**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF ILLINOIS**

| | |
|---|---|
| **IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION** | **CASE NO. 1:14-CV-01748**<br>**MDL 2545**<br><br>**JUDGE MATTHEW F. KENNELLY**<br><br>**This Document Relates to:**<br><br>***Mitchell* v. *AbbVie*,**<br>**Case No. 1:14-cv-09178** |

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

Defendants AbbVie Inc. and Abbott Laboratories (collectively "AbbVie") respectfully move for judgment as a matter of law under Rule 50(a)(1) of the Federal Rules of Civil Procedure. No reasonable jury could find in Mr. Mitchell's favor on any of his three claims. All claims fail because Dr. Ardehali conceded Mr. Mitchell had numerous cardiac risk factors, each of which was sufficient to cause his heart attack. The warnings claims fail because there was insufficient evidence as to whether the Company could change the warnings without FDA approval, and as to whether it was unreasonable not to include cardiovascular warnings at the time of Mr. Mitchell's AndroGel use. Dr. Canzler also expressly warned Mr. Mitchell of the potential CV risk. As expected, Mr. Mitchell's misrepresentation claims cannot go forward. He introduced ***no false statement seen or relied on by Dr. Canzler or Mr. Mitchell***. He also appears to have abandoned the strict-liability claim, because Mr. Mitchell did not introduce evidence to support core elements. Finally, the Court should strike Mr. Mitchell's punitive damage request, for there was no nexus between Mr. Mitchell's AndroGel treatment and the supposed "punitive conduct" identified by plaintiffs' counsel before trial.

## ARGUMENT

### A. MR. MITCHELL HAS NOT OFFERED LEGALLY SUFFICIENT EVIDENCE THAT ANDROGEL WAS A BUT-FOR CAUSE OF HIS HEART ATTACK.

Each of Mr. Mitchell's claims requires proof that AndroGel was a cause of his heart attack. Tr. at 191:23-192:3 (preliminary instructions). To satisfy this burden under Oregon law, Mr. Mitchell had to prove that the heart attack "would not have occurred but for AbbVie's conduct." *Id.*; *see also Joshi v. Providence Health Sys. of Oregon Corp.*, 149 P.3d 1164, 1169 (Or. 2006) (concluding but-for standard applies in majority of cases and requires proof that defendant's conduct "more likely than not caused the plaintiff's harm."). Dr. Ardehali had to rule out the possibility that the heart attack would have occurred even without AndroGel. Tr. at

191:23-192:3 (preliminary instructions); *Joshi*, 149 P.3d at 1169 ("[T]he defendant's conduct is not a cause of the event, if the event would have occurred without it.").[1]

Dr. Ardehali's opinion failed to satisfy this standard. To the contrary, Dr. Ardehali ***conceded*** that any one of Mr. Mitchell's many risk factors would have been sufficient to cause the heart attack. Tr. at 1641:2-5 ("Q: Based on these risk factors, these risk factors as a scientific matter were completely sufficient to cause his heart attack in December of 2012, correct? A: That's fair."). This admission means Dr. Ardehali's causation opinion cannot satisfy the Oregon but-for standard.

It is undisputed that Mr. Mitchell had several cardiac risk factors before he had his heart attack, including a 34-year smoking history, high blood pressure, high cholesterol, high triglycerides, obesity, a family history of heart disease, and lack of exercise. Tr. at 1624:13-16, 1632:2-3, 1632:24-1633:12, 1801:19-1802:19. Dr. Ardehali conceded these risk factors were contributing to plaque formation during the time when Mr. Mitchell was taking AndroGel and leading up to his heart attack in 2012. Tr. at 1810:19-1811:2. Dr. Ardehali also agreed that without AndroGel, Mr. Mitchell's cardiac risk factors gave him a 15-20% 10-year risk estimate for having a heart attack. Tr. at 1635:11-14 (14.7%), Tr. at 1641:14-16 (15-20%). He was 7.5 times more likely to have a heart attack than a similarly-aged man with optimal risk factors. Tr. at 1637:20-24. Mr. Mitchell's risks increased over time, particularly due to his smoking and age. Tr. at 1644:24-1645:3.

[1] The "substantial factor" standard does not apply in this case. Mr. Mitchell does not allege that AndroGel was one of two (or more) concurring causes of his heart attack (e.g., the classic "two fires" example). *Joshi*, 149 P.3d at 1169. Even if the "substantial factor" standard applied, however, Mr. Mitchell still would have to demonstrate that his heart attack would not have occurred without the alleged conduct. *Id.* at 1168 (discussing *Simpson v. Sisters of Charity of Providence*, 588 P.2d 4 (Or. 1978)).

Significantly, Dr. Ardehali conceded that even had Mr. Mitchell not taken AndroGel, any of his modifiable risk factors would have been sufficient to cause his heart attack. Tr. at 1639:4-8, 1639:19-21, 1641:2-5. Dr. Ardehali would have told Mr. Mitchell in 2012 that he was at a risk of a heart attack "any day" due to his history of cardiac risk factors. Tr. at 1641:20-24. Dr. Ardehali could not quantify the degree to which AndroGel allegedly increased the risk of heart attack in Mr. Mitchell. Tr. at 1649:5-9, 16-19 ("Q: But there isn't science that would enable you to say TRTs or AndroGel bump this risk up by 2 percent or 3 percent, correct? A. Well, there is science that says that it increases the risk of heart attack. Q: Okay. But what I'm saying when you take all of that science together, it doesn't give you an additional number to add on to that 15 to 20 percent risk, correct? A. No, it doesn't give you a number. That's correct."). Dr. Ardehali also could not quantify the relative increased cardiac risk to Mr. Mitchell due to his obesity, family history of heart disease, or lack of exercise. Tr. at 1806:1-9, 1806:23-25.

In sum, Dr. Ardehali's opinion failed to rule out the possibility that Mr. Mitchell's heart attack would have occurred even had he never taken AndroGel, as required by Oregon law. *Joshi*, 149 P.3d at 1169. Put another way, Dr. Ardehali did not, and could not, offer the opinion that Mr. Mitchell would have avoided his heart attack had he not taken AndroGel. Tr. at 191:23-192:3 (instructing that Oregon law requires proof that heart attack "would not have occurred but for AbbVie's conduct."). Rather, Dr. Ardehali conceded that any of Mr. Mitchell's risk factors, standing along, could have caused the heart attack. Tr. at 1641:2-5. Similarly, Dr. Ardehali's opinion failed to establish it is more likely than not that AndroGel caused the heart attack, where Dr. Ardehali could not quantify the role that AndroGel allegedly played.

Because Mr. Mitchell's evidence is insufficient to carry his burden on this core causation element, the Court should direct a verdict in AbbVie's favor and discharge the jury.

## B. MR. MITCHELL HAS NOT OFFERED LEGALLY SUFFICIENT EVIDENCE TO SUPPORT HIS CLAIM THAT THE ANDROGEL WARNINGS WERE INADEQUATE.

Mr. Mitchell's strict-liability and negligence claims fail for the independent reason that AndroGel's labeling included "adequate warning or instruction" about the risks of AndroGel. Tr. at 189:11-190:1 (preliminary instruction); *see also McEwen* v. *Ortho Pharmaceutical Corp.*, 528 P.2d 522, 528 (Or. 1974) (requiring manufacturer in negligence action to give "timely and adequate warnings to the medical profession of any dangerous side effects" that were known or reasonably should have been known).

At the beginning of trial, the Court correctly instructed the jury that the claims in this case "are not claims for violation of FDA regulations." Tr. at 193:9-10. Rather, Mr. Mitchell's warnings claims must satisfy Oregon law. This required Mr. Mitchell to prove that the warnings given were unreasonable. *See* Tr. at 189:5-13 (strict-liability claim requires proof that product was "unreasonably dangerous" due to lack of adequate warning or instruction); Tr. at 190:18-21 (describing duty to give "reasonable warning of the dangers that it knew or had reason to know were inherent in the use of AndroGel."). In other words, to recover for an alleged failure-to-warn, Mr. Mitchell had to establish by a preponderance of the evidence that it was unreasonable for the Company[2] not to provide additional cardiovascular warnings at the time of Mr. Mitchell's AndroGel use.[3] He failed to offer this proof. In fact, ***no expert*** offered the opinion that the

[2] AbbVie uses the generic descriptor "the Company" to refer to the entity that had responsibility for AndroGel during the relevant time periods.

[3] Oregon law judges the adequacy of the warnings in light of the scientific knowledge reasonably available at the time of Mr. Mitchell's prescriptions. Tr. at 189:24-190:1 (preliminary instructions); *see generally McEwen*, 528 P.2d at 528-29, 531 (warning obligation extends to "constructive knowledge as measured by scientific literature and other available means of communication" before and during period when plaintiff used drug).

Company's warnings were ***unreasonable*** at the time of Mr. Mitchell's prescriptions. Without this proof, no reasonable jury could conclude the AndroGel warnings were inadequate as a matter of Oregon law.

Plaintiffs' counsel and Mr. Mitchell's experts instead framed the warnings case by reference to the FDA standard of whether there was "reasonable evidence of a causal association" at the time of Mr. Mitchell's AndroGel use. But this is merely the first step in the inquiry. Reasonable evidence of a causal association determines whether the Company had the power unilaterally to change the labeling, because federal law limited the Company's ability to update its labeling to include additional information of cardiovascular risk. The Company had a responsibility to revise its labeling "to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitively established." 21 C.F.R. § 201.57(c)(6)(i). Under FDA Guidance, an adverse event "safety signal," standing alone, is not "reasonable evidence of a causal association." *See* FDA Pharmacovigilance Guidance, at 4 (Ex. 3094); *see also In re Incretin-Based Therapies Prods. Liab. Litig.*, 142 F. Supp. 3d 1108, 1127 (S.D. Cal. 2015) ("[E]xistence of a safety signal is not, without more, indicative of a causal association.").

Importantly, however, the Company had a limited ability to use the "changes being effected" (CBE) process to include "newly acquired" safety information in a warning without first getting FDA approval. 21 C.F.R. § 314.70(c)(6)(iii). A CBE is appropriate only if the "newly acquired" safety information shows reasonable evidence of a causal association. 21 C.F.R. § 314.70(c)(6)(iii)(A) (allowing additional warning by CBE where "the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c).").

This regulatory framework also limits permissible state-law warnings claims. To maintain a non-preempted warning claim under Oregon law, Mr. Mitchell was required to

establish that the Company failed to update its labeling to include "newly acquired" safety information showing reasonable evidence of a causal association. *See Utts v. Bristol-Myers Co.*, __ F. Supp. 3d __, 2017 WL 1906875, at *9 (S.D.N.Y. May 8, 2017) ("*Utts II*") (to avoid preemption of state-law claims, plaintiff "***must show*** that there existed 'newly acquired information'" to support labeling change under CBE regulation) (emphasis added).[4] No reasonable jury could conclude that Mr. Mitchell met his burden, where the FDA itself has not made that finding.

1. Dr. Ardehali's Flawed Adverse Event Analysis Was Insufficient to Establish Reasonable Evidence of a Causal Association as of 2007.

Dr. Ardehali and Dr. Pence testified that a handful of adverse event reports in 2007 were "reasonable evidence of a causal association" sufficient to trigger an obligation under federal law to update the AndroGel cardiovascular warnings. Tr. at 1679:20-1680:5 (Ardehali); Tr. at 1894:15-21 (Pence). Apart from the conceded absence of any methodology underlying Dr. Ardehali's analysis, this adverse event opinion is legally insufficient to support the conclusion that a labeling change would have been allowed or required. Dr. Ardehali received these forms from counsel, and did no independent review of the Company adverse event database. Tr. at 1675:1-12. He acknowledged the adverse events went to the FDA, which independently analyzed them for evidence of a causal association. Tr. at 1672:13-16, Tr. at 1673:1-3. It is undisputed that the FDA did not find reasonable evidence of a causal association based on these reports. Dr. Pence agreed in both 2007 and 2008 (and continuing), the Company provided the FDA a signal evaluation, which concluded the totality of the evidence did not support a finding

[4] AbbVie does not have the burden of demonstrating there is "clear evidence" the FDA would not have approved the CBE, because Mr. Mitchell failed to satisfy his threshold burden to show "newly acquired" information exists that could have been added to the labeling. *Utts II*, 2017 WL1906875, at *9 (citing *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d 268, 283-84 (3d Cir. 2017)).

of increased risk. Tr. at 1941:9-17 (2007); Tr. at 1943:12-17 (2008). Dr. Pence was unaware of the FDA coming to a different conclusion. Tr. at 1941:18-20 (2007); Tr. at 1943:18-20 (2008).

The record establishes that to this day, the FDA reviews all adverse event reports, and "has not arrived at a conclusion of reasonable evidence of a causal association." Tr. at 1934:10-18. Dr. Pence acknowledged that the FDA has cautioned not to "draw any conclusions about drug event causality from post-marketing spontaneous reports for CV events with testosterone use." Tr. at 1933:2-6; Ex. 3258 (FDA Briefing Book). And Dr. Ardehali conceded the FDA Advisory Committee found no reasonable evidence of a causal association in 2014, only a "potential signal." Tr. at 1696:17-25. But evidence of a "potential signal" is insufficient as a matter of law to require a labeling change or to permit the Company to change the labeling through the CBE process. *See* FDA Pharmacovigilance Guidance, at 4 (Ex. 3094); *Incretin*, 142 F. Supp. 3d at 1127; *Utts II*, 2017 WL 1906875, at *17 (finding state-law claims preempted as matter of law despite ongoing FDA Signal Report identifying "potential signal of a 'serious risk/new safety information'"). Accordingly, the 2007 adverse event reports are not "reasonable evidence of a causal association," and federal law preempts any state-law claim based on a failure to provide additional cardiovascular warnings based on those reports.

2. Basaria Was Not Reasonable Evidence Of a Causal Association.

The 2010 Basaria study also is not reasonable evidence of a causal association that would support a labeling change. Indeed, no expert has offered a contrary opinion. Dr. Ardehali acknowledged that Basaria does not allow one to make a definitive assessment of the potential role of testosterone in cardiovascular events. Tr. at 1532:19-23. He also conceded that the FDA did not find a reasonable evidence of a causal association in 2011 after reviewing Basaria. Tr. at 1688:6-8 ("Q: Isn't it a fact that the FDA in—by January 2011 was still saying no association has been shown? A: that statement is correct."). So did Dr. Pence. Tr. at 1958:23-1959:3,

1964:20-1965:9. It is undisputed that the FDA found limitations with Basaria. Tr. at 1708:21-1709:6. Given these concessions, Basaria cannot be "newly acquired" information that would require a labeling change during the time of Mr. Mitchell's AndroGel use.

3. Reasonable Evidence of a Causal Association Does Not Answer Whether AndroGel's Warnings Were Adequate as a Matter of State Law.

There also has been no evidence presented that the Company's CV warning was unreasonable as a matter of state law. *See* Tr. at 1894:16-21 (Pence opining Company was unreasonable because there was "reasonable evidence of a causal association which is the standard for adding a warning to the labeling"). A claim that the Company failed to comply with 21 C.F.R. § 201.57(c)(6)(i), even if it were true, does not mean the warnings were reasonable or unreasonable as a matter of state law. Indeed, plaintiffs' counsel (and this Court) have expressly rejected the suggestion that Mr. Mitchell's state-law claims are in reality an impermissible attempt privately to enforce the FDCA, which contains no private right of action. Tr. at 193:9-10; *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2004). Because of this absence of proof, a directed verdict on Mr. Mitchell's warnings claims is warranted.

4. Mr. Mitchell's Warning Claims Fail Because His Prescribing Physician Expressly Warned Mr. Mitchell of a Potential Heart Attack Risk.

Before prescribing AndroGel, Dr. Canzler gave a "standard warning and clarification" to his hypogonadal patients, including Mr. Mitchell. Canzler Dep. at 39:5-19, Tr. at __.[5] Dr. Canzler "specifically told them that there were risks from heart attack." *Id.* at 39:12-13. When asked about any potential AndroGel risks he specifically remembered discussing with Mr. Mitchell, Dr. Canzler confirmed, "I know we spoke of heart problems." *Id.* at 52:24. Even if the AndroGel cardiovascular warnings were inadequate, Dr. Canzler clearly knew and

[5] As of the filing of this motion, the trial transcript of Mr. Mitchell's and Dr. Canzler's testimony was not yet available. AbbVie relies on the witnesses' deposition transcripts.

appreciated the potential risks, and expressly warned Mr. Mitchell. Dr. Canzler made these prescribing decisions using his independent medical judgment, not on anything the Company said. Canzler Dep. at 86:8-14. This evidence severs any causal link between the allegedly inadequate warning and harm to Mr. Mitchell. *Vaughn* v. *G.D. Searle & Co.*, 536 P.2d 1247, 1250-51 (Or. 1975) (en banc); *see also Canady* v. *Ortho McNeil Pharm., Inc.*, No. 3:11-oe-40011, 2014 WL 1653349, at *4 (N.D. Ohio 2014) (applying Oregon law). No reasonable jury could conclude there was a failure to warn Dr. Canzler that caused injury to Mr. Mitchell, and his warnings-based claims fail as a result.[6]

## C. THE MISREPRESENTATION CLAIM FAILS BECAUSE THERE IS NO CLEAR AND CONVINCING EVIDENCE THAT MR. MITCHELL AND HIS PRESCRIBING PHYSICIAN SAW OR RELIED ON ANY FALSE REPRESENTATION.

Mr. Mitchell was required to prove each element of his fraudulent misrepresentation claim by "clear and convincing evidence." Tr. at 191:4-192:7 (preliminary instruction). He failed to do so.

### 1. No Reasonable Jury Could Conclude the Company Made a False Representation at the Time of Mr. Mitchell's AndroGel Use.

Among other elements, Mr. Mitchell had to prove by clear and convincing evidence that the Company made a "material misrepresentation that was ***false***." *Strawn v. Farmers Ins. Co. of Or.*, 258 P.3d 1199, 1209 (Or. 2011); *see also Oksenholt v. Lederle Labs.*, 656 P.2d 293, 299

[6] Although it is unclear whether Mr. Mitchell advances a claim that AbbVie is liable under Oregon law for failing to clarify the AndroGel indication, no expert offered an opinion that federal law required or permitted such a change. To the contrary, the evidence established that the FDA considered and rejected narrowing the indication in 2007, Tr. at 953:24-954:16, and approved AndroGel 1.62% in 2011 with the same broad indication that accompanied AndroGel 1%. Tr. at 1965:10-14, 1972:6-10. Nor did Mr. Mitchell establish any "newly acquired" information from the 2007-2012 time-period would have supported such a change. Accordingly, an indication-related warning claim similarly fails.

(Or. 1982) ("Misrepresentation requires a false representation."); Tr. at 191:4-9 (instructing that misrepresentation claim requires clear and convincing proof of a "false representation regarding a material matter."). Oregon imposes a "falsity" standard; allegations of "misleading" or "confusion" are not enough to make out a misrepresentation claim.

Dr. Kessler's entire opinion is framed in a way that does not satisfy this "falsity" standard. He believed the Company "***was misleading***" because its "promotional marketing efforts went beyond the approved indication." Tr. at 905:25-906:6; *see also* Tr. at 1081:7-13 ("Q: Was that the two basic points you made? Promoting and marketing went beyond the approved indications, right? And it was misleading. The question was false and misleading. It was misleading because the drug was never found to be safe and effective, as determined by the FDA for the indications promoted, right? A: That's a good summary."). Dr. Kessler paid lip-service to the "falsity" standard, but he did not identify a single purportedly "false" branded AndroGel ad during his direct exam. He conceded the Company submitted all of its branded ads to the FDA for review, and the FDA never told the Company those ads were false or misleading. Tr. at 959:20-25. He identified no instance where the FDA told the Company it was marketing off-label or "over-promoting." Tr. at 956:6-14. There has been no claim or evidence that the Company failed to follow any specific FDA directive to change or discontinue its ads.

Although Dr. Kessler claimed "unbranded" ads were improper because they discussed signs and symptoms of low testosterone without FDA approval, he conceded that branded, FDA-approved ads contained the same information. Tr. 980:8-981:3. Finally, it is notable that Dr. Pence, whose expert report exhaustively cataloged AbbVie's purported marketing fraud, offered no opinions at trial on this subject.

2. There Is No Evidence that Mr. Mitchell or his Prescribing Physician Saw Or Relied On Any False Representation By The Company.

Mr. Mitchell also failed to prove by clear and convincing evidence that he or his prescribing physician saw and relied on any false representation when deciding to prescribe/use AndroGel. Tr. at 191:19-20.[7] Mr. Mitchell conceded he had never heard of AndroGel before Dr. Canzler prescribed it for him. Mitchell Dep. at 116:8-13, Tr. at __. He relied on Dr. Canzler's judgment when deciding to take AndroGel. Mitchell Dep. at 124:5-14. He did not recall seeing advertisements for any particular brand of TRT, and although he had a general recollection of seeing TRT advertisements, he could not remember the content. *Id.* at 115:7-15, 115:19-21. Mr. Mitchell did not ask Dr. Canzler to prescribe AndroGel for him. *Id.* at 116:2-7. Mr. Mitchell also did not recall Dr. Canzler giving him any questionnaire (such as ADAM) before prescribing TRT. *Id.* at 116:19-25.[8] Finally, Mr. Mitchell had no recollection of reading any materials that came with his AndroGel prescriptions. *Id.* at 125:13-14, 125:24-126:4, 128:18-20. No reasonable jury could conclude that Mr. Mitchell relied on any purported false representation by the Company.

The evidence also establishes Dr. Canzler relied on his own training, experience, and medical judgment, rather than anything said by the Company, when making treatment decisions for Mr. Mitchell. Canzler Dep. at 86:8-14 (testifying that he made prescribing decisions for Mr. Mitchell based on experience, "as opposed to something some sales representative told me"). Dr. Canzler received marketing from TRT manufacturers, but he could not recall any of the medical articles that were left behind by sales representatives, *id.* at 80:7-9, and he independently stayed abreast of medical developments. *Id.* at 80:22-81:5. He continued to make independent

[7] AbbVie expressly preserves its argument that the Court should have instructed the jury that misrepresentation claim required proof of reliance by both Mr. Mitchell and his prescriber. *See* July 4, 2017 Objections and Comments on Proposed Jury Instructions, at 4.

[8] Dr. Canzler confirmed that he did not use the ADAM questionnaire with Mr. Mitchell. Canzler Dep. at 171:11-14.

prescribing decisions based on his medical judgment, notwithstanding marketing he received. *Id.* at 81:24-82:8. He never "committed" to using a medication at a sales representative's behest, *Id.* at 112:7-10, and he did not do anything in his practice simply because a representative told him to do so. *Id.* at 176:9-13. Although Dr. Canzler acknowledged that advertising sometimes would influence men to ask for TRT, there is no evidence that occurred in this case. *Id.* at 109:12-110:3. He also could not recall whether he saw any ads for AndroGel. *Id.* at 186:1-6.

Dr. Canzler's testimony established that he was not confused or misled by the scope of AndroGel's indication. He believed "age-related" hypogonadism to be outside the indication, *id.* at 167:2-4, and did not recall any representative telling him he should prescribe for "age-related" hypogonadism. *Id.* at 167:9-13. In any event, plaintiffs' theory of an "age-related" fraud is irrelevant in this case, where Dr. Canzler never diagnosed Mr. Mitchell with "age-related" hypogonadism. *Id.* at 165:16-166:1. Mr. Mitchell was only 43, with unequivocally low testosterone, at the time of his first prescription. *Id.* at 51:11-20. Finally, any suggestion that Dr. Canzler was somehow deceived or misled by the Company's risk information is belied by the fact that he warned Mr. Mitchell of the potential cardiovascular risks. Canzler Dep. at 39:5-19.

### D. THE STRICT-LIABILITY CLAIM FAILS WITHOUT EVIDENCE OF DESIGN DEFECT OR REASONABLE CONSUMER EXPECTATIONS.

Mr. Mitchell's strict-liability claim requires proof that AndroGel was in a defective condition and unreasonably dangerous. Before trial, Mr. Mitchell's counsel contended he would be pursuing a design-defect and warning-defect claim. But Mr. Mitchell presented no evidence to support a design-defect claim. No expert identified a purported design flaw or articulated any theory of defect apart from the claim that the product was unreasonably dangerous because it lacked appropriate warnings and instructions for use. The evidence presented in Mr. Mitchell's

case-in-chief confirms the correctness of the Court's decision to instruct the jury only on a warning-defect theory of strict liability. Tr. at 188:5-190:1.

Mr. Mitchell's remaining warning-defect strict-liability claim also fails. In addition to the failures of proof on the issues of medical causation and warning adequacy, detailed above, Mr. Mitchell has offered no evidence that AndroGel was dangerous to an extent beyond that which would be contemplated by the "ordinary consumer." To the extent this standard is determined solely by reference to Mr. Mitchell's reasonable consumer expectations—which AbbVie maintains would be error—there has been no evidence as to those expectations, and Mr. Mitchell conceded he knew nothing about AndroGel before Dr. Canzler prescribed it for him. Mitchell Dep. at 116:8-13. To the extent this standard examines the reasonable expectations of Dr. Canzler, there is no evidence he believed AndroGel to be unreasonably dangerous. To the contrary, Dr. Canzler believed, in his medical judgment, that AndroGel was a good medication for Mr. Mitchell. Canzler Dep. at 77:10-13. To this day, Dr. Canzler still believes the benefits of AndroGel for Mr. Mitchell outweighed the risks. *Id.* at 77:14-19.

**E. OREGON LAW AND DUE PROCESS BAR ANY PUNITIVE-DAMAGE AWARD.**

Even if the Court allows Mr. Mitchell's claims to proceed, the Court should direct a verdict for AbbVie on the issue of Mr. Mitchell's request for punitive damages. Initially, AbbVie respectfully contends it was error for the Court to apply Illinois punitive-damage law to the claims of an Oregon man who used AndroGel, and had his heart attack in Oregon. Given these significant Oregon contacts, Illinois choice-of-law principles direct Oregon law to apply to all issues in this case, including punitive damages. *Hammond v. Sys. Transp., Inc.*, 879 N.E.2d 893 (Ill. 2007). Under Oregon law, a drug manufacturer "shall not be liable for punitive damages" where the drug "was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal Food and Drug

Administration," or "[i]s generally recognized as safe and effective" by the FDA. O.R.S. § 30.927(1)(a)-(b). There is no dispute that since AndroGel's initial approval in 2000, at all times it has remained approved as safe and effective by the FDA, and has been accompanied by FDA-approved labeling.[9] It would violate Due Process to allow punitive damages here, for Oregon, where Mr. Mitchell resides and had his heart attack, would not permit such damages. *Cf. BMW of N. America, Inc. v. Gore*, 517 U.S. 559, 572-75 (1996).

Plaintiffs also have not shown that the Company's conduct was "fraudulent, intentional, or willful and wanton," as required to impose punitive damages under Illinois law. Tr. at 194:6-12. Mr. Mitchell has not identified any "false" statements. Nor has Mr. Mitchell identified any evidence that the Company intended to cause harm. Mr. Mitchell's counsel promised a punitive-damage case premised on allegations of long-standing "off-label" promotion for "age-related hypogonadism." Plaintiffs' Proffer Regarding The Case Against AbbVie For Punitive Liability, at 3-4 (Doc. No. 390). But counsel used only 10 of the 32 identified "punitive-damage" documents in his case-in-chief, and did not link any of these allegations or evidence to Mr. Mitchell. No advertising influenced his decision to take AndroGel. *See supra* at Section C. Dr. Canzler did not determine Mr. Mitchell suffered from "age-related hypogonadism." *Id.* And there is no direct evidence that Dr. Canzler saw any of the marketing or medical literature submitted by counsel in their punitive-damage proffer. *Id.*

[9] There is a limited statutory exception that permits punitive damages where the plaintiff has proven by clear and convincing evidence that the defendant "knowingly in violation of applicable federal [FDA] regulations withheld from or misrepresented to the agency or prescribing physician information known to be material and relevant to the harm which the plaintiff suffered." O.R.S. § 30.927(2). This exception does not apply to Mr. Mitchell, who has not advanced any preempted "parallel" claim that AbbVie violated FDA regulations or withheld information from the FDA. And as noted above, there is no evidence, much less clear and convincing evidence, to establish AbbVie made misrepresentations, or withheld information from Dr. Canzler.

Because there is no link between counsel's supposed "punitive-damages evidence" and the facts relevant to Mr. Mitchell's care and treatment, it would violate Due Process to allow any punitive-damage award in this case. The Supreme Court has cautioned, "[a] defendant's dissimilar acts, independent from the acts upon which liability was premised, may not serve as the basis for punitive damages. A defendant should be punished for the conduct that harmed the plaintiff, not for being an unsavory individual or business. 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." *State Farm Mut. Auto Ins. v. Campbell*, 538 U.S. 408, 422-23 (2003); *see also Philip Morris USA v. Williams*, 549 U.S. 346, 353-58 (2007) (holding Due Process bars punitive-damages award that punishes for harm caused to others).

## CONCLUSION

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

Dated: July 17, 2017

By: /s/ *David M. Bernick*
David M. Bernick
Paul, Weiss, Rifkind, Wharton & Garrison LLP
1285 Avenue of the Americas
New York, NY 10019-6064
Tel: (212) 373-3000
dbernick@paulweiss.com

***Counsel for AbbVie Inc.***

Nathan E. Hoffman
Dechert LLP
35 W. Wacker Dr., Suite 3400
Chicago, IL 60601-1608
Tel: (312) 646-5800
nathan.hoffman@dechert.com

Hope S. Freiwald
Friedrich-Wilhelm W. Sachse
Michelle Hart Yeary
Dechert LLP
2929 Arch St., Cira Centre
Philadelphia, PA 19104-2808
Tel: (215) 994-4000
hope.freiwald@dechert.com
will.sachse@dechert.com
michelle.yeary@dechert.com

***Counsel for AbbVie Inc. and Abbott Laboratories***

**CERTIFICATE OF SERVICE**

I, David Bernick, hereby certify that on July 17, 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