variety fraud," the Seventh Circuit has held that under Illinois law, the question of punitive damages "***is not even submitted to the jury***." *Roboserve, Inc.* v. *Kato Kagaku Co.*, 78 F.3d 266, 276 (7th Cir. 1996). Illinois courts are particularly skeptical of punitive damages in the products liability context. In such actions, the plaintiff must

[7] Without compensatory damages, Plaintiff cannot prevail on any claim. *See, e.g.*, *Strange* v. *Collins*, 2007 WL 1412541, at *2 (C.D. Ill. May 7, 2007) ("[B]ecause damages are an essential element of a tort claim, the finding of zero damages means that plaintiffs failed to meet their burden of proof. The Judgment on the defamation claim must be vacated and an amended judgment must be entered, showing judgment as a matter of law in favor of defendant and against plaintiffs."); *Ira Green, Inc.* v. *Military Sales & Serv. Co.*, 2013 WL 5912525, at *2 (D.R.I. Oct. 16, 2013) (entering judgment in favor of defendant where jury found liability but no damages).

[8] Because this Court ruled that Illinois law governs punitive damages, AbbVie argues this issue under Illinois law. AbbVie maintains that under Illinois conflict-of-law principles, the law of the place of a plaintiff's residence and injury applies—here, Tennessee. *Townsend* v. *Sears, Roebuck & Co.*, 879 N.E.2d 893, 908–09 (Ill. 2007). Tennessee law prohibits punitive damages if a defendant substantially complied with applicable regulations, and imposes a monetary cap. *See* T.C.A. § 29-39-104(a)(5), (e). AbbVie submits these rules should apply.

demonstrate that the defendant acted "with flagrant indifference to the public safety." *Moore* v. *Remington Arms Co.*, 427 N.E.2d 608, 615–18 (Ill. App. Ct. 1981). Plaintiff must show the manufacturer had "knowledge of the unreasonably dangerous condition," and "knowledge or notice that this condition is likely to cause injury." *See Kopczick* v. *Hobart Corp.*, 721 N.E.2d 769, 775–76 (Ill. App. Ct. 1999).

Here, Plaintiff has not presented substantial evidence that AbbVie acted with a "flagrant indifference to the public safety." Plaintiff's case rests upon a still-debated (and dubious) scientific claim that AndroGel increases the risk of heart attack. The very existence of such a debate forecloses a finding that AbbVie flagrantly disregarded a known risk likely to cause injury. *See Fornoff* v. *Parke Davis & Co.*, 105 Ill. App. 3d 681, 693 (1982) (applying Illinois law to find no reckless disregard for safety and noting in part that "[t]he evidence showed that at least two studies questioned the use of pitocin orally" but "[o]ther studies disputed such findings as did all of defendant's experts").[9] "It is not enough that the manufacturer perceive in a product some possible risk." *See, e.g., Mosser* v. *Fruehauf Corp.*, 940 F.2d 77, 85 (4th Cir. 1991) (applying West Virginia law consistent with "the common law as expressed generally by the Restatement"); *Proffer* v. *Six Flags Great Am., Inc.*, 2000 WL 1741924, at *5–7 (N.D. Ill. Nov. 22, 2000) (finding punitive damages unavailable under Illinois law where defendant did not have knowledge of any "obvious" danger). Additionally, AbbVie consistently provided safety information regarding cardiovascular risks to the FDA, and it complied with all applicable safety

[9] *See also Satcher* v. *Honda Motor Co.*, 52 F.3d 1311, 1316 (5th Cir. 1995) (applying Mississippi law and finding no entitlement to punitive damages where, in part, "there is a genuine dispute in the scientific community"); *Berroyer* v. *Hertz*, 672 F.2d 334, 342 (3d Cir. 1982) (applying Virgin Islands law, which has adopted the "common law, as expressed in the restatements," and reversing punitive damages award in light of the "difference of medical opinion" among experts "on the degree of cancer risk"); *see also McKee* v. *Moore*, 648 P.2d 21, 24 (Okla. 1982) (applying Oklahoma law and finding manufacturer's duty to warn turns on what was known or knowable from "research, adverse reaction reports, scientific literature and other available methods").

regulations. This likewise precludes punitive damages, as it is well-settled that "compliance with a statutory standard" typically "bar[s] liability for punitive damages." *See* Prosser and Keeton on Torts, § 36 at 233 n.41 (5th ed. 1984).[10]

Judgment as a matter of law should further be granted on the issue of punitive damages because the evidence that Plaintiff relies upon in support of his claim has no "nexus" to his own heart attack, which means any punitive damages award would be unconstitutional. *See, e.g.*, *Philip Morris USA* v. *Williams*, 549 U.S. 346, 353 (2007) (holding that the "Due Process Clause forbids a State to use a punitive damages award to punish a defendant for injury that it inflicts upon nonparties"); *BMW of N. Am., Inc.* v. *Gore*, 517 U.S. 559, 585 (1996) (noting that punitive damages award should be related "to the actual harm inflicted on the plaintiff"); *State Farm Mut. Auto Ins.* v. *Campbell*, 538 U.S. 408, 422–23 (2003) (due process does not permit courts, in the calculation of punitive damages, to adjudicate the merits of other parties' hypothetical claims against a defendant under the guise of the reprehensibility analysis."). As explored above, Plaintiff admits he never read the AndroGel labeling that he received, that he never even heard of AndroGel when it was prescribed for him, and he does not recall ever being told he had age-related hypogonadism. (*Supra* pp. 9–10; Tr. 1612:1–4; 1623:6–8.) Plaintiff's doctor admits he already was aware of and may have even discussed possible cardiovascular risks associated with

[10] *See, e.g.*, *Satcher* v. *Honda Motor Co.*, 52 F.3d 1311, 1317 (5th Cir. 1995) (vacating punitive damages award for failure to install leg guards in part because "no government or agency thereof has ever required them"); *Richards* v. *Michelin Tire Corp.*, 21 F.3d 1048, 1059 (11th Cir. 1994) (vacating punitive damages award in part because "the record demonstrates that Appellant complied with all requisite Federal Motor Vehicle Safety Standards"); *Nader* v. *Allegheny Airlines, Inc.*, 626 F.2d 1031, 1035 (D.C. Cir. 1980) (setting aside punitive damages award and finding that "[a]n airline may not be condemned as a wanton wrongdoer for conforming to the standards set and the practices approved by the agency charged with the duty of regulating it"); *Taylor* v. *Mooney Aircraft Corp.*, 464 F. Supp. 2d 439, 448 (E.D. Pa. 2006) (granting summary judgment to preclude punitive damages claim against aircraft manufacturer that "complied with all applicable regulations" including "FAA airworthiness standards"), *aff'd on other grounds*, 265 F. App'x 87 (3d Cir. 2008); *Colombini* v. *Westchester Cty. Healthcare Corp.*, 808 N.Y.S.2d 705, 709 (N.Y. App. Div. 2005) (holding that manufacturer "established its entitlement to judgment as a matter of law" on punitive damages in part because it provided an instruction manual with warnings "in compliance with all applicable industry and regulatory standards").

AndroGel at the time of Plaintiff's prescription, that he never saw any AndroGel marketing material, and that he did not make prescribing decisions based on sales and marketing materials. (*Supra* pp. 10–11.) Any punitive damages award based on these essential components of Plaintiff's case would accordingly be unconstitutional. [11]

CONCLUSION

For the foregoing reasons, AbbVie respectfully requests that the Court enter judgment in AbbVie's favor on Mr. Konrad's claims.

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[11] Plaintiff's failure to prove compensatory damages, *supra* 20–21, also necessarily means he is not entitled to punitive damages. *See Ball* v. *Overton Square, Inc.*, 731 S.W.2d 536, 539 (Tenn. Ct. App. 1987) ("actual, compensatory damages [are] a prerequisite to punitive damages").

CERTIFICATE OF SERVICE

I, David Bernick, hereby certify that on October 3, 2017, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ *David Bernick*
David Bernick