

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC.  
PELVIC REPAIR SYSTEMS  
PRODUCT LIABILITY LITIGATION

MDL No. 2327

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THIS DOCUMENT RELATES TO:

*Nancy Williams v. Ethicon, Inc., et al.*

Civil Action No. 2:12-cv-00511

**MEMORANDUM OPINION AND ORDER**  
**(*Daubert* Motion re: Gregory Bales, M.D.)**

Pending before the court is the Motion to Exclude Certain Opinions and Testimony of Gregory Bales, M.D. [ECF No. 103] filed by the plaintiff. The Motion is now ripe for consideration because briefing is complete.

**I. Background**

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more than 58,000 cases currently pending, approximately 28,000 of which are in this MDL, which involves defendants Johnson & Johnson and Ethicon, Inc. (collectively “Ethicon”), among others.

In this MDL, the court’s tasks include “resolv[ing] pretrial issues in a timely and expeditious manner” and “resolv[ing] important evidentiary disputes.” Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

*Litigation in Products Liability Cases* 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order (“PTO”) No. 217, the court instructed the parties to file general causation *Daubert* motions in the main MDL and specific causation *Daubert* motions, responses, and replies in the individual member cases. To the extent that an expert is both a general and specific causation expert, the parties were advised that that they could file a general causation motion in the main MDL 2327 and a specific causation motion in an individual member case. PTO No. 217, at 4.

## II. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

- (1) whether a theory or technique can be or has been tested;
- (2) whether it has been subjected to peer review and publication;
- (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and
- (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

*Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts “principles and methodology” above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g., Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

In the context of specific causation expert opinions, the Fourth Circuit has held that plaintiffs may use “a reliable differential diagnosis[, which] provides a valid foundation for an expert opinion.” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 263 (4th Cir. 1999).

A reliable differential diagnosis typically, though not invariably, is performed after ‘physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests,’ and generally is accomplished by determining the possible causes for the patient’s symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.

*Id.* at 262 (citations omitted).

Defendants, however, need not conduct a differential diagnosis to identify the specific cause of an injury because they do not bear the burden of proving causation. *See* 3 David Faigman et al. *Modern Sci. Evidence* § 21:6 (2015-2016 ed.). Indeed, a defendant’s specific causation expert’s testimony should not be excluded because it fails to identify the specific cause of a plaintiff’s injury. *See Yang v. Smith*, 728 S.E.2d 794, 800 (Ga. Ct. App. 2012) (refusing to exclude defendant’s specific causation expert

testimony where that testimony did not identify an injury's specific cause because the defendant had no burden to prove the specific cause of the injury). In lieu of conducting traditional differential diagnoses, defendants may instead provide expert testimony suggesting alternative causes for the plaintiff's injury in order to rebut the plaintiff's specific causation testimony. *See Westberry*, 178 F.3d at 265 ("The alternative causes suggested by a defendant 'affect the weight that the jury should give the expert's testimony and not the admissibility of that testimony,' unless the expert can offer 'no explanation for why she has concluded [an alternative cause offered by the opposing party] was not the sole cause.'" (citations omitted)); *see also* Faigman, *supra*, at § 21:4 ("Sometimes, the courts subtly shift the burden of production onto the defendant when determining whether the [plaintiff's] expert has done a sufficient job in ruling out other causes.").

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

### **III. Discussion**

The plaintiff essentially argues that Dr. Bales did not conduct a proper differential diagnosis because the plaintiff contends that Dr. Bales failed to identify a particular cause of the plaintiff's symptoms. However, as a defense specific causation witness, Dr. Bales need not conduct a differential diagnosis. Instead, he is tasked with giving testimony that affects the weight and potentially the admissibility of the plaintiff's specific causation expert. So long as the defense specific causation expert's opinion is a product of his specialized knowledge or training and is reliably

grounded, it should be admissible to rebut the plaintiff's specific causation expert.

Here, Dr. Bales is a urogynecologist who has performed over 1,000 pelvic floor surgeries. Resp. 2 [ECF No. 113]. Dr. Bales's expert report and deposition testimony show that he conducted a detailed review of the plaintiff's medical records and performed a physical examination of the plaintiff. Dr. Bales conducted a thorough, reliably-grounded analysis of the medical evidence and determined that the plaintiff's proffered specific cause was unlikely. He need not take an additional step and prove that another alternative cause caused the plaintiff's injury; causation is the plaintiff's burden. To the extent the plaintiff believes that Dr. Bales's testimony is flawed, she may address those issues on cross-examination and with the testimony of her own specific causation witness.

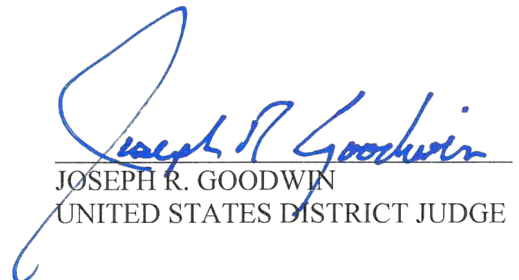
The plaintiff's Motion on this point is **DENIED**, and any remaining issues are **RESERVED** for trial.

#### **IV. Conclusion**

The court **ORDERS** that the Motion to Exclude Certain Opinions and Testimony of Gregory Bales, M.D. [ECF No. 103] is **DENIED in part** and **RESERVED in part**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: January 9, 2017

  
JOSEPH R. GOODWIN  
UNITED STATES DISTRICT JUDGE