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

In re: Testosterone Replacement	**)**	
Therapy Products Liability Litigation	**)**	**Case No. 14 C 1748**
Coordination Pretrial Proceedings	**)**	**MDL No. 2545**
	)	
(This document applies to	**)**	
***Konrad v. AbbVie*, Case No. 15 C 966)**	**)**	

CASE MANAGEMENT ORDER NO. 129
(Memorandum Opinion and Order on post-trial motions in *Konrad v. AbbVie*, No. 15 C 966)

MATTHEW F. KENNELLY, District Judge:

Plaintiff Jeffrey Konrad sued defendants AbbVie, Inc. and Abbott Laboratories, Inc. (collectively, AbbVie), alleging that AbbVie's testosterone replacement therapy (TRT) drug AndroGel caused him to suffer a heart attack. AbbVie is one of several manufacturers of TRT drugs named as defendants in this multidistrict litigation (MDL) proceeding; Konrad's case was selected to be tried as a "bellwether" case.

Konrad contends that when the United States Food and Drug Administration (FDA) approved AndroGel and other TRT drugs, it approved the drug only for the treatment of "classical" hypogonadism in males—that is, abnormally low testosterone resulting from other medical conditions such as injury to the testicles or genetic disorders like Klinefelter's syndrome. Konrad contends that AbbVie inappropriately marketed AndroGel by falsely representing that the drug had been proven safe and effective for the treatment of age-related hypogonadism or "Low T"—that is, signs and symptoms of the normal male aging process and the accompanying natural decline of testosterone levels in the blood. He also alleges that AbbVie failed to provide adequate warnings to his physician about the cardiovascular risks associated with AndroGel use.

Konrad's case was the second bellwether case in this proceeding to be tried to a jury verdict. In the first bellwether case, the jury found for the plaintiff on one of his three liability claims and awarded him zero dollars in compensatory damages and $150 million in punitive damages. This Court ordered a new trial after concluding that the jury's verdicts were logically incompatible. *See In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings* (*In re TRT*), No. 14 C 1748, 2017 WL 6569632, at *1 (N.D. Ill. Dec. 22, 2017). Konrad, a Tennessee resident, asserted four claims against AbbVie under Tennessee law: strict liability, negligence, intentional misrepresentation, and misrepresentation by concealment. The jury found for AbbVie on the strict liability claim but found for Konrad on the remaining claims. It awarded Konrad $140,000 in compensatory damages ($40,000 for medical expenses and $100,000 for pain and suffering) and $140 million in punitive damages.

AbbVie has moved for judgment as a matter of law under Federal Rule of Civil Procedure 50, contending that Konrad failed to present substantial evidence to support his liability claims or an award of punitive damages. In the alternative, AbbVie has moved for a new trial under Federal Rule of Civil Procedure 59(a), arguing that the jury's verdict was internally inconsistent, against the weight of the evidence, and the product of erroneous jury instructions and evidentiary rulings. If the Court decides not to vacate the jury's liability verdict, AbbVie asks for remittitur of the jury's punitive damages award under Federal Rule of Civil Procedure 59(e). For the reasons stated below, the Court denies AbbVie's motion for judgment as a matter of law but grants the motion for a new trial.

Background

A. Evidence at trial

At trial, Konrad presented evidence tending to show that AbbVie attempted to expand the AndroGel market by promoting the drug as a safe and effective treatment for the symptoms of Low T or age-related hypogonadism and that it did so in order to expand the AndroGel market. Evidence from internal AbbVie documents and testimony from AbbVie employees indicated that the company was aware that the FDA had not approved AndroGel to treat the symptoms of aging. Yet Konrad elicited testimony from AbbVie employees and introduced promotional materials tending to show that AbbVie nevertheless promoted AndroGel for the treatment of symptoms of aging such as fatigue and low libido. In addition to evidence of AbbVie's direct marketing to consumers, Konrad presented documentary evidence of AbbVie's campaign to promote AndroGel directly to consumers as a drug that could safely and effectively treat age-related hypogonadism. Dr. David Kessler, former commissioner of the FDA and one of Konrad's expert witnesses, offered his opinion that AbbVie's marketing of AndroGel was false and misleading because it suggested that the drug was safe and effective for treating conditions other than those for which the FDA had approved it. For its part, AbbVie elicited testimony from its own expert witnesses regarding the scope of the FDA's approval. According to these witnesses, at the time Konrad began taking AndroGel in 2010, the FDA had approved the drug for the treatment of low testosterone regardless of the underlying cause of the condition. In addition, AbbVie presented evidence of correspondence between the company and the FDA indicating that the FDA had reviewed advertisements for AndroGel and allowed them to be shown to

consumers.

Konrad also presented evidence concerning the warning label for AndroGel at the time he was prescribed the drug. That label contained no specific warning about the risk of heart attacks or other cardiovascular events, though internal documents from AbbVie presented at trial indicated that the company was aware that reported adverse cardiovascular events may have been associated with AndroGel use. AbbVie notes that the FDA approved the language included in that warning label both before and after Konrad's use of the drug and his heart attack. AbbVie also emphasizes communications from the FDA indicating that, at the time of Konrad's heart attack, the agency determined that adequate information supported the conclusion that AndroGel was a safe and effective drug product. On this issue of warning for cardiovascular risks, Konrad presented expert testimony from Dr. Hossein Ardehali, a cardiologist at Northwestern Memorial Hospital, and Dr. Peggy Pence, a pharmaceutical consultant with an advanced degree in toxicology and pharmacology. Both experts testified that AbbVie had reasonable evidence by 2007, in the form of scientific studies and adverse event reports, of a causal association between AndroGel and heart attacks. Dr. Pence opined that a reasonable company would have changed the AndroGel label to warn about heart attacks prior to the date of Konrad's first use of the drug. The FDA did not require a warning about cardiovascular risk until 2015, she testified, because it did not have complete information about the drug's dangers, due in part, she explained, to AbbVie's failure to conduct adequate testing of the drug's safety.

After seeing an AbbVie advertisement promoting TRT's ability to treat fatigue, low libido, and depressed mood associated with "Low T," Konrad made an appointment with

Dr. Steven Overby. During the appointment, Konrad complained about certain symptoms he was experiencing, including fatigue, and asked Dr. Overby about Low T. Dr. Overby ordered a blood test, which indicated that Konrad had a low testosterone level. Based on the blood test and Konrad's reported symptoms, Dr. Overby diagnosed him with "hypotestosteronism" and prescribed AndroGel 1% at a dose of 5 milligrams per day. Since the 2015 update to the AndroGel label, Dr. Overby has counseled patients about the potential increased risk of heart attack, stroke, and deep vein thrombosis associated with AndroGel use, but he testified that he would not have advised Konrad in 2010 that AndroGel use was associated with increased risk of heart attacks. Konrad contends that Dr. Overby's belief that AndroGel is safe and effective for treating the symptoms of age-related hypogonadism comes from AbbVie's misrepresentations. At trial, Konrad presented evidence indicating that Dr. Overby had met frequently with AbbVie sales representatives and had received AndroGel brochures, patient discounts, questionnaires, and diagnostic devices prior to his diagnosis of Konrad. Dr. Overby himself estimated that he would meet with an AndroGel sales representative once every two months.

Konrad filled his first prescription for AndroGel 1% on May 5, 2010, and he refilled the prescription on June 24 of that year. He testified that he used the drug as instructed, applying the five-gram dose of the gel daily to his skin. But Konrad's own expert, Dr. Phillip Cuculich, acknowledged that it would be impossible for Konrad to have used the prescribed amount every day from May 5 to June 24 when he had only filled a prescription for one 30-day supply during that period. On July 9, fifteen days after refilling his AndroGel prescription for the first time, Konrad suffered a heart attack.

The hospital record indicates that he was currently using AndroGel at the time he was admitted. At trial, Dr. Cuculich testified that AndroGel was a substantial factor in causing the heart attack. Dr. Cuculich explained that a small plaque in Konrad's left anterior descending artery ruptured, a large clot developed on the plaque, and the clot blocked blood flow in the artery and caused the heart attack. Another of Konrad's expert witnesses, Dr. Ardehali, described the ways TRT drugs, in his opinion, can increase the blood's tendency to clot, including by increasing levels of hematocrit, estradiol, and thromboxane A2 receptor density. According to Dr. Cuculich, it was AndroGel's tendency to increase clotting that caused such a vigorous response to the small plaque rupture in Konrad's artery, causing the formation of the large clot that led to the heart attack. Dr. Cuculich also ruled out other risk factors as possible causes of the heart attack and explained why he did not believe other aspects of Konrad's medical history could account for the development of the large clot that triggered the injury.

B. Jury instructions and verdict

The Court instructed the jury on the elements Konrad was required to prove in order for the jury to find in his favor on his claims for strict liability, negligence, intentional misrepresentation, and misrepresentation by concealment. The instruction for the strict liability claim told the jury that Mitchell could prevail only if he proved each of four elements by a preponderance of the evidence: (1) AbbVie was engaged in the business of selling AndroGel, (2) AndroGel was "unreasonably dangerous," (3) AndroGel reached Konrad in substantially the same condition in which it was sold, and (4) AndroGel was "a cause in fact and legal cause of Mr. Konrad's heart attack." Instructions to the Jury at 12. The first and third elements were undisputed.

The instruction for the negligence claim explained that "negligence" means "the failure to use reasonable care" and told the jury that Konrad had to prove each of four elements by a preponderance of the evidence to prevail on the claim: (1) AbbVie owed Konrad a duty of care, (2) AbbVie breached that duty, (3) "AbbVie's breach of the duty of care was a cause in fact and legal cause of Mr. Konrad's heart attack," and (4) AndroGel was "unreasonably dangerous." *Id.* at 13. The instruction for the negligence claim explained further that the manufacturer of a product has a duty to use reasonable care in testing the product and to warn about a product's danger if the manufacturer reasonably should know about that danger. Failure to fulfill either of those duties, the instruction said, constitutes negligence. Following the instruction on negligence, the Court provided a definition for the term "unreasonably dangerous" as it was used in the strict liability and negligence instructions. *Id.* at 15.

The instructions for the intentional misrepresentation and misrepresentation by concealment claims did not list "unreasonable dangerousness" as an element. But both stated that Konrad was required to prove that the purported false representation or concealment of a material fact was "a cause in fact and legal cause of Mr. Konrad's heart attack." *Id.* at 16–17. In an instruction labeled "Causation," the Court reiterated that each of Konrad's claims required him to prove by a preponderance of the evidence that "AbbVie's product or conduct was a cause in fact and a legal cause of his heart attack." *Id.* at 18. In that section of the instructions, the Court also provided definitions of the terms "cause in fact" and "legal cause." *Id.*

The Court also instructed the jury on damages. The instruction on compensatory damages explained that the jury should award compensatory damages only if it found in

Konrad's favor on one of his claims and found that the harm he suffered was caused by the act or omission that formed the basis for the jury's liability finding. The instruction also listed the elements to consider in determining the amount of compensatory damages: medical expenses, pain and suffering, permanent injury, and loss of enjoyment of life. With respect to punitive damages, the Court instructed the jury that it could award an amount of money to punish AbbVie and discourage it and others from similar conduct if it found that AbbVie's conduct was "willful and wanton"; AbbVie's conduct proximately caused injury to Konrad; and justice and the public good required an award of punitive damages. The Court defined "willful and wanton" conduct as "a course of action that shows actual or deliberate intention to harm or that, if not intentional, shows an utter indifference to or conscious disregard for the safety of others." *Id.* at 22. In addition, the instructions listed a number of factors that the jury should consider in determining the appropriate amount of punitive damages.

The verdict form provided two options for each of the four liability claims: a finding "for plaintiff Jeffrey Konrad" or "for defendants AbbVie and Abbott Laboratories." *Id.* at 28. The damages portion of the verdict form provided blank spaces for the jury to enter an amount of money for medical expenses, pain and suffering, permanent injury, loss of enjoyment of life, total compensatory damages, and punitive damages. After deliberating for a day, the jury returned a verdict finding in favor of AbbVie on the strict liability claims and in favor of Konrad on all of the remaining claims. In the spaces provided for damages, the jury entered "$40,000" for medical expenses, "$100,000" for pain and suffering, nothing for permanent injury or loss of enjoyment of life, "$140,000" for total compensatory damages, and "$140,000,000" for punitive damages. The Court

entered judgment consistent with the jury's verdict.

C. AbbVie's post-trial motion

AbbVie has filed a motion for judgment as a matter of law, contending that Konrad failed to present substantial evidence to support any of the claims on which the jury found in his favor. Konrad contends that the jury's verdict is supported by substantial evidence in the trial record. In the alternative, AbbVie seeks a new trial, arguing that the Court erred in its instructions and certain evidentiary rulings and that the jury's verdict is internally inconsistent. Specifically, with respect to the purported inconsistency of the verdict, AbbVie notes that the elements of the strict liability claim that were disputed at trial—that is, whether AndroGel was unreasonably dangerous and whether the drug caused Konrad's heart attack—are identical to elements of the negligence claims. Thus, AbbVie argues, it was inconsistent for the jury to find in AbbVie's favor on the strict liability claim but in Konrad's favor on the negligence claim, which required those elements plus others. AbbVie maintains that the inconsistent verdict requires a new trial on all claims. Konrad, for his part, denies that the verdict is inconsistent, arguing that the instructions for the strict liability and negligence claims have different focuses: the instructions for the strict liability claim focus on the association between AndroGel and the heart attack, he argues, whereas the instructions for the negligence claim focus the jury's attention on AbbVie's conduct. Even if the jury's negligence finding were inconsistent with the strict liability finding, Konrad argues, the other liability findings are not facially inconsistent with the strict liability findings and should therefore be preserved.

If the Court does not grant judgment as a matter of law for AbbVie or award a

new trial, AbbVie has moved for a remittitur of the punitive damages award, contending that the award is unsupported by evidence, inconsistent with state law, and unconstitutionally excessive. Konrad responds that the reprehensibility of AbbVie's conduct and the need to deter a company as large and profitable as AbbVie justify the jury's award.

Discussion

Before determining whether there is any basis to order a new trial, the Court first considers AbbVie's motion for judgment as a matter of law. A court ruling on a motion for judgment as a matter of law considers "whether the evidence, viewed in the light most favorable to the [non-moving party], is sufficient to support the verdict [in that party's] favor." *Venson v. Altamirano*, 749 F.3d 641, 646 (7th Cir. 2014). A court will grant a motion for judgment as a matter of law "[o]nly if no rational jury could have found for the" non-moving party. *Id.*

A. Causation of the heart attack

AbbVie argues that Konrad failed to present evidence to support an element common to all of his claims—namely, that AndroGel caused his heart attack. The evidence at trial, AbbVie contends, would not allow a rational jury to find either that AndroGel causes heart attacks in individuals like Konrad (general causation) or that AndroGel was the cause of his particular heart attack (specific causation). On the issue of general causation, AbbVie emphasizes that Konrad and his experts failed to identify a scientific study showing a statistically significant association between increased cardiovascular risk and TRT use for men under 60 years old or for men who use TRT for only two months. At trial, Dr. Ardehali acknowledged that no particular study

demonstrates an association between TRT use and cardiovascular risk for Konrad's specific age group and usage history. Yet he still concluded that the totality of the available epidemiological literature, plus other scientific evidence, indicates that TRT use does increase cardiovascular risk for users like Konrad. The Court has previously concluded that Dr. Ardehali's opinion in that regard has a reliable scientific basis. *See In re TRT*, No. 14 C 1748, 2017 WL 1833173, at *9–*11, *13 (N.D. Ill. May 8, 2017). There was thus a sufficient evidentiary basis for a jury finding that AndroGel was capable of causing Konrad's heart attack.

Regarding specific causation, AbbVie maintains that the evidence unequivocally shows that Konrad did not use AndroGel consistently after he filled his first prescription, and it argues that Konrad failed to present any evidence that such intermittent use of TRT can cause heart attacks. Dr. Cuculich, Konrad's specific causation expert, did acknowledge that Konrad could not have used the prescribed dose every day between May 5 and June 24. But Konrad testified that he used the drug daily, and the hospital record indicates that he was using AndroGel at the time of his heart attack. In addition, Dr. Ardehali testified that the scientific literature supports an association between TRT use and increased cardiovascular risk at doses much lower than Konrad's prescribed dosage. A reasonable jury could therefore conclude, from Dr. Ardehali's testimony and the literature he relied upon, that Konrad was taking less than the prescribed dose on a daily basis but that such use was still capable of causing his heart attack. And Dr. Cuculich, despite his testimony regarding the amount of AndroGel that Konrad took, testified that AndroGel was a substantial factor in causing Konrad's heart attack.

AbbVie also emphasizes the fact that Dr. Cuculich never expressly opined that

Konrad's heart attack would not have occurred but for his AndroGel use. Tennessee follows the traditional rule that a defendant's conduct or product is not considered the cause in fact of an event unless "the event would not have occurred but for that conduct [or product]." *Tatham v. Bridgestone Americas Holding, Inc.*, 473 S.W.3d 734, 751 (Tenn. 2015). But it does not follow from that rule that a plaintiff can prove causation only through an expert's express testimony that the injury would not have occurred but for the conduct or product at issue. "To require medical expert witnesses to use precise legal language when discussing causation is expecting too much." *Dickson v. Kriger*, No. W201302830COAR3CV, 2014 WL 7427235, at *6 (Tenn. Ct. App. Dec. 30, 2014) (internal quotation marks omitted). During his trial testimony, Dr. Cuculich ruled out other potential causes of Konrad's heart attack, explained how AndroGel caused a large blood clot to form around a ruptured plaque in the artery, and concluded that AndroGel was a "substantial factor" in causing the heart attack. That testimony provides an adequate basis for the jury to conclude that a ruptured plaque in Konrad's artery would not have resulted in the heart attack he suffered had he not been using AndroGel.

AbbVie contends that Dr. Cuculich's ultimate conclusion—that AndroGel was a "substantial factor"—is solely a proximate causation opinion and says nothing about AndroGel's role as a cause in fact. But a medical doctor and a lay jury could certainly conclude that calling a drug a "substantial factor" in causing an injury tends to show that the injury would not have occurred but for the drug. Indeed, even in the law, the "substantial factor" test for legal causation, which requires the conduct at issue to be a substantial factor in bringing about the alleged harm, is thought to "incorporate[] the concept that conduct cannot be a cause in fact of an injury if the injury would still have

occurred even if the conduct had never taken place." *Waste Mgmt., Inc. of Tennessee v. S. Cent. Bell Tel. Co.*, 15 S.W.3d 425, 432 (Tenn. Ct. App. 1997). The Court therefore concludes that there was sufficient evidence at trial, including the testimony of Dr. Cuculich, to support a finding that AndroGel was a but-for cause of Konrad's heart attack.

B. Failure to warn

Under the Tennessee Products Liability Act (TPLA), a plaintiff asserting a claim for products liability, whether the claim is based on strict liability or negligence, must prove that the product at issue was in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller. *See* Tenn. Code Ann. § 29-28-105(a). Konrad argued at trial that AbbVie's failure to warn about the cardiovascular risks associated with AndroGel use made the product unreasonably dangerous for users like him.[1] AbbVie contends that Konrad did not present substantial evidence to show that AndroGel's warning label was inadequate or that a different warning would have prevented his heart attack.

As an initial matter, AbbVie argues that judgment of a matter of law must be granted on Konrad's products liability claims because he did not present evidence concerning ordinary consumer expectations about AndroGel or whether a reasonably prudent manufacturer would have put the drug on the market. The TPLA does define

[1] Konrad also contended that AbbVie's failure to conduct adequate testing of its drug with respect to cardiovascular safety rendered the drug unreasonably dangerous. The Sixth Circuit has stated, however, that a failure-to-test theory effectively "collapses into [a] failure-to-warn claim." *Rodriguez v. Stryker Corp.*, 680 F.3d 568, 574 (6th Cir. 2012). That is, product manufacturers have a duty to warn about risks associated with using a product, including those risks that would be uncovered through the "exercise [of] ordinary and reasonable care in testing a product for potential danger." *Id.*

"unreasonably dangerous" by reference to an ordinary consumer's expectations and, alternatively, the actions of a reasonably prudent manufacturer. *See id.* § 29-28-102(8). But to establish that a product is unreasonably dangerous under the consumer expectations test, a plaintiff need only produce evidence of the product's objective conditions. *Jackson v. Gen. Motors Corp.*, 60 S.W.3d 800, 805 (Tenn. 2001). Once the plaintiff does so, it is the jury's task "to employ its own sense of whether the product meets ordinary expectations as to its safety under the circumstances presented by the evidence." *Id.* at 805–06. In this case, Konrad produced evidence concerning the warning label and the scientific evidence linking TRT use to cardiovascular risk, as well as testimony from Drs. Ardehali and Pence indicating that the drug's warning label was inadequate as of 2007. Konrad therefore satisfied his obligation under Tennessee law to produce evidence of the product's objective conditions, and a reasonable jury could find from the evidence that the drug did not meet ordinary consumer expectations.

Regarding the AndroGel warning label, AbbVie contends that Konrad failed to present evidence of the label's inadequacy; on the contrary, AbbVie argues, the evidence at trial confirmed that the label was appropriate. AbbVie emphasizes that the FDA approved the language included in the AndroGel label both before and after Konrad's use of the drug. In addition, AbbVie argues that Dr. Ardehali's opinion about the adequacy of the warning label does not constitute substantial evidence because he failed to follow the FDA's established pharmacovigilance methods for determining whether a warning about a drug product's risk is required. As for Dr. Pence's opinion about the adequacy of the label, AbbVie notes that she herself admitted that the label already contained a warning about heart attacks at the time Dr. Overby prescribed the

drug for Konrad.

The Court disagrees with AbbVie's contention that the FDA's approval of the AndroGel label conclusively establishes its adequacy. Konrad produced evidence of reports indicating that the agency has limited resources, and Dr. Pence testified that the FDA was not in possession of complete information regarding TRT's cardiovascular risks when it reviewed the AndroGel label prior to 2015. And Drs. Ardehali and Pence, both experts in their own right like the officials at the FDA, expressed disagreement with the FDA's conclusion that the prior AndroGel labels were adequate. Though Dr. Ardehali did not follow the FDA's guidelines for evaluating a drug's safety risks, the Court has explained previously why Dr. Ardehali's opinion based on a different method can still constitute appropriate evidence concerning what risks AbbVie should have been aware of and included in its warning. *See In re TRT*, No. 14 C 1748, 2017 WL 1836435, at *13 (N.D. Ill. May 8, 2017). And though Dr. Pence acknowledged that the AndroGel label in 2010 warned about a potential mechanism by which the drug might cause thromboembolic events (which can include heart attacks), she also noted that that label did not contain any express warning that the drug had been specifically associated with an increased risk of heart attacks. In sum, FDA's approval of the drug's label does tend to show that the label's warning was adequate, and AbbVie's criticisms of Konrad's experts could reasonably cause a jury to discount their opinions. But the record still contains substantial evidence from which a reasonable jury could conclude that the AbbVie should have known and provided stronger warnings about the association between AndroGel use and increased risk of heart attacks.

AbbVie maintains that Dr. Overby already knew about possible cardiovascular

risks of AndroGel use when he prescribed the drug to Konrad. Thus even if the warning label were inadequate, AbbVie argues, Konrad cannot establish that any change in the warning would have prevented him from using the drug or suffering a heart attack. *See King v. Danek Med., Inc.*, 37 S.W.3d 429, 453 (Tenn. Ct. App. 2000) ([T]he plaintiffs' claims . . . fail because they have failed to establish that, had additional warnings been given, the plaintiffs would not have sustained their injuries."). At the time Dr. Overby prescribed AndroGel for Konrad, the label warned that increases in hematocrit (the ratio of the volume of red blood cells to the total volume of blood) while using the drug may indicate increases in red blood cell mass, which may increase the risk of thromboembolic events. Dr. Overby testified that it was routine for him, even at the time he prescribed the drug to Konrad, to monitor a patient's hematocrit levels because of the associated risk of heart attack of stroke. This testimony, however, does not conclusively establish that an additional warning would have had no effect on Konrad's decision to take AndroGel. On the contrary, Dr. Overby's testimony indicated that, even if he would have monitored patients' hematocrit levels, he likely would not have advised Konrad of the risk of heart attacks associated with TRT use in 2010. But the new label for AndroGel specifically instructs physicians to counsel their patients about the risk of heart attack associated with using the drug, and Dr. Overby testified that he would have had a conversation with Konrad about the risk of heart attacks had he been aware of information about that risk in 2010. Thus a reasonable jury could have concluded, on the basis of substantial evidence, that a change in the AndroGel warning label would have prevented Konrad from taking the drug and suffering a heart attack.

C. Misrepresentation

AbbVie contends that Konrad also failed to present substantial evidence to support his claims for misrepresentation. None of the evidence at trial, AbbVie argues, shows that it made a materially false statement of fact or intentionally concealed material information. AbbVie notes that Konrad's expert, Dr. Kessler, opined only that AbbVie's marketing of AndroGel as a treatment for symptoms of aging symptoms *implied* that the drug's safety and efficacy for that use had been established. And AbbVie emphasizes that even Dr. Kessler failed to identify any affirmative misrepresentation on AbbVie's part or any piece of material information that AbbVie intentionally concealed. AbbVie's advertisements for AndroGel could not be misleading, it contends, because the messages in those advertisements tracked the language in the drug's warning label, which had been approved by the FDA. In addition, AbbVie argues that any claim for misrepresentation by concealment is undermined by the fact that the FDA approved the language included in the AndroGel warning label and never required disclosure of any additional information. AbbVie also argues that Konrad failed to present substantial evidence showing that either he or Dr. Overby relied on any false representation.

As an initial matter, AbbVie appears to be mistaken that a plaintiff must present direct evidence of an affirmative false statement to prove misrepresentation under Tennessee law. In Tennessee, a "positive fraud" exists if "a party intentionally misrepresents a material fact *or produces a false impression* in order to mislead another or to obtain an undue advantage over him." *Brown v. Birman Managed Care, Inc.*, 42 S.W.3d 62, 66 (Tenn. 2001) (emphasis added). And "Tennessee courts have

recognized that fraud by its nature is often difficult to prove and thus may be properly proved by wholly circumstantial evidence." *Id.*

Substantial evidence at trial, in the form of internal company documents and testimony from AbbVie employees, indicated that AbbVie intended to create the impression through its promotional efforts that AndroGel was safe and effective for the treatment of symptoms associated with the male aging process. And Konrad presented numerous examples of marketing and promotional materials touting the ability of AndroGel and other TRT drugs to treat those symptoms. A jury thus could reasonably find that AbbVie intentionally produced the false impression that AndroGel had been proven safe and effective for the treatment of age-related hypogonadism. There was also substantial evidence at trial to support the inference that Konrad relied on AbbVie's representations when he decided to visit to Dr. Overby to obtain TRT or that Dr. Overby relied on AbbVie's representations when he prescribed AndroGel to Konrad. This evidence includes the fact that Konrad visited Dr. Overby after viewing an AbbVie advertisement indicating that fatigue may be caused by a treatable condition called Low T, the numerous contacts Dr. Overby had with AndroGel sales representatives, and the fact that Dr. Overby prescribed AndroGel to treat symptoms that were routinely marketed as "Low T" symptoms. In addition, as discussed above with respect to AbbVie's alleged failure to warn, substantial evidence supports the inference that AbbVie knew about reports of cardiovascular injuries associated with AndroGel but failed to disclose that information to the public in order to suggest that the drug was safe. Thus the evidence also supports a finding of misrepresentation by concealment.

D. Punitive damages

The Court has determined previously that Illinois law governs Konrad's request for punitive damages. *See In re TRT*, 2017 WL 1836435, at *21–*22. "Under Illinois law, 'punitive or exemplary punitive or exemplary damages may be awarded when torts are 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.'" *Parker v. Four Seasons Hotels, Ltd.*, 845 F.3d 807, 812 (7th Cir. 2017) (quoting *Kelsay v. Motorola, Inc.*, 74 Ill. 2d 172, 186, 384 N.E.2d 353, 359 (1978)). In the products liability context, "a manufacturer's awareness that its product is unreasonably dangerous coupled with a failure to act to reduce the risk amounts to willful and wanton conduct." *Kopczick v. Hobart Corp.*, 308 Ill. App. 3d 967, 974, 721 N.E.2d 769, 775 (1999).

AbbVie contends that Konrad failed to present substantial evidence to support a finding that AbbVie engaged in willful and wanton conduct. As discussed above, however, a reasonable jury could determine from the evidence, including the testimony of Drs. Ardehali and Pence, that AbbVie was aware that AndroGel was associated with increased risk of heart attack as early as 2007. In addition, a reasonable jury could conclude that the company failed to disclose that information and actively sought to promote the drug as safe and effective, including for purposes for which the drug had not been approved. Based on those findings, a reasonable jury could further conclude that AbbVie's conduct "indicate[d] a wanton disregard of the rights of others," including people like Konrad. *Parker*, 845 F.3d at 812. In determining that there was sufficient evidence to support an award of punitive damages under Illinois law, the Court at this

time need not express an opinion about whether the evidence at trial was sufficient to support the size of the jury's award.

E. Inconsistency of the verdict

In the alternative to its motion for judgment as a matter of law, AbbVie argues that a new trial is necessary because the jury's verdict is internally inconsistent. "As a rule civil juries must return consistent verdicts." *Deloughery v. City of Chicago*, 422 F.3d 611, 617 (7th Cir. 2005). "[W]hen jury verdicts are logically incompatible, thereby indicating that the jury was confused or abused its power, the district court errs when it fails to order a new trial." *Stone v. City of Chicago*, 738 F.2d 896, 899 (7th Cir. 1984). Nevertheless, a court "should be slow to impute to juries a disregard of their duties," and thus a court "should do what [it] can to save the [jury's] verdict against the specter of inconsistency." *Am. Cas. Co. of Reading, Pa. v. B. Cianciolo, Inc.*, 987 F.2d 1302, 1306 (7th Cir. 1993); *see also Gallick v. Baltimore & O. R. Co.*, 372 U.S. 108, 119 (1963) ("[I]t is the duty of the courts to attempt to harmonize the [jury's] answers, if it is possible under a fair reading of them . . . . We therefore must attempt to reconcile the jury's findings, by exegesis if necessary[.]").

AbbVie contends that the jury's finding in its favor on the claim for strict liability was inconsistent with the jury's finding in Konrad's favor on the claim for negligence. The Court instructed the jury that Konrad had to prove four elements by a preponderance of the evidence to prevail on his claim for strict liability, but two of those elements were undisputed at trial.[2] Thus by finding for AbbVie on that claim, AbbVie

[2] The parties did not, and do not, dispute that AbbVie was engaged in the business of selling AndroGel or that AndroGel was expected to and did reach Konrad without substantial change in the condition in which it was sold.

argues, the jury necessarily found that Konrad failed to prove one or both of two elements: (1) that AndroGel was unreasonably dangerous or (2) that AndroGel was a cause in fact and legal cause of Konrad's heart attack. As AbbVie notes, the instruction on the claim for negligence stated that to prevail on that claim, Konrad had to prove those same two elements by a preponderance of the evidence. It was therefore logically inconsistent, AbbVie argues, for the jury to find that Konrad failed to prove at least one of the contested elements of his strict liability claim but succeeded in proving all the elements of his negligence claim.

Konrad denies that the jury's verdict was necessarily inconsistent; he maintains that a plausible interpretation of the verdict can reconcile the strict liability and negligence findings. Specifically, Konrad emphasizes that the instructions for the strict liability claim have a different focus from the instructions for the negligence claim. He argues that the instructions for the strict liability claim focus on AndroGel itself—in particular, whether AndroGel was unreasonably dangerous and whether it caused Konrad's heart attack. By contrast, he contends, the instructions for the negligence claim focus on AbbVie's conduct—for example, whether AbbVie exercised reasonable care, including by conducting adequate testing of the drug, and whether the company's negligence caused Konrad's heart attack. Given those different focuses, Konrad argues, "[i]t is entirely plausible that the jury determined that AndroGel was unreasonably dangerous, but found the necessary causal connection on Mr. Konrad's negligence claim satisfied upon consideration of the relationship between AbbVie's conduct in failing to reasonably test AndroGel for the purpose for which it was promoted and used by Mr. Konrad, and his injury—conduct-related considerations not relevant to

the strict liability claim." Pl.'s Resp. at 16.

The Court understands Konrad to be arguing that the jury could have consistently found that AndroGel did not cause Konrad's heart attack for purposes of the strict liability claim but that AbbVie's negligent conduct caused the heart attack for purposes of the negligence claim. That interpretation would appear to be consistent with the language of the instructions: whereas the causation element for the strict liability instruction says "*AndroGel* was a cause in fact and legal cause of Mr. Konrad's heart attack," the causation element for the negligence instruction says "AbbVie's *breach of the duty of care* was a cause in fact and legal cause of Mr. Konrad's heart attack." Jury Instructions at 12–13 (emphasis added). The problem with Konrad's proposed interpretation is that a theory advanced to reconcile a jury's verdict must be "reasonable [and] consistent with the evidence and its fair inferences." *Gallick*, 372 U.S. at 125. Konrad has not articulated any theory, supported by evidence, of how AbbVie's breach of its duty of care could have been the cause in fact and legal cause of Konrad's heart attack unless AndroGel itself was a cause in fact and legal cause of the heart attack. As AbbVie put the point in its reply, regardless of what the elements of each claim "focus on," the claims share an essential causation question—whether AndroGel caused Konrad's heart attack.

In the abstract, a finding for a plaintiff on a claim for negligence in the products liability context does not require a finding for the plaintiff on a claim for strict liability. A jury could reject a strict liability finding on the basis that a product's benefits outweigh its dangers while simultaneously concluding that a company was negligent for failing to make its product safer. *See Connelly v. Hyundai Motor Co.*, 351 F.3d 535, 541 (1st Cir.

2003). But by requiring proof of the same "unreasonably dangerous" element for both the strict liability and negligence claims, the instructions given in this case leave little room for a reconciling interpretation of that sort. The interpretation advanced in *Connelly*, for example—that the product was not unreasonably dangerous—would preclude a finding for Konrad on the negligence claim in this case.

This overlapping of elements appears to be a feature of Tennessee law. Specifically, the Tennessee statute cited earlier appears to require a plaintiff asserting a claim for damages caused by a product, at least a claim based on a failure-to-warn theory, to prove that the product at issue is "unreasonably dangerous," irrespective of whether the claim is for strict liability or for negligence. *See* Tenn. Code Ann. § 29-28-105(a) ("A manufacturer or seller of a product shall not be liable for any injury to a person or property caused by the product unless the product is determined to be in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller."); *Bradley v. Ameristep, Inc.*, 800 F.3d 205, 212 (6th Cir. 2015) ("An action [in Tennessee] based on an inadequate warning requires not only that the warning itself be defective, but that the plaintiff establish that the product is unreasonably dangerous by reason of defective warning and that the inadequate labelling proximately caused the claimed injury."). Konrad cites a number of cases in which courts have reconciled a finding of negligence with a finding of no strict liability, but none addresses the situation where unreasonable dangerousness or a similar finding is an element of both claims. Indeed, in one case Konrad cites, the court notes the impossibility of reconciling a split verdict in that situation. *See Randall v. Warnaco, Inc., Hirsch-Weis Div.*, 677 F.2d 1226, 1231 (8th Cir. 1982) ("Because negligence

focuses on the conduct of the defendant and strict liability on the condition of the product, it becomes conceptually impossible to say that a verdict for the defendant in a strict liability count always disposes of plaintiff's negligence claim based on the same alleged defect, *unless one assumes that to be negligent the conduct of the manufacturer must render the product unreasonably dangerous in the strict liability sense*.") (emphasis added).

In sum, Konrad has not advanced any "reasonable theory consistent with the evidence and its fair inferences" to reconcile the jury's finding on the claim for strict liability with its finding on the claim for negligence, *Gallick*, 372 U.S. at 119, and the Court has not independently uncovered any plausible reconciling interpretation. The verdicts on these claims are inconsistent under the instructions given to the jury. When this happens, the Court cannot accept one of the two inconsistent verdicts while discarding the other; both of them have to go. *See In re TRT, supra*, 2017 WL 6569632 at *4 (citing *Timm v. Progressive Steel Treating, Inc.*, 137 F.3d 1008, 1010 (7th Cir. 1998); *Am. Cas. Co.*, 987 F.2d at 1305).

That leaves the verdicts in Konrad's favor on the misrepresentation claims. As Konrad correctly notes, the instructions for these claims did not list a finding that AndroGel was "unreasonably dangerous" among the require elements. A reasonable jury could have determined that AndroGel was not *unreasonably* dangerous—perhaps because its benefits outweigh its risks for the ordinary user—but that AbbVie misrepresented its risks and benefits for a user like Konrad. In other words, the verdict adverse to Konrad on the strict liability claim is not irreconcilable with its verdicts in his favor on the misrepresentation claims. Konrad therefore contends, citing *American*

Casualty, that if the Court determines that the negligence and strict liability verdicts are inconsistent, the Court should excise the verdict for AbbVie on the strict liability claim—or, perhaps, both the strict liability and negligence verdicts—but uphold the misrepresentation verdicts in his favor, rather than ordering a new trial. The court in *American Casualty*, however, suggested the possibility of setting aside one of a jury's conflicting verdicts only "if that verdict is unsupported by the evidence." *Id.* As discussed above, however, each of the jury's findings in Konrad's favor has sufficient evidentiary support. Where a jury has returned inconsistent verdicts that are otherwise supported by the evidence, the appropriate remedy is a new trial. *Deloughery*, 422 F.3d at 617.

The scope of the new trial is arguably a separate question. Konrad—citing the non-inconsistency of the misrepresentation verdicts—argues that if a new trial is required, it should be limited to the claims on which the verdicts were inconsistent (strict liability and negligence), with the misrepresentation verdicts in his favor remaining intact. AbbVie argues that a new trial cannot be limited to the claims for strict liability and negligence because all of the claims have overlapping elements and also because one cannot determine whether the jury would have awarded the same damages had it found in Konrad's favor on just the misrepresentation claims. The Court does not find the latter contention persuasive. The damages recoverable on each claim were the same, and there was a single injury, not separate harms.

That said, the Court does not believe that it can appropriately order a new trial limited to the negligence and strict liability claims while keeping the misrepresentation verdicts intact. A court may order a partial new trial only if "it clearly appears that the

issue to be retried is so distinct and separable from the others that a trial of it alone may be had without injustice." *Gasoline Prods. Co. v. Champlin Ref. Co.*, 283 U.S. 494, 500 (1931). In this case, one of the key disputed issues was causation, specifically whether AndroGel cased Konrad's heart attack. The jury was given a single causation instruction that covered all of the claims. Thus the issue of causation on the two claims that have to be retried due to the inconsistency of the jury's verdicts is anything but "distinct and separable" from the issue of causation on the misrepresentation claims. For this reason, the Court concludes, it would be impossible to limit a new trial to the inconsistent claims "without injustice." The appropriate remedy for the jury's inconsistent verdicts on the strict liability and negligence claims is "[a] new trial on all claims." *Deloughery*, 422 F. 3d at 617.[3]

Because all claims will be retried, the Court need not, and does not, address AbbVie's additional arguments for a new trial or for a remittitur of the punitive damages award.

Conclusion

For the reasons stated above, the Court denies AbbVie's motion for judgment as a matter of law but grants its motion for a new trial [dkt. no. 118]. The Court vacates the judgment entered on October 5, 2017 and orders a new trial on all claims. The case will be retried in the fall of this year (October, November, or December 2018) on a specific

[3] If the instructions, which as discussed earlier essentially make the contested elements of strict liability and negligence identical or virtually so, were correct, then one wonders whether it makes sense—at least from the perspective of the plaintiff—to actually allow both of those claims to go to the jury in a retrial.

date to be set after discussion with counsel.

Date: July 5, 2018

MATTHEW F. KENNELLY
United States District Judge