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 <u>CLASS ACTION</u> REPLY 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

I. INTRODUCTION

Plaintiffs moved to exclude certain opinions of defendants' purported experts, Dr. Sunil Panchal ("Panchal"), William W. Holder ("Holder"), Jack T. Tanselle ("Tanselle"), and John C. Coates IV ("Coates"). For the reasons set forth in plaintiffs' moving papers and below, plaintiffs' motion to exclude, in-part, the opinions of these experts should be granted.

Dr. Panchal's testimony should be excluded on the basis that: (i) he lacks the requisite experience under Fed. R. Evid. 702 to offer an expert opinion on physician prescribing behavior in response to off-label promotional activities or the safety and efficacy of Pfizer's drugs Bextra and Lyrica for off-label uses; (ii) his opinions offered in rebuttal to plaintiffs' expert, Dr. Avorn, are unreliable and irrelevant under Fed. R. Evid. 401, 402 and 702; (iii) his fact witness testimony should be barred pursuant to Fed. R. Civ. P. 37(c)(1) for failure to timely disclose Dr. Panchal as a fact witness; and (iv) the prejudicial and confusing nature of his testimony outweighs any probative value under Fed. R. Evid. 403.[1] Defendants' efforts to claim Dr. Panchal is offering qualified expert testimony or that it is relevant to the issues in this case fail. Further, their failure to even address the prejudice of his testimony speaks for itself.

Mr. Holder lacks a basis to offer as expert testimony his speculation that the annual audit response letters ("Legal Letters") state that the litigation loss related to the Government Investigation was not probable. Defendants' opposition provides no law to support Mr. Holder's opinion concerning the Legal Letters.

Defendants' proffered healthcare compliance expert, Mr. Tanselle, lacks a sufficient knowledge of Pfizer's competitor's Class Period compliance programs to properly compare them to

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[1] *See* Plaintiffs' Memorandum of Law in Support of Motion *in Limine* to Exclude Certain Testimony of Defendants' Experts Sunil Panchal, William W. Holder, Jack T. Tanselle and John C. Coates IV (Dkt. No. 386) at 3-10.

Pfizer's. Defendants provide no testimony or argument suggesting Mr. Tanselle indeed had knowledge of Pfizer's competitor's speaker programs, risk assessment programs, and other compliance program areas, further supporting plaintiffs' argument that his testimony concerning where in the industry Pfizer's healthcare compliance programs ranked is unreliable.

Defendants agree that their legal proceeding disclosure process expert, Mr. Coates, cannot offer testimony concerning whether Pfizer's Government Investigation disclosures violated the securities laws. Moreover, Mr. Coates is not an accountant, thus he cannot testify concerning Pfizer's Government Investigation FAS 5 reserves or Pfizer's process in establishing the reserves. Defendants do not refute this limitation on Mr. Coates's testimony.

II. ARGUMENT

A. Dr. Panchal's Opinions Should Be Precluded

Notably missing from defendants' opposition to exclude Dr. Panchal's testimony regarding physician prescribing behavior is his utter failure to provide an opinion beyond a single conclusory reference in his report and a sentence coerced in his deposition by defense counsel. Dkt. No. 386 at 5-7. This is not an issue of the weight of his testimony or the lack of data or textual support, it is an issue about the failure to provide ***any basis*** for his opinion as is required under Fed. R. Evid. 702. Quite simply, defendants have not demonstrated that Dr. Panchal's "testimony as to . . . physician perception would be the product of reliable principles or methods or that he has reliably applied the principles and methods to the facts of the case" under Fed. R. Evid. 702. *Calisi v. Abbott Labs.*, No. 11-10671-DJC, 2013 U.S. Dist. LEXIS 139257, at *32 (D. Mass. Sept. 27, 2013); *Bridgeway Corp*

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v. Citibank, 201 F.3d 134, 142 (2d Cir. 2000) (conclusory opinions not admissible); *Pretter v. Metro N. Commuter R.R.*, 206 F. Supp. 2d 601, 603 (S.D.N.Y. 2002) (same).[2]

Further, Dr. Panchal's experience as an anesthesiologist and his "discussions" with undisclosed colleagues do not render him qualified to testify about a topic that is outside of his area of expertise. *See* Dkt. No. 386 at 4-5. Instead, it proves plaintiffs' point that he is a fact witness, whom defendants will attempt to (i) illicit impermissible hearsay from based on his discussions with colleagues and (ii) have testify as to his personal experiences with the safety and efficacy of Pfizer's drugs Bextra and Lyrica for off-label uses.[3] Dr. Panchal's "teaching" role some 10 years ago also does not help his qualifications or his purported opinions on physician prescribing behavior – he has neither taught nor published in pharmacoepidemiology (*i.e.*, the study of the patterns and determinants of drug utilization and the influence of promotion on physician prescribing behavior).[4]

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[2] Defendants' cited cases are factually inapposite. *Figueroa v. Boston Sci. Corp.*, 254 F. Supp. 2d 361, 365-69 (S.D.N.Y. 2003) (admission of expert testimony where qualifications were not challenged and the testimony was based on several factors); *Emig v. Electrolux Home Prods.*, No. 06-CV-4791 (KMK), 2008 U.S. Dist. LEXIS 68811, at *3-*4, *22-*33 (S.D.N.Y. Sept. 11, 2008) (admission of expert testimony of engineer with experience in authoring and evaluating assembly instructions who compared instructions used by competitors in concluding that refrigerator assembly instructions were defective over objections that he could have provided more support).

[3] Dr. Panchal's report unequivocally states that his testimony is based on anecdotal evidence: "[i]n my practice, I found Bextra [and Lyrica] to be . . . safe and effective medication[s]". 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 IV (Dkt. No. 387) ("Llorens Decl."), Ex. 2 (Panchal Report) at 5, 7; Llorens Decl., Ex. 1 at 125:11-15 ("I personally did not have any adverse event concerns"). Defendants' general references to his curriculum vitae are not helpful.

[4] Llorens Decl., Ex. 2 (Panchal Report Ex. A at 1-2); *see also* Dkt. No. 386 at 4-5; Llorens Decl., Ex. 3 at 17:11-21.

Further, defendants fail to explain how any "experience" Dr. Panchal may have is tied to any relevant expert opinion in this case.[5]

Dr. Panchal lacks the expertise to offer relevant testimony in this case because he has zero experience with off-label promotion or its influence. To the extent that defendants seek to introduce expert testimony that physicians prescribe drugs off-label, numerous fact witnesses have already testified to this point, including certain defendants and Pfizer employees.[6] Adding to Dr. Panchal's cumulative testimony under Fed. R. Evid. 403 is the testimony of two other defense experts on this point. *See* Motion *in Limine* to Exclude Defendants' Cumulative Expert Testimony (Dkt. No. 374); *see also* Llorens Decl., Ex. 5 (Expert Report of David Feigal), ¶45 ("medical doctors are free to, and very often do, prescribe medications for uses that are not contained in the FDA-approved label");

[5] The admission of expert testimony in the cases cited by defendants do not help Dr. Panchal. In *SR Int'l Bus. Ins. Co. v. World Trade Ctr. Props., LLC*, 467 F.3d 107, 132-34 (2d Cir. 2006), the court affirmed the testimony of an expert in the insurance industry as to the meaning of a "per occurrence" provision in an insurance policy who explained how his experience tied to the definition. *Id*. at 132. While he was not aware of instances where this custom and practice was applied in a terrorism case, the court found this "hardly surprising given the unprecedented nature of the September 11 attacks." *Id*. at 132-33. Likewise, in *Reach Music Publ'g, Inc. v. Warner Chappell Music, Inc*., 988 F. Supp. 2d 395 (S.D.N.Y. 2013) an entertainment lawyer explained how his experience tied to his testimony as to a lawyer's behavior in connection with a copyright dispute. *Id*. at 399-405. Dr. Panchal cannot testify as to the custom and practice of physicians in response to off-label promotion because he has no experience. Further, any attempts to compare off-label promotion to the "unprecedented" September 11 attacks is absurd. Dkt. No. 386 at 5-7.

[6] *See, e.g*., Declaration of Ryan A. Llorens in Further Support of Plaintiffs' Motion to Exclude Certain Testimony of Defendants' Experts Sunil Panchal, William W. Holder, Jack T. Tanselle and John C. Coates IV ("Reply Decl."), Ex. 19, filed herewith, at 80:13-23 (11/13/13 McKinnell Depo.) ("off-label prescribing is fine, physicians do this all the time, they prescribe drugs that in their independent medical judgment is an appropriate risk benefit tradeoff for an individual patient"); Reply Decl., Ex. 20 at 140:24-141:20 (12/6/13 Kindler Depo.) ("drugs can be prescribed off-label in a perfectly legal and appropriate way by physicians"); Reply Decl., Ex. 21 at 303:4-304:2 (Cawkwell Depo.) (describing her impression of why physicians like her, would write Bextra off-label "regardless of promotional activities").

Dkt. No. 377, Ex. 5 (Expert Report of Sean Nicholson), ¶24 (the FDA "allows physicians to prescribe drugs for off-label").

Defendants admit they did not disclose Dr. Panchal as a fact witness as required by Fed. R. Civ. P. 26 and, as a result, his testimony based on his personal experience is impermissible under Fed. R. Civ. P. 37(c)(1). *See* Dkt. No. 386 at 8-10. Dr. Panchal should be barred from testifying about his personal "interactions" with Pfizer, any impermissible hearsay "discussions with other physicians" regarding the same, the impact of Pfizer's influence on prescribing decisions as well as his claims that sales representatives do not detail off-label. *Id.*; *see also* Fed. R. Evid. 802. Moreover, his lay witness testimony concerning the safety and efficacy of Bextra and Lyrica for uses not approved by the FDA should also be barred, as they are based on anecdotal evidence and will confuse the jury.

Finally, defendants ignore the prejudicial effect of Dr. Panchal's dual role as an expert and lay witness, failing to explain how his testimony will be helpful to a jury given this prejudice, which certainly outweighs any probative value of his opinions. Fed. R. Evid. 403; Dkt. No. 386 at 9-10.

B. Mr. Holder's Opinion Concerning the Legal Letter Should Be Excluded

Defendants have provided no legal basis that would allow Mr. Holder to speculate that the Legal Letters state that a litigation loss related to the Government Investigation was not probable. Dkt. No. 395 at 6-7. Defendants concede the Legal Letters do not explicitly say a loss was not probable. Defendants and Mr. Holder, moreover, are fully capable of reading the English language. *Id.* at 7. Yet, to date, defendants and Mr. Holder have failed to reconcile Mr. Holder's "interpretation" of the Legal Letters with the undisputable fact that each document states in plain English that Pfizer's criminal counsel was "***not expressing an opinion on the outcome***" of the Government Investigation. Dkt. No. 386 at 10 (emphasis added). Mr. Holder has either misread the

Legal Letters or his opinion is pure speculation. Rule 702, therefore, compels preclusion of Mr. Holder's opinion.

C. Mr. Tanselle's Opinions Lack a Sufficient Basis and Should Be Excluded

Defendants' opposition to plaintiffs' motion to exclude Mr. Tanselle's testimony at trial does nothing to assure the Court that Mr. Tanselle has a basis to support his assertions that Pfizer's healthcare compliance program during the Class Period compared favorably to its competitors' programs. Plaintiffs do not criticize Mr. Tanselle because he failed to rely on academic research to support his testimony that Pfizer's healthcare compliance program ranked higher than most pharmaceutical companies' healthcare compliance programs during the Class Period. Instead, plaintiffs' argument concerns the fact that Mr. Tanselle did not rely on ***anything*** – neither academic research, industry articles or his personal experience working with Pfizer's competitors – to support his comparison opinions.

In order to compare Pfizer's Class Period compliance program with that of another company, Mr. Tanselle would need information concerning Pfizer's program and the other company's program during the Class Period. Given his access to materials produced in this litigation, plaintiffs do not deny that Mr. Tanselle could have knowledge of Pfizer's compliance program.[7] However, Mr. Tanselle's deposition testimony made it clear that he has no knowledge of other pharmaceutical companies' compliance programs from 2006 through 2009. *See* Dkt. No. 386 at 15-17. The compliance work Mr. Tanselle does now for pharmaceutical companies is of little value to support

[7] Although, it is not clear that Mr. Tanselle even has the requisite knowledge of Pfizer's Class Period compliance program, as his report is factually inaccurate about key aspects of Pfizer's program. Dkt. No. 386 at 15.

his opinions that particular portions of Pfizer's healthcare compliance program were the industry standard during the Class Period.

Mr. Tanselle's failure to recall information concerning the healthcare compliance program of any other major pharmaceutical company from 2006 to 2009 does not go to the weight of his testimony. Instead, it goes directly to his lack of a basis to make these comparison opinions

Defendants' argument supporting Mr. Tanselle's opinions sums up perfectly the reason why his comparison opinions are sorely lacking. Defendants claim that plaintiffs "quibble" over Mr. Tanselle's factually inaccurate "assumption" that Pfizer's speaker cap was instituted in 2005, rather than 2006. Dkt. No. 395 at 9. Defendants are correct that Mr. Tanselle is making "assumptions," which is inappropriate when providing expert opinion. *See Boucher v. United States Suzuki Motor Corp.*, 73 F.3d 18, 22 (2nd Cir. 1996) (expert testimony cannot be based on an "unrealistic and speculative assumption"); *Beastie Boys v. Monster Energy Co.*, 983 F. Supp. 2d 369, 374 (S.D.N.Y. 2014) (under Rule 702 and *Daubert*, an expert cannot provide reliable expert testimony when it is based on "speculative assumptions"). Mr. Tanselle's testimony will only mislead the jury if his comparison opinions are based on assumptions he is making about Pfizer's and other pharmaceutical companies' health care compliance programs during the Class Period.

D. Defendants Concede that Mr. Coates Will Not Offer Legal Opinion Concerning the Government Investigation Disclosures

Defendants concede that it would be improper for Mr. Coates to offer testimony concerning whether Pfizer's Government Investigation disclosures complied with the securities laws. Dkt. No. 386 at 9-10. Nonetheless, as argued in plaintiffs' motion to exclude Mr. Coates's legal opinions, he offers a number of legal opinions in his report. Dkt. No. 386 at 17-19. Defendants suggest that the reason Mr. Coates offers expert testimony is in response to legal opinions offered by Mr. Buthusiem

and Mr. Regan. Defendants' argument is nonsensical, as they made no motion to exclude Mr. Buthusiem's testimony and Mr. Regan offers accounting opinions, not legal opinions.

Defendants' attempt to compare Mr. Coates's testimony to Mr. Regan's opinions concerning Pfizer's failure to disclose contingent losses under GAAP misses the mark. A testifying accounting expert is permitted to offer expert testimony concerning GAAP violations. Mr. Regan's testimony concerning Pfizer's failure to create a contingent liability for the Government Investigations is an accounting opinion, which is well within his expertise. *See* Dkt. No. 411. Mr. Coates has acknowledged that he is not an accountant and will not offer any opinions concerning Pfizer's FAS 5 reserves. Dkt. No. 386 at 18.

III. CONCLUSION

For the foregoing reasons and the reasons argued in Dkt. No. 386, the Court should grant plaintiffs' motion to exclude certain testimony of Dr. Panchal, Mr. Holder, Mr. Tanselle and Mr. Coates.

DATED: December 30, 2014

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