UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MARY K. JONES, Individually and on Behalf of All Others Similarly Situated, Plaintiff vs. PFIZER INC., et al., Defendants.	Civil Action No. 1:10-cv-03864-AKH CLASS ACTION PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE CERTAIN TESTIMONY OF DEFENDANTS' EXPERTS SUNIL PANCHAL, WILLIAM W. HOLDER, JACK T. TANSELLE AND JOHN C. COATES IV

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Pursuant to Federal Rules of Evidence 402, 403 and 702, plaintiffs Stichting Philips Pensioenfonds and Mary K. Jones, respectfully submit this memorandum of law in support of their motion to exclude certain testimony of defendants' experts Dr. Sunil Panchal ("Dr. Panchal"), William W. Holder ("Holder"), Jack T. Tanselle ("Tanselle") and John C. Coates ("Coates").

I. INTRODUCTION

Four of defendants' expert witnesses do not meet the rigorous standards set forth by Fed. R. Evid. 702 and the Second Circuit. Defendants' experts Dr. Panchal, Holder, Tanselle and Coates either do not have the required expertise in the subject they are proffered to offer testimony on or they rely on a faulty basis for their opinions. Dr. Panchal has proven to lack the experience or expertise in off-label promotion needed to offer testimony concerning the relationship between off-label detailing and off-label prescribing. Moreover, along with being a testifying expert, Dr. Panchal is a percipient witness as he was a highly paid speaker on the benefits of Bextra for Pfizer Inc. ("Pfizer" or the "Company") during the period January 19, 2006 to January 23, 2009 (the "Class Period"). Thus, any testimony from him as a fact witness would also be improper.

Both Holder and Tanselle rely on a faulty basis to support at least portions of their opinions. Holder relies on a letter provided by Pfizer's outside Government Investigation[1] counsel to KPMG LLP ("KPMG") to support an opinion that the Statement of Financial Accounting Standards No. 5 ("FAS 5") probable loss prong was not satisfied during the Class Period. Holder's misinterpretation of the letter is readily apparent, and his opinion relying on the letter should be precluded. Tanselle relies on vague discussions at industry conferences to support his opinion that Pfizer's compliance program during the Class Period was the best in the industry. When his opinions were tested at his

[1] "Government Investigation" means the government's investigation into alleged misbranding ("off-label promotion") of Bextra, Geodon, Lyrica and Zyvox.

deposition, however, it was not clear that Tanselle had any first-hand knowledge of any of Pfizer's competitor's compliance programs during that period. Moreover, he did not rely on any published articles, industry surveys or other facts to support his conclusory opinions ranking Pfizer's compliance program during the Class Period.

As even he admits, Coates' testimony at trial must be limited to Pfizer's process for drafting its legal proceeding disclosures. Coates has confirmed that he is offering no opinions on the adequacy of Pfizer's Government Investigation disclosures, the adequacy of Pfizer's Government Investigation FAS 5 reserves or Pfizer's process in determining its FAS 5 reserves. Thus, his testimony should also be limited.

II. ARGUMENT

A. Legal Standard

Defendants' experts do not meet the requirements of Rule 702 to proffer expert testimony on their respective subjects. Rule 702 provides that:

> 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;
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> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. The evidentiary rule imposes on the trial court the obligation to ensure that a witness proffered as an expert is qualified and that his expert testimony is "not only relevant, but reliable." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 588-89 (1993).

Here, defendants cannot demonstrate by a preponderance of the evidence, as they are required to do, that their experts' opinions satisfy Rule 702. *See Atl. Specialty Ins. v. AE Outfitters*

Retail Co., 970 F. Supp. 2d 278, 288 (S.D.N.Y. 2013). They also cannot demonstrate that their opinions on these subjects are relevant to the issues in the case under Rule 402.

B. Dr. Panchal's Unqualified and Conclusory Opinions Should Be Precluded

One of the issues in this case is the off-label marketing of Pfizer's drugs – Bextra, Lyrica, Geodon and Zyvox – and the illicit profits stemming from Pfizer's illegal promotional efforts directed at those drugs. In part, Dr. Panchal rebuts Dr. Jerry Avorn's opinion that Pfizer's wide-spread off-label promotional activities were designed to successfully increase the sales of Pfizer's drugs and Professor Meredith Rosenthal's opinion on the impact of Pfizer's alleged unlawful promotional practices on Pfizer's revenues and profits.

Dr. Panchal, however, is not qualified to offer testimony regarding physician prescribing behavior in response to off-label promotional activities because he has no experience with off-label detailing and physician prescribing behavior as a result of being detailed off-label. He is also not qualified to opine on the safety and efficacy of Pfizer's drugs for off-label uses, because his opinions are strictly based on anecdotal evidence. *See, e.g.*, Declaration of Ryan A. Llorens in Support of Plaintiffs' Motion to Exclude Certain Testimony of Defendants' Experts Sunil Panchal, William W. Holder, Jack T. Tanselle and John C. Coates ("Llorens Decl."), Ex. 1 at 125:6-23, filed concurrently herewith. In addition to not being qualified to render expert testimony on these topics, Dr. Panchal's critique of Dr. Avorn in his report is limited to the following: "I have been asked to review and respond to the report[] submitted by Dr. Jerry Avorn . . . ." Llorens Decl., Ex. 2 at 2. This unspecified critique is precisely the type of "*ipse dixit*" that courts preclude. *Nimely v. City of New York*, 414 F.3d 381, 396 (2d Cir. 2005).

Moreover, the opinions proffered by Dr. Panchal are irrelevant to the issues in the case and thus inadmissible pursuant to Rule 402. Dr. Panchal's testimony regarding physician prescribing

behavior does not address what is at issue – off-label promotion. Similarly, the safety and efficacy of Pfizer's drugs are not at issue in this case, except as found by the U.S. Food and Drug Administration ("FDA"). Accordingly, Dr. Panchal's testimony on these topics will not be helpful to a jury and should be excluded. *Daubert*, 509 U.S. at 591.

1. Dr. Panchal Is Not Qualified to Offer an Opinion on Physician Prescribing Behavior

An expert cannot offer an opinion if they are not qualified "by knowledge, skill, experience, training, or education." Fed. R. Evid. 702; *see also Stagl v. Delta Air Lines*, 117 F.3d 76, 81 (2d Cir. 1997) (A court must ensure that an expert will be proffering opinions on issues or subject matters that are within his or her area of expertise.). Indeed, if an expert lacks the proper qualifications, analyzing the remaining *Daubert* factors "seems almost superfluous." *Zaremba v. Gen. Motors Corp*., 360 F.3d 355, 360 (2d Cir. 2004).

Dr. Panchal's own testimony illustrates he is wholly unqualified to offer an expert opinion regarding physician prescribing behavior. *Dreyer v. Ryder Auto Carrier Grp., Inc*., 367 F. Supp. 2d 413, 425-32 (W.D.N.Y. 2005) (finding with the benefit of the expert's deposition testimony that the expert lacked "any relevant or sufficient experience, training, skill or specialized technical knowledge" to the issues in the case). Dr. Panchal testified that he does not know how physicians react to off-label detailing. Llorens Decl., Ex. 1 at 160:19-161:7, 166:8-11 ("I wouldn't know how a particular individual responded to that."). Further, he has never analyzed the impact that pharmaceutical company marketing has on physician prescribing behavior.[2] Nor has he ever participated in any studies related to the impact medical journal advertising or sampling have on

[2] Dr. Panchal testified: "I have not researched in terms of behavior in marketing." Llorens Decl., Ex. 1 at 14:9-10; *see also id*. at 12:9-16 ("I have not acted as an investigator for such a study."); *id.* at 13:2-3 ("I don't recall ever working on that type of a study.").

physician prescribing behavior. *Id*. at 13:4-16. Nor did he consult with anyone with expertise in these areas in preparing his report. *Id*. at 20:13-20. Likewise, his opinions regarding the safety and efficacy of Pfizer's drugs for off-label uses are solely based on his limited personal experience. *Id.* at 123:23-126:23; Llorens Decl., Ex. 2 at 5, 7.

Dr. Panchal's "experience," which purports to serve as the foundation for his opinions, is simply his background as an anesthesiologist prescribing drugs, not a pharmacoepidemiologist who studies patterns of medication utilization by doctors and by patients, or an economist. *See id.* at 1; Llorens Decl., Ex. 3 at 17:11-21. Because Dr. Panchal cannot satisfy the requirements of Rule 702 to offer expert opinion on physician prescribing behavior, his testimony on that topic should be precluded at trial. *Highland Capital Mgmt., L.P. v. Schneider*, 379 F. Supp. 2d 461, 469 (S.D.N.Y. 2005) ("'an expert basing his opinion solely on experience "must do more than aver conclusory that his experience led to his opinion," and . . . must do more than "propound a particular interpretation of [particular] conduct."'").[3]

2. Dr. Panchal's Opinions Lack the Requisite Specificity and Are Unreliable and Irrelevant

Plaintiffs' expert Dr. Avorn opines that Pfizer's marketing strategy was to promote the use of its drugs for unapproved indications and that such strategy was successfully implemented. *See generally* Llorens Decl., Ex. 4. Dr. Panchal's opinion criticizing Dr. Avorn lacks any specificity. *Pretter v. Metro N. Commuter R.R.*, 206 F. Supp. 2d 601, 603 (S.D.N.Y. 2002) (excluding expert opinion that was "so vague as to be meaningless"). The single sentence in Dr. Panchal's nine-page report indicating that he was "asked to review and respond" to Dr. Avorn's report renders it impossible to test his expert opinion. *See* Llorens Decl., Ex. 2 at 2; Llorens Decl., Ex. 1 at 17:9-

[3] Citations are omitted and emphasis is added, unless otherwise noted.

18:2. Dr. Panchal was afforded the time to draft a specific response to Dr. Avorn's report and he failed to do so. The conclusory opinions he now attempts to offer are inadmissible. *Bridgeway Corp. v. Citibank*, 201 F.3d 134, 142 (2d Cir. 2000).

As providing some detail, Dr. Panchal cannot point to peer reviewed literature to buttress his opinion that "promotional activities, detailing, represents an insignificant factor in the decision-making for therapy choice by physicians." Llorens Decl., Ex. 1 at 225:24-226:12. Nor can he point to any evidence that this opinion is the product of any widespread acceptable technique. By his own admission, Dr. Panchal's opinion is not premised on any peer-reviewed journal articles, adequate investigation, "formal analysis or research study" or any other recognized methodology, but rather on his "experience being on faculty at several major university institutions" and "listening to discussion from other colleagues there." *Id.* at 164:17-165:5, 230:20.[4] Indeed, none of this experience is related to off-label detailing. Llorens Decl., Ex. 1 at 69:16-70:14, 105:12-15. His lack of any relevant experience or application of a reliable methodology is exacerbated by his failure to even review the evidence of off-label promotion in this case. *See, e.g.*, *id.* at 76:13-77:6 (not aware of Pfizer's guilty plea for the off-label promotion of Bextra).

"[G]aping omissions of real world events that [are] highly material" renders Dr. Panchal's expert testimony "irretrievably unreliable and indefensible." *Point Prods. A.G. v. Sony Music Entm't, Inc.*, No. 93 Civ. 4001 (NRB), 2004 U.S. Dist. LEXIS 2676, at *24-*25 (S.D.N.Y. Feb. 23, 2004). Dr. Panchal's conclusory and unfounded opinions on physician prescribing behavior should be precluded. *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) (stating that failure "to explain information that otherwise would tend to cast doubt on that theory is

[4] Note that, in contrast, plaintiff's expert Dr. Avorn's "study of how physicians make prescribing choices has been a core component of [his] research activities for 35 years." Llorens Decl., Ex. 4, ¶8.

inherently suspect"); Fed. R. Evid. 702 advisory committee's note (stating that courts also consider "[w]hether the expert has adequately accounted for obvious alternative explanations" "in determining whether expert testimony is sufficiently reliable to be considered by the trier of fact")

Because Dr. Panchal does not take into account off-label promotion, his opinions on physician prescribing behavior are also irrelevant (*i.e.*, will be unhelpful to a jury). *United States v. Williams*, 506 F.3d 151, 160 (2d Cir. 2007) (trial court should ensure "'that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand'"). He holds himself out as an expert because of his experience as a physician, yet testified: "I have not seen any off-label detailing. In my interaction with colleagues, I have not heard of instances where they were being detailed off-label." Llorens Decl., Ex. 1 at 105:12-15; *see also id.* at 69:16-70:14. Because, by his own admission, neither he nor any of his colleagues have any experience with off-label promotion, Dr. Panchal cannot offer relevant testimony on physician prescribing behavior as it relates to off-label promotion, which is the crux of this case.[5]

Likewise, Dr. Panchal's proffered testimony as to the safety and efficacy of Lyrica and Bextra is irrelevant to the issues in this case. Whether Pfizer promoted its drugs off-label is necessarily defined by the labels that the FDA approved for these drugs and is not an area which Dr. Panchal has any expertise.[6] Dr. Panchal's "expert" testimony regarding his experience with the off-label use of Pfizer's drugs (*i.e.*, they are safe and effective) will not help a jury determine whether

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[5] In contrast, Dr. Avorn's opinion is based on a review of Pfizer's off-label marketing strategies and his extensive studies of prescribing behavior of physicians. Llorens Decl., Ex. 3 at 303:16-21 ("[P]art of [my research] has been the influence of a variety of sources on shaping doctors' prescribing, including pharmaceutical promotion.").

[6] Defendants' other expert, David Feigal, opines "[t]he . . . prescription drug label is to provide physicians with a clear and concise statement of the data and information necessary for the safe and effective use of the drug." Llorens Decl., Ex. 5, ¶26.

Pfizer promoted its drugs off-label but will serve to confuse a jury regarding what is at issue in the case. *United States v. DiDomenico*, 985 F.2d 1159 (2d Cir. 1993) (psychiatrist's testimony beyond medical concepts to legal constructs would confuse a jury).

C. Dr. Panchal's Testimony as a Fact Witness Is Also Impermissible

Dr. Panchal's testimony as a fact witness must be excluded because defendants never disclosed Dr. Panchal on their initial disclosures or as a trial witness as ordered by the Court.[7] *See* Fed. R. Civ. P. 37(c)(1) (failure to "identify a witness as required by Rule 26(a)" precludes a party from using that witness at trial). Dr. Panchal's "'sweeping conclusions' and interpretations" about Pfizer's drugs and promotional activities based on his first-hand knowledge are precisely the type of prejudicial and inadmissible testimony that the Second Circuit has warned of when a party seeks to introduce a fact witness as an expert. *United States v. Dukagjini*, 326 F.3d 45, 50-54 (2d Cir. 2002). As such, Dr. Panchal's personal observations that Pfizer sales representatives do not detail off-label and that Bextra and Lyrica are safe and effective for off-label uses should also be precluded. Llorens Decl., Ex. 1 at 69:16-70:14; Llorens Decl., Ex. 2 at 5-8.

Dr. Panchal was a member of Pfizer's Advisory Board for Bextra and authored a study regarding the off-label use of Bextra. Llorens Decl., Ex. 1 at 33:25-34:3, 93:7-16, 173:10-174:1; Llorens Decl., Ex. 2, Ex. A at 20. Although he did not include it in his report, Dr. Panchal testified that he will "be able to answer questions regarding my interactions with Pfizer personnel and anything that I had discussions with other physicians" with respect to whether Pfizer marketed Bextra on or off-label. Llorens Decl., Ex. 1 at 122:7-16. Any such testimony should be barred because Dr. Panchal was not listed on Pfizer's initial disclosures or as a witness defendants intend to

[7] *See* Llorens Decl., Exs. 6-7; *see also* Dkt. No. 157. Defendants identified no third-party treating physicians in any of their disclosures.

call at trial.[8] Fed. R. Civ. P. 37(c)(1); *Lujan v. Cabana Mgmt.*, 284 F.R.D. 50, 75-76 (E.D.N.Y. 2012) (striking declarations of witnesses that were not disclosed pursuant to Rule 26); *Carolina Cas. Ins. Co. v. R.L. Brown & Assocs.*, No. 1:04-cv-3537-GET, 2007 U.S. Dist. LEXIS 5115, at *10-*11 (N.D. Ga. Jan. 19, 2007) (exclusion of fact witnesses not timely disclosed pursuant to Rule 26). Further, such lay witness testimony given by a proffered expert would prejudice plaintiffs. Fed. R. Evid. 403. The prejudice here is particularly harmful to plaintiffs because they were not on notice that they should depose other physicians and patients with experience with these drugs.

Dr. Panchal's fact-based testimony is prejudicial because of his dual role as expert and lay witness that confers upon him "'the aura of special reliability and trustworthiness surrounding expert testimony.'" *Dukagjini*, 326 F.3d at 53; *United States v. Garcia*, 413 F.3d 201, 215 (2d Cir. 2005) ("conflating expert and lay opinion testimony [ ] confer[s] an aura of expertise on a witness"). This prejudice extends to his irrelevant testimony that Bextra and Lyrica were safe and effective. Llorens Decl., Ex. 2 at 6-7. Such testimony is fact-based, not expert-based stemming from studies of the safety and efficacy of these drugs or any other reliable methodology. Moreover, the testimony is particularly suspect and confusing to a jury because Dr. Panchal indicates that these drugs were safe and effective for conditions not approved by the FDA. *Id.* As the Supreme Court explained in *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999), a district court's function is "to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Given that the FDA is the gatekeeper for approving a drug as safe and effective for specific indications, patient populations and doses, Dr. Panchal's limited personal experience cannot qualify him as an expert on the safety and efficacy of Bextra and Lyrica. This is

[8] *See* Llorens Decl., Exs. 6-7; *see also* Dkt. No. 157.

particularly true in the case of Bextra, where Pfizer concedes that the drug was withdrawn from the market for safety concerns. Accordingly, Dr. Panchal should be precluded from presenting any fact testimony related to his personal experience with Pfizer's drugs.[9]

D. Certain Testimony of Defendants' Expert Holder Should Be Precluded

One of the factual issues at trial will be defendants' alleged misleading statements and omissions concerning Pfizer's Class Period financial results. Plaintiffs will prove at trial that Pfizer failed to adequately disclose and accrue for, pursuant to FAS 5, the U.S. Department of Justice's ("DOJ") investigation into the Company's alleged illegal and rampant off-label promotion of Bextra and other drugs.

Holder was retained by defendants to opine concerning, *inter alia*, the reasonableness of Pfizer's accounting and disclosure judgments. *See* Llorens Decl., Ex. 8 at 4-6. Although plaintiffs disagree with Holder's analysis and opinions generally, this motion seeks to exclude only one of his opinions under *Daubert*. Specifically, Holder opines that "Legal Letters" issued by Pfizer's criminal defense counsel and submitted to KPMG in 2006, 2007 and 2008 contradict the opinions of plaintiffs' accounting expert, D. Paul Regan. *Id*. at 39.

In support of this opinion, Holder speculates that the Legal Letters indicate Pfizer's criminal counsel "concluded that a litigation loss contingenc[y] related to the Government Investigation was not 'probable.'" *Id*., ¶97. However, that opinion ignores that each of the Legal Letters actually state Pfizer's criminal counsel was "not expressing an opinion on the outcome" of the Government Litigation. Llorens Decl., Ex. 9 at KPMG-PFIZ-DS 017648A, 000597A, 0004289. Holder did not

[9] Dr. Panchal does not mention the other two drugs at issue in this case, Geodon and Zyvox, and by his own admission, did nothing related to these drugs. Llorens Decl., Ex. 1 at 171:9-11. Thus, he should also be precluded from offering any opinion as to these drugs.

ask Pfizer's criminal counsel what "we are not expressing an opinion" meant; neither Pfizer nor its criminal counsel produced any documents relevant to what "we are not expressing an opinion" meant; and Pfizer's criminal counsel, Ethan Posner ("Posner"), was not deposed in this case. Then, when pressed concerning his interpretation of the Legal Letters, Holder changed his opinion and clarified that the Legal Letters meant an unfavorable outcome in the Government Investigation was "reasonably possible." Not only is Holder's opinion based on pure speculation, but defendants are attempting to use Holder as a conduit for an opinion he is not qualified to give. Indeed, Holder's opinion concerning the Legal Letters is precisely the type that Rules 702 and 403 are designed to preclude at trial.

As the Second Circuit has made clear, when an opinion is "based on data . . . simply inadequate to support the conclusion[] reached, *Daubert* and Rule 702 mandate exclusion of that unreliable opinion testimony." *Amorgianos v. AMTRAK*, 303 F.3d 256, 266 (2d Cir. 2002). As such, the question before the Court is simple. Does Holder rely on sufficient facts to conclude that Pfizer's Legal Letters stated that the likelihood of an unfavorable outcome in the Government Investigation was either "not probable" or "reasonably possible"? As demonstrated below, the answer to that question is no.

Each of the Legal Letters explicitly states that Posner was "not expressing an opinion on the outcome" of the Government Investigation. *See* Llorens Decl., Ex. 9 at KPMG-PFIZ-DS 017648A, 000597A, 0004289. In light of that fact, Holder was provided ample opportunity during deposition to identify any additional factual support for his attenuated interpretation of the phrase "we are not expressing an opinion." He could not identify a single fact and defendants did not take the opportunity to redirect him. In the effort to salvage an opinion disconnected from the record, Holder then testified that the Legal Letters really reflect Posner's conclusion that the likelihood of an

unfavorable outcome was "reasonably possible." Llorens Decl., Ex. 10 at 214:5-215:4. Not only is that opinion absent from Holder's report, but the language "reasonably possible" appears nowhere in the Legal Letters.

Before Holder signed his report, he declined to inquire of Posner concerning the meaning of the clause "we are not expressing an opinion." *Id.* at 221:24-222:4. Defendants have withheld communications between themselves and Posner regarding the status of the Government Investigation and Posner was not deposed in this case. As such, it is impossible to cross-examine any witness concerning what Posner was thinking when he stated "we are not expressing an opinion." Further, an opinion concerning what was in a person's mind is generally not admissible, particularly when defined by an accounting expert. *See SEC v. Badian*, 822 F. Supp. 2d 352, 357-58 (S.D.N.Y. 2011).

Holder's speculation concerning the meaning of the Legal Letters also defies common sense. In October 2007, Pfizer's outside disclosure counsel and the Company's in-house accountants again acknowledged that the loss associated with the Government Investigation was probable under FAS 5. *See, e.g.*, Llorens Decl., Ex. 11 (October 17, 2007 Paul Brockie e-mail). As such, Posner's January 2008 Legal Letter cannot be interpreted rationally to mean that the same loss contingency was not probable. Here, Holder has misinterpreted the factual record or engaged in speculation to create a record where none exists. *See Boucher v. U.S. Suzuki Motor Corp.*, 73 F.3d 18, 21 (2d Cir. 1996) (holding expert testimony based on a speculative assumption must be rejected under Rule 702). It, therefore, should be excluded.

Holder is an accountant, not a lawyer. Yet, defendants seek to use Holder as a conduit to bring in Posner's legal assessments and opinions concerning the Government Investigation into Pfizer's unlawful off-label promotion of pharmaceutical products. This form of "expert" testimony

runs afoul of Rule 702 and should be precluded. *See, e.g.*, *Louis Vuitton Malletier v. Dooney & Bourke, Inc.*, 525 F. Supp. 2d 558, 573 (S.D.N.Y. 2007) (observing "conduit testimony from an expert on a matter outside his field of expertise" is inadmissible); *see also* Dkt. No. 288 at 38-39.

E. Defendants' Expert Tanselle's Opinions Comparing Pfizer's Compliance Program with Others in the Industry Are Unreliable and Should Be Precluded

Defendants have proffered Tanselle to opine on the effectiveness of Pfizer's healthcare compliance program. In general, Tanselle will testify that "[t]hroughout the Class Period, Pfizer's healthcare compliance program was comprehensive, effective and robust." Llorens Decl., Ex. 12, ¶7(a). Throughout Tanselle's report, he compares Pfizer to other pharmaceutical companies to support his faulty opinions of Pfizer's healthcare compliance program. When examined at his deposition, however, it became clear that his opinions regarding Pfizer's healthcare compliance program were unfounded and lacked a sufficient factual basis for admissibility. As the Second Circuit has held, an expert's testimony is "inadmissible under Federal Rule of Evidence 702" if it is not "'accompanied by a sufficient factual foundation.'" *Boucher*, 73 F.3d at 22.

Tanselle did not rely on academic research regarding the relative strengths and weaknesses of pharmaceutical companies' compliance programs, surveys of industry compliance programs or any other reliable data. Instead, his opinions are largely based on comments of unidentified representatives of other pharmaceutical companies made during industry conferences. Llorens Decl., Ex. 13 at 60:24-61:4. When further questioned about his familiarity with other company's healthcare compliance programs – which is critical to his ability to compare them to Pfizer's – it became apparent that Tanselle was merely relying on industry scuttlebutt.

Moreover, Tanselle's opinions are belied by Pfizer's internal documents – a fact that he conveniently ignores.[10] Given that Tanselle based his opinions on unreliable sources, his testimony is not useful to a jury and should be excluded under Rules 702 and 403. *See Munn v. Hotchkiss Sch.*, No. 3:09-cv-919 (SRU), 2014 U.S. Dist. LEXIS 76594, at *123 (D. Conn. June 5, 2014) (the court excluded an expert who, instead of using survey results as he claimed, "drew on isolated conversations with one to four other [competitors], represented his individual practice as an industry-wide standard without validation or evidence to substantiate his representations, gave *ipse dixit* testimony regarding matters for which he had not information or basis").

Logic dictates that Tanselle cannot express an opinion as to whether Pfizer was the industry leader in a particular area without knowing anything about the other pharmaceutical companies' practices in the same area. However that is precisely what Tanselle attempts to do, providing only vague and conclusory reasoning for his opinion: "I was present at discussions where Pfizer's compliance program was talked about and speaker programs were talked about, and what Pfizer was doing was as fast or earlier than others. But I cannot tell you if other companies, specifically as you're asking me the questions, were or were not instituting caps at that point in time." Llorens Decl., Ex. 13 at 92:2-9. An expert's opinion must be based on fact and not what was "talked about" at industry conferences. *See Boucher*, 73 F.3d at 22 (plaintiff's expert's testimony was inadmissible because it was based on an "unrealistic and speculative assumption" and "was not 'accompanied by a sufficient factual foundation'").

[10] *See, e.g.*, Llorens Decl., Ex. 14 (Pfizer's head of Internal Audit drafted a memo to the Audit Committee that states, "[w]e concluded that the lack of monitoring controls contributed to an ineffective regulatory compliance function within USPO."), *compared* to Llorens Decl., Ex. 12, ¶73 (Tanselle opined that "[b]efore and throughout the Class Period, Pfizer had an effective compliance auditing and monitoring function.").

Tanselle tries to buttress his opinion by claiming to have done consulting work for a number of pharmaceutical companies, including work related to their healthcare compliance programs. His deposition testimony, however, illustrates that he did not have enough familiarity with Pfizer's competitors' healthcare compliance programs during the Class Period to support his comparison opinions. For example, when discussing his opinion that Pfizer's compliance program during the Class Period was one of the most robust and sophisticated in the industry, Tanselle provided the following answers:

> Q. Who was head of compliance at GSK between 2006 and 2009?
> A. I don't recall.
>
> * * *
>
> Q. Who at AstraZeneca did you discuss AstraZeneca's compliance program with during the class period?
> A. I don't recall.
>
> * * *
>
> Q. Were you familiar with Johnson & Johnson's compliance program during the class period?
> A. Not as much as I would have been some others.
>
> * * *
>
> Q. Were you familiar with Allergan's compliance program during the class period?
> A. I don't recall.
> Q. Were you familiar with Elan's compliance program during the class period?
> A. I don't recall.

Llorens Decl., Ex. 13 at 63:17-64:15, 67:25-68:18.

Similarly when discussing Pfizer's speaker program to support his opinion that Pfizer had a robust and sophisticated healthcare compliance program, Tanselle claimed that "Pfizer was one of the first in the industry" to impose a cap on the amount of an honorarium that could be paid to a speaker. Llorens Decl., Ex. 12, ¶51. Again, Tanselle had no basis for this opinion. First, Tanselle's assumption that Pfizer's speaker program cap was instituted in 2005 was factually inaccurate. A number of Pfizer documents show that the Pfizer's speaker cap was not effective until 2006. *See*

Llorens Decl., Exs. 15-16.[11] Second, Tanselle had no factual evidence to support his assertion that Pfizer was one of the first companies to institute a speaker cap. When asked about his knowledge of other pharmaceutical companies' speaker caps, Tanselle had the following responses:

Q. In 2005 did Eli Lilly have a speaker cap?
A. I don't recall.

* * *

Q. When did Abbott institute its speaker caps?
A. I don't know.

* * *

Q. Do you know if Allergan had a speaker cap in 2005?
A. I don't recall.

* * *

Q. Do you know if GSK had a speaker cap in 2006?
A. I don't recall.
Q. Do you know if Schering-Plough had a speaker cap in 2005?
A. I don't.

Llorens Decl., Ex. 13 at 86:23-25, 89:10-12, 90:18-20, 91:14-19.

Tanselle's opinion that Pfizer's Class Period risk assessment process was industry-leading is likewise unfounded. Llorens Decl., Ex. 12, ¶¶52-53. Tanselle did not cite to a single academic research, article, industry survey or other reliable data to support his opinion, and he was not familiar with any of Pfizer's competitor's risk assessment programs. When asked about Pfizer's competitors' risk assessment process, Tanselle provided the following testimony:

Q. Are you familiar with Abbott's risk assessment process from 2006 through 2007?
A. I don't recall.
Q. Are you familiar with Merck's risk assessment process from 2006 through 2009?
A. I don't recall. . . .

[11] At his deposition, Tanselle admitted that "it certainly looks like these two memos are stating something different than what I had found elsewhere, and so it could – I'd be happy to amend it. It says, for example, in 2006 Pfizer instituted an annual speaker cap and discounted paid memberships." Llorens Decl., Ex. 13 at 97:14-19.

Q. Are you familiar with Johnson & Johnson's risk assessment process from 2006 through 2009?
A. I don't recall.
Q. Are you familiar with Lilly's risk assessment process from 2006 through 2009?
A. I don't recall.

* * *

Q. Do you have any knowledge of Norvatis's risk assessment process from 2006 through 2009?
A. I'm not at liberty to say.

Llorens Decl., Ex. 13 at 115:17-117:18.

Tanselle failed again when asked to provide a basis for his opinion that Pfizer recognized the benefit of centralizing key monitoring groups earlier than most of its peer group:

Q. Are you familiar with the monitoring functions at Abbott between 2006 and 2009?
A. I don't recall.
Q. Are you familiar with the monitoring function at GSK between 2006 and 2009?
A. I'm not at liberty to talk anymore about GSK.
Q. Are you familiar with the monitoring function at Johnson & Johnson between 2006 and 2009?
A. I don't recall.
Q. Are you familiar with monitoring function at Sanofi between 2006 and 2009?
A. I'm not at liberty to say.

Id. at 146:14-147:2.

Tanselle's deposition testimony makes it clear that his testimony at trial will simply be "unsupported, personal lay opinions disguised as industry standards." *Munn*, 2014 U.S. Dist. LEXIS 76594, at *118. This is the type of expert testimony that Rules 702 and 403 were designed to prevent. As such, Tanselle should be precluded from testifying at trial.

F. Defendants' Expert Coates' Legal Conclusions Should Be Excluded

At the July 7, 2014 hearing, defendants' counsel stated that their expert Coates would be "opining on the . . . adequacy of the disclosures and whether [h]e reasonably believed they were adequate." July 7, 2014 Hearing Transcript at 23:20-23. The Court should exclude Coates'

testimony concerning the adequacy of Pfizer's legal proceeding disclosures. At his deposition, Coates conceded that whether Pfizer's legal proceeding disclosures violated the securities laws is a legal conclusion that should be deferred to the Court and jury. Llorens Decl., Ex. 17 at 28:6-29:12. Coates seems to understand what defense counsel does not: the adequacy of Pfizer's Government Investigation disclosures is a legal conclusion that should be reserved for the jury. This Court has expressed the same view. *See* July 7, 2014 Hearing Transcript at 23:24-25 ("THE COURT: Why is an expert opining on that issue? That's my issue to decide. The jury's issue to decide.").

Despite acknowledging that an opinion on the adequacy of Pfizer's Government Investigation disclosures is a legal conclusion, Coates' report suggests that he intends to offer such testimony. For example, Coates opines that Pfizer's receipt "of the target letter did not add to the mix of information already in the public market." Llorens Decl., Ex. 18, ¶117. Of course, an opinion that undisclosed information concerning the Government Investigation would not have added to the "'total mix' of information" is a legal opinion on materiality. *TSC Indus. v. Northway, Inc.*, 426 U.S. 438, 449 (1976). Coates also improperly opines on whether the securities laws required Pfizer to disclose the names of the other drugs being investigated, which is also a legal conclusion on the adequacy of Pfizer's Government Investigation disclosures. Llorens Decl., Ex. 18, ¶123. Neither of these opinions nor any other opinion from Coates concerning the adequacy of Pfizer's legal proceeding disclosures should be permitted at trial. *See United States CFTC v. Moncada*, No. 12 Civ. 8791 (CM), 2014 U.S. Dist. LEXIS 88884, at *4 (S.D.N.Y. June 30, 2014) ("For expert testimony to be admitted . . . his opinion must not contain legal conclusions.").

Coates has also conceded that he is not qualified to offer expert testimony on Pfizer's process for establishing its FAS 5 reserves or the adequacy of Pfizer's FAS 5 reserves. Llorens Decl., Ex. 17 at 29:13-24, 32:6-32:19. Coates makes similar concessions in his report: "As noted at the outset of

the report, I do not express an opinion on Pfizer's accounting, nor have I reviewed documents relating to how Pfizer established its contingency reserves for every quarter in the Class Period." Llorens Decl., Ex. 18, ¶85. As such, Coates should also be precluded from offering at trial any testimony concerning Pfizer's FAS 5 reserve process and the adequacy of its FAS 5 reserves for the Government Investigation.

III. CONCLUSION

For the foregoing reasons, the Court should preclude trial testimony from Dr. Panchal, Holder, Tanselle and Coates as discussed above.

DATED: December 10, 2014

Respectfully submitted,

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I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on December 10, 2014.

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