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

In re: Testosterone Replacement Therapy Products Liability Litigation Coordination Pretrial Proceedings	)	**Case No. 14 C 1748** **MDL No. 2545**
(This document applies to all cases and *Mitchell v. AbbVie*, Case No. 14 C 9178)	)	

CASE MANAGEMENT ORDER NO. 105
(Memorandum Opinion and Order on plaintiff's motion to exclude cumulative expert testimony in *Mitchell v. AbbVie*, No. 14 C 9178)

MATTHEW F. KENNELLY, District Judge:

In the first trial in the *Mitchell v. AbbVie* case—one of the AbbVie-only bellwether cases selected for trial—AbbVie called four witnesses who gave expert opinion testimony on the question of general causation, that is, whether AbbVie's drug AndroGel causes or increases the risk of an adverse cardiovascular (CV) event in a person taking the drug. The witnesses were Dr. William French, Dr. Mohit Khera, Dr. Linda Scarazzini, and Dr. Laurentius Marais.

Dr. French, a cardiologist, testified at length about the results of studies regarding testosterone replacement therapy (TRT), attempting to debunk or explain studies that showed an increased incidence of adverse CV events, and referencing studies that showed positive benefits from TRT. Dr. French opined that there is no statistically significant association between TRT and CV events and thus no causation. He also testified about the alleged biological mechanisms by which TRT is claimed to cause an increased incidence of CV events, as well as studies about that topic. He gave testimony regarding non-TRT risk factors that lead to an increased risk of CV

events. Dr. French also testified regarding an analysis of studies of adverse events conducted by Dr. Marais.

Dr. Khera, a urologist, testified regarding the diagnosis and management of "hypogonadism" and the risks and benefits of TRT. He discussed at least one of the adverse event studies that Dr. French had addressed. Dr. Khera testified about his involvement in the "Androgen Study Group." He also discussed the proposition that the same or similar risk factors that lead to hypogonadism are also risk factors for cardiovascular disease. He testified about studies regarding the risks and benefits of TRT. He opined that TRT leads to a *decreased* incidence of CV events. Dr. Khera also testified regarding medical literature about CV risks and what he tells patients before prescribing TRT to them.

Dr. Scarazzini is a medical doctor who previously worked for the Food and Drug Administration (FDA) and now works for AbbVie. She is in charge of "pharmacovigilance" for AbbVie, which involves, among other things, looking for safety-related "signals" associated with the company's products (including AndroGel) and evaluating reports of adverse events. She testified regarding safety findings made by the FDA. She also gave testimony regarding a "white paper"—a detailed safety assessment—prepared by AbbVie that included a review of literature regarding whether TRT is safe, as well as AbbVie's response to inquiries by an FDA advisory committee. Dr. Scarazzini also discussed some of the same literature addressed by the other AbbVie general causation-related witnesses. She testified that she agreed with what she characterized as conclusions (favorable to AbbVie) reached by the FDA after evaluating reports of adverse events following use of TRT.

Dr. Marais is a statistician. He testified about how to properly design studies to evaluate causation and about the topic of statistical significance. During his testimony on direct examination, plaintiff's counsel objected on the basis of cumulativeness. The Court overruled the objection, finding that plaintiff had waited too late to assert the point. During his ensuing testimony, Dr. Marais discussed a significant number of studies regarding TRT usage and CV events. He opined that the studies show no statistically significant association between TRT and CV events.

During the first *Mitchell* trial, AbbVie also called a separate specific-causation witness, in other words a witness who testified regarding whether AbbVie had caused the plaintiff's heart attack.

At the next bellwether trial in this MDL regarding a CV injury—the *Konrad* case—AbbVie called the same four witnesses discussed above, and each of them again gave testimony bearing on general causation. AbbVie called them in a different sequence, conceivably in an effort to avoid the cumulativeness objection regarding Dr. Marais cited in the first *Mitchell* trial. Specifically, Dr. Marais was called first. His testimony did not differ significantly from his testimony in the first *Mitchell* trial. Dr. Scarazzini was called second. Her testimony likewise involved the same topics as her testimony in the first *Mitchell* trial.

Dr. French testified third among these witnesses. He, too, gave general causation testimony, as he had done in the *Mitchell* trial. But unlike in the *Mitchell* trial, Dr. French did double duty, also providing specific causation testimony regarding the plaintiff. Defense counsel steered around *some* of the general causation testimony that Dr. French had given in the *Mitchell* trial. Nonetheless, Dr. French again testified

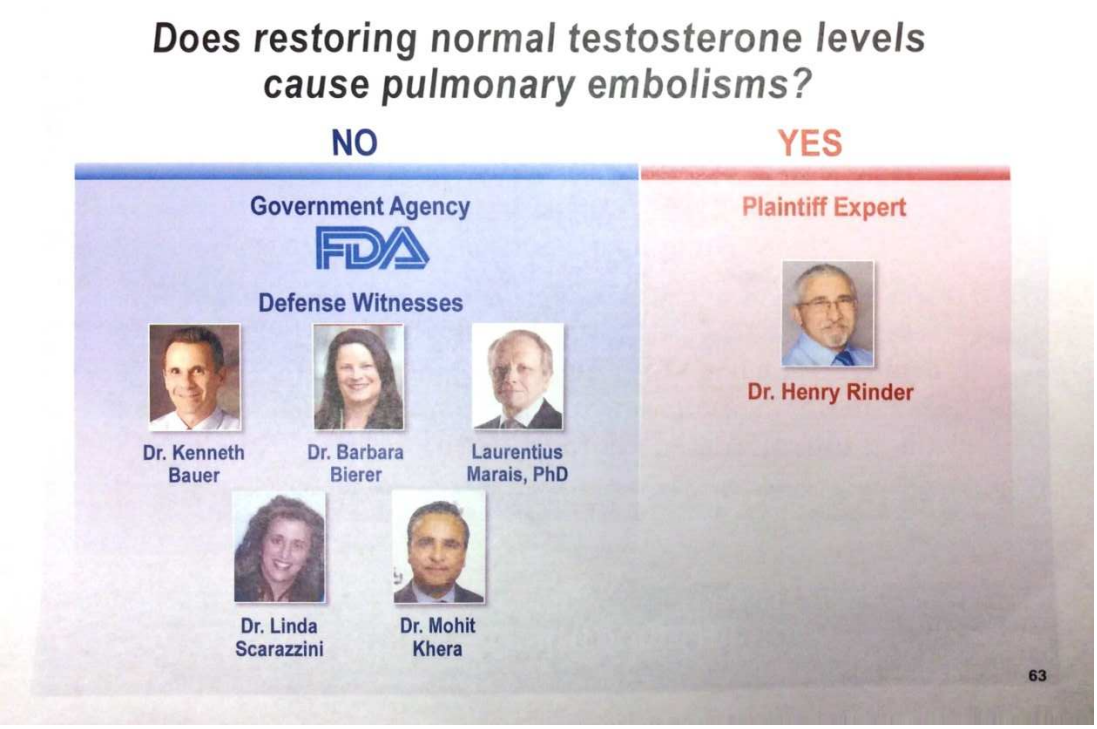
regarding what, in his opinion, scientific studies had shown regarding whether TRT causes adverse CV events, which was plainly general causation testimony. In doing so, Dr. French made reference to—and in effect incorporated—Dr. Marais' testimony regarding the statistical significance of study results. Dr. French was specifically asked about studies that relate to men like plaintiff Konrad who were under 55 years old and had, like him, used TRT for 45 to 60 days; he stated that none of them found an association with CV events or any statistically significant impact from TRT. Dr. French also rendered testimony regarding studies concerning the alleged mechanisms by which TRT is claimed to cause CV events.

Dr. Khera testified last among the defense general causation witnesses during the *Konrad* trial. His testimony was very similar to the testimony he gave during the first *Mitchell* trial. He also testified that the FDA agreed with the Androgen Study Group's comments regarding TRT use and safety. His ultimate opinion was, again, that the benefits of TRT to patients outweigh its risks.

A third bellwether trial with AbbVie as a defendant, the *Nolte* case, was tried in January 2018. This case involved a pulmonary embolism allegedly caused by AndroGel. AbbVie again called multiple witnesses who testified regarding whether AndroGel causes adverse events—this time clotting events—specifically, five such witnesses. Plaintiff's counsel again sought to bar Dr. Marais as cumulative—and again did this at or around the start of his testimony—and the Court again denied the motion, primarily based on the late timing of the request.

During closing argument in the *Nolte* case, AbbVie's counsel emphasized the number of causation witnesses it had called as compared with the number the plaintiff

had called. Counsel pointed out that AbbVie had presented testimony from five experts, all of whom testified that AndroGel does not cause adverse events, but that the plaintiff had called only one. Counsel also used a slide that presented this in a dramatic way:



The nature of the argument made by defense counsel during closing argument in *Nolte* led the Court to consider the issue of whether AbbVie was presenting unduly cumulative expert testimony regarding causation. In anticipation of the retrial in *Mitchell*, the Court raised this issue with the parties during a case management conference. Plaintiff included a motion to this effect in his pretrial motions *in limine* prior to the second *Mitchell* trial. The Court made an oral ruling on that motion at the outset of the trial and now memorializes its decision in writing.

Under Federal Rule of Evidence 403, a court may exclude relevant evidence "if its probative value is substantially outweighed by a danger of one or more of the

following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. This rule applies to expert testimony just as it applies to any other evidence. Indeed, this district's local rules—specifically the final pretrial order form—have for decades contained a provision stating that "[o]nly one expert witness on each subject for each party will be permitted to testify absent good cause shown." N.D. Ill. LR 16.1.1, Final Pretrial Order form at n.7, *see* http://www.ilnd.uscourts.gov/_assets/_documents/_forms/_legal/NewRules/New00152.htm (last visited Mar. 11, 2018).

In both the *Mitchell* and *Konrad* trials, AbbVie presented not one, not two, but *four* witnesses who gave expert testimony on the subject of general causation; in *Nolte*, AbbVie presented five such witnesses. In two of the previous trials, the plaintiffs made a last-minute objection to some of this evidence—specifically, the testimony of Dr. Marais—but the Court overruled the objections based on their timing. In anticipation of the *Mitchell* retrial, the plaintiff made a timely objection, raising the issue prior to trial. Thus the question is properly presented.

Each of the AbbVie witnesses who testified about general causation approached this from his or her own perspective, but that does not diminish the fact that AbbVie called several witnesses who all gave testimony on the subject of general causation. And, as discussed, there has been a significant amount of overlap in the testimony of these witnesses.

The Court concludes that the presentation of this many expert witnesses on the subject of general causation amounts to the needless presentation of cumulative

evidence, and it also unfairly prejudices the plaintiff, who has limited himself in each of the cases tried thus far to one general-causation expert witness. This risk of harm significantly outweighs the probative value of the duplicative or cumulative evidence. A trial should not reduce itself to an exercise of counting up and comparing the number of witnesses who testify for each side on a particular topic. That, however, is what AbbVie's presentation of cumulative general-causation expert testimony has encouraged. AbbVie itself brought the point home in exactly this way during closing argument in the *Nolte* trial, but even without that express endorsement, there is a significant risk that a jury will perform the same calculation, consciously or unconsciously.

Perhaps the most significant overlap in the testimony of the AbbVie witnesses has involved testimony about studies regarding whether TRT causes an increased incidence of CV events, and the import and significance of those studies. In this regard, Dr. Marais' testimony has nearly completely overlapped with that of Dr. French. To put it another way, Dr. Marais' testimony on this point has been needlessly cumulative of that of Dr. French (and, to some extent, of other opinion witnesses called by AbbVie). By way of example, Dr. Marais' testimony in the first *Mitchell* trial added nothing material—aside from an additional voice—to the testimony of Dr. French about the studies. The Court wishes to make it clear, however, that this particular overlap is not the sole basis for the finding of needless cumulativeness. The Court is looking both at the forest—the multiple witnesses testifying about general causation—and the trees—the testimony about studies and medical literature.

With regard to the testimony of Dr. Marais, at least, AbbVie's presentation of

expert general-causation testimony has amounted to the needless presentation of cumulative evidence. The Court appreciates that, as a matter of trial strategy, it is more advantageous to have two experts from different fields interpret and assess a body of evidence. But that does not make their testimony any less needlessly cumulative or unfairly prejudicial. Even in the *Konrad* trial—after the cumulativeness issue had been raised by plaintiff in *Mitchell*—Dr. French, despite the carve-back of the length of his testimony on general causation, adopted and supplemented Dr. Marais' conclusions regarding scientific studies on causation of CV events and statistical significance. There is nothing at all wrong with one expert relying on and incorporating another expert's analysis if a reasonable expert would do so, *see* Fed. R. Evid. 703, but that does not mean that both of them can appropriately testify at trial on the same subject. Nor can AbbVie avoid this by calling Dr. Marais first, as it did in the *Konrad* trial.

Conclusion

For the reasons stated above, the Court excludes Dr. Marais as a witness. The Court reserves the right to make additional cumulativeness findings as the MDL bellwether trial process progresses. The Court also acknowledges that the exact same general causation witnesses will not necessarily be called in each bellwether trial, so if clarification is required for subsequent trials regarding which witnesses may be called, it will be incumbent upon the parties to seek such clarification.

Date: March 14, 2018

MATTHEW F. KENNELLY
United States District Judge