

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF KENTUCKY  
CENTRAL DIVISION  
LEXINGTON

CONNIE J. THACKER,  
Plaintiff,

v.

ETHICON, INC. and JOHNSON &  
JOHNSON,  
Defendants.

CIVIL ACTION NO. 5:20-50-KKC

OPINION AND ORDER

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This matter is before the Court on the motion (DE 128) by defendants (together, “Ethicon”) to exclude certain opinions of the plaintiff’s expert, Dr. Bruce Rosenzweig.

This is a medical device product liability action for damages allegedly arising from Plaintiff Connie Thacker’s implantation on May 8, 2009, with Prolift and TVT-S, two surgical mesh devices manufactured by defendant Ethicon, Inc. and designed to treat pelvic organ prolapse and stress urinary incontinence in women.

This motion asks the Court to exclude Dr. Rosenzweig’s opinion that the defendants failed to provide Thacker’s implanting physician, Dr. James Guiler, with sufficient information about Prolift and TVT-Secur. The motion also asks the Court to prohibit Dr. Rosenzweig from offering any opinions on general causation.

As to the defendants’ motion to exclude Dr. Rosenzweig’s opinion regarding whether the defendants gave Dr. Guiler sufficient information about Prolift and TVT-Secur, the defendants point to the following statements in Dr. Rosenzweig’s report:

Based upon my review of Ms. Thacker’s medical records, my experience and education, my review of depositions, internal Ethicon documents, and review of the available medical literature, I currently hold the

following opinions to a reasonable degree of medical certainty:

1. Ms. Thacker was not able to make a fully informed medical decision regarding the implantation of the TVT-S and Prolift mesh because Ethicon failed to fully disclose the risks and complications (both early and late) in the TVT-S and Prolift Instructions for Use. As discussed above, and elsewhere in this report, Ms. Thacker did not receive information about the above risks because Ethicon did not disclose them fully in its IFUs, and surgeons, including the implanting surgeon in Ms. Thacker's case, were not made aware of them. This is true despite information readily available to Ethicon about these risks, which predate the launch of the devices. Because of this, Ms. Thacker's implanting surgeon could not pass this information on to her and properly consent her about the risks associated with the TVT-S and Prolift devices. Ms. Thacker was unable to make a fully informed decision about having the devices implanted. As a result, to a reasonable degree of medical certainty, Ms. Thacker suffered injuries that were not disclosed by Ethicon, and the inadequate disclosure of these risks was a substantial factor and/or cause of Ms. Thacker's injuries.
2. Ms. Thacker's implanting surgeon, Dr. Guiler, was not able to provide the necessary and required information to Ms. Thacker for an informed consent because Ethicon failed to fully reveal such information and failed to fully evaluate said information prior to launch.

(DE 128-1, Rosenzweig Report at 80-81)

Defendants object to these opinions only on the grounds that Dr. Rosenzweig should not be able to testify as to Dr. Guiler's state of mind. Defendants argue that "Dr. Rosenzweig has no insight or expertise into Dr. Guiler's specific knowledge or state of mind . . . ." (DE 128, Motion at 1-2.) Defendants do not object in this motion to Dr. Rosenzweig's qualifications to opine as to whether Ethicon adequately disclosed the risks and complications of its products.

The Court agrees that Dr. Rosenzweig should not be permitted to testify as to Dr. Guiler's knowledge or state of mind. Plaintiff asserts that she will call Dr. Guiler as a witness

at trial. Dr. Guiler can testify himself as to his knowledge and state of mind. The above portion of Dr. Rosenzweig's report does not, however, contain an opinion as to Dr. Guiler's knowledge or state of mind. Instead, it contains an opinion as to whether Ethicon adequately disclosed the risks and complication of its products to physicians, including Dr. Guiler. Dr. Rosenzweig opines that Ethicon did not and that, as a result, physicians could not have adequately disclosed the risks and complications, and patients could not have given informed consent. The Court will permit this testimony. To the extent that Dr. Rosenzweig's testimony about what Ethicon disclosed to Dr. Guiler is inconsistent with Dr. Guiler's own testimony, that would be proper material for cross examination. In this motion, Ethicon points to no evidence that is the case.

As to Dr. Rosenzweig's opinion regarding general causation, Ethicon argues that plaintiff Thacker has not designated Dr. Rosenzweig as an expert on general causation and, thus, the Court should preclude him from testifying on the topic.

The Court will deny this motion because the defendants have not presented the Court with sufficient evidence that Thacker failed to properly designate Dr. Rosenzweig as an expert on general causation.

This case was originally filed in this Court but, on July 31, 2012, it was transferred to the Southern District of West Virginia as part of a multidistrict litigation ("MDL"). *In re: Ethicon, Inc. Pelvic Repair Systems Product Liability Litigation*. (DE 3, Conditional Transfer Order). The MDL court grouped cases into various "Waves." It designated Thacker's case as part of "Wave 4." (DE 44, Pretrial Order #243.) The pretrial order for the Wave 4 cases required that the plaintiff disclose experts by January 17, 2017; that defendants disclose experts by February 15, 2017, and that *Daubert* motions be filed by April 13, 2017. The pretrial order further provided that each side was limited to a maximum of five experts in each case. (DE 44, Pretrial Order # 243.)

In compliance with the MDL court's pretrial order, On January 17, 2017, plaintiffs' counsel in the MDL served on defense counsel a designation and disclosure of general expert witnesses. The disclosure listed 25 "general retained experts," including 13 urogynecologists. Among the experts identified was Dr. Rosenzweig, also a urogynecologist. (DE 186-4, Expert Disclosures.)

Defendants argue that the January 17, 2017 expert disclosure in the MDL did not satisfy the plaintiff's obligation to designate Dr. Rosenzweig as a general causation expert in her particular case. They argue that the disclosure could not have identified the general causation experts who Thacker intended to call in her case because she clearly did not intend to call all 25 doctors identified, especially given that the MDL Court limited each side to five retained experts in each case. Defendants assert that, with the January 17, 2017 expert disclosure, the Plaintiff Steering Committee ("PSC") in the MDL identified all general causation experts that would be retained in every Wave 4 case. Defendants argue that each individual plaintiff was then required to serve a separate disclosure identifying the general causation experts retained for that plaintiff's particular case. (DE 245, Reply at 3, n.2.)

Defendants do not point to any order by the MDL Court setting out this procedure. The only order that the defendants have pointed to is the Pretrial Order for the Wave 4 cases, which requires that plaintiffs disclose their experts by January 17, 2017.

To the extent that the MDL court did enter additional orders for plaintiffs' expert disclosures, it is not clear any such orders would have applied to Thacker's case. This is because, on June 28, 2017, the MDL court placed Thacker's case on the "inactive docket" after counsel advised the MDL court that the parties had agreed to a settlement model. The MDL court also continued all discovery deadlines for Thacker's case. (DE 56, Inactive Docket Order.) The case remained on the inactive docket in the MDL court until it was remanded to this Court. (DE 66, Suggestion of Remand.)

Accordingly, the Defendants have not presented this Court with sufficient evidence to find that Thacker failed to properly designate Rosenzweig as a general causation expert in the manner required by the MDL court. As to whether Thacker disclosed general causation experts in the manner required by this court, the scheduling order in this case was issued by Judge Joseph Hood, who presided over the case until he retired. That scheduling order set deadlines for Thacker and the defendants to provide “case-specific expert witness reports” and for defendants to “designate general causation experts and testimony developed and existing in” the MDL, but it did not set any deadline for the plaintiff to designate general causation experts. (DE 87, Scheduling Order at 2-3.) It is unclear why. Perhaps Judge Hood determined that Thacker had already identified general causation experts in the MDL in the manner established by that court. Regardless, Thacker did not miss any deadline set by this Court to identify general causation experts.

Thus, the Court will permit Dr. Rosenzweig to testify as a general causation expert on Thacker’s behalf.

Defendants assert that, because Thacker did not identify Dr. Rosenzweig as a general causation expert after the case was remanded, they did not file a *Daubert* motion to challenge the substance of Dr. Rosenzweig’s general causation opinions. While Defendants filed a motion in the MDL court to exclude Dr. Rosenzweig’s testimony on general causation, it appears that issue was litigated when Thacker’s case was on the inactive docket in the MDL. (DE 186-5, *Daubert* motion.) The MDL court provided that its *Daubert* ruling did not apply to Thacker’s case. (DE 186-6, MDL *Daubert* Ruling.) Accordingly, the Court will grant the defendants 30 days to file a *Daubert* motion challenging Dr. Rosenzweig’s testimony on general causation, with response and reply times as provided in the Local Rules.

To the extent that Defendants seek to exclude the general causation opinion of any expert not identified by name in their motion, any such request is too vague for the Court to address it. Accordingly, the Court denies any such request.

For all these reasons, the Court hereby ORDERS as follows:

- 1) Defendants' motion in limine no. 17 to exclude improper testimony from plaintiff's experts is DENIED; and
- 2) Defendants may file a motion to exclude the substance of Dr. Rosenzweig's general causation opinion. Any such motion must be filed within 30 days of the entry date of this order with response and reply times as provided in the Local Rules.

This 9<sup>th</sup> day of January, 2024.



*Karen K. Caldwell*  
KAREN K. CALDWELL  
UNITED STATES DISTRICT JUDGE  
EASTERN DISTRICT OF KENTUCKY