UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *et al.*, *ex rel.* MICHAEL BAWDUNIAK,	*	
Plaintiff-Relator,	*	
	*	Civil Action No. 1:12-cv-10601-IT
v.	*	
BIOGEN IDEC, INC.,	*	
Defendant.	*	

MEMORANDUM & ORDER

July 8, 2022

TALWANI, D.J.

Plaintiff-Relator Michael Bawduniak's Third Amended Complaint ("Complaint") [Doc. No. 132] charged Defendant Biogen Idec, Inc. ("Biogen") with causing healthcare providers ("HCPs") to file fraudulent Medicare and Medicaid reimbursement claims in violation of the False Claims Act, 31 U.S.C. § 3729, *et seq.*, and various state laws, by paying kickbacks to influence them to prescribe Biogen's multiple sclerosis ("MS") products in violation of Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b.

Pending before the court are Relator's Daubert Motions [Doc. Nos. 497, 498, 499, 500, and 501] and Biogen's Daubert Motions [Doc. Nos. 509, 510, 511, 512, 513, 514, and 515]. In this Memorandum and Order, the court addresses common issues raised in the Daubert motions. The court then addresses several of Biogen's motions individually, and will address the remainder of the motions separately.

I. Legal Standard

At the outset, "[t]he court must decide any preliminary question about whether a witness is qualified, a privilege exists, or evidence is admissible." Fed. R. Evid. 104(a). A witness

"qualified as an expert by knowledge, skill, experience, training or education" may offer expert testimony only 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 has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702. The party proffering expert testimony must show, by a preponderance of the evidence, that the testimony satisfies the requirements of Rule 702. See Bricklayers & Trowel Trades Int'l Pension Fund v. Credit Suisse Secs. (USA) LLC, 752 F.3d 82, 96 (1st Cir. 2014). Courts have a "gatekeeping responsibility" to determine whether the testimony an expert seeks to offer satisfies these criteria. Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 589 n.7, 592 n.10 (1993).

The district court has "considerable latitude" in "deciding whether expert testimony is helpful to the jury." United States v. Monell, 801 F.3d 34, 45 (1st Cir. 2015). Further, "trial judges may evaluate the data offered to support an expert's bottom-line opinions to determine if that data provides adequate support to mark the expert's testimony as reliable." Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co., 161 F.3d 77, 81 (1st Cir. 1998). "Nothing 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." Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997).

With respect to the reliability of the principles and methods applied, "[i]n Daubert, the Supreme Court set forth four general guidelines for a trial judge to evaluate in considering whether expert testimony rests on an adequate foundation: (1) whether the theory or technique

can be and has been tested; (2) whether the technique has been subject to peer review and publication; (3) the technique's known or potential rate of error; and (4) the level of the theory or technique's acceptance within the relevant discipline." Beaudette v. Louisville Ladder, Inc., 462 F.3d 22, 26 (1st Cir. 2006) (internal quotation marks and citation omitted). "However, these factors do not 'constitute a definitive checklist or test,' and the question of admissibility 'must be tied to the facts of a particular case.'" Id. (quoting Kumho Tire Co. v. Carmichael, 526 U.S. 137, 150 (1999)). "The object of Daubert is 'to make certain that an expert, whether basing testimony on professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" Milward v. Acuity Specialty Prod. Grp., Inc., 639 F.3d 11, 15 (1st Cir. 2011) (quoting Kumho Tire, 526 U.S. at 152).

"So long as an expert's scientific testimony rests upon good grounds, based on what is known, it should be tested by the adversarial process, rather than excluded for fear that jurors will not be able to handle the scientific complexities." Id. (internal quotation marks and citation omitted). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Id. (quoting Daubert, 509 U.S. at 596).

In a civil case, "[a]n opinion is not objectionable just because it embraces an ultimate issue." Fed. R. Evid. 704. However, "the Daubert Court imposed a special relevancy requirement." Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co., 161 F.3d 77, 81 (1st Cir. 1998). "To be admissible, expert testimony must be relevant not only in the sense that all evidence must be relevant, but also in the incremental sense that the expert's proposed opinion, if

admitted, likely would assist the trier of fact to understand or determine a fact in issue." Id. (internal quotation marks and citations omitted).

Moreover, the court may exclude "relevant evidence if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury." Daubert, 509 U.S. at 595. "[I]n weighing possible prejudice against probative forces under Rule 403 . . . [the court] exercises more control over experts" than lay witnesses. Id. (internal quotation omitted).

II. Discussion

A. *Common Issues*

1. Statements Regarding Intent

Biogen moves to exclude certain portions of testimony of Dr. Samuel Pleasure[1], Dr. Richard Schwarztein[2], Dr. Joseph Ross[3], Margie Kuo[4], Mark Scallon[5], and Janis Crum[6] because

---

[1] Dr. Pleasure opines, in part, on whether speaker and consultant programs were held by Biogen with educational or legitimate medical purpose. Pleasure Rep. [Doc. No. 516-1].

[2] Dr. Schwarztein opines, in part, on the educational value of speaker programs based on certain markers identified in his report. Schwartzstein Rep. [Doc No. 516-2].

[3] Dr. Ross opines, in part, on what constitutes a modest meal with respect to speaker programs and the temporal impact of payments on prescribing by practitioners. Ross Rep. [Doc. No. 516-3]. Dr. Ross also responds to the expert rebuttal testimony of Dr. Eric Gaier, Biogen's damages expert. Ross Rebuttal Rep. [Doc. No. 516-4].

[4] Kuo opines, in part, on whether speaker, consultant, and training programs were designed for legitimate needs based on certain markers identified in her expert report. Kuo Rep. [Doc. No. 516-6].

[5] Scallon opines, in part, on the blending methodology Biogen relied upon for its fair market value ("FMV") analysis with respect to the appropriateness of payments made to consultants. Scallon Rep. [Doc. No. 516-7].

[6] Crum opines, in part, on Biogen's compliance programs. Crum Rep. [Doc. No. 516-8]. Crum also responds to the expert rebuttal testimony of Katherine Norris, Biogen's compliance expert. Crum Rebuttal Rep. [Doc. No. 516-9].

they, to some extent, opine on Biogen's intent. See Mots. [Doc. Nos. 509, 510, 511, 512, 513, 514].[7] Relator too moves to exclude certain portions of expert testimony of Nathan Basseen[8] for impermissibly opining on Biogen's intent. See Mot. [Doc. No. 498].

"A party's intent or state of mind is not the proper subject of expert testimony." OneBeacon Am. Ins. Co. v. Com. Union Assurance Co. of Can., 804 F. Supp. 2d 77, 85 (D. Mass. 2011), aff'd, 684 F.3d 237 (1st Cir. 2012). For one, "an expert cannot bring any scientific, technical, or specialized knowledge to bear on another person's knowledge." U.S. ex rel. Dyer v. Raytheon Co., 2013 WL 5348571, at *13 (D. Mass. Sept. 23, 2013). Accordingly, questions regarding a party's intent "presents the type of judgment that jurors historically have made without the assistance of expert testimony." United States v. Pires, 642 F.3d 1, 12 (1st Cir. 2011). Moreover, "[b]ecause [expert] testimony can carry with it an unwarranted 'aura of special reliability and trustworthiness', courts must guard against letting it intrude in areas that jurors," armed with "common experience, are uniquely competent to judge without the aid of experts." Id. (quoting United States v. Fosher, 590 F.2d 381, 383 (1st Cir. 1979)).

---

[7] Biogen cites passages from each report to illustrate Relator's experts opining on the ultimate question of Biogen's intent. See e.g., Pleasure Rep. 22 [Doc. No. 516-16] ("[I]t is my opinion that Biogen's Speaker Programs were designed in part to influence the prescribing behavior of speaker and attendees"); Schwartzstein Rep. 15 [516-2] ("Were the intent of the sessions to maximize learning, organizers would not…"); Ross Rpt. 6 [Doc. No. 516-3] ("[I]n my opinion, Biogen intended that the payments it provided to speakers . . . would reward and induce prescriptions for Biogen's products indicated for the treatment of multiple sclerosis"); Kuo Rep Doc. 5 [Doc. No. 503-36] ("Biogen knowingly exploited legitimate marketing tools and concepts"); Scallon Rep. 105 [Doc. No. 516-7] ("[I]t is my professional opinion that Biogen intentionally inflated the HCP meals caps in 2009"); Crum Rep. 43 [Doc. No. 516-8] ("[T]he purpose of [certain consultant] meetings was to inform and persuade rather than to gather input…").

[8] Basseen seeks to rebut Scallon's expert testimony and opines, in part, whether the evidence related to the FMV analysis supports finding Biogen's intent to pressure for higher rates and whether an industry practice of rate blending methodology exists. Basseen Rep. [Doc. No. 502-11].

Relator generally contends that his experts' testimony is admissible where the experts merely opine about facts from which a jury might infer intent rather than on the ultimate question of intent. To be sure, an expert may opine on industry standards and what constitutes deviations from such standards. But an expert may not then opine on Biogen's intent in light of any alleged non-conformance with standards. For "[i]nferences about the intent or motive of parties or others lie outside the bounds of expert testimony." In re Zofran (Ondansetron) Prod. Liab. Litig., 2019 WL 5685269, at *9 (D. Mass. Nov. 1, 2019) (citing In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., 2018 WL 734655, at *2 (D. Mass. Feb. 6, 2018). As the examples above show, the testimony of Relator's experts goes a step too far and leaves no room for the jury to draw its own inferences as to Biogen's intent. While Relator's experts may opine about standards and alleged non-conformance with such standards from which a jury might infer intent, the experts may not offer their opinions as to what inferences can be drawn. Such testimony is excluded.

With respect to Basseen, a portion of Basseen's testimony at issue is offered to rebut Scallon's assertions. See e.g., Basseen Rep. 27 [Doc. No. 502-11] ("Mr. Scallon lacks any basis to conclude that Biogen applied pressure on Huron or Navigant to provide higher rates"). That issue is rendered moot where Scallon may not opine on Biogen's intent. The remaining testimony cited by Relator, such as that certain evidence "supports the notion that Biogen did not pressure Huron and Navigant to increase rates or have undue influence in the rate setting process" is not testimony as to Biogen's intent but testimony as to alleged facts from which the jury may infer intent.

Accordingly, Biogen's Daubert motions are granted to the extent they seek to exclude portions of testimony of experts opining on Biogen's intent. Relator's motion to exclude certain portions of Basseen's expert testimony is denied.

2. Narrative Summaries of the Evidence

Courts generally do not permit experts to narrate the record by characterizing and summarizing documents and the testimony of other witnesses. "[A] narrative summary of [a company's] documents" should "be presented directly to a factfinder" through a fact witness, not an expert. In re Zofran, 2019 WL 5685269, at *9. Narrative testimony by expert witnesses usurps the role of fact witnesses. See Raytheon Co., 2013 WL 5348571 at *12. Such testimony also usurps the role of the jury to weigh the evidence and to draw credibility assessments and ultimate conclusions. Specifically, "[c]redibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions." Hunt v. Cromartie, 526 U.S. 541, 552 (1999).

Biogen moves to exclude certain portions of testimony of Dr. Pleasure, Dr. Ross, Scallon and Crum that Biogen contends are narrative summaries of the record evidence and their interpretations. See Mots. [Doc. Nos. 509, 511, 513, 514]. In the case of Dr. Pleasure, Biogen further contends that Dr. Pleasure improperly makes credibility determinations. See Mot. [Doc. No. 509]; see also Pleasure Rep. 48 [Doc. No. 516-1] ("Witnesses attempted to explain such troubling documents, but I found the witnesses explanations of their own documents and emails non-credible").

In response, Relator makes three general arguments: (i) there is no need to make any ruling at this time as the information cited by experts is likely to be in evidence prior to the expert testifying, removing the need for the expert to reprise it; (ii) the experts set forth the full basis of their opinions in their report as required, citing to "particularly relevant passages" of evidence, and (iii) expert testimony about record evidence is appropriate when it involves

inferences that would not be apparent without the benefit of experience or specialized knowledge, or when it involves complex frameworks.

Biogen is correct that experts may not assume the role of counsel in making narrative arguments or cherry-picking documents, and the court will ensure that documents in the record relied upon by the experts will be presented directly through fact witnesses. Similarly, the court may exclude expert testimony if the court determines it is unhelpful to the jury when the issue arises. Specifically, expert testimony that either characterizes the evidence or makes credibility determinations will be excluded. See e.g., Pleasure Rep. 40 [Doc. No. 516-1] ("A Biogen witness rationalized HCP Speakers subsequently attending a Speaker Program on the same subject on which they had presented…"). However, to the extent that Biogen's objections constitute disagreement with expert opinions after an expert's review of the record, such disagreement is more appropriate for cross-examination at trial. For instance, Scallon identified a specific piece of evidence, a note between Biogen and its third-party consultant, Huron, as part of the basis for his conclusions that Biogen was involved in calculating FMV rates in 2011 in a manner inconsistent with industry practice. Scallon Rep. 54 [Doc. No. 516-7]. Scallon may rely on his expertise to explain the inferences he made from such document to arrive at his conclusion.

Accordingly, Biogen's Daubert motions are granted to the extent they seek to exclude narrative summaries of the record evidence and credibility determinations. Biogen's Daubert motions are denied to the extent they seek to exclude expert testimony explaining why the expert found certain evidence meaningful for his or her conclusion.

3. Opinions on Legal Issues

Although "there is no blanket prohibition on expert testimony concerning the law," Adams v. New England Scaffolding, Inc., 2015 WL 9412518, at *5 (D. Mass. Dec. 22, 2015), a

"district court has broad discretion to exclude expert opinion evidence about the law that would impinge on the roles of the judge and the jury." Pelletier v. Main St. Textiles, LP, 470 F.3d 48, 54 (1st Cir. 2006). However, "[t]he line between testimony regarding what the law requires and testimony describing how an industry practice typically operates is not always clear." Ji v. Bose Corp., 538 F. Supp. 2d 354, 358 (D. Mass. 2008). Testimony from an expert that describes industry practices may incorporate the expert's "understanding of the law," but "the expert cannot testify as to what the law requires." Bacchi v. Massachusetts Mut. Life Ins. Co., 2016 WL 1170958, at *3 (D. Mass. Mar. 23, 2016).

Biogen contends that Kuo offers an opinion concerning a legal question where she opines on whether conduct violated AKS or falls within a safe harbor provision. See e.g., Kuo Rep. 69 [Doc. No. 516-6] (Kuo opines that nine markers "were known in the industry to be indicia of violations of the Anti-Kickback Statute"). Relator contends that pharmaceutical marketers operate in a highly regulated setting and Kuo should be able to talk about marketers' perceptions of such industry practices, including standards pharmaceutical marketers respected to avoid violations of AKS.

The court finds that Kuo's testimony is admissible to the extent she opines on industry standards used to avoid AKS violations, but she cannot opine as to what does or does not constitute an AKS violation.

B. *Challenges to Experience, Reliability and Relevance*

"Rule 702 has been interpreted liberally in favor of the admission of expert testimony." Levin v. Dalva Bros., Inc., 459 F.3d 68, 78 (1st Cir. 2006). "As such, expert witnesses need not have overly specialized knowledge to offer opinions." Id. Further, expert testimony supported by relevant experience and third-party authorities is permitted under the Federal Rules of Evidence.

See Fed. R. Evid. 702 advisory committee notes, 2000 amend. ("Nothing in this amendment is intended to suggest that experience alone— or experience in conjunction with other knowledge, skill, training or education—may not provide a sufficient foundation for expert testimony"). "If a witness relies primarily on experience, she must 'explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.'" U.S. ex rel. Jones v. Brigham & Women's Hosp., 678 F.3d 72, 94 (1st Cir. 2012) (quoting Fed. R. Evid. 702 advisory committee note).

"[E]xpert testimony must be predicated on facts legally sufficient to provide a basis for the expert's opinion." Damon v. Sun Co., 87 F.3d 1467, 1474 (1st Cir. 1996) (internal citations and quotations omitted). While "an expert should not be permitted to give an opinion that is based on conjecture or speculation from an insufficient evidentiary foundation," id., "Rule 702 does not demand that experts rely on all data that could be deemed relevant. It does not even require the expert to seek out the best possible source of relevant information." Lawes v. CSA Architects & Engineers LLP, 963 F.3d 72, 101 (1st Cir. 2020).

Furthermore, "[n]otwithstanding the deep dive that courts often take to adequately assess the reliability of expert methodology . . . they must stop short of weighing the evidence, evaluating credibility, or unnecessarily picking sides in a battle between experts. Id. at 98. "In carrying out this responsibility [of determining whether to admit or exclude relevant expert testimony], the trial court must bear in mind that an expert with appropriate credentials and an appropriate foundation for the opinion at issue must be permitted to present testimony as long as the testimony has a 'tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.'" Pages-Ramirez v. Ramirez-Gonzalez, 605 F.3d 109, 115 (1st Cir. 2010) (quoting

Fed. R. Evid. 401). "An unduly restrictive review of the relevant expertise of a[n] [expert] is incompatible with what we have characterized as a liberal standard of relevance." Id.

Further, "mindful of the wide variety of matters on which expert testimony may be useful, Federal Rule of Evidence 702 demands that the inquiry into an expert's methodology must be tailored to fit the circumstances of each particular case." United States v. Encarnacion, 26 F.4th 490, 505 (1st Cir. 2022). "Especially outside of scientific fields, factors bearing on the reliability of an expert's methodology will vary." Id; see also Fed. R. Evid. 702 advisory committee notes ("[S]ome types of expert testimony will not rely on anything like a scientific method, and so will have to be evaluated by reference to other standard principles attendant to the particular area of expertise").

1. Dr. Pleasure

In his expert report, Dr. Pleasure identified ten characteristics of activities that lack medical educational purpose or educational value. Pleasure Rep. 7-8 [Doc. No. 516-1]. In addition to challenging Dr. Pleasure's opinions regarding Biogen's intent as discussed above, Biogen moves to exclude Dr. Pleasure's expert testimony regarding the markers he uses to identify speaker programs that purportedly lack educational value. Specifically, Biogen contends that Dr. Pleasure's opinions are not supported by any external guidance or standard and Dr. Pleasure cannot rely on his professional experience where he has no experience in the private sector and has not attended a Biogen speaker program.

As already noted, Federal Rule of Evidence 702 does not preclude expert opinions based on the expert's experience alone. Relator contends that in assessing the educational value of speaker programs, Dr. Pleasure applied his experience as a neurologist treating patients with MS, including prescribing the Biogen drugs at issue, as well as decades of experience designing

educational programming. Further, Dr. Pleasure has previous experience evaluating the educational value of speaker programs materials by way of his expert testimony in another trial. Relator contends that Dr. Pleasure relied on that experience, and his experience as a researcher and scientist designing and implementing medical studies, in his opinion on the legitimacy of consulting programs. For his opinion on consultant programs, Dr. Pleasure also reviewed medical literature regarding MS and purported "regional differences."

The court finds that Dr. Pleasure's professional career in an academic setting is sufficient to allow him to opine regarding markers to identify speaker programs that purportedly lack educational value.

Biogen further moves to exclude as unreliable portions of Dr. Pleasure's testimony that speaker programs with certain markers lacked educational value for attendees. Specifically, Biogen argues that Dr. Pleasure (i) relies on arbitrary thresholds unrelated to the educational value of speaker programs and (ii) forms opinions not based on his expertise.

Relator contends that Dr. Pleasure's opinion is not arbitrary where he relies on objective criteria or industry standards. For instance, in setting a 6-month temporal threshold for when repeat attendance becomes educationally unjustified, Dr. Pleasure explained that guidelines surrounding MS treatment usually change no more than once a year, HCPs typically retain information effectively, and decks that do not present new scientific information are redundant. Pleasure Rep. 36-39 [Doc. No. 516-1]. The fact that Dr. Pleasure set each threshold using what he contends is a conservative measure (less than a year) is not a basis for excluding his testimony. Having found that Dr. Pleasure has sufficient experience to form the bases for his opinion with respect to educational value of speaker programs, all else that is required of Dr. Pleasure is that he explain how he applied his experience to the facts to reach his conclusions.

The court finds that Dr. Pleasure has done so sufficiently here to allow his testimony. Accordingly, Biogen's motion is denied to the extent it seeks to exclude Dr. Pleasure's testimony on the basis that his markers are arbitrary or not based on his expertise. Biogen's concerns are best suited for cross-examination.

Biogen argues further that Dr. Pleasure (i) offers generalized opinions about the educational value of thousands of Biogen programs and (ii) forms opinions based on speculation with respect to what occurred at speaker meetings. Relator counters that the fact that Dr. Pleasure has not attended a Biogen speaker program does not preclude him from applying relevant educational principles to Biogen's programming where he explains in detail the speaker related materials he reviewed and how he formed their conclusions. Where Dr. Pleasure's expertise is generalized and not based on direct observation of Biogen's programs, he may testify based on his expertise as to the standards he would apply to such programs, and how the programs compare with those indicia, leaving the jury to determine for itself the purpose of Biogen's speaker programs.

2. Dr. Schwartzstein

Dr. Schwartzstein's expert report opines on (i) standards and best practices for medical education based on cognitive theory and relevant literature and (ii) whether specific activities have educational value and benefits based on application of principles of adult learning and education. Schwartzstein Rpt. 3 [Doc. No. 516-2]. Specifically, Dr. Schwartzstein opines that the following six activities lack educational value: (1) an HCP attends two or more events on the same slide deck within 6 months; (2) an HCP speaks and then attends an event on the same subject within 12 months; (3) a speaker program that fails to present a slide deck or presentation to attendees; (4) speaker programs held at immodest restaurants, resorts, or other lavish venues;

(5) speaker programs where the only audience member is a Biogen employee; (6) speaker programs where an educationally inappropriate deck is presented to an inappropriate attendee**.** Id. at 9.

As a threshold issue, Biogen moves to exclude the entirety of Dr. Schwartzstein's testimony as irrelevant to the jury's evaluation of Biogen's speaker programs. Biogen contends that his opinions regarding cognitive theory and best practices impose inapplicable educational standards to pharmaceutical companies' speaker programs that are both promotional and educational in nature. Biogen further contends that Dr. Schwartzstein's testimony is irrelevant as he opines on whether Biogen's speaker programs were optimally educational rather than whether they lacked educational value altogether. Regardless of whether Biogen's speaker programs had a dual purpose, one purpose proffered by Biogen was to educate. Dr. Schwartzstein's expert testimony is relevant to inform the jury of educational principles that it may then rely upon in determining whether Biogen intended for the program to be educational. However, Dr. Schwartzstein's testimony that Biogen's speaker programs were designed for optimal education is not only irrelevant, and thus inadmissible for that reason, but also unhelpful to the jury where the jury can make such determinations based on expert testimony put forth regarding educational principles.

Second, Biogen moves to exclude portions of Dr. Schwartzstein's expert opinion for reasons similar to the challenge to Dr. Pleasure's testimony: that Dr. Schwartzstein (i) relies on arbitrary thresholds unrelated to the educational value of speaker programs and (ii) forms opinions not based on his expertise.

Relator largely refutes Biogen's motion in a similar manner as he did for Dr. Pleasure's testimony regarding educational markers. Dr. Schwartzstein is a Harvard Medical School

("HMS") professor specializing in medical education in university settings. He serves as the Vice President for Education at Beth Israel Deaconess Medical Center ("BIDMC") and Executive Director of the Carl J. Shapiro Institute for Education and Research at BIDMC and HMS. Within these roles, Dr. Schwartzstein designs curricula and educational activities for HCPs and medical students, studies the effectiveness of educational activities, and works to broaden and strengthen scholarship and innovation in medical education. As with Dr. Pleasure, the court finds that Dr. Schwartzstein has sufficient experience to opine on the educational value of speaker programs.

Relator further contends that in forming his opinions regarding the educational value of the speaker programs based on certain thresholds, Dr. Schwartzstein relied on his experience designing educational programming and educational standards. For instance, Dr. Schwartzstein stated that, "in [his] experience, when educating HCPs on drugs or therapies, the most engaging programming includes information on new medical breakthroughs, clinical trials, or the latest safety information." Schwartzstein Rep. ¶ 22 [Doc. No. 516-2]. Dr. Schwartzstein explained that he found "attending two or more events on the same slide deck within six months serves no educational purpose and provides no educational benefit to the attendees" id. at ¶ 25, especially where "board-certified neurologists, nurses, and physician assistants, treat MS patients with some regularity and would already have experience with the MS drugs at issue, id. at 26. Relator has sufficiently demonstrated that Dr. Schwartzstein properly applied his experience and explained how he reached his conclusions such that he should be allowed to testify. Biogen's contentions that Dr. Schwartzstein's markers are arbitrary are best suited for cross-examination.

Biogen also objects to Dr. Schwartzstein's testimony where he has not attended a Biogen speaker program. As with Dr. Pleasure, the court finds that not attending such programs does not prevent him from applying relevant educational principles to Biogen's programming where he

explains in detail the speaker related materials he reviewed and how he formed his conclusions. Biogen's argument that the data Dr. Schwartzstein reviewed was "cherry-picked" is unavailing where Biogen does not provide additional detail as to why such a characterization is appropriate. To be sure, "[i]f an expert 'cherry picks' favorable data . . . ignor[ing] a significant quantity of other important facts, the trial court would be justified in concluding that the expert's testimony is not based on sufficient facts or data." 29 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 6268 (2d ed. 2017). But Biogen does not claim that the sample Dr. Schwartzstein or any of the other experts reviewed is not representative of the speaker programs, and thus the allegation that his opinion is based on a skewed perspective of speaker program materials is unsupported.

Accordingly, the court finds that expert testimony is admissible, and does not constitute speculation, where the expert reviews representative materials (or lack thereof) related to speaker programs and opines on whether the materials could facilitate an educational experience for attendees. To the extent that Biogen argues that the markers identified by the expert are arbitrary or illogical, such objections are better suited for cross-examination. Again, however, the court will limit Dr. Schwartzstein's testimony based on his expertise to indicia that programs lack educational value and assessment of how Biogen programs compare with those indicia, leaving the jury to determine for itself the purpose of Biogen's speaker programs.

3. Margie Kuo

Margie Kuo is the founder and principal of MK Insights LLC, a strategic healthcare marketing consultancy specializing in product launches and repositionings. Her clients include or have included large pharmaceutical companies such as Pfizer, Boehringer Ingelheim and AbbVie, as well as a number of smaller biotech companies. She is also a curricula designer and

an adjunct instructor at New York University School of Professional Studies Division of Programs in Business. Since 2014, she has taught the first and last required courses, Campaign Strategy and Execution and the Business Planning Capstone, in the University's Master of Science, Integrated Marketing Communications program. More recently, she designed and developed New York University's Certificate in Healthcare Marketing and Communications, and its Executive Master of Science in Strategic Marketing and Communications.

Kuo is offering expert testimony to provide background on the standards for evaluating HCP consultants, speaker trainings and speaker programs in the United States, how to translate those standards into evaluative criteria, and how those standards are applied in practice. Kuo Rep. 7 [Doc. No. 516-6]. Kuo identifies characteristics and other indicia that suggest that an HCP engagement does not meet the standards for legitimate need and/or reasonable necessity to achieve a commercially reasonable business purpose.

In addition to moving to exclude portions of Kuo's testimony that Biogen argues opine on Biogen's intent and on questions of law, Biogen moves to exclude Kuo's expert testimony regarding three markers based on speaker program attendance thresholds that Biogen contends are arbitrary, and without any external support or reliance on Kuo's experience. To be clear, Biogen does not challenge Kuo's opinions that the underlying conduct is inappropriate, but contests where she drew the line as to those practices.

In response, Relator cites to testimony from Kuo that provides her basis for the attendance-based markers. For instance, Kuo testified that based on her experience there is little educational value for an HCP to see the same program within a short period of time, particularly in the case of a drug with which the HCP is already familiar with and which (like Tysabri and Avonex) had been on the market for a long time. Kuo testified that she did have experience with

the issue of repeat attendance at Pfizer, where such a practice was discouraged and policies on the point were covered in their handbook, and at Adamis, where a one seating policy was employed. Kup Dep., Tr. at 155:1-5, 162:6-9 [Doc. No. 533-3]. The fact that Kuo could not readily distinguish the commercial reasonableness of allowing an HCP to attend the same presentation at six, seven or eight months is of no importance where in her opinion there would likely be no reasonable business purpose to invite an HCP to view the same program at any of those intervals. Again, that Kuo selected the threshold conservatively is not a basis for excluding her testimony. Relying on her relevant experience, Kuo provided her reasoning as to the other two attendance-based markers that Biogen seeks to challenge. See e.g., Kup Rep. 60 [Doc. No. 516-6] ("Events should not occur where fifty percent or more of the attendees are employees or office colleagues of the speaker. In these cases, the speaker's own employees, staff and colleagues padded the attendance of a program and made it appear that there was sufficient demand for the program, justifying the payment made to the speaker").

Even if Kuo arrives at her attendance-based markers based on relevant professional experience rather than peer-reviewed studies, "[v]igorous cross examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Lawes, 963 F.3d at 99. Accordingly, Biogen's motion to exclude Kuo's testimony based on the disputed markers is denied.

III. Conclusion

For the foregoing reasons, Biogen's Motion to Exclude Testimony of Dr. Samuel Pleasure [Doc. No. 509], Motion to Exclude Testimony Dr. Richard Schwartzstein [Doc. No. 510], and Motion to Exclude the Testimony of Margie Kuo [Doc. No. 512] are GRANTED IN

PART and DENIED IN PART. Biogen's Motion to Exclude the Testimony of Dr. Joseph Ross [Doc. No. 511], Motion to Exclude the Testimony of Mark Scallon [Doc. No. 513], and Motion to Exclude the Testimony of Janis Crum [Doc. No. 514] are GRANTED IN PART and DENIED IN PART and remain under advisement in part. Biogen's Motion to Exclude the Testimony of Dr. Meredith Rosenthal [Doc. No. 515] remains under advisement. Relator's Motion to Exclude Portions of the Report and Testimony of Nathan S. Basseen [Doc. No. 498] is DENIED. Relator's Motion to Exclude Portions of the Expert Report and Testimony Dr. Eric Gaier [Doc. No. 497], Motion to Exclude Portions of Expert Report and Testimony of Dr. Maria Houtchens [Doc. No. 499], Motion to Exclude Portions of Expert Report and Testimony of Katherine Norris [Doc. No. 500], and Motion to Exclude Portions of Expert Report and Testimony of Dennis Kowalski [Doc. No. 501] remain under advisement.

IT IS SO ORDERED.

July 8, 2022

/s/ Indira Talwani
United States District Judge