

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.

* * * * *

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 ("FCA"), 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, the parties have filed myriad motions, including motions to exclude expert testimony. This opinion adjudicates one such motion: Allergan's Motion to Exclude the Opinions of Christopher L. Haney, Relator's damages expert, ECF 201. This Court has considered the motion, Relator's opposition, ECF 235, and Allergan's reply, ECF 250, along with the exhibits thereto. After considering the parties' positions, Allergan's motion to exclude Haney's testimony will be GRANTED IN PART and DENIED IN PART. 1

1 In his opposition and in other motions, Relator makes an argument evidencing a misunderstanding of a portion of this Court's scheduling order. See ECF 235 at 7-8. 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

I. RELEVANT BACKGROUND

Relator's damages expert, Christopher Haney, is a certified public accountant and certified fraud examiner, who also holds a certification in healthcare compliance. ECF 235-1 at 5.² He has almost twenty years of experience in those areas. *Id.* Relator retained Haney to calculate the government's financial damages relating to Allergan's locator. *Id.* at 4.

A cursory summary of Haney's damages calculations follows: Haney assumes, for purposes of his analysis, that any initial operations reimbursed by Medicare involving a LAP-BAND from 2008-2013 were "inducement-tainted."³ *Id.* at 16, 18. He posits, therefore, that the government would not have made any payments for those operations had it known the claims were the result of violative conduct. *Id.* at 18. In an effort to determine the number of LAP-BAND initial operations installed by surgeons during times they appeared on the locator, he reviewed spreadsheets maintained by Allergan, which he acknowledges "only provide reliable data for certain timeframes during the relevant period." *Id.* at 20. In other words, Haney had no records establishing exactly when any particular surgeon was added to or removed from the locator. He acknowledges that, at various times, Allergan removed significant numbers of surgeons from its locator. *Id.* at 25-26. Haney then compiled a list of the surgeons and the time frames when he believes they were on the locator, erring conservatively by including a particular surgeon only

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.

² In referring to various exhibits, this Court cites to the "ECF" page numbers at the header of the page and not to the actual page numbers on the underlying document. In the case of Haney's report, the ECF page number is generally one number greater than the report's own page number.

³ "Inducement-tainted" means reimbursement claims that violated the Anti-Kickback Statute ("AKS") and/or FCA.

when the surgeon had been included in the locator spreadsheets immediately preceding and immediately following the date of a surgery. *Id.* at 27.

To determine whether a procedure was reimbursed by the government, Haney reviewed Centers for Medicare and Medicaid Services (“CMS”) data for over 40,000 patients and over 84,000 claims associated with CPT code 43770, indicating gastric banding surgery. *Id.* at 21. Haney recognizes that CMS reimbursement data do not distinguish between LAP-BAND and REALIZE band (a competitor brand) operations.

In an effort to determine the number of “inducement-tainted Lap-Band devices,” Haney matched Allergan’s locator spreadsheets and CMS’s procedure data with Business Reply Card (“BRC”) data Allergan solicited from patients implanted with LAP-BANDs from 2008-2014. *Id.* at 20–21. There were BRCs for 43,920 patients in that time frame, although Allergan’s sales and shipping records showed over 294,000 LAP-BANDs shipped. *Id.* Through his process, Haney identified 1,584 procedures performed by surgeons he identified as listed on the locator (1,271 inpatient and 313 outpatient). *Id.* at 27–28. However, because this matching exercise captured only those procedures reflected in BRC data, Haney then compared just the locator spreadsheets and CMS procedure data to identify remaining Medicare claims relating to LAP-BAND implementations. *Id.* at 28–29. Haney also weighed LAP-BAND’s share of the gastric banding market during the relevant time frame by looking at Allergan’s internal marketing information, shipment records, records of product sales from Allergan and the manufacturer of the REALIZE band, and by analyzing LAP-BAND’s sales data as compared to the number of gastric banding surgeries each year. *Id.* at 24. Because those sources yielded roughly comparable numbers, Haney came up with a market share percentage to subtract to account for REALIZE band surgeries. *Id.* at

24, 28. The locator spreadsheets reflected 95,459 operations during the relevant time period, resulting in 5,623 additional operations. *Id.* at 30–31.

Haney then undertook de-duplication efforts to ensure he did not double count the 1,584 operations from the BRC data. *Id.* at 31. After that effort, Haney reduced the number of additional operations to 4,736, for a total of 6,320. *Id.* He then tried to estimate how many were inpatient and outpatient using the Place of Service Code in the CMS data. *Id.* Ultimately, Haney concluded that 6,320 surgeries had been reimbursed by Medicare (4,946 inpatient and 1,374 outpatient). *Id.* at 32.

Having opined as to the number of claims, Haney next endeavored to determine the Medicare reimbursement amount for an inpatient or outpatient initial operation. With respect to outpatient surgeries, Haney used the physician and facility fee reimbursement schedules from Medicare itself to estimate the amount to be reimbursed for outpatient operations. *Id.* at 32–33. With respect to inpatient surgeries, Haney used \$12,345, a figure he obtained from Ibrahim, A.M. et al., *Reoperation and Medicare Expenditures After Laparoscopic Gastric Band Surgery*, 152(9) JAMA SURGERY 835–42 (2017). ECF 201-6. That article evaluated reimbursements for 25,042 Medicare beneficiaries who received a gastric band between 2006 and 2013 to determine the average amount for an inpatient operation. *Id.* Haney noted that the figure is less than that found in three other studies evaluating gastric banding costs. ECF 235-1 at 32.⁴

Haney then multiplied the number of claims he found by the estimated claim value for each category of surgeries (inpatient and outpatient) to arrive at his total damages figure in Opinion 1. *Id.* at 33.

⁴ Haney did not cite, and the parties have not provided, Medicare’s physician fee schedules or reimbursement rates for *inpatient* gastric banding surgeries.

As to Opinion 2, Haney calculated what he believed to be the government's payment of Medicare claims associated with reoperations for inducement-tainted LAP-BAND devices. *Id.* at 35. Using the same JAMA Surgery article, Haney found that almost 20% of Medicare patients who received gastric bands underwent reoperations, and those patients had an average of 3.8 reoperations each. *Id.* at 8–9, 35. Haney then multiplied his total initial operations (6,320) by 18.5% (to represent the percentage of persons who had reoperations) by the average total cost of a reoperation from the article, \$19,657, to arrive at a damages figure. *Id.* at 35–36.

Allergan challenges the admissibility of Haney's opinions under Federal Rule of Evidence 702.

II. 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,

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).

III. ANALYSIS

a. Number of “Inducement-Tainted” Initial Operations

Procedurally, this Court has ruled more than once, but most recently in August, 2022, regarding the causation standard that will apply in this case, making clear that Relator must show “that the surgeons who appeared on the locator were aware that they were listed and that, therefore, they were aware that they were receiving the unlawful remuneration that allegedly violated the AKS (*i.e.* free marketing).” ECF 140 at 23 n.8; *see also* ECF 118 at 20 (“[A]n AKS violation cannot be causally related to a claim for reimbursement if the provider was never aware of the alleged kickback in the first place.”); ECF 125 at 15–16 (“As the cases this Court discussed make

clear, the causation element requires something more than a showing that a claim was merely ‘tainted’ by an AKS violation but something less than a showing that the provider would not have made the referral but for the kickback. At a minimum, this standard appears to require that the relevant provider in an AKS-based FCA case was aware of the alleged kickback.”).

Relator unequivocally states, and Haney agrees, that he is not offering an opinion on legal causation. ECF 235 at 13. Haney further concedes that he made no effort to ascertain whether any surgeon was aware they were on the locator at the time of the surgery. ECF 235-1 at 16 n.36 (“The term *causation*, as it is used in my report, is distinct from the legal elements of causation under the FCA.” (emphasis in original)). In light of this Court’s causation rulings, that failure renders Haney’s “number of claims” calculations unhelpful, in that they would have “greater potential to mislead than to enlighten” the jury. *Westberry*, 178 F.3d at 261.

Indeed, with discovery concluded, Relator has offered no evidence to reasonably permit such an inference to be made on a universal basis for all surgeons performing LAP-BAND operations throughout the more than five-year period at issue. Instead, Relator has submitted myriad emails between Allergan and some individual surgeons, along with certain correspondences sent by Allergan to all surgeons who were listed on its locator at particular points in time. Relator seems to contend that a factfinder could infer from those distinct pieces of evidence (taken in their totality) that all surgeons were aware of their listing status throughout the duration of the relevant window. Even viewing the evidence in the light most favorable to Relator, such an inference is not reasonable, especially given Relator’s own unequivocal testimony that he himself was unaware of his status on the locator at some relevant times. *See* ECF 210-13 at 11 (Dep. Tr. of Matthew A. Fitzer at 156:3–20). With the regular addition and deletion of names to and from the locator without notice, even periodic correspondences with a surgeon do not reflect that

surgeon's continuous awareness of his listing status throughout the entire relevant period. While this Court will address causation more comprehensively in deciding the parties' competing summary judgment motions, for the purposes of analyzing Haney's opinion testimony, his failure to account for that critical element of causation means that his blanket calculations regarding the number of claims at issue are irrelevant and offer no value to the factfinder. Even assuming that Haney's calculations would have otherwise been reliable (setting aside the numerous other assumptions and approximations Haney used to reach his totals), this Court will preclude Haney's "number of claims" opinions from being presented to the jury.

b. Reoperations

The same fatal deficiency, relating to a lack of evidence to establish every surgeon's awareness that the surgeon was on the locator at the time of the LAP-BAND prescription or surgery, also requires this Court to disallow Haney's testimony regarding the number of reoperations that he deemed inducement-tainted. Using the premise that about 18.5% of patients who have LAP-BAND operations later have reoperations, Haney simply took 18.5% of his overbroad total initial operations figure, which did not consider surgeon awareness of the locator. He then used what he calls a "conservative" methodology by accounting for only a single reoperation per patient instead of using the average of 3.8 that are generally necessary for patients who undergo reoperations. Just because an approach is conservative does not mean it is reliable. The faulty premise regarding the number of initial operations means that the reoperations total is equally flawed.

Additionally, as this Court will reiterate in its summary judgment ruling, this Court agrees with Allergan that reoperations, as a general matter, constitute consequential damages not recoverable under the FCA. *Cook Cnty. v. United States ex rel. Chandler*, 538 U.S. 119, 131 (2003)

(noting that the FCA does not “expressly provide for the consequential damages that typically come with recovery for fraud” and that Congress adopted the treble damages provision as a substitute for consequential damages). Consequential damages means “[l]osses that do not flow directly and immediately from an injurious act but that result indirectly from the act.” BLACK’S LAW DICTIONARY (11th ed. 2019). In fact, while not determinative, Haney specifically refers to the reoperations as “consequential damages” in his opinion. ECF 235-1 at 35–36. It is clear that reoperations are not an expected part of initial LAP-BAND surgery, given that less than 20% of patients require reoperations at all. Moreover, the reasons for reoperations vary from patient to patient. For example, some are simply a matter of patient preference. *See* ECF 201-6 at 9. Reoperations resulting from an intervening cause are not direct damages caused by Allergan’s alleged inducement. Thus, reoperation costs are consequential damages not recoverable under the FCA.

c. Reimbursement Amount for Inpatient and Outpatient Procedures

Finally, Allergan argues that Haney should not be permitted to testify regarding his proposed per-claim damage amount, even assuming Relator is able to establish liability as to some number of claims.⁵ Allergan protests that Haney derived his inpatient claim reimbursement amount, \$12,345, solely from the 2017 JAMA Surgery article and derived his outpatient claim reimbursement amount from CMS’s publicly available physician and facility fee schedule, rather than using CMS’s actual claim reimbursement data as produced in discovery. Relator (and Haney)

⁵ Clearly, this Court’s ruling on other pending motions, such as the summary judgment motions and the argument regarding the public disclosure bar, could impact whether viable claims remain. In this Court’s view, however, it will facilitate expeditious resolution of the parties’ myriad motions to issue opinions as they are drafted rather than in an omnibus fashion.

counter that the CMS reimbursement data were provably incomplete and would not provide a viable approximation of the claims the government paid.

While Haney’s per-claim calculations will be subject to obvious lines of cross-examination, they are not so unreasonable or so lacking in reliability as to be excludable under this Court’s gatekeeping function. The article Haney relies upon is a peer-reviewed article from a well-known medical journal, and it compiles and analyzes a large number of Medicare claims. *See* ECF 235-1 at 32–33; ECF 201-6. Similarly, use of the outpatient fee schedules from CMS itself arguably provides a reasonable approximation of what the reimbursement amount would be. Thus, this Court will permit Haney to testify (and, of course, be cross-examined) as to the appropriate amount for reimbursement for inpatient and outpatient initial operations. This Court is not persuaded that its exclusion of Haney’s “number of claims” testimony requires a blanket exclusion of all of Haney’s opinions.⁶

IV. CONCLUSION

For the reasons set forth above, Allergan’s Motion to Exclude the Opinions of Christopher L. Haney is GRANTED as to his calculations regarding the number of “inducement-tainted” initial operations and as to his Opinion #2 in its entirety, and DENIED as to his opinions regarding the appropriate amount of reimbursements for inpatient and outpatient initial operations, should Relator be able to establish liability as to some number of procedures. A separate order follows.

Dated: March 18, 2024

/s/
Stephanie A. Gallagher
United States District Judge

⁶ While Haney also opined as to the appropriate amount for civil penalties, that is not an appropriate topic for expert testimony and can be determined by the Court if warranted.