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

In re: Testosterone Replacement	**)**	
Therapy Products Liability Litigation	**)**	**No. 14 C 1748**
Coordinated Pretrial Proceedings	**)**	**MDL No. 2545**
	)	
(This document applies to all cases)	**)**	

CASE MANAGEMENT ORDER NO. 64
(Ruling on motion for reconsideration of
***Daubert* ruling concerning Dr. Ardehali's testimony)**

Following a mistrial in the first bellwether trial (*Konrad*) and just before the start of the second bellwether trial (*Mitchell*), defendants AbbVie Inc. and Abbott Laboratories (AbbVie) filed a motion seeking to preclude plaintiffs' expert Dr. Hossein Ardehali from relying on certain adverse event reports in his trial testimony. AbbVie characterizes its filing as partly a motion to enforce one of the Court's prior rulings and partly a request to reconsider a prior ruling.

Prior to the bellwether trials against AbbVie, the Court denied AbbVie's motions to exclude Dr. Ardehali's testimony concerning general causation (whether AbbVie's testosterone replacement therapy (TRT) drug AndroGel causes the cardiovascular injuries plaintiffs allege) and notice (whether, and at what point, AbbVie should have been aware that a causal association existed between AndroGel and cardiovascular injuries). AbbVie maintains that it would be inappropriate for Dr. Ardehali to rely on certain adverse event reports referred to as "Medwatch forms" in support of either his causation or his notice opinion.

With respect to his causation opinion, AbbVie argues that the Court's ruling already precluded Dr. Ardehali from referencing the Medwatch forms, because the

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Court relied on plaintiffs' representation that those forms did not inform Dr. Ardehali's opinion and his consideration of them thus did not render his opinion unreliable. *See In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, 2017 WL 1833173, at *12 (N.D. Ill. May 8, 2017) (denying motion to exclude Dr. Ardehali's causation opinion and noting plaintiff's representation that adverse event reports did not inform that opinion). AbbVie now seeks enforcement of that ruling.

With respect to Dr. Ardehali's notice opinion, AbbVie argues that the Court's prior ruling focused on whether Dr. Ardehali's reliance on adverse event reports was sufficient to create a genuine dispute of fact for trial but that the Court failed to consider whether his notice opinion was based on a reliable methodology. AbbVie also argues that Dr. Ardehali's testimony in the *Konrad* trial provides new evidence demonstrating that he is unqualified to offer an opinion about notice and that the opinion he does offer is not based on a reliable methodology.

A. Causation

The Court disagrees with AbbVie that the prior ruling precludes Dr. Ardehali from testifying about how the data in the Medwatch forms impact his opinion regarding causation. The Court made clear in its ruling that an expert's causation opinion may rely on relatively weak sources of evidence, such as case reports and adverse event reports, as long as those are not the only sources on which the expert relies. *See id.* at *15. Indeed, under the "totality of the evidence" approach employed by Dr. Ardehali in this case, an expert may properly consider different sources of scientific evidence, of varying weight and reliability, as long as the expert "explains how the weight of the

various pieces of evidence led him to his conclusion." *Id.* at *9.

It may be the case, as plaintiffs represented to the Court in their response to AbbVie's *Daubert* motion, that Dr. Ardehali did not initially consider the Medwatch forms for the purpose of forming his causation opinion and that he would reach the same opinion whether or not he considered any adverse event reports. But that would not preclude Dr. Ardehali from opining on how the adverse event reports he did ultimately consider would fit into the "totality of evidence" concerning the causal relationship between TRT and cardiovascular injuries.

B. Notice

With respect to Dr. Ardehali's notice opinion, the Court is not persuaded that its prior ruling was based on a misunderstanding of AbbVie's position or that Dr. Ardehali's testimony in the *Konrad* trial provides new evidence warranting reconsideration. In its ruling on AbbVie's motion concerning plaintiffs' failure-to-warn claims, the Court considered whether it was permissible for a witness who is not an expert in pharmacovigilance to review adverse event reports in forming an opinion that a defendant was on notice of a causal association. The Court rejected AbbVie's argument that Dr. Ardehali's lack of training in pharmacovigilance or adherence to FDA guidelines rendered his analysis of adverse event reports unreliable. *See In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, 2017 WL 1836435, at *13 (N.D. Ill. May 8, 2017). Though with respect to Dr. Ardehali's opinion, the Court said that those purported deficiencies in his opinion did not "prevent Dr. Ardehali's opinion from giving rise to a genuine dispute of fact," *id.*, its discussion of Dr. Henry Rinder's opinion made clear that those same purported

deficiencies did not render an expert's notice opinion inadmissible. *See id.* at *15. As with Dr. Ardehali's causation opinion, the Court determined that his notice opinion, based on his review of "both the scientific literature and the adverse event reports that would have been available to AbbVie" provided a sufficiently reliable basis for the opinion he offered: an expert in the field reasonably should have known in 2007 that there was a causal association between AndroGel and increased cardiovascular risk. *Id.* at *13.

None of the testimony from the *Konrad* trial that AbbVie cites qualifies as the kind of new evidence that would warrant reconsideration. Dr. Ardehali testified during the *Konrad* trial that he was not an expert in pharmacovigilance and did not adhere to the FDA guidelines for analyzing the adverse event reports, but that was known to the parties and to the Court at the time of the initial ruling. AbbVie points to other testimony from Dr. Ardehali that it says undermines his analysis of the Medwatch forms—such as his admission that he received the reports from counsel or that medical records are more reliable than the adverse event reports he reviewed—but that testimony goes to the weight to be given to his testimony, not its admissibility.

Finally, AbbVie contends that Dr. Ardehali's opinion does not "fit" the law and facts of this case because he does not opine about whether the method AbbVie used to analyze the adverse event reports was reasonable. But as plaintiffs point out, this is an argument AbbVie could have made in its initial motion. "A motion for reconsideration is not an opportunity for a party to plug gaps in its earlier briefing." *Valero Energy Corp. v. United States*, No. 06 C 6730, 2008 WL 4104367, at *3 (N.D. Ill. Aug. 26, 2008) (Kennelly, J.).

Conclusion

For the reasons discussed above, the Court denies AbbVie's motion for reconsideration [dkt. no. 2066].

MATTHEW F. KENNELLY
United States District Judge

Date: July 11, 2017