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

In re: Testosterone Replacement Therapy Products Liability Litigation Coordinated Pretrial Proceedings	)	**No. 14 C 1748**
	)	**MDL No. 2545**
This Document relates to all cases and to:	)	
***Konrad v. AbbVie, Inc.*, Case No. 15 C 966 & *Mitchell v. AbbVie, Inc.*, Case No. 14 C 9178**	)	

**CASE MANAGEMENT ORDER NO. 59
(rulings on omnibus motions *in limine* in AbbVie bellwether cases and case-specific motions *in limine* in *Konrad v. AbbVie, Inc.,* Case No. 15 C 966 and *Mitchell v. AbbVie, Inc.*, Case No. 14 C 9178)**

In separate cases in this multidistrict litigation proceeding, plaintiffs Jeffrey Konrad and Jesse Mitchell have sued AbbVie Inc. and Abbott Laboratories (collectively AbbVie). Konrad and Mitchell both allege that they suffered heart attacks as a result of taking AbbVie's testosterone replacement therapy (TRT) drug AndroGel. The Court has selected Konrad's and Mitchell's cases as bellwether trial cases and has scheduled the cases, respectively, as the first and second bellwether trials in this proceeding. Both sides have filed motions *in limine*, many of which relate to all of the AbbVie-specific bellwether trial cases against AbbVie, and some of which relate only to Konrad's and Mitchell's cases. In ruling on the parties' motions, the Court assumes familiarity with its prior decisions.

A. Evidence AbbVie has moved to exclude

1. "Waived claims"

AbbVie argues that plaintiffs should be barred from introducing evidence that

AbbVie's submissions to the FDA were misleading or incomplete because plaintiffs waived any claim that the FDA was misled by AbbVie's submissions or that the FDA would have acted differently had AbbVie disclosed complete or accurate information. On this issue, the Court has already ruled that plaintiffs may not assert a claim that AbbVie defrauded the FDA or that the FDA would have acted differently on the basis of other information. *See In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, 2017 WL 1836443, at *20 (N.D. Ill. May 8, 2017) (*In re TRT* Off-Label Marketing Ruling). The Court has also ruled, however, that evidence of what information AbbVie provided to, and withheld from, the FDA is relevant to plaintiffs' claims that AbbVie misled the public, including plaintiffs and their prescribing physicians. *Id.* AbbVie argues that any information it withheld from the FDA is information it was not required to submit, and thus withholding that information was not misleading. AbbVie will be free to press this point on cross-examination. Plaintiffs may introduce evidence that AbbVie's submissions to the FDA misled the public; AbbVie's arguments to the contrary go to the weight, rather than the admissibility, of that evidence. AbbVie's motion to exclude evidence of information it submitted to the FDA is denied.

2. FDA activity subsequent to the dates plaintiffs stopped using AndroGel

Konrad stopped using AndroGel in 2010, and Mitchell stopped using the drug in 2012. AbbVie moves to exclude evidence of changes to the AndroGel label or other regulatory activity that occurred after plaintiffs stopped using the drug. In their response, plaintiffs argue that they should be allowed to present evidence about revisions to the AndroGel label that took place in 2015. AbbVie contends that evidence

regarding subsequent strengthening of its warnings labels is inadmissible as a subsequent remedial measure under Federal Rule of Evidence 407. As a number of courts have ruled, however, Rule 407's exclusion of evidence regarding subsequent remedial measures does not extend to measures that are mandated, rather than undertaken voluntarily. *See, e.g.*, *Lolie v. Ohio Brass Co.*, 502 F.2d 741, 744 (7th Cir. 1974) (primary basis for Rule 407 inapplicable where evidence offered against party that did not initiate remedial measures); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & PMF Prod. Liab. Litig.*, No. 3:09-CV-10012-DRH, 2011 WL 6740391, at *8 (S.D. Ill. Dec. 22, 2011) (concluding Rule 407 did not apply where FDA asked pharmaceutical company to take corrective action); *In re Levaquin Prod. Liab. Litig.*, No. 08-5743 JRT, 2010 WL 4882595, at *1 (D. Minn. Nov. 24, 2010) ("Rule 407 does not bar evidence of subsequent remedial measures that are mandated by a governmental agency[.]"). Because the FDA required AbbVie to make the 2015 changes to its label, the Court concludes that Rule 407 does not apply. "[T]he policy goal of encouraging remediation would not necessarily be furthered" by excluding that evidence. *O'Dell v. Hercules, Inc.*, 904 F.2d 1194, 1204 (8th Cir. 1990).

AbbVie maintains that even if Rule 407 does not apply, evidence of label changes or other regulatory activity that post-dates plaintiffs' use of AndroGel is irrelevant to any of plaintiffs' claims. The Court disagrees. To the extent the changes FDA required indicate its views on AndroGel's ability to cause heart attacks, the evidence is relevant on the issue of causation. The 2015 label revisions are also relevant, when considered with evidence of how plaintiffs' prescribing physicians and other physicians changed their prescribing practices in response to those revisions, on

the question of what plaintiffs' prescribing physicians would have done had AndroGel's label been different at the time they prescribed the drug to plaintiffs. AbbVie's motion to exclude is denied with respect to the 2015 revisions to the AndroGel label.

3. Marketing materials other than those seen or relied upon by plaintiffs or their prescribing physicians

AbbVie moves to exclude AndroGel marketing materials that neither plaintiffs nor their prescribing physicians viewed or relied upon in deciding to take or prescribe the drug. According to AbbVie, the only marketing materials relevant to plaintiffs' claims are those with some causal link to plaintiffs' decision to use the drug or their doctors' decision to prescribe. Thus AbbVie seeks to exclude all other marketing materials, including internal marketing plans, communications between AbbVie and its marketing firm, drafts of advertisements that were never used, notes of meetings between sales representatives and doctors other than plaintiffs' prescribing doctors, evidence of educational programs AbbVie sponsored, and marketing materials targeting conditions plaintiffs did not actually suffer. There is evidence that plaintiffs and their prescribing physicians were aware of AndroGel marketing materials and that some of those materials may have influenced their decisions to take or to prescribe the drug. Plaintiffs maintain that the materials viewed by plaintiffs and their physicians were part of a larger, extensive marketing campaign that used false or misleading statements to create a market for off-label AndroGel use.

The Court concludes that even if certain marketing materials played no direct causal role in plaintiffs' use of the drug, those materials may still be relevant on the question of AbbVie's knowledge that its marketing was misleading or its intent to create an off-label market. *See, e.g.*, *In re TRT* Off-Label Marketing Ruling, 2017 WL

1836443, at *15 (admitting testimony regarding AbbVie's knowledge, motivations, and intent in marketing); *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, No. 3:09-CV-10012-DRH, 2011 WL 6812683, at *2–*3 (S.D. Ill. Dec. 27, 2011) (admitting evidence of internal market conversations as relevant on claims involving off-label marketing). AbbVie represents that plaintiffs have identified over 100 examples of marketing materials on their exhibit list, most of which were never viewed by plaintiffs or their physicians. Although the Court has found these materials generally relevant and admissible, at some point the Rule 403 balance will tip toward exclusion based on cumulativeness or, perhaps, the danger of unfair prejudice. The tipping point may vary depending on whether plaintiffs' claims for punitive damages will be presented to the jury along with their liability claims in a unitary trial or will be bifurcated. With these caveats, however, the Court denies AbbVie's motion to exclude other marketing materials.

4. Other AbbVie drugs and TRT manufacturers other than AbbVie

AbbVie moves to exclude evidence relating to AbbVie drugs other than AndroGel and to other manufacturers of TRT products. Except with respect to communications from the FDA to other TRT manufacturers that AbbVie received and which put AbbVie on notice of its marketing obligations, the Court grants AbbVie's motion. Evidence of AbbVie's alleged improper conduct with respect to Depakote, another of its drugs, is inadmissible evidence of AbbVie's corporate character. *See* Fed. R. Evid. 404(b). Plaintiffs argue that a "corporate integrity agreement" that AbbVie entered into in connection with Depakote is relevant because it shows that AbbVie agreed, in general, that it would act to deter off-label activity and other improper conduct by its sales

representatives. Had AbbVie entered into the corporate integrity agreement prior to the dates that plaintiffs began taking AndroGel, the agreement likely would be relevant to show that AbbVie had notice of the need to police its sales representatives and yet failed to live up to the standards to which it had agreed. The agreement, however, was signed in May 2012, after plaintiffs' physicians had prescribed AndroGel. Plaintiffs argued at the final pretrial conference that the agreement still is admissible to establish a certain standard of care, but because there is no evidence the standard was established or agreed upon at the time plaintiffs were prescribed AndroGel, the agreement is not relevant and is thus inadmissible in Konrad and Mitchell's cases.

AbbVie also moves to exclude evidence related to a drug it was developing using dihydrotestosterone (DHT) to treat hypogonadism. AbbVie abandoned development of the drug in the early 2000s. Plaintiffs argue that evidence regarding AbbVie's DHT drug is relevant because communications from the FDA in 1997 about DHT show that the FDA was concerned about the need to study DHT (a metabolite of testosterone) in older men. The Court is not persuaded that the FDA's concern this far in the past has significant probative value on the issue of AbbVie's obligation to study the effects of TRT. Any probative value the evidence has is outweighed by its potential to confuse the jury. *See* Fed. R. Evid. 403.

Evidence regarding other manufacturers of TRT has similar potential for confusion or unfair prejudice. Other manufacturers' TRT products have different marketing and regulatory histories, and thus testimony or other evidence about those products may be misleading unless it is placed in the proper context. Establishing that context would take up a significant amount of time and would also be unfairly prejudicial

to AbbVie, as plaintiffs have access—through discovery with other defendants in the MDL—to information about other TRT manufacturers that AbbVie lacks.

The Court concludes, however, that at least one item of evidence regarding another manufacturer of TRT is relevant and does not pose a substantial risk of unfair prejudice or confusion. A 2010 letter from the FDA to Slate Pharmaceuticals explains that Slate was engaging in improper marketing of its own TRT product. Plaintiffs contend that the alleged improper marketing was parallel to AbbVie's marketing and that AbbVie received a copy of the letter soon after Slate did, thus giving AbbVie notice that its own off-label marketing was inappropriate. Because evidence introduced for that purpose can be understood without the need for extended background on Slate's TRT drug, it is admissible.

5. "Unofficial" public statements made by Dr. Daniel Shames

AbbVie moves to exclude evidence of "unofficial" public statements made by Dr. Daniel Shames, who worked for the FDA at the time as its Deputy Director for the Office of Drug Evaluation III. AbbVie argues that Dr. Shames' statements in the mainstream media have little probative value because they were informal and did not represent the FDA's official position. According to AbbVie, plaintiffs' true purpose for introducing the evidence is to show that alleged off-label marketing had a public profile, which AbbVie contends would be unfairly prejudicial. The Court concludes, however, that the statements' probative value outweighs the potential for unfair prejudice and therefore denies AbbVie's motion. The statements are relevant on the question of AbbVie's notice of the alleged need to conduct additional studies regarding TRT and of its alleged off-label promotion, and plaintiffs' experts, Drs. David Kessler and Peggy Pence, have

appropriately relied on Dr. Shames' statements in forming their own expert opinions, which the Court has already deemed admissible.

The Court defers ruling on AbbVie's general hearsay objection to Dr. Shames' statements until the Court can evaluate the context in which plaintiffs seek to introduce specific statements at trial.

6. Foreign regulatory actions and labeling

AbbVie moves to exclude evidence of AndroGel labels used in foreign countries and foreign regulatory action regarding the drug. The Court denies the motion in part. The Court generally agrees with AbbVie that foreign labeling or regulatory actions have little relevance on the question of whether a defendant's U.S. label is adequate. In addition, the Court acknowledges the danger that allowing evidence of foreign regulatory procedures could "result in a series of 'mini-trials'" that might confuse the jury and waste time. *In re Seroquel Prod. Liab. Litig.*, 601 F. Supp. 2d 1313, 1318 (M.D. Fla. 2009). Yet the Court is persuaded that the evidence plaintiffs seek to offer regarding a particular action by Canadian regulators regarding AndroGel is sufficiently narrow in scope that it can be admitted without the need for an extended discussion of Canadian regulatory procedure. Specifically, plaintiffs seek to counter AbbVie's contention that it was unaware that different categories of hypogonadism might be interpreted as having separate indicated uses. According to plaintiffs, communications between AbbVie and a Canadian regulatory agency reflects that AbbVie knew hypogonadism could be separated into different categories with different corresponding indications. Evidence of those communications is relevant regarding whether AbbVie knew that it was engaging in off-label marketing, and understanding the evidence does not require extensive

understanding of Canadian regulatory procedure. Its probative value thus outweighs its potential to be misleading or to unfairly prejudice AbbVie.

7. Wealth, profits, or employee compensation of AbbVie

AbbVie seeks to exclude evidence of its wealth or compensation levels of its employees. The Court grants AbbVie's motion. The Court has already ruled that, to the extent punitive damages claims are presented to the jury, plaintiffs may present evidence of AbbVie's net worth but that other evidence of AbbVie's wealth is unnecessary. As discussed in that ruling, the probative value of AbbVie's wealth and profits and of its employees' compensation is outweighed by the substantial danger of unfair prejudice. *See* Fed. R. Evid. 403. The potential bias or interest of particular AbbVie employees who testify is sufficiently shown by their connection to the company; admission of their salaries is unnecessary.

8. General criticisms of the FDA

AbbVie moves to exclude general criticisms of the FDA that are unrelated to its specific regulation of AndroGel, such as arguments that the FDA is ineffective or lacks adequate resources. The Court grants AbbVie's motion in part and denies it in part. Plaintiffs concede that they may not elicit testimony regarding why the FDA acted or failed to act with respect to AndroGel's marketing materials. Nevertheless, should AbbVie argue or introduce evidence suggesting that FDA's actions or inactions indicate FDA's approval of AbbVie's marketing or conduct, plaintiffs will be permitted to rebut that evidence by suggesting that, for example, FDA's resources do not allow it to address all actions or misconduct by drug manufacturers.

9. Prescriber misconduct

AbbVie seeks to exclude evidence of prescriber misconduct. Specifically, AbbVie argues that plaintiffs should be precluded from offering evidence about "men's clinics," which some doctors established to administer and prescribe TRT off label, as well as allegedly inaccurate statements by doctors about TRT's benefits. According to AbbVie, though that evidence may show that certain physicians acted inappropriately, it does not tend to show that AbbVie acted inappropriately.

The Court grants AbbVie's motion. Plaintiffs contend that evidence of this alleged misconduct of physicians is relevant because it is the direct outgrowth of AbbVie's off-label marketing plan. Plaintiffs, however, have not established that the connection between AbbVie's off-label marketing and the actions taken by physicians is sufficiently direct that the evidence's probative value outweighs its potential for unfair prejudice. The Court notes that there is no evidence that Mitchell or Konrad attended a "men's clinic" or that either of their physicians made statements about AndroGel similar to the statements plaintiffs seek to introduce. The connection between AbbVie's marketing and the allegedly inappropriate conduct of physicians is too attenuated and too far removed from the facts of this case to outweigh the significant potential for unfair prejudice.

10. Use of the phrase "bought the doctors"

The Court denies AbbVie's motion to bar plaintiffs from arguing that AbbVie "bought the doctors," without prejudice to AbbVie's ability to raise the issue prior to closing argument.

11. Documents whose relevance has not been established by a witness

AbbVie moves to exclude conditionally relevant documents whose foundation has not been established by what AbbVie refers to as "a reliable fact witness." The Court denies AbbVie's motion without prejudice to AbbVie's ability to object at trial to admission of particular documents. The Court has previously rejected AbbVie's contention that each document admitted into evidence must have a "sponsor."

12. Fact testimony from AbbVie's designated expert witnesses

AbbVie has moved to bar plaintiffs from eliciting fact testimony from witnesses AbbVie has designated as experts. Plaintiffs contend that AbbVie's purpose in designating the witnesses in question as experts was to prevent plaintiffs from calling them as fact witnesses. The Court has ordered the parties to submit further briefing on this issue.

13. Expert opinions that were not timely disclosed

Some of plaintiffs' expert witnesses have recently provided supplements to their original expert reports. AbbVie argues that these supplements contain discussion of information that was available to the experts at the time they issued their initial reports and that they are thus not timely supplemental disclosures under Federal Rule of Civil Procedure 26(e). On that basis, AbbVie moves to bar any expert opinions contained in the allegedly untimely supplements.

The Court denies AbbVie's motion. It appears that much of the information contained in the supplemental submissions comes from studies and documents that were not available at the time of the initial expert disclosure deadline. In addition, it does not appear that any of plaintiffs' experts have altered their opinions in any

significant way such that AbbVie would be unfairly prejudiced by the admission of their testimony. In any event, plaintiffs' experts submitted their supplemental reports by the deadlines set by Federal Rules of Civil Procedure 26(e) and 26(a). Opinions contained in those reports will be admissible.

AbbVie also urges the Court to exclude any opinion outside the scope of the initial or supplemental expert reports. Opinions not disclosed in an expert's report(s) are inadmissible unless the failure to disclose the opinions was substantially justified or harmless. Fed. R. Civ. P. 37(c). The Court declines to rule prospectively and in the blind on the admissibility of purportedly undisclosed expert opinions; a party with an objection along these lines will have to assert it during the trial.

14. Evidence of marketing relating to conditions plaintiffs did not have

AbbVie moves to exclude any marketing materials suggesting that TRT could be used to treat erectile dysfunction, diabetes, HIV, or other conditions from which neither Konrad nor Mitchell suffered. AbbVie argues that those materials are not relevant because Konrad and Mitchell did not have those conditions and did not use AndroGel for the purpose of treating those conditions. According to AbbVie, introduction of marketing relating to other conditions would mislead the jury into thinking that Konrad and Mitchell did suffer from those conditions. The Court disagrees and denies AbbVie's motion. As discussed above, evidence relating to off-label marketing is generally admissible to show AbbVie's intent, motivation, and knowledge with respect to marketing. The risk that the jury will be misled about plaintiffs' conditions is minimal and can be easily addressed via cross-examination or the admission of contrary evidence.

15. Evidence or testimony referring to the term "widow maker"

AbbVie moves to exclude any references to Konrad's heart attack using the phrase "widow maker." The type of heart attack that Konrad suffered, resulting from a blockage in the left anterior descending coronary artery, is sometimes colloquially referred to as a "widow maker." AbbVie argues that the phrase is inflammatory and prejudicial, as well as misleading because Konrad did not die from the heart attack, and his wife thus did not become a widow. The Court agrees and grants AbbVie's motion. Use of the phrase "widow maker" has little probative value, and any probative value it has is outweighed by the substantial danger of unfair prejudice and misleading the jury. *See* Fed. R. Evid. 403.

16. Testimony from Konrad's children

AbbVie moves to exclude testimony from Konrad's children because his children are not plaintiffs in the case. Even if they were named as plaintiffs, AbbVie notes, children cannot recover for loss of parental consortium under Tennessee law. Konrad responds that his children will not be called to testify about their own damages but to provide accounts of how Konrad's heart attack affected his life. Testimony along these lines is relevant. It may end up being cumulative and inadmissible under Rule 403, but any such objections will have to be assessed at trial.

17. Evidence of Mitchell's spouse's lost income

Mitchell concedes that evidence of his spouse's lost income is not relevant, and the Court therefore grants AbbVie's motion to exclude that evidence.

18. Evidence supporting claims for profit disgorgement

Plaintiffs concede that they do not have claims for profit disgorgement and that

any evidence offered to support such claims is therefore irrelevant. The Court therefore grants AbbVie's motion to exclude that evidence.

19. Certain evidence regarding pain and suffering

AbbVie requests that the Court limit the type of evidence plaintiffs may introduce relating to pain and suffering. Specifically, AbbVie argues that Konrad should not be able to offer evidence that amounts to speculation about pain he will suffer in the future, because speculative or conjectural evidence is not admissible for determining damages under Tennessee law. AbbVie also argues that Mitchell should be barred from introducing evidence in support of a separate claim for loss of enjoyment of life because such a claim does not exist under Oregon law. The Court grants AbbVie's motion in part and denies it in part. Konrad represents that he does intend to offer speculative evidence, and the Court expects him not to do so. But Konrad may offer evidence of a non-speculative nature in support of an award for future damages. Exactly where this line gets drawn cannot be determined in advance, so AbbVie should assert any appropriate objections at trial.

With regard to evidence of loss of enjoyment in Mitchell's case, the Court does not understand Mitchell to be offering a separate, stand-alone claim for loss of enjoyment. AbbVie has not offered any authority for the proposition that evidence that would suggest loss of enjoyment is inadmissible under Oregon law with regard to the types of claims Mitchell is pursuing. The Court therefore denies AbbVie's motion with respect to that evidence.

20. Testimony that a doctor "smashed" a "trash can" on Mitchell's chest

During her deposition, Mitchell's wife explained that it looked like Mitchell's doctor

"smashed" a "garbage can" on Mitchell's chest when treating his heart attack. AbbVie argues that this testimony should be excluded because it is inflammatory and prejudicial and because Mitchell's doctor testified that he did not use a garbage can when treating Mitchell and did not "smash" anything on his chest. Rather, he merely leaned on Mitchell's chest using an insulated plastic box. Mitchell responds that his wife should be permitted to provide her own eyewitness account of her husband's injury. The Court disagrees. Mitchell's doctor will already be testifying about his treatment of Mitchell. The account of Mitchell's wife—specifically, her subjective perception of what was happening—has little if any probative value, and its admission would pose a significant risk of unfair prejudice. The Court grants AbbVie's motion.

B. Evidence plaintiffs have moved to exclude

1. Letter from Public Citizen to the FDA and FDA's response

Plaintiffs move to exclude a 2014 letter from consumer advocacy group Public Citizen to the FDA, as well as the FDA's response to the letter. In the letter, Public Citizen asked the FDA to require TRT manufacturers to strengthen their warnings in specific ways regarding the connection between TRT and increased cardiovascular risk. The FDA declined to take any of the requested actions, in part because it did not believe there was sufficient evidence of a causal link between TRT and adverse cardiovascular events.

Plaintiffs argue that admission of the Public Citizen letter and the FDA's response would unfairly prejudice plaintiffs because it would suggest that the FDA has already conclusively determined two of the issues in this case: whether AndroGel causes cardiovascular injuries, and whether AbbVie sufficiently warned about the risk of

cardiovascular injuries. According to plaintiffs, the FDA's response does not establish either proposition, because the response only represented the FDA's interim, non-final opinion on the matter and because the FDA was responding to Public Citizen's specific warning recommendations, not assessing the adequacy of TRT warning labels as a whole. AbbVie responds that the letter and the FDA's response are relevant on causation regardless of whether the response was the agency's final opinion on the matter.

The Court denies plaintiffs' motion. Just as plaintiffs will be permitted to offer evidence regarding AbbVie's subsequent label changes as evidence of causation, AbbVie should be permitted to offer evidence of this FDA activity that suggests TRT does not cause cardiovascular injuries. Through cross-examination, plaintiffs can attempt to demonstrate that the FDA's opinion was non-final and that it did not conclusively adjudicate the adequacy of AndroGel's label at the time. The Court is not persuaded that the evidence's potential to mislead or confuse the jury is so great that it should be excluded.

2. Communications between AbbVie and FDA regarding "unbranded" promotional activities

Plaintiffs move to exclude evidence regarding communications between the FDA and AbbVie regarding AbbVie's "unbranded" marketing of TRT products. Plaintiffs provide only one example of the type of communications they wish to exclude, an email from an AbbVie employee indicating that the FDA had no comments on a piece of unbranded promotional material AbbVie had submitted to the FDA. Plaintiffs argue that this evidence would misleadingly suggest that the FDA had approved AbbVie's unbranded promotional activities. AbbVie argues that the evidence is relevant to rebut

plaintiffs' assertion that AbbVie's purpose in engaging in unbranded promotion was to skirt FDA oversight. Because the email gives no indication regarding why the FDA purportedly did not comment (and thus does not suggest that this has any meaning at all), its probative value is virtually nonexistent and is far outweighed by its potential to mislead the jury.

3. FDA's 1996 webpage regarding other TRT drug

Plaintiffs move to preclude AbbVie from offering a screenshot or printout of a page from the FDA's website that discusses Androderm, another TRT drug. The webpage is dated January–February 1996. AbbVie notes that the webpage includes a statement that only 5 percent of the estimated 4 to 5 million men in the United States with hypogonadism receive TRT treatment. According to AbbVie, this statement is relevant because it rebuts plaintiffs' contention that AbbVie and other TRT manufacturers created a market for TRT products that did not previously exist, and AbbVie argues that references to Androderm can be redacted to minimize the possibility of confusion or prejudice. But even if the name of the other TRT product were redacted, the potential for misleading and confusing the jury would outweigh the webpage's probative value. It is unclear how the FDA came to issue the statement contained on the page or what the source of its data was. If data exists regarding the number of men with untreated hypogonadism in 1996, the original source of the data would have much greater probative value. But without the proper context, a jury might give undue weight to an informal statement on the FDA's website. The Court grants plaintiffs' motion.

4. Evidence or argument suggesting FDA has ultimate responsibility for drug's label

Plaintiffs move to exclude evidence or argument suggesting that the FDA, rather

than the product manufacturer, bears the ultimate responsibility for a drug's warning label. AbbVie concedes that a drug manufacturer may change its warning label and that it would thus be incorrect to say that the FDA has "ultimate" responsibility for the label's content. Nevertheless, AbbVie contends that the FDA does have some responsibility over the content of a drug's label—for example, in approving labels the manufacturers suggest. The Court agrees that it would be misleading to argue or suggest that FDA has ultimate responsibility for the content of a drug's warning label and thus grants plaintiffs' motion on that general basis. With respect to the more specific issue of what roles the FDA and the manufacturer play in the labeling process, the Court has directed the parties to confer and attempt to agree upon an instruction for the Court to provide to the jury regarding a manufacturer's labeling responsibilities under FDA regulations and other federal law.

5. Argument that "overwarning" dilutes the effectiveness of warnings

Plaintiffs move to prohibit AbbVie from arguing that "overwarning," or providing too much warning information on a label, can dilute the effectiveness of warnings. The Court agrees with plaintiffs that it would be unfairly prejudicial for AbbVie to offer evidence or argument suggesting that personal injury claims of the type plaintiffs are bringing lead manufacturers to include false or unsubstantiated warnings on their labels to protect against lawsuits. AbbVie, however, has not indicated that it intends to make such an argument. With respect to the question of whether AbbVie may argue that including too much information may dilute a warning's effectiveness, the Seventh Circuit has recognized that diluted warnings resulting from overwarning is a legitimate concern. *See Mason v. SmithKline Beecham Corp*., 596 F.3d 387, 392 (7th Cir. 2010). For this

reason, the Court denies plaintiffs' motion.

6. Expert testimony from AbbVie's corporate fact witnesses

Plaintiffs move to bar AbbVie's fact witnesses from offering undisclosed expert testimony. Plaintiffs concern arises from a letter from AbbVie's counsel indicating some of its fact witnesses would be offering expert testimony at trial. AbbVie represented at the final pretrial conference that it was a mistake to suggest that its fact witnesses would offer expert testimony. Although some of its fact witnesses will be testifying about their experience working in complex, technical fields, AbbVie maintains that those witnesses will not testify on matters outside the scope of their work experiences or otherwise offer expert opinions.

The Court grants plaintiffs' motion, to the extent that undisclosed expert testimony is inadmissible unless the failure to disclose the testimony in a timely manner is harmless or substantially justified. *See* Fed. R. Civ. P. 37(c). Given AbbVie's representations about the type of fact testimony it intends to elicit from its witnesses, however, the Court does not expect that AbbVie will attempt to elicit from fact witnesses testimony that would require disclosure under Federal Rule of Civil Procedure 26(a). If this happens, plaintiffs should interpose an objection, and the Court will address it and will take whatever remedial action is appropriate.

7. New opinions about causes of plaintiffs' injuries

Plaintiffs seek to prohibit AbbVie's experts from testifying about potential causes of plaintiffs' injuries that they failed to reference in their expert reports. AbbVie argues that plaintiffs' motion is too vague for it provide a meaningful response. The Court agrees—plaintiffs have not provided any reason to expect that any of AbbVie's experts

intends to offer undisclosed opinions along these lines. The admission of undisclosed expert testimony is governed by Federal Rule of Civil Procedure 37(c); it will be admissible only if the failure to disclose it was harmless or substantially justified. A party aggrieved by an attempt to offer undisclosed opinion testimony should object and request a sidebar.

8. "Good company" conduct

Plaintiffs move to exclude evidence of AbbVie's good corporate conduct as unfairly prejudicial to plaintiffs under Federal Rule of Evidence 403 and inadmissible character evidence under Federal Rule of Evidence 404. The Court agrees that the categories of "good conduct" plaintiffs identify—evidence regarding benefits of other drugs AbbVie produces, donations to charitable organizations, or philanthropic activity—is inadmissible character evidence. Though AbbVie seeks to inform the jury about its company by explaining that it focuses on addressing immunological disorders, oncology, neuroscience, and virology, this evidence would also be inadmissible as character evidence whose probative value is outweighed by its potential prejudice to plaintiffs. It is conceivable that some evidence that might be considered "good conduct" evidence may be admissible to rebut assertions of bad conduct, such as a generalized argument that AbbVie put profits over people. But whether plaintiffs open the door to any such "good conduct" evidence is an issue better left for determination at trial.

9. Expert compensation

Plaintiffs maintain that if AbbVie questions plaintiffs' expert witnesses about their compensation, plaintiffs should be permitted to elicit testimony that the experts' work was on behalf of numerous plaintiffs as a part of this large multidistrict proceeding. The

Court has directed the parties to confer and attempt to agree on how the issue of each expert's compensation should be presented to the jury, if at all. The Court defers ruling on plaintiffs' motion pending a further report on the parties' attempt to reach an agreement.

10. Negligence by plaintiffs' healthcare providers

Plaintiffs move to exclude evidence or argument that their healthcare providers were negligent or committed malpractice. AbbVie responds that it has no intention of making that argument or offering any such evidence. It maintains, however, that it may properly introduce testimony that certain risk factors for plaintiffs' injuries were not adequately controlled. The Court agrees with AbbVie. Whether plaintiffs' risk factors for heart attack were adequately controlled is relevant on the issue of causation, and its probative value is not significantly outweighed by any factor considered under Rule 403. The Court denies plaintiffs' motion.

11. Statements by non-party medical associations

Plaintiffs seek to exclude statements from guidelines published by the Endocrine Society and the American Association of Clinical Endocrinologists on the basis that they constitute inadmissible hearsay. According to AbbVie, it intends to offer statements from the guidelines not to establish the truth of what is contained in the guidelines but to rebut plaintiffs' contentions that AbbVie made up an indicated use for AndroGel by showing that a medical society independently reached the same conclusion. The statements are not inadmissible hearsay if admitted for this purpose (plaintiffs may propose an appropriate limiting instruction if they wish). In addition, the statements may be presented to the jury for their truth (though not admitted into evidence) under the

learned treatise exception to the hearsay rule as long as an expert lays the foundation required by Federal Rule of Evidence 803(18).

12. Circumstances surrounding plaintiffs' retention of counsel

Plaintiffs move to exclude evidence or testimony about the circumstances surrounding plaintiffs' retention of counsel—for example, whether plaintiffs viewed attorney advertising before filing their cases. The Court agrees that such evidence has no, or virtually no, probative value and that its potential for unfair prejudice is great. The Court grants plaintiffs' motion.

13. Slides created by Dr. Laurentias Marais

Plaintiffs move to prohibit the presentation of slides made by Dr. Marais to summarize some of the analysis he performed in this case. In addition to asking the Court generally to bar Dr. Marais' slides, plaintiffs argue (1) that AbbVie should not be allowed to present the slides during opening statement because the jury will lack the proper context for the material and (2) that the slides should not be admitted into evidence to be sent to the jury room because they contain summaries of learned treatises, which would themselves be barred from admission into evidence as hearsay. Federal Rule of Evidence 1006 allows a party to "use a summary, chart, or calculation to prove the content of voluminous writings." Fed. R. Evid. 1006. The slides prepared by Dr. Marais will be admissible under Rule 1006 to the extent they summarize otherwise admissible evidence. Plaintiffs may be correct that some of the demonstratives summarize evidence that is not separately admissible under Rule 803(18) or otherwise, and thus the Court cannot address that issue at this juncture. In addition, because neither side has provided sufficient background on this point, the

Court cannot determine whether the slides are admissible into evidence or instead may be used only as demonstrative exhibits that are not admitted. Thus AbbVie is precluded from using the slides during its opening statement.

14. Dr. Overby's testimony regarding cause of Konrad's heart attack

Konrad moves to exclude the testimony of his treating physician, Dr. Steven Overby, regarding whether AndroGel was the cause of his heart attack. An opinion about the specific cause of the plaintiff's injury is undoubtedly an expert opinion requiring disclosure under Federal Rule of Civil Procedure 26(a). Indeed, AbbVie challenged the adequacy of plaintiffs' experts' specific causation opinions in every bellwether case. AbbVie, however, failed to identify Dr. Overby as a witness who would be providing expert testimony, and it has failed to explain how that failure to disclose was harmless or substantially justified. *See* Fed. R. Civ. P. 37(c). The Court grants Konrad's motion.

15. Konrad's use of other prescription drugs

Konrad moves to exclude evidence that he took prescription drugs other than AndroGel because there is no evidence that those other drugs caused his heart attack. AbbVie responds that it does not intend to offer evidence regarding Konrad's other prescription drugs to show causation. Rather, AbbVie argues, Konrad's willingness to take prescription drugs that warned of serious side effects is relevant to the question of whether the stronger warning label plaintiffs believe was necessary would even have deterred Konrad from taking AndroGel. AbbVie, however, has not explained how the risks warned of on those drugs' labels compares to the cardiovascular risk at issue here, and it similarly has not explained how the benefits of those drugs compares to

AndroGel's purported benefits. The probative value of these drugs and Konrad's decision to use them appears to be minimal at best. The potential to confuse or mislead the jury, by contrast, is significant. The Court therefore grants Konrad's motion.

16. Speculative testimony regarding other risk factors for heart attack

Konrad seeks to exclude certain evidence and testimony by Dr. William French, one of AbbVie's experts, suggesting risk factors for Konrad's heart attack that Konrad argues have no basis in his medical records. The Court notes that plaintiffs did not move to exclude this testimony from Dr. French at the *Daubert* stage and that in general, Konrad's criticisms of the evidence and testimony AbbVie intends to offer go to the weight, rather than the admissibility, of the evidence. *See Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000) ("The soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact."). At trial, Konrad will be free to cross-examine Dr. French and question whether his opinions have adequate support in his medical records.

Konrad also argues that Dr. French should be barred from listing metabolic syndrome as a risk factor for Konrad's heart attack while simultaneously listing discrete symptoms of metabolic syndrome as separate risk factors; that testimony, according to Konrad, would be cumulative. Dr. French opines, however, that each risk factor he has identified is a separate risk factor for a heart attack and that the combination of the risk factors in the form of metabolic syndrome is also its own risk factor. Plaintiffs may challenge that opinion during cross-examination, but the opinion itself is not unduly cumulative or otherwise inadmissible. The Court denies Konrad's motion.

17. Konrad's family medical history

Konrad moves to preclude AbbVie from offering evidence or argument regarding his family's medical history unrelated to his heart attack. The Court grants his motion in part. Though Dr. French mentioned in his expert report that Konrad's father had prostate cancer and that his mother had a fatty liver, neither Dr. French nor AbbVie explains why that history is relevant for assessing the cause of Konrad's heart attack. That evidence is inadmissible. The relevance of Konrad's grandfather's heart attack is clearer and thus admissible.

18. Mitchell's use of other prescription drugs

For the same reasons that Konrad's use of other prescription drugs will not be admitted, the Court grant's Mitchell's motion to exclude evidence about his use of drugs other than AndroGel that are unrelated to his injury.

19. Expert testimony from Mitchell's treating physician

For the same reasons that undisclosed expert testimony from Konrad's treating physician will not be admitted, the Court grants Mitchell's motion to bar his treating physician from offering undisclosed expert opinions.

20. Mitchell's use of alcohol and marijuana

Plaintiffs move to exclude evidence that Mitchell used alcohol and marijuana. AbbVie does not contend that alcohol and marijuana use caused Mitchell's heart attack, but it argues that use of alcohol and marijuana demonstrates his penchant for taking risks, as well as the likelihood that he lived a sedentary lifestyle, which is a risk for heart attack. The latter point is a stretch, to say the least. That aside, any probative value the evidence has, however, is far outweighed by its potential for unfair prejudice. *See* Fed.

R. Evid. 403; *see also* Fed. R. Evid. 404. The Court thus grants plaintiffs' motion to exclude evidence of Mitchell's alcohol and marijuana use.

21. Mitchell's conviction for driving under the influence of alcohol (DUI)

Mitchell's DUI conviction has even greater potential for unfair prejudice than his alcohol or marijuana use, but its probative value is no greater. The Court thus grants plaintiffs' motion to exclude that evidence.

MATTHEW F. KENNELLY
United States District Judge

Date: May 29, 2017