

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA, *et al.*,
ex rel. MATTHEW A. FITZER, M.D.,

Plaintiffs,

v.

Civil Case No. 1:17-cv-00668-SAG

ALLERGAN, INC., *et al.*

Defendants.

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MEMORANDUM OPINION

Relator Matthew A. Fitzer (“Relator”) filed this case against Defendant Allergan, Inc. (“Allergan”), alleging that Allergan conducted an unlawful kickback scheme in violation of the False Claims Act, 31 U.S.C. § 3729, *et seq.*, by maintaining a surgeon locator on the website for its LAP-BAND product. ECF 1. At this post-discovery stage of the case, both parties have filed myriad motions, including various motions to exclude expert testimony. This opinion adjudicates two such motions in whole or part: Allergan’s Motion to Exclude the Opinions of Dr. Ian Larkin, ECF 200, and Relator’s *Daubert* Motion to Exclude / Strike Expert Testimony, ECF 197, as to three of the five experts discussed therein.¹ This Court has considered the motions, the oppositions, and the replies, along with the exhibits thereto. ECF 198, 220, 221, 230, 255, 258. No hearing is necessary as to the issues addressed herein. *See* Loc. R. 105.6 (D. Md. 2023). Allergan’s motion

¹ There are motions to exclude other experts on each side: Allison Hoffman for Relator and Katherine Norris and Benjamin Scher for Allergan. Those motions will be addressed at an upcoming motions hearing and are not adjudicated herein.

to exclude Dr. Larkin's testimony will be DENIED, and Relator's motion to exclude Allergan's expert testimony will be GRANTED IN PART, DENIED IN PART, and DEFERRED IN PART.²

I. LEGAL STANDARDS

Federal Rule of Evidence 702 governs the admissibility of expert witness testimony. A qualified expert may give testimony if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

FED. R. EVID. 702. In essence, the trial court must ensure the proposed expert testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993). In *Daubert*, the Supreme Court provides five non-exhaustive factors a court may weigh in making this assessment: (1) "whether a theory or technique . . . can be (and has been) tested," (2) "whether the theory or technique has been subjected to peer review and publication," (3) "the known or potential rate of error," (4) "the existence and maintenance of standards controlling the technique's operation," and (5) whether the technique or theory has gained "general acceptance." *Id.* at 593-94; *Pugh v. Louisville Ladder, Inc.*, 361 F. App'x 448,

² As this Court explained in an earlier opinion, Relator again makes an argument evidencing a misunderstanding of a portion of this Court's scheduling order. *See* ECF 197-1 at 3 n.1; ECF 297 at 1-2 n.1. This Court noted that *Daubert* motions relating only to trial testimony could be filed with motions *in limine*, but that any such motions also seeking to exclude an expert's testimony from consideration at the summary judgment stage needed to be filed with the dispositive motions. ECF 185. Allergan filed three expert disclosure motions on the earlier timetable, ECF 200, 201, 202, and Relator has responded, in part, that the motions are premature. In this Court's view, there is no such thing as a premature *Daubert* motion, as they can be filed at any time prior to the Court's scheduling deadline. And to the extent this Court finds that all or part of a witness's testimony should be excluded under the relevant standards, that ruling applies both at the summary judgment stage and at trial.

452 (4th Cir. 2010). However, ultimately, the inquiry is “a flexible one” and relevant factors can vary with the needs of each case. *Daubert*, 509 U.S. at 594.

For the proffered evidence to be sufficiently reliable it “must be derived using scientific or other valid methods” and not based on mere “belief or speculation.” *Casey v. Geek Squad Subsidiary Best Buy Stores, L.P.*, 823 F. Supp. 2d 334, 340 (D. Md. 2011) (quoting *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999)). The court’s analysis focuses on experts’ methods, not their conclusions, but an expert opinion that relies on “assumptions which are speculative and are not supported by the record,” is inadmissible. *Tyger Const. Co. v. Pensacola Const. Co.*, 29 F.3d 137, 142 (4th Cir. 1994); *see also Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (“[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.”). For the proffered opinion to be relevant, it “must be ‘sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute.’” *Casey*, 823 F. Supp. 2d at 341 (quoting *Daubert*, 509 U.S. at 591). Expert testimony “is presumed to be helpful unless it concerns matters within the everyday knowledge and experience of a lay juror.” *Anderson v. Home Depot U.S.A., Inc.*, Civ. No. GJH-14-2615, 2017 WL 2189508, at *4 (D. Md. May 16, 2017) (quoting *Kopf v. Skyrms*, 993 F.2d 374, 377 (4th Cir. 1993)).

The proponent of the expert testimony bears the burden of establishing admissibility, or “coming forward with evidence from which the trial court could determine that the evidence is admissible under *Daubert*.” *Id.* at *3 (quoting *Main St. Am. Grp. v. Sears, Roebuck, & Co.*, Civ. No. JFM-08-3292, 2010 WL 956178, at *3 (D. Md. Mar. 11, 2010)); *see also Casey*, 823 F. Supp.

2d at 340; *Daubert*, 509 U.S. at 592 n.10 (explaining admissibility must be established by a “preponderance of proof”).

In determining the admissibility of expert testimony, the court considers two “guiding, and sometimes competing, principles.” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999). On the one hand, Rule 702 was “intended to liberalize the introduction of relevant expert evidence,” and the court need not ensure the expert’s proposed testimony is “irrefutable or certainly correct.” *Id.* (explaining that admissible expert testimony can still be vigorously tested before the jury by “cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof” (quoting *Daubert*, 509 U.S. at 596)). On the other hand, “due to the difficulty of evaluating their testimony, expert witnesses have the potential to ‘be both powerful and quite misleading.’” *Id.* (quoting *Daubert*, 509 U.S. at 595). The court must determine whether the disputed expert testimony “has a greater potential to mislead than to enlighten.” *Id.* If so, the testimony should be excluded. *Id.*; *see also Casey*, 823 F. Supp. 2d at 341 (noting such testimony would be barred by Federal Rule of Evidence 403).

II. ANALYSIS

a. Allergan’s Motion to Exclude the Opinions of Dr. Ian Larkin

Relator intends to use Dr. Larkin, a business school professor, to establish, *inter alia*, that incentives are a fundamental driver of human and physician behavior, that pharmaceutical and medical device companies frequently use physician incentives to try to influence treatment decisions, that surgeons are particularly susceptible to incentives, and that Allergan’s use of a quota and some other features of the locator (such as the icons and the “trial period”) constituted strong incentives influencing physician decision-making. *See generally* ECF 221-1. Allergan contends that Dr. Larkin did not rely on sufficient data to support his analysis. This Court

disagrees. Dr. Larkin's proposed expert testimony is supported by his experience as a professor of strategy and behavioral decision-making. In rendering his opinion, he relied on various studies and social science principles, along with evidence relating to Allergan's actions, motivations, and discussions regarding its locator. While Allergan raises numerous criticisms about Dr. Larkin's failure to collect specific surgeon data regarding the locator's impact, if any, on surgeons' decisions to prescribe the LAP-BAND, *see* ECF 200, those criticisms are proper subjects of cross-examination.³ The motion to exclude his testimony will be denied.⁴

b. Relator's Motion to Exclude the Testimony of Dr. Thomas A. Gustafson

Dr. Gustafson, an economist and policy expert with experience working at the Centers for Medicare and Medicaid Services, offers two opinions on behalf of Allergan: (1) that Medicare does not distinguish between gastric band brands when paying reimbursement claims and (2) that Allergan's standards for surgeon experience to improve the quality of LAP-BAND procedures are among a number of reasonable quality and outcome considerations for structuring its locator as it did. *See* ECF 198-2 at 8. This Court agrees with Relator that Dr. Gustafson's first opinion should be excluded as unhelpful and unnecessary, because the parties can stipulate what appears undisputed: that the relevant Medicare code applies to both LAP-BAND and REALIZE band procedures without differentiation. This Court declines to exclude the remainder of Dr.

³ The Court disagrees with Allergan's assertion that Dr. Larkin's failure to conduct an empirical or statistical analysis renders his "conclusion as to causation" unreliable. ECF 255 at 8-9. Unlike the excluded opinions of Relator's damages expert, the appropriate causation standard in this case allows Dr. Larkin ample room to testify at trial (subject to cross-examination) about physician behavior and decision-making. For individual claims where Relator is able to make a sufficient showing of causation to survive summary judgment and get to trial, Dr. Larkin's testimony will still be relevant to whether Relator can sustain his burden of proof at that trial.

⁴ This Court also rejects Relator's contention that Dr. Larkin's deposition cannot be used because the attorney who took the deposition had not yet been admitted *pro hac vice*. *See* ECF 220 at 10 n.2. Relator failed to timely raise the issue on the record as required by Fed. R. Civ. P. 30(c)(2).

Gustafson's opinions which, like the opinions offered by Dr. Larkin, are based on his experience and a variety of medical literature and studies. Relator will be free to challenge those opinions on cross-examination.

c. Relator's Motion to Exclude the Testimony of Dr. W. David Bradford

Dr. Bradford, an economist and a professor of public administration and policy who focuses his research on healthcare economics, opines for Allergan that Allergan's interest in promoting high-volume surgeons aligns with good patient outcomes, surgeon competence, and the government's interest in paying less in Medicare reimbursements for corrective actions. ECF 198-1 at 6. Dr. Bradford also rebutted the opinion of Relator's damages expert, Christopher Haney, particularly as to Mr. Haney's decision to include "all procedures performed by physicians listed on the locator." *Id.* This rebuttal opinion will be excluded as moot, because this Court has excluded Mr. Haney's opinion testimony regarding the number of "tainted procedures" as violative of the causation standards elucidated by this Court. *See* ECF 297. This Court does not read Relator's motion to challenge Dr. Bradford's other affirmative opinions. Accordingly, the motion will be denied as to the remainder of Dr. Bradford's opinions for Allergan.

d. Relator's Motion to Exclude the Testimony of Vernon Lee Vincent

Allergan designated Vernon Vincent, the inventor of the LAP-BAND, as a hybrid fact / expert witness. He has decades of experience with the device he invented, designed, and patented. ECF 210-16 ¶ 4. Although he is not a medical doctor, he personally observed surgeries using prototype devices and was intimately involved in the process for seeking, procuring, and maintaining FDA approval and preparing training courses and best practices for physicians. *Id.* ¶¶ 5–11. He has spent thousands of hours in the clinical setting with LAP-BAND surgeons and their patients. *Id.* ¶¶ 13–14.

Relator argues that Mr. Vincent should not be allowed to offer testimony about clinically appropriate practices, patient outcomes, and the circumstances under which surgeons are “well-positioned” to provide effective patient care. ECF 198 at 22–23. Given Mr. Vincent’s unparalleled familiarity with the LAP-BAND including its safety record, his involvement in the clinical training for surgeons, and his observation of thousands of surgeries, this Court declines to exclude him from rendering expert opinions of that nature. Relator is free to challenge the basis of Mr. Vincent’s expertise on cross-examination.

III. CONCLUSION

For the reasons set forth above, Allergan’s Motion to Exclude the Opinions of Dr. Ian Larkin, ECF 200, is DENIED. Relator’s *Daubert* Motion to Exclude / Strike Expert Testimony, ECF 197, is GRANTED as to the first opinion by Dr. Gustafson but DENIED as to the remainder of his opinions, GRANTED AS MOOT as to Dr. Bradford’s rebuttal opinions relating to Mr. Haney’s causation opinions but DENIED as to the remainder of Dr. Bradford’s opinions, DENIED as to the opinions rendered by Mr. Vincent, and DEFERRED as to the opinions offered by Katherine Norris and Benjamin Scher. A separate order follows.

Dated: March 27, 2024

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Stephanie A. Gallagher
United States District Judge