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 MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION *IN LIMINE* TO EXCLUDE DEFENDANTS' CUMULATIVE EXPERT TESTIMONY

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I. INTRODUCTION

Plaintiffs respectfully submit this memorandum of law in support of their motion *in limine* to exclude the cumulative testimony of defendants' designated expert witnesses. Defendants have submitted four reports from purported disclosure expert witnesses – John C. Coates IV ("Coates"), Jack T. Tanselle ("Tanselle"), Nicholas C. Theodorou, Esq. ("Theodorou") and William Holder ("Holder"). All four of these experts were retained by defendants to opine, at least in part, on the adequacy of Pfizer disclosures concerning the DOJ's investigation of the alleged off-label marketing of Bextra and other drugs and to rebut the opinions of D. Paul Regan ("Regan").

Three of defendants' other experts – Sunil Panchal ("Panchal"), Sean Nicholson ("Nicholson") and David Feigal ("Feigal") – all purport to offer expert testimony, at least in part, on the differences between off-label promotion and off-label prescriptions including the various reasons why physicians prescribe off-label. Each of these experts attempt to rebut the opinions offered by plaintiffs' expert, Meredith Rosenthal ("Rosenthal"), concerning the economic impact of Pfizer's unlawful promotional activities based, in part, on her identification of physician specialties who would not typically be the primary writers of on-label prescriptions. Nicholson and Feigal also criticize Rosenthal's use of ICD9 codes to reach her conclusions.[1] Panchal and Feigal also both criticize the expert witness report of Jerry Avorn ("Avorn") by, *inter alia*, claiming that Pfizer's use of advisory boards and consultants were not promotional in nature.

[1] ICD9 (International Classification of Diseases, 9th edition) refers to a set of recognized codes used by physicians and hospitals to indicate diagnosis and indications. Declaration of Trig R. Smith in Support of Plaintiffs' Motion *in Limine* to Exclude Defendants' Cumulative Expert Testimony ("Smith Decl."), Ex. 1 at 23 n.92, filed concurrently herewith.

Pursuant to Federal Rule of Evidence 403's prohibition against "needlessly presenting cumulative evidence," the Court should preclude defendants from offering needlessly repetitive expert testimony.

II. ARGUMENT

A. Cumulative Evidence May Be Excluded Under Federal Rule of Evidence 403

Otherwise relevant evidence may be excluded under Rule 403 if its probative value is substantially outweighed by, among other things, the danger of "unfair prejudice," "wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. This Court has broad discretion to exclude evidence under Rule 403. *See United States v. LaFlam*, 369 F.3d 153, 155 (2d Cir. 2004). Multiple expert witnesses expressing virtually identical opinions is the type of needlessly cumulative, time-wasting, and unfairly prejudicial evidence Rule 403 is designed to eliminate. Expert testimony that "substantial[ly] overlap[s]" with the testimony of another expert is routinely excluded. *See Price v. Fox Entm't Grp., Inc.*, 499 F. Supp. 2d 382, 390 (S.D.N.Y. 2007). *See also Commonwealth Ins. Co. v. Stone Container Corp.*, No. 99 C 8471, 2002 U.S. LEXIS 4033, at *21 (N.D. Ill. Mar. 12, 2002). As one court has observed:

> Multiple expert witnesses expressing the same opinions on a subject ***is a waste of time and needlessly cumulative***. It also raises the unfair possibility that jurors will resolve competing expert testimony by ***"counting heads"*** rather than evaluating the quality and credibility of the testimony.

Sunstar, Inc. v. Alberto-Culver Co., No. 01 C 0736, 2004 U.S. Dist. LEXIS 16855, at *75 (N.D. Ill. Aug. 23, 2004) (emphasis added and internal citations omitted).

B. The Opinions of Coates, Tanselle, Theodorou and Holder Are Cumulative and Allowing Them to Offer Identical Opinions at Trial Would Unduly Prejudice Plaintiffs

On behalf of plaintiffs, Regan submitted a 94-page report in which he reached the following opinions: (1) Pfizer failed to disclose and take an appropriate accrual for the DOJ investigation as of

December 31, 2005; (2) Pfizer failed to provide adequate disclosure of the nature of the DOJ investigation as of December 31, 2005 and; (3) Pfizer's internal controls over financial reporting suffered from a material weakness between September 30, 2006 and September 30, 2007. *See* Smith Decl., Ex. 2 at 1-2. Holder offers competing opinions on the identical subjects. *See* Llorens Decl., Ex. 8 at 4-5.[2]

Defendants have designated expert witnesses Coates, Tanselle and Theodorou to bolster Holder's opinions by offering identical and cumulative opinions concerning Pfizer's alleged misleading Class Period disclosures. Specifically, defendants have proffered Holder, Coates, Tanselle and Theodorou to testify, in part, regarding: (1) Pfizer's FAS 5 disclosure and accrual judgments concerning the DOJ's investigations; and (2) Pfizer's internal controls over financial reporting. Holder, however, is the only expert with a relevant background regarding disclosure under U.S. GAAP. Because such cumulative and repetitive testimony is a waste of both the Court and jury's time, only one of these experts should be permitted to testify at trial regarding these subjects. *See United States v. Mermelstein*, 487 F. Supp. 2d 242, 266 (E.D.N.Y. 2007) (to avoid duplicative testimony, courts may limit each side to one expert concerning a specific area of expertise).

There are numerous examples of overlap between Holder, Coates, Tanselle and Theodorou's critiques of Regan. For instance, Coates opines that Regan has not "identified any material misstatement in or omission from the Investigation of Marketing Disclosures" and "offer[s] unreliable and mistaken conclusions" regarding those disclosures. Llorens Decl., Ex. 18 at 3, 58, 61, 65-66, 68, 70. Holder opines that Regan has not identified any evidence that Pfizer's FAS 5

[2] "Llorens Decl." refers to the 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, filed December 10, 2014.

disclosures were false and misleading pursuant to GAAP. *See* Llorens Decl., Ex. 8 at 25-26. Holder adds, "I disagree with Mr. Regan that Pfizer failed to report [a] material weakness." *Id.* at 85.

Tanselle offers similarly cumulative and redundant opinions concerning internal controls. Specifically, Tanselle opines "[p]laintiffs' expert[] suggest[s] that the growth in investigation activity is a weakness in controls. The opposite is true . . . ." Llorens Decl., Ex. 12 at 34 & n.57. Tanselle opines that he disagrees with Regan's opinion that the Company's increased number of unsatisfactory audit opinions concerning health care compliance equate to an ineffective compliance program. *Id.* at 44. Finally, Tanselle opines that he disagrees that Pfizer's recognition of control gaps in the review committee process is evidence of an internal control deficiency. *Id.* at 61. Holder's opinions concerning internal controls are virtually identical. *See* Llorens Decl., Ex. 8 at 5-6, 76-108.

Theodorou claims "it would have been inappropriate for Pfizer to attempt to use 'the Neurontin methodology' as a basis to estimate" the potential loss Pfizer faced as a result of the DOJ's investigation of Bextra. Smith Decl., Ex. 3 at 13. Finally, Theodorou adds, "contrary to the opinion[] of . . . Regan . . . Pfizer could not accurately state . . . that the Company was facing simply an 'off-label marketing' investigation." *Id.* at 28. Holder offers the same opinions. *See* Llorens Decl., Ex. 8 at 4-5, 25-75.

Defendants' expert reports make clear that if Coates, Tanselle and Theodorou are permitted to testify regarding the issues of FAS 5 and internal controls, they will express identical opinions to those proffered by Holder. Defendants undoubtedly want to parade as many experts as possible in front of the jury to offer the same opinion – but no justification exists for presenting these experts' cumulative and repetitive testimony.

C. The Opinions of Nicholson, Panchal and Feigal Are Cumulative and Allowing Them to Offer Identical Opinions at Trial Would Unduly Prejudice Plaintiffs

Plaintiffs' expert Rosenthal uses economic theory and empirical studies in examining whether Pfizer's alleged unlawful promotional practices had an impact on Pfizer's revenue and profits for Bextra, Lyrica, Geodon and Zyvox. *See* Smith Decl., Ex. 1 at 1. She also uses economic analysis to quantify what portion of Pfizer's revenue and profits was due to the allegedly unlawful behavior. *Id*. In doing so for the drugs Bextra, Lyrica and Geodon, she uses ICD9 codes as means of determining whether uses were on or off-label. *See* Smith Decl., Ex. 4 at 116:4-117-3. Rosenthal also uses Pfizer's marketing effort to challenged physician specialties as a proxy for Pfizer's overall off-label marketing effort for these drugs. *See id.* at 129:4-8.[3]

In an attempt to counter Rosenthal's conclusions, each of defendants' drug related experts also seek to expound on why a physician might prescribe a drug off-label, while ignoring the fact that Pfizer spent enormous sums of money to encourage such prescriptions. For example, Panchal opines that "scientific literature," "discussions with colleagues" and experience, among other factors, are the reasons physicians prescribe drugs. Llorens Decl., Ex. 2 at 5. Defendants similarly proffer Feigal to testify that "[d]octors prescribe medications off-label for all sorts of reasons . . . including their own experiences with patients, discussions with colleagues, and reports in the scientific literature." Llorens Decl., Ex. 5 at 16, ¶50. Nicholson repeats this mantra opining that the reasons for prescriptions off-label include physicians "read[ing] articles published in medical journals," "prescrib[ing] drugs for off-label uses when on-label alternatives do not exist" or "may not work," as well as being influenced by peers. Smith Decl., Ex. 5 at 7-9, 29-34. Such cumulative testimony

[3] *See In re Neurontin Mktg. & Sales Practices Litig.*, No. 04-cv-10739-PBS, 2011 U.S. Dist. LEXIS 99593, at *93-*94 (D. Mass. Aug. 31, 2011).

should be precluded as "unfairly prejudicial." *Williams v. Cnty. of Orange*, No. 03 Civ. 5182 (LMS), 2005 U.S. Dist. LEXIS 46051, at *18-*19 (S.D.N.Y. Dec. 13, 2005) (excluding testimony of a physician whose testimony would only serve to buttress the testimony of another proffered expert).

Defendants' experts also unnecessarily overlap in their critique of Rosenthal's classification of physician specialties. For example, Panchal opines that Rosenthal is "simply wrong" that "several categories of specialists typically would not treat any patients for Bextra's on-label conditions." Llorens Decl., Ex. 2 at 6. Feigal echoes defendants' attack on Rosenthal declaring that many of her classifications of "physicians who wouldn't have reason to prescribe on label . . . just are not correct."[4] Smith Decl., Ex. 6 at 18:25-19:18. Likewise, Nicholson criticizes Rosenthal's identification of challenged specialties claiming that the challenged specialties "in fact write on-label prescriptions." *See, e.g.*, Smith Decl., Ex. 5 at 3, ¶13. In doing so, he relies on the expert report of Dr. Panchal for his critique. *Id.* at 10-11, ¶¶30-31.

Likewise, defendants' experts Feigal and Nicholson offer cumulative testimony in their disagreement with Rosenthal's use of ICD9 codes. Feigal raised in his deposition that he did not think that the "ICD-9 coding process that [Rosenthal] used . . . is one that can be relied upon." Smith Decl., Ex. 6 at 18:25-19:11. Nicholson similarly criticizes Rosenthal's use of ICD-9 codes. *See, e.g.*, Smith Decl., Ex. 5 at 36-37, ¶¶92-94.

The cumulative attack on plaintiffs' experts does not stop with Rosenthal. Plaintiffs' expert, Avorn, opines that Pfizer engaged in pervasive illegal off-label promotional activities. Llorens Decl., Ex. 4 at 1, ¶1. These promotional activities included "company-sponsored targeted continuing

[4] Despite the fact that Dr. Rosenthal is mentioned only once in Dr. Feigal's expert report in the context of his discussion of the difference between a Warning Letter and a communication from the FDA (Llorens Decl., Ex. 5 at 13, ¶43), Feigal's critique of Rosenthal greatly expanded in his deposition.

education activities" as well as "promotional sessions for physicians who specialize in conditions for which a drug has not been approved to discuss such off-label use" that are "thinly disguised" as advisory boards and consultant meetings. *See, e.g.*, *id.* at 10, ¶19, 14-15, ¶¶28-29. Panchal, a paid member of Pfizer's Bextra advisory board, disagrees with Avorn's characterization of "the functioning of advisory boards." Llorens Decl., Ex. 1 at 33:25-34:3, 42:1-12, 173:23-174:1.[5] Feigal also disagrees. He also seeks to offer an opinion as to the propriety of advisory boards and consultant meetings in rebuttal to Avorn. Llorens Decl., Ex. 5 at 19-22.

Defendants have paid three different experts to opine (contrary to Pfizer's own internal off-label promotion strategies) that off-label prescriptions of Pfizer's drugs were not influenced by Pfizer. Defendants have also paid two of these experts to critique diagnosis codes used by Rosenthal without any explanation by either of them of which codes would be appropriate. Likewise, defendants paid two of these experts to disclaim that Pfizer's advisory boards and consultant meetings were promotional in nature. Defendants' multiple experts expressing the same opinions on the same subjects proffered should not be permitted. *Price*, 499 F. Supp. 2d at 390.

III. CONCLUSION

For the foregoing reasons, plaintiffs respectfully request that the Court preclude the overlapping testimony of defendants' experts.

Further, plaintiffs ask the Court to order defendants to provide plaintiffs the following information immediately: (a) identify the single expert who will opine on whether plaintiffs' accounting expert has identified any material misstatements in Pfizer's Class Period FAS 5 legal proceedings disclosures (*i.e.*, Holder, Coates, Tanselle or Theodorou); (b) identify the single expert

[5] Panchal mentions Avorn once in his report, merely claiming he was asked to review and respond to his report. Plaintiffs are separately moving to exclude Panchal's rebuttal to Avorn on other grounds.

who will opine on whether calculating an estimated loss contingency using the Neurontin methodology during the Class Period would have been appropriate (*i.e.*, Holder or Theodorou); (c) identify the single expert who will opine that Pfizer had effective healthcare compliance controls during the Class Period (*i.e.*, Holder or Tanselle); (d) identify the single expert who will opine about physician prescribing behavior (*i.e.*, Nicholson, Panchal or Feigal); (e) identify the single expert who will explain why Dr. Rosenthal's classification of physician specialties is flawed (*i.e.*, Nicholson, Panchal, or Feigal); and (f) identify the single expert who will explain why advisory boards and consultant meetings are not promotional activities (*i.e.*, Panchal or Feigal)

DATED: December 10, 2014

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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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