NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, *et al.*, *ex rel.* JESSICA PENELOW and CHRISTINE BRANCACCIO, Plaintiffs, v. **JANSSEN PRODUCTS, LP**, Defendant.	Civil Action No. 12-7758 (ZNQ) (LHG) **MEMORANDUM OPINION**

QURAISHI, District Judge

This matter comes before the Court upon several motions to exclude opinions and testimony filed by Janssen Products, LP ("Janssen"), and Relators Jessica Penelow and Christine Brancaccio (collectively, "Relators"). The parties seek to exclude expert reports and testimony under the admissibility requirements of Federal Rule of Evidence 702 and the principles espoused in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). The Court has carefully considered the parties' submissions and decides the matter without oral argument pursuant to Federal Rule of Civil Procedure 78 and Local Civil Rule 78.1. For the reasons set forth below, the parties' motions to exclude expert testimony will be granted in part and denied in part.

I. BACKGROUND & PROCEDURAL HISTORY

On December 18, 2012, Relators[1] filed this action on behalf of the federal government, twenty-six states, and the District of Columbia (collectively, "Government Plaintiffs") alleging fifty-six counts under the Federal False Claims Act ("FCA"), the Federal Anti-Kickback Statute ("AKS"), and the false claims acts of various states. (ECF No. 1.) The United States and certain States declined to intervene. (ECF Nos. 46, 48, 55.) On October 3, 2016, Johnson & Johnson ("J&J") and Janssen filed Motions to Dismiss. (ECF Nos. 56, 57.) On May 31, 2017, the Court granted in part and denied in part Janssen's motion but dismissed all claims against J&J. (ECF Nos. 86, 87.) Relators subsequently filed the Second Amended Complaint on June 30, 2017. ("Second Am. Compl.," ECF No. 90.) On October 14, 2020, Janssen filed a Motion for Summary Judgment. ("Summary Judgment," ECF No. 187.) Around the same time, Relators and Janssen filed several motions to exclude expert testimony and opinions. (ECF Nos. 179, 181, 183, 192, 194, 196, 198, 200, 202.) Thereafter, the Court stayed the matter to afford the parties the opportunity to attend private mediation, but the mediation was not successful. (ECF Nos. 233, 236.)

The claims in this action arise from Janssen's purported kickback scheme and off-label ("OL") promotion of two HIV/AIDS drugs: Prezista and Intelence. (Second Am. Compl. at 1–2.) With respect to Prezista, Relators allege that Janssen, through its sales representatives and managers, delivered false and misleading messages to physicians by: (1) promoting Prezista as "lipid neutral"; and (2) misstating Prezista's superiority, efficacy, and potency based on the

[1] Between 2006 and 2013, Relator Jessica Penelow worked as a sales consultant for Tibotec Therapeutics, a subsidiary of Johnson & Johnson that became known as Janssen in 2011. ("Second Am. Compl." ¶ 47, ECF No. 90.) While working for Tibotec, she marketed several HIV drugs, including Prezista and Intelence, to doctors in Manhattan. (*Id.*) Similarly, in 2006, Relator Christine Brancaccio started working for Janssen as a sales representative and marketed Prezista and Intelence to providers in Long Island and Queens. (*Id.* ¶ 49.)

uniqueness of its "binding affinity." (*Id.* ¶¶ 2, 105.) Relators claim Prezista presents a serious risk of cardiovascular disease because Prezista increases lipids, such as cholesterol and triglycerides. (*Id.* ¶¶ 3–4, 106–08.) They allege Janssen misrepresented that Prezista "would not affect or increase a patient's cholesterol or triglyceride levels, which is directly contradicted by the FDA-approved label for Prezista." (*Id.* ¶¶ 3, 106.) Relators also allege Janssen misrepresented Prezista as having superior "binding affinity," which prevents HIV from mutating and becoming resistant. (*Id.* ¶¶ 6, 126.) Furthermore, Relators contend Janssen's representations about Prezista's superior binding affinity were based on a clinical study that was of limited scientific value and was not included in the drug's FDA-approved labeling. (*Id.*) Relators allege numerous instances where Janssen sales representatives and managers misrepresented Prezista's effect on lipids and its superior binding affinity. (*Id.* ¶¶ 124–25, 137, 183.) The OL promotion concerning Prezista as a lipid-neutral drug began in 2006 and continued through approximately 2014, and the OL promotion concerning its superior "binding affinity" began around 2007 and continues through present. (*Id.* ¶¶ 4–5, 106, 126.)

As for Intelence, Relators allege that Janssen, through its sales representatives and managers, provided false and misleading statements to physicians by marketing the drug as safe and effective for: (1) once-daily dosage; and (2) safe and effective for "treatment-naïve patients," which refers to patients who have never taken any antiretroviral medication. (*Id.* ¶ 9.) Relators allege Janssen promoted Intelence for once-daily dosing, contrary to its FDA-approved label specifying twice-daily dosing. (*Id.* ¶ 10.) This is significant because "if a patient does not carefully follow the FDA-indicated dosing drug regimen, their HIV viral load can increase, potentially weakening the drug's ability to fight the disease." (*Id.*) In addition, Relators allege that Intelence was "only indicated for treatment-experienced patients," not treatment-naïve patients. (*Id.* ¶ 11.)

Prescribing Intelence to treatment-naive patients is harmful because it could prematurely "cause [them] to run out of drug options as their diseases progresses." (*Id.* ¶ 12.) Relators allege numerous instances where Janssen sales representatives and managers engaged in OL promotion concerning Intelence "from the time of its launch in 2008, continuing through September 2014." (*Id.* ¶¶ 150, 154, 159.)

Relators allege that Janssen's OL "marketing of Prezista and Intelence was widespread." (*Id.* ¶¶ 13, 160.) According to Relators, Janssen instructed its national sales force to market the drugs OL during pod calls, district calls, district meetings, trial meetings, and plan of action meetings. (*Id.* ¶¶ 161–78.) During these calls and meetings, upper management and district managers encouraged OL marketing, and sales representatives from different districts to share sales strategies and tips about marketing Intelence and Prezista OL. (*Id.* ¶¶ 162–64.) As a result, Janssen representatives engaged in OL marketing during sales calls with physicians, dinner programs, and Speaker Programs. (*Id.* ¶¶ 13, 179–205.) In addition, Relators claim the Speaker Programs amounted to kickbacks in violation of the AKS because Janssen paid speakers at the dinner programs. (*Id.* ¶¶ 13, 71.) According to Relators, the physician-speakers were paid an increasing honorarium based on the number of prescriptions they wrote and their market share of the drugs, which Janssen calculated by determining the percentage of Janssen drugs a doctor prescribed as compared to non-Janssen drugs in the same class. (*Id.*)

Relators allege that Janssen knowingly and misleadingly influenced physicians' medical judgments through its OL promotion of Prezista and Intelence. (*Id.* ¶ 15.) Moreover, they allege Janssen knew the Government Plaintiffs reimbursed a substantial portion of Prezista and Intelence prescriptions. (*Id.* ¶ 16.) Because a significant percentage of HIV/AIDS patients are enrolled in

Medicaid and Medicare, Janssen allegedly caused claims tainted by the OL marketing and kickback schemes to be submitted to the Government Plaintiffs for reimbursement. (*Id.*)

II. LEGAL STANDARD

Federal Rule of Evidence 702 governs the admissibility of expert testimony and provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise 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. "Rule 702 embodies three distinct substantive restrictions on the admission of expert testimony: qualification, reliability, and fit." *Karlo v. Pittsburgh Glass Works, LLC*, 849 F.3d 61, 80 (3d Cir. 2017) (quoting *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000)). The party offering the expert testimony bears the burden of establishing the existence of each factor by a preponderance of the evidence. *In re TMI Litig.*, 193 F.3d 613, 665 (3d Cir. 1999), *amended by* 199 F.3d 158 (3d Cir. 2000).

The Third Circuit has "interpreted Rule 702's qualification requirement liberally." *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008) (citing *Schneider ex rel. Est. of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003); *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994)). A "broad range of knowledge, skills, and training qualify an expert as such." *Paoli*, 35 F.3d at 741. Because both the "substantive" and "formal" qualifications of an expert are viewed

liberally, the Third Circuit has "eschewed imposing overly rigorous requirements of expertise and [has] been satisfied with more generalized qualifications." *Id.* Therefore, "[i]f the expert meets [the] liberal minimum qualifications, then the level of the expert's expertise goes to credibility and weight, not admissibility." *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 809 (3d Cir. 1997) (citation omitted). "[I]t is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have specialization that the court considers most appropriate." *Pineda*, 520 F.3d at 244 (alteration in original) (quoting *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 782 (3d Cir. 1996)). However, while "background, education, and training may provide an expert with general knowledge to testify about general matters, more specific knowledge is required to support more specific opinions." *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 322 (3d Cir. 2003).

As for the "reliability" requirement, the Third Circuit has interpreted reliability "to mean that an expert's testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable." *Pineda*, 520 F.3d at 244 (internal quotations omitted) (quoting *Paoli*, 35 F.3d at 742). Rule 702 imposes a "gatekeeping" obligation on the trial court to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert*, 509 U.S. at 598; *see also Kumho Tires Co., Ltd. v. Carmichael*, 526 U.S. 137, 147 (1999) (gatekeeping obligation "applies to all expert testimony"). The purported expert's testimony "must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'; the expert must have 'good grounds' for his [or] her belief." *Schneider*, 320 F.3d at 404 (citation omitted). Admissibility turns "on the expert's methods and reasoning; credibility decisions arise after admissibility has been determined." *Kannankeril*, 128 F.3d at 806.

"The evidentiary requirement of reliability is lower than the merits standard of correctness." *Paoli*, 35 F.3d at 744.

To satisfy the "fit" requirement, "the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact." *Schneider*, 320 F.3d at 404. The expert testimony meets the "fit" requirement when it "help[s] the trier of fact to understand the evidence or to determine a fact in issue . . . ." Fed. R. Evid. 702. "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591 (citation omitted). "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Id.* at 591–92. The Third Circuit has also instructed that:

> A judge frequently should find an expert's methodology helpful even when the judge thinks that the expert's technique has flaws sufficient to render the conclusions inaccurate. He or she will often still believe that hearing the expert's testimony and assessing its flaws was an important part of assessing what conclusion was correct . . . .

Paoli, 35 F.3d at 744–45. *See Heller v. Shaw Indus. Inc.*, 167 F.3d 146, 152–53 (3d Cir. 1999) (finding the trial court should admit expert testimony "if there are 'good grounds' for the expert's conclusion" even if the court believes "there are better grounds for some alternative conclusion").

Notably, the court also "must ensure that an expert does not testify as to the governing law of the case." *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006). In *Berckeley*, the Third Circuit explained that "the line between admissible and inadmissible expert testimony as to the customs and practices of a particular industry often becomes blurred when the testimony concerns a party's compliance with customs and practices that implicate legal duties." *Id.* at 218. "Although Federal Rule of Evidence 704 permits an expert witness to give expert testimony that 'embraces an ultimate issue to be decided by the trier of fact,' an expert witness is prohibited from

rendering a legal opinion." *Id.* at 217 (quoting *United States v. Leo*, 941 F.2d 181, 195–96 (3d Cir. 1991)).

III. DISCUSSION

Janssen moves to exclude certain opinions and testimony of the following experts: James T. O'Reilly, George P. Sillup, Kenneth W. Schafermeyer, Aaron E. Glatt, Virginia B. Evans, Israel Shaked, and Ian Dew. (ECF Nos. 192, 194, 196, 198, 200, 202.) Relators move to exclude certain opinions and testimony of the following rebuttal experts: Jon Smollen, Anupam Jena, and Eric S. Rosenberg. (ECF Nos. 179, 181, 183.) The Court addresses each expert in turn.

A. Janssen's Motion to Exclude the Testimony of James T. O'Reilly

Janssen filed a motion to exclude the expert report and testimony of James T. O'Reilly, ("O'Reilly Motion," ECF No. 192), along with a brief in support of the Motion, ("O'Reilly Moving Br.," ECF No. 192-1). Relators opposed the Motion, ("O'Reilly Opp'n Br.," ECF No. 282), to which Janssen replied ("O'Reilly Reply," ECF No. 251). Relators identified O'Reilly as an expert in FDA law, regulatory issues under the FCA, and government reimbursement. (Chuderewicz Decl., Ex. A, ECF No. 194-3.)

According to Janssen, the problematic nature of O'Reilly's expected testimony becomes evident as early as the third paragraph of his opinion, where he summarizes his conclusion:

> In my opinion, based on the evidence and my education and professional experience, Janssen misbranded Prezista and Intelence and engaged in off[-]label marketing of the drugs that was contrary to their FDA-approved labels, and, thus, the claims submitted to the government healthcare programs for these drugs were false because they were ineligible for reimbursement. Further, this conduct was material to the government's payment decision for reimbursement of claims for Prezista and Intelence.

(Chuderewicz Decl., Ex. A, "O'Reilly Report" ¶ 3, ECF No. 263.) Janssen counts three legal conclusions in that statement alone. (O'Reilly Moving Brief at 1, 4.) Beyond these concerns as

to potentially improper legal advocacy, Janssen challenges O'Reilly's opinions on the grounds that they believe "he is not qualified to offer any non-legal opinions about the marketing of Intelence and Prezista or about government reimbursement for Intelence and Prezista prescriptions," and Janssen contends "he does not tie any non-legal opinions to reliable principles or methods." (O'Reilly Moving Br. at 2–10.)

In opposition, Relators maintain that O'Reilly does possess the necessary qualifications and that his opinions are reliable. (O'Reilly Opp'n Br. at 2.) Relators argue that O'Reilly's opinions "are grounded in well-supported citations to relevant authority." (*Id.* at 11.) His "report meets [the good grounds] standard and contains detailed citations to the relevant statutes, regulations, guidelines, policy documents, etc. relevant to his opinions regarding the government regulatory scheme at issue in this case." (*Id.*) They note that O'Reilly has the educational, academic, and industry background to explain FDA and Centers for Medicare & Medicaid Services ("CMS") regulatory issues. (*Id.* at 10.) In addition, with respect to Janssen's argument that O'Reilly provided a legal opinion, Relators fault Janssen for focusing on O'Reilly's conclusion while ignoring the rest of his opinion that explains the complex regulatory environment at issue in this case. (*Id*. at 12.) They cite instances where other courts have allowed experts to opine about the complex Medicare regulatory scheme. (*Id*. at 13.) Relators have their own view of what constitutes inadmissible legal conclusions: they insist that O'Reilly's opinions are proper because "they do not go to the ultimate issue to be decided by the jury in the case," *i.e.*, whether Janssen is liable. (*Id.* at 15.) Relators temper their position by proposing that the Court defer assessing the admissibility of O'Reilly's potentially legal testimony until trial when there is more context and after hearing Janssen's objections. (*Id*. at 15 n.1.)

In its reply, Janssen focuses on O'Reilly's testimony regarding intent, stating that it is inadmissible legal advocacy. (*Id.* at 4.) Janssen emphasizes that "O'Reilly intends to instruct the jury on what the law requires and to tell the jury that Janssen violated the law." (O'Reilly Reply at 1.) It argues that "[i]nstructing the jury on what the law requires is exclusively within the province of this Court." (*Id.* at 3.) Furthermore, Janssen argues that O'Reilly is not qualified to reliably opine on matters because his experience is unrelated to the opinion he intends to offer. (*Id.* at 6–7.)

The Court has reviewed O'Reilly's qualifications. He has advised on over-the-counter drug, pharmaceutical, and medical device issues, taught an FDA course as an adjunct law professor for twenty-five years, and currently chairs the FDA committee of the American Bar Association ("ABA"). (O'Reilly Report ¶ 7.) He teaches medical and public health for graduate students at the University of Cincinnati, College of Medicine, and he has authored over 50 textbooks and 220 articles. (*Id.* ¶ 5; *see also Id.* ¶¶ 4–9.) He has also authored the drugs chapter of the special textbook on AIDS for the ABA's Coordinating Committee on AIDS. (*Id.* ¶ 8.) O'Reilly can be reasonably characterized as a lawyer with a specialization in healthcare public policy. (*Id.* at 41–49.) Thus, based on his education and experience, the Court finds that O'Reilly satisfies the liberal minimum qualifications required for expert testimony admissibility. *Paoli*, 35 F.3d at 741. He is, therefore, qualified to speak on general topics concerning FDA regulations and reimbursement. Likewise, his experience is sufficient to render his testimony "reliable." *Pineda*, 520 F.3d at 244

Notwithstanding his qualifications, the question of "fit" remains. The Court must determine whether O'Reilly's testimony will help the trier of fact. *Berckeley*, 455 F.3d at 217. This determination necessarily includes ensuring that he will not provide improper legal opinions that will intrude on the Court's role in explaining the law to the jury. *Berckeley*, 455 F.3d at 218.

Although experts can testify about business customs and background information that they have developed through their personal experience and expertise, they cannot give opinions "as to what was required under the law, or whether the defendant complied with the [law]." *Id.* (quoting *Leo*, 941 F.2d at 196–97); *see also Casper v. SMG*, 389 F. Supp. 2d 618, 621 (D.N.J. 2005)). In *Berckeley*, the Third Circuit confirmed that an expert, a former SEC lawyer with experience in the crucial matter in the case, could testify about customs and business practices in the securities industry at the time the parties entered into their contested agreement. 455 F.3d at 218. However, the Third Circuit reversed the district court's decision to permit the expert to testify regarding the defendant's compliance with legal duties that arose under the federal securities laws because such testimony represented improper legal opinions. *Id.*

As a first matter, and consistent with *Berckeley*, the Court rejects Relators' proposed "ultimate issue" test for the admissibility of the portions of O'Reilly's testimony that verge on legal opinion. 455 F.3d at 217. "Ultimate issue" is inconsistent with the rules of evidence. Rule 704 expressly states that "[a]n opinion is not objectionable just because it embraces an ultimate issue." The correct question in this context is whether, and to what extent, O'Reilly's opinion attempts to introduce improper legal testimony.

The Court has reviewed O'Reilly's report and finds acceptable those portions that provide background information regarding the drug approval process, misbranding in general, and the mechanism by which the government reimburses for prescriptions. Such background information could be helpful to the jury. Likewise, O'Reilly's observations regarding Janssen's compliance efforts could also prove helpful. Unfortunately, however, his report quickly devolves into his opinion as to legal issues. These include but are not limited to: how Janssen's activities constituted OL promotion and therefore misbranding, (O'Reilly Rep. ¶¶ 29–34, 47–49); Janssen's purportedly

purposeful manipulation of Medical Information Requests, (*id*. ¶¶ 40, 42); how Janssen's OL promotion can form the basis for a violation of the FCA, (*id*. ¶¶ 61–62, 70); and the legal test for materiality and its application, (*id*. ¶¶ 71, 73, 84–85). Because these portions of the O'Reilly report, and others like them, risk usurping the Court's primary role in articulating the law to the jury, the Court will exclude them. Under the circumstances, Relators' proposal that the Court defer its decision as to admissibility until trial is unsatisfactory. There are likely to be close cases requiring an admissibility determination at trial, but permitting O'Reilly to testify, in the first instance, as to what are clearly legal opinions would be prejudicial to Janssen. For these reasons, Janssen's motion to exclude the testimony of James T. O'Reilly will be granted in part and denied in part.

B. Janssen's Motion to Exclude Certain Opinions of George P. Sillup

Janssen filed a motion to exclude the testimony of George P. Sillup, ("Sillup Motion," ECF No. 194), along with a brief in support of the Motion, ("Sillup Moving Br.," ECF No. 194-1). Relators opposed the Motion, ("Sillup Opp'n Br.," ECF No. 284), to which Janssen replied, ("Reply," ECF No. 249). Relators identified Sillup as an expert in pharmaceutical marketing issues relating to Janssen's marketing of Prezista and Intelence, and its Speaker Programs. (Chuderewicz Decl., Ex. A, ECF No. 194-3; Sillup Opp'n Br. at 4.) Sillup's report provides the following summary of the opinion he intends to offer at trial:

> In my professional opinion and based on my understanding of the impact of pharmaceutical marketing and my review of the evidentiary record, I believe that Janssen's widespread and top-down campaign of off-label marketing for Prezista and Intelence was a substantial factor in driving the volume of OL prescribing for Prezista and Intelence.

(Chuderewicz Decl., Ex. B, "Sillup Report" at 8, ECF No. 264.) Sillup organized his report in two sections: (1) Janssen's management took multiple actions to facilitate or encourage OL marketing

("Marketing Opinion"), and (2) the increased numbers of OL scripts were the foreseeable and intended result of Janssen's OL marketing ("Causation Opinion"). (*Id.* ¶¶ 36–134).

Janssen argues that Sillup's Marketing and Causation Opinions are inadmissible because he does not tie the opinions to any reliable principles and methods. (Sillup Moving Br. at 2, 7.) Janssen also contends that Sillup's Causation Opinion is inadmissible because "he is not qualified to offer it" and the opinion "is an impermissible legal opinion." (*Id.* at 4–7.)

In opposition, Relators argue that "Sillup is qualified to offer all of his opinions, and his opinions are reliable." (Sillup Opp'n Br. at 8.) Relators explain that, in analyzing and evaluating Janssen's marketing conduct, Sillup "reviewed extensive evidence in the case and broke down his conclusions into multiple prongs that a jury can readily follow and assess." (*Id.* at 12.) He analyzed highly technical documents, such as the FDA-approved labels for Prezista and Intelence, the eligible patient population, and Janssen's sales forecasts. (*Id.* at 12.) Relators also argue that Sillup's opinion concerning causation "is both within [his] expertise and reliably based on his experience in pharmaceutical marketing, from both the academic and industry perspectives." (*Id.* at 20.) They note that Sillup has the educational, academic, and industry background to explain the marketing surveys Janssen commissioned. (*Id.* at 22.) In addition, with respect to Janssen's argument that Sillup provided a legal opinion, Relators argue that courts have allowed pharmaceutical marketing experts to opine about OL marketing campaigns as a "significant contributing factor" to OL sales. (*Id.* at 22–23.) In the alternative, Relators contend the phrase "substantial factor," the term Sillup used in his report, is a common phrase such that "its use does not take [his] expert opinions into the realm of legal conclusions." (*Id.* at 23.)

In its reply, Janssen reiterates that Sillup's Marketing Opinion "usurps the role of the jury and is untethered from reliable principles and methods." (Sillup Reply at 2–4.) Janssen likewise

reiterates that "Sillup's Causation Opinion is inadmissible because it impinges on the role of the jury, . . . he is unqualified to opine on what caused doctors to prescribe HIV medications for HIV patients, . . . [and] he fails to apply reliable causation methodology." (*Id.* at 5–8.)

Sillup is a Professor in the Pharmaceutical & Healthcare Marketing Department at St. Joseph's University and served as chair of the Department from 2010 through 2017. (Sillup Report ¶¶ 4, 5; Sillup Report at 79.) Sillup holds an M.S. in Human Behavior and Development and a Ph.D. in Human and Organizational Structures. (Sillup Report ¶ 6; Sillup Report at 78.) He teaches courses on pharmaceutical marketing, publishes on the topic, and provides marketing consulting for pharmaceutical companies. (Sillup Report ¶ 5.) His research focuses on strategic planning, forecasting, market practices of pharmaceutical companies, and the effects of those practices on prescription medications. (*Id.*) Notably, he "transitioned to academia full time in 2004 after working 28 years in the pharmaceutical, diagnostic and medical device industry." (*Id.* ¶ 4.) While working in the pharmaceutical industry, he held positions from salesman to Chief Operating Officer and "guided numerous product launches for drugs and devices, which included developing product forecasts, marketing materials and sales training program to support products" across the United States and global market. (*Id.*) The Court finds that Sillup's qualifications are substantial.

According to Sillup, Relators retained him to opine on the following issues: (1) how pharmaceutical manufacturers promote the sale and use of drugs, especially when there are competing drugs in the market; (2) whether Janssen's management facilitated or encouraged the OL marketing done by its sales force and the paid speakers; and (3) whether Janssen's OL promotion and conduct a significant contributing factor in causing physicians to prescribe Prezista and Intelence for OL uses. (*Id.* ¶¶ 8–9.) In reaching his Marketing and Causation Opinions, Sillup

assessed Janssen's strategic corporate documents, financial records, testimony, and relevant academic research. (*Id.* at ¶¶ 5; Sillup Report, at 94–102.)

As to whether Sillup used reliable principles and methods to reach opinions, the Court finds *Smith v. Pfizer*, 714 F. Supp. 2d 845 (M.D. Tenn. 2010), persuasive. In that case, the court denied the defendants' motion to exclude testimony of a marketing expert who also concluded that the defendants' OL marketing campaign led to an increase in OL prescriptions. *Id.* at 855. The defendants argued that he employed no ascertainable methodology. *Id.* However, the court found his testimony reliable because he "relie[d] on and frequently cite[d] scholarly articles and studies," applied his "understanding of the drug marketplace and how marketing campaigns generally influence doctors," and examined sales and data. *Id.* at 857. *See also* Fed. R. Evid. 702 Advisory Committee Notes to 2000 Amendments (explaining that when an expert witness relies primarily on experience rather than a scientific study, the expert 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"); *United States v. Ford*, 481 F.3d 215, 219 (3d Cir. 2007) (reliability may turn on the proposed expert's "personal knowledge or experience").

Here, like the expert in *Smith*, Sillup reviewed extensive evidence and broke down his conclusions into multiple prongs. (Sillup Report ¶¶ 5, 18–49; Sillup Report, Ex. A, at 94–102.) In his report, Sillup explained that Janssen's management took the following actions to facilitate or encourage OL marketing: (1) developed unrealistic sales forecasts before it launched Prezista and Intelence; (2) instructed and trained its national sales force to promote Prezista and Intelence for OL uses; (3) encouraged physicians to write OL scripts through the Speaker Programs where OL promotion took place; (4) set compensation policies for sales staff that was based on an expectation of OL marketing; (5) encouraged sales staff to use unapproved studies when promoting

Prezista and Intelence; and (6) failed to discipline its sales staff or managers for OL marketing. (Sillup Report ¶¶ 18–49.) Indeed, Sillup reached these conclusions by analyzing the FDA-approved labels for Prezista and Intelence, the eligible patient population, and Janssen's sales forecasts. (*Id.* ¶ 12.) His report explained the highly technical process of creating sales forecasts for pharmaceutical products, and he relied on this same process to determine that Janssen created unrealistic sales forecasts for Prezista and Intelence. (*Id.* ¶¶ 18–28.) Sillup also analyzed documents tracking Prezista and Intelence sales to show that a significant proportion of sales were OL. (*Id.* ¶¶ 32–34.) Throughout his report, he referenced documents and testimony to show that Janssen's training of its sales force, its bonus incentive, and corporate culture all encouraged OL marketing. (*Id.* ¶¶ 34–49.) To the extent Janssen disagrees with the evidence and testimony Sillup relies upon to render his expert opinions, disagreement about his assumptions "go[] to the weight given to his testimony, rather than [its] admissibility." *Leonard v. Stemtech Int'l Inc.*, 834 F.3d 376, 391 (3d Cir. 2016). *See also Breidor v. Sears, Roebuck & Co.*, 722 F.2d 1134, 1138–139 (3d Cir. 1983) ("Where there is a logical basis for an expert's opinion testimony, the credibility and weight of that testimony is to be determined by the jury, not the trial judge."); Fed. R. Evid. 702 Advisory Committee Notes to 2000 Amendments. Similarly, for the reasons stated above, this Court finds that Sillup used reliable principles and methods to reach his Marketing Opinion.

In the causation portion of his report, Sillup concludes that the increased numbers of OL scripts of Prezista and Intelence were the foreseeable and intended result of Janssen's OL marketing. (Sillup Report ¶ 45.) First, the Court finds that Sillup is qualified to offer his opinion based on the specialized knowledge he has acquired through his many years of training, education, and experience. *Calhoun*, 350 F.3d at 322. Not only is he a professor in pharmaceutical marketing, but he worked in the pharmaceutical industry for nearly three decades and developed product sales

forecasts, marketing materials, and sales training programs for new drugs. (Sillup Report ¶ 6.) In addition, his research focuses on strategic planning, sales forecasting, market practices of pharmaceutical companies, and the impact of those practices on prescription medications. (*Id.*)

Second, as to the reliability of Sillup's Causation Opinion, the Court notes that he relied on the following: (1) guidance from courts, federal agencies, and the Office of the Inspector General that recognize OL marketing can cause physicians to write OL scripts; (2) academic and marketing literature that shows OL marketing influences prescribers; and (3) Janssen's internal and external marketing surveys showing that its OL marketing was causing physicians to write OL scripts. (*Id.* ¶¶ 49–66.) The Court, therefore, finds that Sillup's opinion concerning causation is tied to reliable methods and principles. *See Smith*, 714 F. Supp. 2d at 857.

Third, courts have allowed experts to opine as to the causal link between pharmaceutical OL marketing efforts and doctors' prescribing decisions. *See, e.g.*, *Smith*, 714 F. Supp. 2d at 856; *United States ex rel. Brown v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1039–40 (C.D. Cal. 2016); *Hanrahan v. Wyeth, Inc.*, Civ. No. 04-1255, 2012 WL 2395986, at *5 (E.D. Mo. June 25, 2012). Accordingly, the Court will deny Janssen's motion to exclude the expert report and testimony of George P. Sillup.

C. Janssen's Motion to Exclude Certain Opinions of Kenneth W. Schafermeyer

Janssen filed a motion to limit the testimony of Kenneth W. Schafermeyer, ("Schafermeyer Motion," ECF No. 196), along with a brief in support of the Schafermeyer Motion, ("Schafermeyer Moving Br.," ECF No. 196-1). Relators opposed the Motion, ("Schafermeyer Opp'n Br.," ECF No. 282), to which Janssen replied ("Schafermeyer Reply," ECF No. 247). Relators identified Schafermeyer as a rebuttal expert to Janssen's expert, Dr. Babette Edgar, who intends to testify

about the statutory and regulatory framework for Medicare Part D ("Part D"). (Chuderewicz Decl., Ex. A, "Schafermeyer Report" ¶ 3, ECF No. 265.)

Schafermeyer's report provides the following summary of the opinion he intends to offer at trial: "It is my opinion that CMS does maintain a 'medically necessary and reasonable' requirement for services under Part D and, based on Dr. Glatt's opinion, that prescriptions relying on Janssen's false and misleading marketing do not meet this standard and should not be covered." (Schafermeyer Report ¶ 59.) Schafermeyer organized his report in two sections: (1) issues pertaining to Part D, including administration of the drug benefit, funding sources, drug coverage, and utilization management tools; and (2) the financial implications of Janssen's alleged behavior on Part D for promoting Prezista and Intelence for OL and/or medically unnecessary use (the "Coverage and Reimbursement Opinions"). (*Id.* ¶¶ 6–58.)

Janssen contends that Schafermeyer's Coverage and Reimbursement Opinions are inadmissible because he "does not have [the] relevant expertise to offer these Opinions." (Schafermeyer Moving Br. at 3.) Although "Schafermeyer's experience may be sufficient for him to walk the jury through the Medicare Part D statutory framework, he has no expertise to opine on how CMS makes coverage and reimbursement decisions for antiretroviral medications under Medicare Part D." (*Id.* at 1.) Janssen notes that Schafermeyer has not worked or consulted for CMS or a Part D sponsor, has not specifically taught about such topics, and has reimbursement knowledge that is not at issue here. (*Id.* at 2–4.) Janssen argues that Schafermeyer's Coverage and Reimbursement Opinions are based *solely* on his understanding of the regulatory framework and of CMS' factors in making coverage and reimbursement decisions. (*Id.* at 4.) Janssen concludes that Schafermeyer's education and experience do not "qualify him to testify on the more

specific subject of how CMS makes coverage and reimbursement decisions under Medicare Part D for antiretroviral medications such as Prezista and Intelence." (*Id.* at 4.)

In opposition, Relators argue that Janssen overstated the qualification requirement for expert testimony admission. (Schafermeyer Opp'n Br. at 3, 11.) Noting that precedents show that "rejection of expert testimony is the exception rather than the rule," Relators state that "the liberal standards for admissibility have supported acceptance of expert[s'] opinions outside their narrow area of expertise in many different settings, including with regard to regulatory schemes." (*Id.* at 3–5.) To disprove Janssen's argument that Schafermeyer's Coverage and Reimbursement Opinions are based *solely* on his understanding, Relators point to Schafermeyer's basis for understanding the topic, including materials that Dr. Babette Edgar (Janssen's own expert) uses in her report. (*Id.* at 8–10.) Relators further argue that Janssen's arguments regarding Schafermeyer's lack of experience working or consulting for CMS go to the weight of his testimony, not its admissibility. (*Id.* at 11–12.)

In its reply, Janssen emphasizes four points to prove that "none of [Schafermeyer's] experience is relevant to his Coverage and Reimbursement Opinions." (Reply at 1.) According to Janssen, Schafermeyer does not explain which courses involved teaching Part D, how his teaching history relates to his Coverage and Reimbursement Opinions, or whether his courses taught Part D policy issues in great depth. (*Id.* at 3–4.) Janssen notes that Schafermeyer has neither advised agencies nor private companies on Part D nor consulted for a pharmaceutical company on managed care or reimbursement since 1995, over a decade before Part D existed. (*Id.* at 5.) Janssen then argues that Schafermeyer's previous expert testimony centered on over-inflated drug prices instead of coverage and reimbursement of HIV medications. (*Id.* at 6.) Finally, Janssen argues that Relators attempt to buttress Schafermeyer's credentials by pointing to alleged errors,

which is an inappropriate factor to consider when determining the qualification of an expert. (*Id.* at 7–8.)[2]

As mentioned above, the qualification requirement of Rule 702 is interpreted liberally with a "broad range of knowledge, skills, and training qualify[ing] an expert." *Pineda*, 520 F.3d at 244 (quoting *Paoli*, 35 F.3d at 741). The qualification prong of Rule 702 requires "that the witness possess specialized expertise." *Id.* (quoting *Schneider*, 320 F.3d at 404). "Unlike an ordinary witness, . . . an expert is permitted wide latitude to offer opinions, including those that are not based on first[-]hand knowledge or observation." *Daubert*, 509 U.S. at 592.

Schafermeyer earned an M.S. and Ph.D. in Pharmacy Administration, is a licensed pharmacist, has earned credits in business, economics, and marketing, and is currently a Professor of Pharmacy Administration at St. Louis College of Pharmacy. (Schafermeyer Report, Ex. A, at 23.) In a previous role, he "served as the Director of Graduate Studies and headed a Master's degree program in Managed Care Pharmacy." (*Id.* ¶ 1.) Since 1976, Schafermeyer has worked with, taught about, and analyzed the operations of pharmacies, their financial performance, their costs of dispensing, and their reimbursement by private and public prescription programs, including government-supported health care programs such as Medicare, Medicaid, TRICARE, and the Federal Employees Health Benefits Program. (*Id.*) He has also worked with and taught about the operations of managed care organizations and pharmacy benefit managers ("PBMs"). (*Id.*) Furthermore, Schafermeyer has testified in four cases since 2015, but Janssen alleges they

[2] In its reply, Janssen appears to raise the issue of reliability for the first time. (Reply at 3–6.) "An issue is waived unless a party raises it in its opening brief, and for those purposes 'a passing reference to an issue . . . will not suffice to bring that issue before this court.'" *Laborers' Int'l Union of N. Am., AFL-CIO v. Foster Wheeler Energy Corp.*, 26 F.3d 375, 398 (3d Cir. 1994). In addition, although both parties argue these points, the Court does not have a sufficient basis to rule whether Schafermeyer's testimony is reliable because the argument was, at best, unclear in the moving brief. This finding is supported by the fact that neither party has effectively argued for or against the factors for the reliability of Schafermeyer's testimony. *See In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 854 (3d Cir. 1990) ("The adversarial process upon which our legal system is based assumes that a fact finder will give the parties an adequate opportunity to be heard; if it does not, it cannot find facts reliably.").

were related to over-inflated drug prices and not the issues in this current matter. (*Id.*; Schafermeyer Reply at 6.) According to Janssen, he has not taught such a course since 2005, around when Part D was enacted. (Schafermeyer Moving Br. at 2–4; Reply at 5.)

Schafermeyer has been involved in pharmacy administration for approximately forty-five years. (Schafermeyer Report ¶ 1.) He has taught classes in pharmacy administration, which included reimbursement by private and public prescription programs. (*Id.*) Moreover, he has consulted on matters related to reimbursement. (*Id.*) Even if Janssen's concerns are taken as true, Schafermeyer's long and storied career in pharmacy administration gives him the specialized knowledge required to qualify as an expert under Rule 702. *See Paoli*, 35 F.3d at 741 ("We have eschewed imposing overly rigorous requirements of expertise and have been satisfied with more generalized qualifications."). Although the time since Schafermeyer taught or worked in the field may be pertinent, the Court finds that these concerns go to the credibility and weight of his testimony, a function better left to trial before a jury. *Daubert*, 509 U.S. at 596 ("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."). With the policy of liberal admissibility in mind, the Court finds that Schafermeyer is qualified to testify about his Coverage and Reimbursement Opinions.

The Court finds that Janssen's argument regarding Schafermeyer's qualifications is unpersuasive and primarily goes to the weight and credibility of Schafermeyer's testimony. As such, the Court will deny Janssen's motion to limit the expert testimony of Kenneth W. Schafermeyer.

D. Janssen's Motion to Exclude Certain Opinions of Aaron E. Glatt

Janssen filed a motion to limit certain testimony of Aaron E. Glatt, ("Glatt Motion," ECF No. 198), along with a brief in support of the Motion, ("Glatt Moving Br.," ECF No. 198-1). Relators opposed the Motion, ("Glatt Opp'n Br.," ECF No. 285), to which Janssen replied ("Glatt Reply," ECF No. 246). Relators identified Glatt as an expert in the approved labels of Prezista and Intelence, Janssen's marketing of Prezista and Intelence, and the Speaker Programs. (Chuderewicz Decl., Ex. A, ECF No. 194-3.) Glatt's report provides the following summary of the opinion he intends to offer at trial:

> I conclude, with a reasonable degree of medical certainty, that none of these types of promotional messaging were clinically appropriate given the limited FDA approval, available recommendations and guidelines by respected professional and regulatory agencies, and the standard of care for treatment of HIV/AIDS patients in the infectious disease and broader medical community . . . .

(Chuderewicz Decl., Ex. A, "Glatt Report" ¶ 9, ECF No. 266.) Glatt's report also contains the following opinion: "There was considerable significance of Janssen's marketing in terms of likely impact on physician's prescribing decisions, potential patient harm, and expansion of the potential market for Prezista and Intelence." (*Id.* ¶ 11.) Janssen argues that "Glatt opines repeatedly in his report that those practices likely caused physicians to write Intelence and Prezista prescriptions that they would not otherwise have written" ("Causation Opinion"). (Glatt Moving Br. at 1.) Janssen argues that Glatt's Causation Opinion should be excluded from his report, and he should not be permitted to testify about his Causation Opinion at trial. (*Id.* at 2.) Janssen contends Glatt's Causation Opinion is inadmissible because: (1) "he is not qualified to offer it" and (2) it "is not reliable." (*Id.* at 2, 4.)

In opposition, Relators argue that the challenged testimony is "both within Dr. Glatt's expertise and reliable based on Dr. Glatt's broad experience in the field of drug treatment for HIV-

AIDS patients . . . ." (Glatt Opp'n Br. at 7–8.) Relators explain that Glatt's experience is further evidenced by his "years of teaching and consultation with other physicians and students, including specifically about the appropriate selection of drug therapies for HIV/AIDS patients" and "career on hospital committees," which dealt with the potential impacts of pharmaceutical marketing on physicians and other prescribers. (*Id.* at 8.) Relators explain that Glatt draws on his previous experience but also "carefully describes how the substance or content of Janssen's messaging could mislead physicians and influence their selection and use of Janssen's drugs." (*Id.* at 10–11.) In addition, with respect to Janssen's argument that Glatt's opinion is not reliable, Relators argue that he meets the standard applied to expert witnesses relying on experience because he explains how his experience helped shape his conclusions, why his experience is a sufficient basis, and how his experience is "reliably applied to the facts." (*Id.* at 16.)

In its reply, Janssen argues that "Glatt's Causation Opinion extends beyond the factors that physicians generally consider when making prescribing decisions and impermissibly speculates how all physicians weigh and interpret marketing information when prescribing Prezista and Intelence to HIV patients." (Glatt Reply at 2.) Janssen emphasizes that Glatt does not have experience in pharmaceutical marketing to support his opinion. (*Id.* at 3.) Further, Janssen focuses on Glatt's methodology, stating "Glatt does not identify any methodology that he used to reach his Causation Opinion." (*Id*. at 5.)

Glatt is a Clinical Professor of Medicine at Icahn School of Medicine at Mount Sinai. (Glatt Report ¶ 1.) Glatt is the Chairman of the Department of Medicine and Chief of Infectious Diseases and Hospital Epidemiologist at South Nassau Communities Hospital. (*Id.*) He is a fellow of the Infectious Disease Society of America, the American College of Physicians, and the Society of Healthcare Epidemiologists of America. (*Id.*) He has practiced in the infectious disease field

for over thirty-three years with a "significant focus on treating patients with HIV/AIDS." (*Id.* ¶ 2.) He has authored numerous articles related to HIV/AIDS drugs and treatment. (*Id.* at 74–81.) Glatt has been the spokesperson for the Infectious Diseases Society of America since 2002 and is a member of several Infectious Disease and HIV committees. (*Id.* at 71–73.)

According to Glatt, Relators retained him to opine on the following issues: (1) the drug treatment for patients with HIV/AIDS during the "Relevant Time Period[3]"; (2) the clinical issues related to the HIV/AIDS drug regimen that are particularly important to patients and physicians; (3) the FDA-approved labels and marketing indications for Prezista and Intelence; and (4) the education value of the Speaker programs. (*Id.* ¶¶ 5–7.) In reaching his opinion, Glatt used his professional experience and educational background to assess the FDA label, "the weight of medically accepted standards and the significance of Janssen's messaging, including the likely impact of physician's prescribing decisions," and the "potential patient harm and likely expansion of the market for the drugs." (*Id.* ¶ 6.)

As mentioned above, an expert's testimony is admissible when the expert is qualified, the testimony is reliable, and the testimony fits the facts of the case. When an expert relies primarily on experience rather than a scientific study, the expert 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." Fed. R. Evid. 702 Advisory Committee Notes to 2000 Amendments. *See also Ford*, 481 F.3d at 219 (reliability may turn on the proposed expert's "personal knowledge or experience"). However, the party seeking admission for expert testimony must prove (and a court must find) that the expert has sufficient bases to make specific conclusions. *See Pfizer Inc. v. Teva Pharm. USA, Inc.*, 461 F. Supp. 2d 271, 275 (D.N.J. 2006).

[3] As used by the parties and their experts, "Relevant Time Period" (as well as "Review Period" or "relevant periods") refers to the period of 2006 to 2014, when Janssen's alleged misconduct occurred. (Glatt Report ¶ 2.)

In *Pfizer Inc. v. Teva Pharmaceuticals USA, Inc.*, Pfizer filed a motion to exclude a rheumatologist's testimony regarding a medicine's therapeutic properties, the absence of therapeutic advantages over other non-steroidal anti-inflammatory drugs ("NSAID"), and physician prescribing practices, specifically the role of marketing materials in influencing physicians to prescribe the drug. 461 F. Supp. 2d at 275. Plaintiff argued that the rheumatologist's testimony should have been excluded in its entirety because it was speculative and not based on a reliable methodology. *Id*. at 275–76. The defendant argued that the rheumatologist should have been permitted to testify because his opinions were "based on his 20 years [of] practicing rheumatology and prescribing NSAID therapies for the treatment of chronic pain." *Id*. at 276.

In *Pfizer*, the court granted narrow exclusions where the rheumatologist did not have a reliable basis for his testimony. *Id.* at 275–78. The court found that the expert's "20 years practicing rheumatology and prescribing NSAID therapies for the treatment of chronic pain" was "not a sufficiently reliable basis for his broad opinions on the prescribing practices and general understanding of all physicians." *Id*. at 277. Moreover, the court found that the rheumatologist could "render an opinion on the accuracy of Celebrex's marketing materials" but "not opine as to physicians' . . . understanding of these materials or the effect that these materials had on their prescription choices" because the latter opinions "are speculative and not based on a reliable methodology." *Id*. Finally, the court found that the rheumatologist did not have a sufficiently reliable basis for his opinions that "prescriptions were heavily influenced by advertising and promotion" because his personal knowledge and experience did not persuade the court that he could "form[] a sufficient basis for his broad conclusions concerning the impact of sales and marketing efforts on . . . prescriptions." *Id*. at 277–78. Ultimately, the court drew a distinction between reliable and unreliable expert testimony from physicians. *Id.* at 275. Because of a

physician's training and expertise, they can opine on prescribing medication, label accuracies, marketing accuracies, comparisons between various medications, and how they would act in a certain situation. *Id*. at 275–77. However, physicians cannot go beyond their expertise to opine about the effect of marketing materials or put forth broad opinions about prescribing practices and the general understanding of all physicians without more expertise. *Id.* at 277.

The Court has considered Glatt's qualifications and the opinion he intends to offer. The Court finds that Glatt has extensive personal knowledge and expertise in the field of HIV/AIDS drugs and their labels. Glatt is a practicing physician, has practiced medicine for almost forty years, has been involved with infectious disease departments for much of his practice, and has been in several teaching and head positions over the course of his career. (Glatt Report ¶ 1.) He also sat as chair on various hospital committees that dealt "with the potential impact of pharmaceutical advertising on appropriate usage of medications both in the hospital and in the community." (*Id*. ¶ 5.)

Glatt has personal knowledge of pharmaceutical marketing and advertising throughout his career, including "setting up policies and practices that the hospital should engage in in terms of allowing, not allowing pharmaceutical industry representatives to come into the hospital" to prevent undue influence on physicians. (*Id.* ¶¶ 7, 27.) In his current position, Glatt continues to consult with other physicians about recommended drug treatments for patients, and he has seen on numerous occasions the increased usage of a drug for no medical indication after pharmaceutical representatives have visited. (*Id.* ¶¶ 25–30.) Contrary to Janssen's argument, Glatt's personal knowledge and expertise are far greater in comparison to the physician in *Pfizer* on the testimony involved. The Court finds that Glatt's personal knowledge and expertise indicate that he is generally qualified to offer his opinion with respect to HIV, its drugs, its labels, and its marketing.

However, the Court finds inadmissible Glatt's opinions about the effects of Janssen's OL promotions on physicians' prescribing decisions. Although Glatt has some experience with pharmaceutical marketing in hospitals and has firsthand knowledge of many concerns regarding HIV/AIDS due to his career in infectious diseases, he does not have the same qualifications as Sillup, for example, to opine on the effects of OL promotion and marketing. (Glatt Report ¶¶ 1–5; Glatt Report at 91–97.) Relying on the court's guidance in *Pfizer*, this Court will bar Glatt from opining on how Janssen's OL promotion and marketing impacted the physicians' prescribing decisions. 461 F. Supp. 2d at 277–78. Accordingly, the Court grants Janssen's motion to limit the testimony of Aaron E. Glatt.

E. Janssen's Motion to Exclude the Testimony of Virginia B. Evans

Janssen filed a motion to exclude the expert report and testimony of Virginia B. Evans ("Evans Motion," ECF No. 200), along with a brief in support of the Motion, ("Evans Moving Br.," ECF No. 200-1). Relators opposed the Motion, ("Evans Opp'n Br.," ECF No. 281), to which Janssen replied, ("Evans Reply," ECF No. 244). Relators identified Evans as "an expert in the field of health care compliance." (Evans Opp'n Br. at 9.) Evans' report provides the following summary of the opinion he intends to offer at trial:

> [I]t is my opinion that Janssen's Prezista and Intelence Speaker Programs did not comply with applicable government and industry standards, and that Janssen did not have an effective compliance program to prevent and detect Speaker Program misconduct. Based on my review and analysis, I conclude that Janssen used its Speaker Programs to pay doctors to induce them to prescribe Prezista and Intelence, and/ or to reward them for doing so. I further conclude that Janssen paid its Speaker physicians to promote the off-label use of these drugs to other prescribing physicians.

(Chuderewicz Decl., Ex. A, "Evans Report" ¶¶ 5–6, ECF No. 267.) According to her expert report, Relators asked Evans to opine on whether the Speaker Programs were conducted in compliance

with the laws, regulations, and guidance in the pharmaceutical industry, and whether Janssen's compliance program was "effective" as that term is understood in the healthcare and pharmaceutical industries. (*Id.* ¶ 5.)

Janssen argues that Evans intends to "offer[] legal advocacy, rather than specialized knowledge, that would not help the trier of fact to understand the evidence or to determine a fact in issue." (Evans Moving Br. at 2–7.) Aside from the legal conclusions, Janssen also argues that Evans' "opinion that Janssen's compliance program was 'ineffective' is inadmissible because she fails to tie her opinions to reliable methods or principles." (*Id.* at 7–14.)

In opposition, Relators argue that Evans did not provide legal conclusions. (Evans Opp'n Br. at 11.) They contend Evans "analyzed the evidence in the record under applicable government and industry standards, offered her expert opinion in a written expert report, and provided testimony." (*Id.* at 11–12.) They argue that Evans' report does not improperly summarize evidence and usurp the role of the jury. (*Id.* at 20–23.) Moreover, Relators contend Evans used reliable methods to form her opinions. (*Id.* at 23–35.)

In its reply, Janssen emphasizes that Evans offers legal advocacy that would usurp the role of the jury and the Court. (Evans Reply at 2.) Also, Janssen reiterates that Evans failed to apply reliable methodology to render her non-legal opinions admissible. (*Id.* at 6.)

The Court has reviewed Evans' qualifications because her specialized knowledge and experience in health care compliance is relevant to understanding how she formed her opinions and deciding the issue of reliability. Evans graduated from New York University School of Law and is admitted as a member of the bar in several states. (Evans Report ¶ 7; *id.* at 78.) She worked as a federal prosecutor for over twenty-five years but transitioned into private practice in 2005 and started providing health care consulting services. (*Id.* ¶¶ 5–6.) When she first transitioned into

private practice, she "managed several Independent Review Organization engagements for health care clients under Corporate Integrity Agreements, conducted compliance risk assessments and internal investigations, and worked with Audit Committees and Internal Audit Departments of large health care providers including hospitals, insurers, a national retail pharmacy chain, and an international pharmaceutical company." (*Id.* ¶ 6.) In 2010, she became partner at a large firm's Health Law practice where she represented health care providers in civil and criminal investigations. (*Id.* ¶¶ 6–7.) During that time, she also became a compliance resource for pharmaceutical companies, drug manufacturers, and physician practices. (*Id.* ¶ 6.) She wrote and reviewed compliance policies for many clients and negotiated settlements with state and federal health care agencies in cases involving the FCA, FDA, and other health care matters. (*Id.*) At one point, Evans served as a Vice President, Compliance Officer, and General Counsel for a hospital system. (*Id.* ¶ 7.) Evans also has experience working as a Senior Legal Editor for ThomsonReuters' Health Care & Life Science legal journal, and she is certified in Health Care Research Compliance. (*Id.*)

In her report, Evans used specialized knowledge as a health care compliance expert to determine whether Janssen maintained an effective compliance program by reviewing its compliance policies. Evans noted that she reviewed numerous documents before reaching her conclusions, including but not limited to Janssens' compliance policies on the Speaker Programs, documents concerning its Speaker Programs (*e.g.*, procedures, promotional policies, management guide, and internal emails and communications), summary reports of investigations, honoraria reports, return on investment reports, data collection efforts, transcripts of depositions of witnesses, and Janssen's responses to discovery request. (*Id.* ¶ 8; *id.* at 81–84.) More specifically, Evans reviewed Janssen's Speaker Programs to determine if they complied with the standards set

forth in the Compliance Program Guidance for Pharmaceutical Manufacturers ("OIG Guidance") written by the Office of Inspector General ("OIG") of the Department of Health and Human Services. (*Id.* ¶¶ 8–9.) She sought to determine whether Janssen implemented "controls," as recommended by OIG guidance, to prevent its Speaker Programs from being used to improperly influence physicians' prescribing behavior. (*Id.* ¶ 9.) Evans also reviewed Janssen's compliance program and other internal documents to determine whether Janssen complied with its own policies. (*Id.*) In addition to the OIG Guidance, Evans also relied on other materials about industry standards and practices that help manufacturers implement and maintain effective compliance programs. (*Id.* ¶¶ 9–10.)

After reviewing Evans' approach, the Court rejects Janssen's argument that Evans' methodology was "unreliable and litigation-driven." (Evans Moving Br. at 9.) To the extent Janssen takes issue with the evidence Evans relies upon to render her non-legal opinions, Janssen may cross-examine her and present evidence to the contrary at trial. *Krys v. Aaron*, 112 F. Supp 3d 181, 192 (D.N.J. 2015) (quoting *Daubert*, 509 U.S. at 595). *See also MicroStrategy Inc. v. Business Objects, S.A.*, 429 F.3d 1344, 1355–356 (Fed. Cir. 2005) (explaining that an expert "must consider *enough* factors to make his or her opinion sufficiently reliable in the eyes of the court . . . [but the] expert need not consider *every* possible factor to render a 'reliable' opinion"). The Court is not required to preclude Evans' expert testimony simply because Janssen believes she "could have performed . . . her analysis in a better manner." *Pfizer*, 461 F. Supp 2d at 274. For the reasons stated above, the Court finds that Evans used "reliable principles and methods" to reach her conclusion concerning the effectiveness of Janssen's compliance program, and her opinion is supported by "sufficient facts and data." *See* Fed R. Evid. 702(b), (c).

Moreover, Evans' testimony about the industry compliance standards and her opinion that Janssen did not have an effective compliance program is admissible because it would help "the trier of fact to understand the evidence [and] to determine a fact in issue . . . ." Fed. R. Evid. 702(a). Evans' opinion would help the jury determine whether Janssen's "conduct or actions meet the underlying bases for an ultimate issue" to be decided in this case. *Krys*, 112 F. Supp. 3d at 193. However, Evans' opinion that "Janssen used its Speaker Programs to pay doctors to induce them to prescribe Prezista and Intelence" is inadmissible because it is a legal conclusion. *Berckeley*, 455 F.3d at 217. Whether Janssen used its Speaker Programs to induce doctors to prescribe Prezista and Intelence is an issue for the jury because it decides an element of the AKS claims. *See* 42 U.S.C. § 1320a-7b(b)(2)(B). Although Federal Rule of Evidence 704(a) allows an expert to proffer testimony that "embraces an ultimate issue to be decided by the trier of fact," the ultimate issue rule does not enable an expert to tell the jury what result to reach. *Krys*, 112 F. Supp. 3d at 192. The Court agrees with Janssen that this is a question of intent for the jury, and Evans cannot provide testimony concerning state of mind or culpability. *Id*. at 203.

The Court, therefore, will grant in part and deny in part Janssen's motion to exclude the expert testimony of Virginia Evans.

F. Janssen's Motion to Exclude the Testimony of Israel Shaked and Ian Dew

Janssen filed a motion to exclude the testimonies of Israel Shaked and Ian Dew, ("Shaked Motion," ECF No. 202), along with a brief in support of the Motion, ("Shaked Moving Br.," ECF No. 202-1). Relators opposed the Motion, ("Shaked Opp'n Br.," ECF No. 280), to which Janssen replied, ("Shaked Reply," ECF No. 248). Relators retained "Shaked to perform statistical analyses of the prescription claims data and to opine on issues of causation and damages." (Shaked Opp'n Br. at 1.) Shaked's expert report provides many opinions he intends to offer at trial, including: the

positive relationship between compensation paid to physicians and subsequent prescriptions written for Prezista and Intelence; the opinion that Janssen's conduct "influenced" OL prescriptions that were then reimbursed by the government for the relevant periods; and the total damages related to Janssen's alleged violation of the FCA and AKS. (Chuderewicz Decl., Ex. A, "Shaked Report" ¶¶ 13–145, ECF No. 268.) Shaked performed twelve different analyses in which he calculated various metrics to explain the relationships between payments to speakers, effects of payments on prescribing physicians, and the relationship between speakers and non-speakers. (*Id.* at 35–63.) In reaching his conclusions, Shaked relied on Ian Dew for analytical support.[4] (*Id.* ¶ 14; Chuderewicz Decl., Ex. D, "Dew Rebuttal Report" at 3, ECF No. 268-2.)

Janssen challenges the reliability of Shaked's opinions and, by proxy, of Dew's opinions. (Shaked Moving Br. at 4.) Janssen also seems to challenge Shaked's qualification by claiming that he does not have the requisite experience to opine on medical claims because his work centers on financial analyses.[5] (*Id.* at 4.) First, Janssen argues that "Shaked's general causation opinions relating to [OL] promotion and speaker payments should be excluded because they are based on an unreliable methodology for assessing causation." (*Id.* at 10–20.) It contends that Shaked's "[c]correlation analyses are not generally accepted methods for assessing causation" and fails to consider "confounding factors that may affect physicians' prescribing decisions." (*Id.* at 11, 15.) Second, Janssen argues that "Shaked's general causation opinions relating to [OL] promotion also should be excluded because the two variables being measured in his correlation analyses are based on unsupported assumptions that do not fit the facts of this case and result in an unreliable

[4] Ian Dew is a partner at Steck Consulting and has over twenty years of experience in data analysis. (*Id.* ¶ 17, n.6) Shaked utilized Dew to query databases of ADAP, Medicaid, and Medicare. (*Id.*) Shaked describes the data he requested from Dew throughout his report. (*Id.*)

[5] Janssen also asks the Court to exclude Dew because of his alleged lack of qualifications. (Shaked Moving Br. at 9–10.) The Court declines to address this argument because Dew supports Shaked's opinion, has no independent opinion, and Janssen has asked this Court to posit Dew's exclusion on Shaked's exclusion.

methodology." (*Id.* at 20–27.) Janssen contends that Shaked's definition of an "influenced" prescriber and his attribution of a patient's lifelong prescriptions to the first prescriber are both variables based on unsupported assumptions. (*Id.* at 20, 24.) Third, Janssen argues that "Shaked's specific causation opinions identifying false claims and estimating damages resulting from Janssen's alleged improper promotion should be excluded because they are based on unsupported assumptions and errors that do not fit the facts of this case and result in an unreliable methodology." (*Id.* at 27–30.)

In opposition, Relators argue that "Shaked has excellent support for his analyses and opinions here, and his opinions easily satisfy the applicable standards of reliability and admissibility." (Shaked Opp'n Br. at 3.) They argue that Shaked accounted for confounding variables, has a basis for assumptions and definitions for his damages and causation analyses, and can prove causation under the FCA through a general causation analysis rather than a "but for" analysis. (*Id.* at 3–6.) In addition, Relators explain that Shaked is an expert in statistics and uses "common and well-established methods to perform his analyses," applying the methods to comparable groups. (*Id.* at 2.) They note that Shaked has the educational, academic, and industry background necessary to qualify as an expert. (*Id.*)

In its reply, Janssen reiterates that Shaked's general causation opinions are inadmissible because they fail to satisfy the reliability requirement of Federal Rule of Evidence 702. (Shaked Reply at 2.) Janssen argues that Shaked cannot prove any existence of a causal relationship because his assumption that all of Janssen's contacts "influenced" physicians has no reliable basis in the facts. (*Id.* at 4; *see id.* at 11, n.8.) Emphasizing its point that two-variable correlation analyses are not a generally accepted method for assessing causation, Janssen argues that the lack

of a randomized control experiment and the lack of multiple regression analyses cause his general causation opinion to be unreliable. (*Id.* at 5–11.)

The parties' disagreement centers on whether Shaked's analyses have "good grounds" for his conclusions. The "good grounds" analysis implicates the reliability prong; once determined, the fit of the testimony to the facts of the should be adjudged. *See Daubert*, 509 U.S. at 598. "The evidentiary requirement of reliability is lower than the merits standard of correctness." *Paoli*, 35 F.3d at 744. "An expert is . . . permitted to base his opinion on a particular version of disputed facts and the weight to be accorded to that opinion is for the jury." *Walker v. Gordon*, 46 Fed. App'x 691, 695–96 (3d Cir. 2002). An expert's report and testimony are reliable if the expert has "good grounds" for his or her opinions. *Paoli*, 35 F.3d at 744. When evaluating whether a particular scientific methodology is reliable, the Third Circuit has instructed district courts to consider the following non-exhaustive factors: (a) whether a method consists of a testable hypothesis; (b) whether the method has been subject to peer review and publication; (c) the known or potential rate of error; (d) the existence and maintenance of standards controlling the technique's operation; (e) whether the method is generally accepted; (f) the relationship of the technique to methods which have been established to be reliable; (g) the qualifications of the expert witness testifying based on the methodology; and (h) the non-judicial uses to which the method has been put. *Id.* at 742, n.8 (citation omitted). *See also Pineda*, 520 F.3d at 247–48.

The Court reviewed Shaked's report to determine whether he used methods with good grounds to reach his general causation opinions. The Difference of Two Population Means Test (the two-factor correlation analysis Janssen references) determines whether there is a statistically significant difference between two independent population means. (Shaked Report at 73.) If the z-score is higher than the critical value, then there is a statistically significant difference between

the two populations. (*Id.* at 73.) Here, Shaked clearly explains his rationale for setting up tests, tests each of his hypotheses (*e.g.*, whether payments "influenced" physicians) against the negative hypotheses (*e.g.*, whether payments did not "influence" physicians), and used z-scores to determine whether the results were statistically significant. (Shaked Report ¶¶ 76, 96, 105, 131, 140.) Moreover, Shaked calculated the Spearman Rank Correlation values for dollar amounts paid to speakers and their dollar amount of prescriptions. (*Id.* at 36.) As understood by the Court and expressed by Shaked, the Spearman Correlation Test measures the positive relationship between two variables; a value of "-1" implies a weak association, a value of "0" implies no association, and a value of "1" implies a positive association. (Shaked Report at 73–74.) The Spearman Rank Correlation Significance Test analyzes the strength of the correlation test and the possibility that the correlation is by chance. (*Id.* at 74.) Furthermore, contrary to Janssen's argument that Shaked did not run regressions, Shaked ran multiple regressions on the data when challenged by Anupam Jena; however, Shaked chose not to include it in the supplemental report because he believed that the identical results did not need to be included in his report. (Chuderewicz Decl., Ex B., "Shaked Dep." 291:10–25, ECF No. 202-4.) With positive values, high z-scores, and high t-values, the values are statistically significant (*i.e.*, cannot be rejected) under accepted statistical checks.[6] (Shaked Report at 74.) As such, the Court finds that Shaked's report has "good grounds" and is, therefore, reliable. Since Shaked uses data pertinent to the facts of the case, the Court finds that his analysis is also relevant to the case at hand.

[6] When applying the Rank Correlation Significance Test, Shaked calculated a correlation of 0.235 and a t-value of 4.212 for the correlation between a change in total compensation and average annual prescription; he also calculated a correlation of 0.406 and a t-value of 31.944 for the correlation between a change in marketing contacts and OL prescriptions. (Shaked Report ¶¶ 89, 119.) According to the t-score table found, the t-values for 99.995% confidence in the result is 3.97 for a data set of 200 values and 3.92 for a data set of 500 values. https://faculty.washington.edu/heagerty/Books/Biostatistics/TABLES/t-Tables/. As such, the Court finds that the values calculated are reliable.

The *Reference Manual on Scientific Evidence* does note that randomized controlled experiments generally are a better measure of causation than observational studies. Federal Judicial Center, 220 (3d ed. 2011). Although the Court does not doubt that Shaked has the capacity to make such a decision, it would be prudent to probe the reason for his choice. Shaked collected the data for his analyses from a variety of sources, including state databases, and explains that his analysis is a controlled experiment due to the nature of the data. (Reply at 9; Shaked Dep. 290:7-9.) Each of Shaked's checks for significance imply that the values are not insignificant. (Shaked Report ¶¶ 76, 89, 96, 105, 119, 131, 140.) Furthermore, Shaked ran multiple checks on his analyses to determine whether the conclusions were sound. (Shaked Dep. 291:18-25.) Holding that the lack of complete control over all aspects of a study is sufficient to defeat the reliability of the study would mitigate the use of studies in many cases heard in this Court. *See*, *e.g.*, *In re Johnson & Johnson Talcum Powder Products Mktg.*, 509 F. Supp. 3d 116, 166–67 (3d Cir. 2020) ("The Court cannot deem Plaintiffs' experts' opinions unreliable simply because they determined that the case-control studies were entitled to greater weight than the cohort studies, particularly since the experts' explanations of their methods were supported by scientific reasons.").

Considering that Shaked has proven that the variables are strongly correlated through a reliable methodology, the question becomes whether Shaked has a strong basis for asserting that the kickbacks resulted in physicians writing more prescriptions for Prezista and Intelence. That is a question of weight, not of reliability. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 167 ("Defendants may disagree with the experts' interpretations of those studies and their usefulness, but such issues go to the weight of the experts' testimony, and not their reliability."). Many of Janssen's arguments attack Shaked's assumptions and question his choice of methodology: the proper venue for such arguments is at trial during cross-examinations. *See Daubert*, 509 U.S. at

596. The Court's role at this point is to determine whether the methodology is reliable. *Id.* As it has, the Motion to exclude Shaked's and Dew's report and testimony is denied.

G. Relators' Motion to Exclude the Testimony of Jon Smollen

Relators filed a motion to exclude the expert report and testimony of Jon Smollen ("Smollen Motion," ECF No. 179), along with a brief in support of the Motion, ("Smollen Moving Br.," ECF No. 276). Janssen opposed the Smollen Motion, ("Smollen Opp'n Br.," ECF No. 210), to which Relators replied, ("Smollen Reply," ECF No. 254). Janssen identified Smollen as a rebuttal expert to Relators' compliance expert, Virginia Evans, and as an individual who has "specialized knowledge" and analysis regarding "Janssen's efforts to comply with the AKS." (Smollen Opp'n Br. at 1.) Smollen's report provides the following summary of the opinion he intends to offer at trial:

> Based on my professional experience and expertise, it is my opinion that throughout the Review Period, Janssen proactively identified compliance risks arising from its Speaker Programs, designed and implemented compliance policies and controls to mitigate those risks, and effectively operationalized its policies.

(Ellerbe Decl., Ex. 1, "Smollen Report" at 4, ECF No. 279.) Smollen opined on (1) whether Janssen had effective compliance policies in place to minimize the risk that its Speaker Program violated the AKS ("Effective Compliance Opinion"), and (2) whether Janssen had effective compliance policies in place overall ("Overall Compliance Opinion"). (Smollen Motion at 4.) After considering OIG and PhRMA ("Pharmaceutical Research and Manufacturers of America") Code guidance, the testimony and evidence provided by Janssen, and his own professional judgment, Smollen concluded the following: (1) Janssen had effective compliance policies to prevent violation of the AKS; and (2) Janssen had effective compliance policies in place overall. (*Id.* at 4.)

Relators argue that Smollen's Effective Compliance Opinion is unreliable because his opinions regarding Janssen's effective compliance "is based on a skewed and unreliable consideration of very limited select evidence in the case and simply ignores a wealth of evidence that contradicts his opinions." (Smollen Moving Br. at 7.) Relators also argue that Smollen's Overall Compliance Opinion is irrelevant, unreliable, and likely to confuse the jury because "it is not relevant to any issues in this case[,] fails to even consider the issue of [OL] marketing at all[,] . . . fails to consider the overwhelming evidence regarding Janssen's [OL] marketing scheme[,] and is likely to confuse the jury." (*Id*.) Relators point to examples of "Smollen providing superficial opinions without ever delving into the underlying facts in the record." (*Id*. at 24.)

In opposition, Janssen argues that Smollen's testimony "would help the jury 'understand the evidence' and 'determine a fact in issue' (that is, whether Janssen intended to violate the AKS)." (Smollen Opp'n Br. at 1.) Janssen argues that Smollen's reluctance to adopt Relators' view of the case for his Effective Compliance Opinion is not a basis for reliability. (*Id.* at 3.) He "reviewed Relators' witnesses' testimony, the testimony from other witnesses, and hundreds of documents, including Relators' witnesses' emails, compliance monitoring and investigation logs, compliance trainings, compliance communications, compliance risk assessments, and compliance policies." (*Id.* at 4–5.) Janssen states that "Smollen did not ignore key deposition testimony" and gave "thoughtful consideration" to all the evidence. (*Id.* at 7, 9.) With respect to Smollen's Overall Compliance Opinion, Janssen argues that Smollen's opinion is relevant and that he opined on the same relevant topics as Evans. (*Id*. at 10.) According to Janssen, Smollen "considered how Janssen operationalized compliance across the company and across all risk," which was also considered in Evans' expert report. (*Id.* at 12.)

In its reply, Relators reiterated that Smollen "ignored substantial deposition testimony" from Mark Wilhelm and Sara Strand[7] and, when asked about this testimony, Smollen "admitted that Janssen's practices violated its own written policies, applicable industry standards, and the law." (Smollen Reply at 1–2.) Relators also allege that Smollen made credibility determinations among witnesses, which was inappropriate for experts to do. (*Id.* at 5–8.)

The Court first considers Smollen's qualifications before addressing the reliability of his opinions. Smollen is qualified to opine on compliance issues due to his education and experience. He held leadership and advisory positions in several pharmaceutical companies, assisted in establishing and enhancing U.S. and global compliance programs, and currently teaches compliance and ethics at Temple Law School. (Smollen Report at 10–12.) In reaching his opinions, he thoroughly walks through Janssen's regulatory procedure, applies the PhRMA Code and OIG recommendations, compares Janssen's policies to the industry standard, and applies the same framework—like Relators' expert, Evans—to come to a different conclusion. (*Id.* at 67.) In this instance, Smollen's report is relevant because it discusses a pertinent issue of the case (compliance), rebuts Relators' experts, and provides helpful information to the jury. As the Court previously mentioned, "the line between admissible and inadmissible expert testimony as to the customs and practices of a particular industry often becomes blurred when the testimony concerns a party's compliance with customs and practices that implicate legal duties." *Berckeley*, 455 F.3d at 217. Here, the Court finds that the Overall Compliance Opinion and Effective Compliance Opinion are reliable because Smollen applied his professional judgment and expertise in a reliable manner.

[7] Mark Wilhelm was a Key Account Director for Janssen's Western Division from 2007 and 2009. Sara Strand was a Regional Business Director for the Eastern Division from 2006 to 2011. Relators included them as witnesses with first-hand knowledge of Janssen's practices. (Smollen Reply at 1–2.)

Relators argue that Smollen should have taken note of Wilhelm's and Strand's testimony in his expert opinion. As a reminder, "[a]n expert is . . . permitted to base his opinion on a particular version of disputed facts and the weight to be accorded to that opinion is for the jury." *Walker*, 46 Fed. App'x at 695–96. *See In re Johnson & Johnson*, 509 F. Supp. 3d at 167 ("Defendants may disagree with the experts' interpretations of those studies and their usefulness, but such issues go to the weight of the experts' testimony, and not their reliability."). Although he did not mention Wilhelm, Smollen took note of Strand's testimony.[8] (Smollen Report at 56.) Smollen's failure or unwillingness to respond to testimony from certain witnesses is an issue for cross-examination. Moreover, to the extent Relators assert that Smollen agreed Janssen violated its policies, a quick look at Smollen's deposition reveals that Smollen *only* agreed that certain facts, if proven true, could hypothetically constitute violations of written policies and statutes. (Ellerbe Decl., Ex. 2, "Smollen Dep." 77:10-80:21, 82:15-89:21, 93:3-95:23, 97:8-101:23, ECF No. 279-1.)

Relators raise other arguments that attack assumptions and do not go to the reliability of Smollen's report; as mentioned above, the proper venue for such arguments is trial, not a *Daubert* motion. *Daubert*, 509 U.S. at 596. Accordingly, Relators' motion to exclude Smollen's report and testimony is denied.

H. Relators' Motion to Exclude Certain Opinions of Anupam Jena

Relators filed a motion to limit the opinions of Anupam Jena, ("Jena Motion," ECF No. 181), along with a brief in support of the Motion, ("Jena Moving Br.," ECF No. 277). Janssen opposed the Motion, ("Jena Opp'n Br.," ECF No. 215), to which Relators replied ("Jena Reply," ECF No. 253). Janssen identified Jena to opine on issues of causation and damages, and to respond

[8] Evans focuses on Strand's testimony that she would occasionally send OL Intelence studies to the sales force. However, Evans ignored that Strand testified that she sent OL studies with a directive to her team that the studies were for background only and could not be used on sales calls with HCPs.

to Shaked's opinions and analyses on those same topics. (Chuderewicz Decl., Ex. A, ECF No. 194-3.)

Jena organized his report into three main sections: (1) HIV treatment background; (2) assessing causation with respect to Janssen's alleged improper promotion in the current case; and (3) assessing causation with respect to Janssen's speaker payments in the current case. (Ellerbe Decl., Ex. 25, "Jena Report" ¶¶ 16–63, ECF Nos. 279-6.) Jena organized his rebuttal report in two main sections: (1) a discussion of Shaked and Dew's causation conclusions ("Causation Opinion"), and (2) a discussion of Shaked's damages estimates ("Damages Opinion"). (Ellerbe Decl., Ex. 24 "Jena Rebuttal Report" ¶ 3, ECF. No. 279-5.) In sum, Jena's reports conclude: (1) Shaked's analysis with respect to causation is flawed because he did not use the appropriate data, methods, and accounting for external factors to correctly conclude that Janssen caused false claims to be written through speaker payments and OL marketing; and (2) the correct damages calculation for Relators' claims is approximately $0 once the analyses accounts for the purported issues. (Jena Report ¶¶ 10–15, Jena Rebuttal Report ¶¶ 12, 14, 63, 122–125.)

Relators seek to strike portions of Jena's reports and testimony that "are based on erroneous legal principles or which implicate such principles."[9] (Jena Moving Br. at 4.) Relators contend that certain parts of Jena's report are inadmissible because: (1) he "applies a standard that is contrary to the law"; (2) he "ignored substantial evidence in the record"; and (3) his opinions on damages "have no basis in the law and do not support reducing damages to zero." (*Id.* at 8, 17, 19.) Relators argue that Jena's requirement of a "direct causal link" is "directly contrary" to the law regarding liability and causation under the FCA. (*Id.* at 12.) Thus, Relators argue that Jena's

[9] Relators have asked this Court to exclude the following paragraphs of Jena's Expert Report: ¶¶ 11, 25, 27–29, 33–34, 54, 57–58, 60, 62, and 64. (Jena Moving Br. at 4–5.) Relators have also asked to exclude the following paragraphs of Jena's Expert Rebuttal Report: ¶¶ 3, 5-8, 11 (bullets 3–5), 12–17, 20, 37–40, 43–45, 52–54, 63–65, 84, 86–87, 91, 93–97, 99, 100–15, and 118–25. (*Id.* at 5.)

opinions are unreliable, irrelevant, and confusing to a jury. (*Id.* at 14.) Relators also argue that Jena failed to review evidence and reviewed only five of the eighteen depositions taken in this case. (*Id.* at 17.) Relators contend that these purported issues cause Jena's Damages Opinion to be unsupported and thus inadmissible. (*Id.* at 20.)

In opposition, Janssen argues that "Jena appropriately evaluated the issues of causation and claimed damages from a scientific perspective using his broad experience in the fields of economics, statistics, and medicine." (Jena Opp'n Br. at 1.) According to Janssen, Jena opines on whether Shaked's correlation analyses are sufficient to show a causal relationship between promotion and prescription numbers or payment and prescription numbers, not whether there is a direct causal relationship between each respectively. (*Id.* at 3–4.) As such, Janssen argues that Jena's opinion is consistent with the generally accepted standards in economics and medicine, as well as the relevant legal standards under the FCA and admission of scientific evidence. (*Id.* at 9.) Janssen further argues that Jena's opinions are based on a sufficient factual foundation, consisting of what he considered to be pertinent court documents and publicly available materials. Finally, Janssen argues Jena's removal of and reductions to Shaked's damages estimates are appropriate under FCA law. (*Id.* at 22–27.)

In its reply, Relators emphasize that Jena applies a direct "but for" test rather than the "substantial factor" test. (Jena Reply at 1–2; Ellerbe Decl., Ex. 23, "Jena Dep." 59:4-60:4, ECF No. 279-5.) Relators argue that Jena's opinions are premised on the application of a "but for" causation; to this point, Relators argue that Jena admitted to using "but for" causation analysis in his deposition. (Jena Reply at 2–3; *see* Jena Dep. 59:4-60:4.) Furthermore, Relators take issue with Jena's position that "prescriptions written 6 months after Janssen's unlawful conduct should not be included in the case for purposes of causation or damages[,]" arguing that the FCA and

AKS do not impose strict temporal cutoffs for false claims. (Jena Reply at 9–10.) Relators also argue that Jena should have considered Wilhelm's and Strand's testimony when considering causation and damages. (*Id*. At 11–13.) Finally, Relators argue that certain of Jena's Damages Opinion is contrary to applicable law because legal precedents do not support his damages calculations. (*Id.* at 13–15.)

Jena is appropriately qualified to opine on the matters in his report. Though Jena does not hold any degrees in statistics, he holds a Ph.D. in Economics and has extensive experience studying and analyzing physician behavior in the microeconomic context. (Jena Report at 35, 41–42, 44–60.) Jena uses the same data as Shaked, "corrects" Shaked's data, methodology, and conclusions (an appropriate subject for a rebuttal expert and an important point of view for the jury), and puts forth calculations based on Jena's expertise *and* Janssen's defense. (*Id.* at ¶¶ 60–63; Jena Rebuttal Report ¶¶ 22–45, 66–125.) Thus, Jena reliably applies his expertise to his Causation Opinion and Damages Opinions, raising criticisms and concerns about Shaked's methodologies. (*Id*.) Although Relators may critique Jena's assumptions, the Court finds that Jena's Causation Opinion and Damages Opinions are reliable because they stem from Jena's analytical modeling expertise and arise from the same set of data Shaked utilized. Furthermore, the Court finds that Jena's opinions are relevant because they provide Janssen's views of causation and damages based on Janssen's view of the facts.

Relators' motion and reply focus heavily on Jena's supposed improper application of a legal standard to the facts of the case. (Jena Reply at 5–6.) Relators argue that the application of an improper legal standard causes Jena's opinion to not fit the facts of the case. (*Id.* at 1–3.) If this were true, it would be a cause for concern. The Court does not find support for Relators' argument that Jena is applying the incorrect legal standard to reach his conclusion. In his report,

Jena points to other factors that doctors may consider, which are supported by his own study of doctors' behavior and his own practice of medicine. (Jena Report at 35, 41–42, 44–60.) He discusses his rationale for excluding certain calculations and how his method differs from Shaked's. (*See, e.g.*, Jena Rebuttal Report at ¶¶ 114–24.)

Where Relators point to Jena's testimony as bases for exclusion, the testimony does not support what Relators argue. As one of their primary bases for exclusion, Relators argue that Jena agreed that he applied direct ("but for") causation principles during his deposition. (Jena Dep. 59:19-60:4.) Jena admitted several times that he is testifying as a doctor and economist, not as a lawyer. (Jena Dep. 61:6-12.) As such, his testimony's reliability and relevance should be considered with respect to his expertise in these fields. The Court does not find it surprising that Janssen's expert, opining in support of Janssen's defense with respect to causation, discusses at length the absence of direct evidence in the record as to causation. However, to the extent that Relators believe that Jena applies the incorrect legal test with respect to causation, that issue can be adequately tested by cross-examination. Ultimately, the Court will articulate the proper legal standard for causation to the jury.

Relators criticize Jena's damage reductions as contrary to law. (Jena Reply 13–15.) In part, Relators point to *ZF Meritor* as proof that Jena's report and testimony should be excluded because it apparently shows that an expert cannot form a reliable opinion through a selective review of the evidence. (Jena Moving Br. at 17–18.) *ZF Meritor* supports the notion that existence of conflicting evidence is not a basis on which to exclude an expert's testimony. 696 F.3d 254, 290 (3d Cir. 2012). "The respective credibility of Plaintiffs' and [Defendant]'s experts [is] a question for the jury to decide." *Id.* at 290. The damages expert in *ZF Meritor* was excluded because he could not reliably estimate damages from speculative assumptions and the facts on the

record. *Id.* at 294. Here, the facts are bare insofar; as noted in this Court's recent decision denying Summary Judgment, most of the material facts in this case are in dispute. Additionally, the assumptions arise from each party's view of the case; because no facts have been proven at this point, it is difficult for the Court to determine whether Jena's (or Shaked's) assumptions are indeed speculative.

"[E]xclusion of critical evidence is an 'extreme' sanction . . . ." *Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710 (3d Cir. 1997). Although Relators may disagree, Jena's opinions are informed by Janssen's version of events, which is not a basis to exclude an otherwise reliable and relevant opinion. Accordingly, the Court will deny Janssen's motion to exclude the expert testimony of Anupam B. Jena.

I. Relators' Motion to Limit the Testimony of Eric S. Rosenberg

Relators filed a motion to limit the testimony of Eric S. Rosenberg, ("Rosenberg Motion," ECF No. 183), along with a brief in support of the Motion, ("Rosenberg Moving Br.," ECF No. 278). Janssen opposed the Motion, ("Rosenberg Opp'n Br.," ECF No. 209), to which Relators replied ("Rosenberg Reply," ECF No. 255). Janssen identified Rosenberg as an expert in infectious diseases, HIV therapies, and strategies surrounding the management of HIV-infected individuals. (Ellerbe Decl., ECF No. 187-3 at 3–4; Rosenberg Reply at 1.)

Rosenberg is Janssen's HIV expert and the opposing expert to Relators' HIV expert, Dr. Aaron Glatt. (Ellerbe Decl., Ex 28, "Rosenberg Rebuttal Report" ¶ 3, ECF No. 279-8.) Rosenberg's report provides an overview of a general practitioner's choices when treating a patient with HIV/AIDS, goals of treatment, materials doctors may use to reach their goals of treating patients with HIV/AIDS, and Rosenberg's experience treating patients with HIV/AIDS. (Ellerbe Decl., Ex. 29, "Rosenberg Report" ¶¶ 9–13, ECF No. 279-9.) Rosenberg's rebuttal report provides

additional context on the treatment of HIV/AIDS patients with OL uses of medications, comments on Glatt's report, and provides Rosenberg's personal experience with treating such patients. (Rosenberg Report ¶¶ 34, 42–46; Rosenberg Rebuttal Report ¶¶ 3, 7, 13, 14–16, 19.)

Relators have asked the Court to preclude Rosenberg from testifying beyond clinical or medical background about HIV/AIDs and the types of drugs used in its treatment. (Rosenberg Moving Br. at 5.) Relators assert Rosenberg's report and testimony is inadmissible because: (1) Rosenberg's personal approach to prescribing drugs and utilizing multiple sources of information is irrelevant, and unreliable with no fit to the issues of the case; and (2) testimony about appropriate OL use of drugs is irrelevant to drug marketing practices at issue in the case and is likely to mislead the jury. (*Id*. at 13–14.) Relators do not challenge the use of Rosenberg's testimony for "providing medical background and explanations about HIV/AIDS and the drugs used to treat it," but they do request that this Court limit Rosenberg's testimony when he goes beyond this function. (Rosenberg Reply at 4.)

In opposition, Janssen argues that Rosenberg's testimony is reliable due to his experience and his testimony is relevant because it is a key component of Janssen's causation defense. (Rosenberg Opp'n Br. at 1.) Janssen contends Rosenberg's testimony is reliable because it comes from his experience as a physician specializing in HIV/AIDS. (*Id.* at 4.) Furthermore, Janssen claims that Rosenberg does not opine on inadmissible topics, such as testimony "concerning what all doctors generally consider." (*Id.* at 5.) Finally, Janssen claims that Rosenberg's testimony is relevant because it would help the jury understand Janssen's causation defense. (*Id.* at 7–8.)

Relators argue there are three "fatal problems" with Janssen's argument. (Rosenberg Reply at 6.) First, Janssen attempts to use Rosenberg to opine as to the effects of OL marketing even though Rosenberg himself readily admits he does "not feel qualified to offer an expert opinion

regarding the effects of promotional marketing." (*Id.* at 5.) Second, Janssen improperly attempts to misconstrue Rosenberg's testimony as applicable to other doctors. (*Id.* at 7.) Relators contend Rosenberg did not offer his opinion to speculate on how other HIV experts treat HIV patients; instead, Rosenberg's report explains what sources of information he relies on when deciding which medication to prescribe. (*Id.*) Third, the court should reject the general concept that doctors glean knowledge from various sources because it is well within an average layperson's understanding. (*Id.* at 7–8.) For these points, Relators ask the Court to exclude all aspects of Rosenberg's opinions beyond the clinical or medical background he provides about HIV/AIDS and the types of drugs used to treat it.[10] (*Id.* at 15.)

The Court has reviewed Rosenberg's qualifications. He has a plethora of experience diagnosing and treating patients with HIV/AIDS and has many journal articles on treating HIV/AIDS. (Rosenberg Report at 24–26, 30–40.) The Court finds that Rosenberg is qualified to opine on treating and prescribing HIV/AIDS patients. As such, the Court finds that Rosenberg's professional opinions on HIV/AIDS are very reliable. Rosenberg's personal opinions about prescribing drugs, using multiple sources of information, and the appropriate OL use of drugs are relevant to Janssen's causation defense. Accordingly, the Court finds that Rosenberg's opinions also fit the facts of the case.

The Court agrees with Relators that any attempt to move beyond the purviews of explaining how Rosenberg reaches his prescription decision would be inadmissible. However, Rosenberg has not. He clearly delineates what his testimony and report opine on (his methods for prescribing

[10] Relators have asked this Court to exclude "Dr. Rosenberg's testimony to the extent that it ventures beyond explanations of the disease state and the drugs themselves." (Rosenberg Reply at 4.) Among other examples, Relators point to several examples that Rosenberg may move beyond his medical and professional expertise to opine on inadmissible points. (Rosenberg Report, ¶¶ 34, 42-46; Rosenberg Rebuttal Report, ¶¶ 7, 16; Ellerbe Decl., Ex. 27, "Rosenberg Dep." 12:22-25, 22:5-7, 25:19-25, 29:8-20, 41:18-42:14, 90:23-92:8, 93:2-14, 134:24-135:5, ECF No. 279-7.)

HIV/AIDS medications to patients) and what it does not (marketing, what the average doctor should do). (Rosenberg Report ¶¶ 34, 42–46; Rosenberg Rebuttal Report ¶¶ 3, 7, 13, 14–16, 19.) As the Court found above, Rosenberg is qualified to opine on the subject through his credentials and experience, has good grounds to discuss such topics due to his extensive experience as an HIV/AIDS specialist, and it fits a point that Janssen is raising as a defense (that a doctor considers a variety of factors in prescribing medicine). The Court finds that these concerns can be raised at trial if they are salient. *See Daubert*, 509 U.S. at 596. Therefore, the Court will deny Relators' Motion to limit certain opinions of Eric S. Rosenberg.

IV. CONCLUSION

For the foregoing, the Court rules as follows:

1. Janssen's Motion to Exclude the Testimony of O'Reilly is GRANTED in part and DENIED in part. Specifically, O'Reilly's testimony is limited to background information regarding the drug approval process, misbranding in general, the mechanism by which the government reimburses for prescriptions, and his observations regarding Janssen's compliance efforts. As discussed, O'Reilly is not permitted to provide legal conclusions.
2. Janssen's Motion to Exclude the Testimony of Sillup is DENIED.
3. Janssen's Motion to Exclude Certain Opinions of Schafermeyer is DENIED.
4. Janssen's Motion to Exclude Certain Opinions of Glatt is GRANTED. Glatt will not be permitted to opine on how Janssen's OL promotion and marketing impacted physicians' prescribing decisions.
5. Janssen's Motion to Exclude the Testimony of Evans is GRANTED in part and DENIED in part. Evans will not be permitted to testify that Janssen used its Speaker Programs to induce doctors to prescribe Prezista and Intelence.

6. Janssen's Motion to Exclude the Testimony of Shaked and Dew is DENIED.

7. Relators' Motion to Exclude the Testimony of Smollen is DENIED.

8. Relators' Motion to Exclude Certain Opinions of Jena is DENIED.

9. Relators' Motion to Exclude Certain Opinions of Rosenberg is DENIED.

An appropriate order follows.

Dated: January 10, 2022

s/ Zahid N. Quraishi
ZAHID N. QURAISHI
UNITED STATES DISTRICT JUDGE