

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MARY K. JONES, Individually and on Behalf
of All Others Similarly Situated,

Plaintiff,

v.

PFIZER INC., et al.,

Defendants.

Civil Action No. 1:10-cv-03864-AKH

Hon. Alvin K. Hellerstein

ECF CASE

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

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Plaintiffs' assertions that the opinions of certain of Defendants' experts are cumulative and/or identical are demonstrably mistaken. As Plaintiffs are well aware, these experts have differing areas of expertise, and each draws from their own expertise in responding to different allegations made by Plaintiffs and their experts. In attempting to create an issue where there is none, Plaintiffs entirely mischaracterize the nature of the opinions that Defendants' experts offer.

For example, the four defense experts Plaintiffs claim are overlapping with regard to the opinions of Plaintiffs' accounting expert, Paul Regan, are:

- *William Holder (GAAP)*: Mr. Holder, the Dean of the Leventhal School of Accounting at the University of Southern California, specializes in financial and managerial accounting.¹ His opinions, accordingly, concern accounting matters—he will offer opinions regarding Pfizer's accounting disclosure and loss contingency reserve judgments concerning the Government Investigation. Plaintiffs have abandoned claims regarding Pfizer's internal controls over financial reporting,² though they repeat such allegations now in their Motion. See Memorandum of Law in Support of Plaintiffs' Motion *in Limine* to Exclude Defendants' Cumulative Expert Testimony ("Mot.") 3. To the extent Plaintiffs are permitted to make allegations regarding these abandoned claims, Mr. Holder will offer opinions regarding Pfizer's disclosures concerning internal controls over financial reporting.³
- *John Coates (Securities Disclosures)*: Professor Coates is a Professor of Law and Economics and Research Director of the Program on the Legal Profession at Harvard Law School, and specializes in corporate control and governance and securities laws and regulation, including corporate disclosures.⁴ Unlike Mr. Holder, he does not offer any accounting opinions. Instead, he will offer opinions regarding, *inter alia*, the process

¹ December 10, 2014 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 ("Llorens Decl.") Ex. 8 (Expert Report of William Holder, CPA dated July 15, 2014) ("Holder Rep.") ¶¶ 3–5, Ex. A.

² See Memorandum of Law in Support of Defendants' Motion *in Limine* No. 12 to Preclude Plaintiffs from Arguing at Trial that the Abandoned Statements and Omissions Support any Finding of Liability Against Any of the Defendants, at 2.

³ Llorens Decl. Ex. 8 (Holder Rep.) ¶ 13.

⁴ Llorens Decl. Ex. 18 (Expert Report of Professor John C. Coates IV, dated July 15, 2014) ("Coates Rep.") ¶¶ 4–6, Ex. A.

through which Pfizer drafted its securities disclosures. He will also rebut opinions offered by Mr. Regan (as well as Plaintiffs' proffered disclosure expert, Edward Buthusiem) regarding alleged material misstatements or omissions within those disclosures.⁵

- *Jack Tanselle (Pharmaceutical Compliance Programs)*: Mr. Tanselle is a Managing Director with Navigant Consulting, Inc., and specializes in designing, implementing and assessing pharmaceutical healthcare compliance programs.⁶ He will offer opinions regarding Pfizer's healthcare compliance program during the Class Period, and will rebut opinions by Plaintiffs' proffered experts' (including Mr. Regan and another of Plaintiffs' experts, Kevin O'Brien) regarding Pfizer's compliance program and related healthcare compliance controls.⁷ Unlike Mr. Holder and Professor Coates, he offers no opinions on accounting issues or securities disclosure issues.
- *Nicholas Theodorou (Government Investigations)*: Mr. Theodorou is a former federal prosecutor and a partner at the law firm of Foley Hoag LLP, who specializes in government investigations matters, including in the healthcare space.⁸ He will offer opinions regarding, *inter alia*, the nature of such government investigations, including the government's investigation of Pfizer. He will also offer opinions rebutting several of Plaintiffs' experts. Unlike Mr. Holder, Professor Coates, and Mr. Tanselle, he offers no opinions on accounting issues, securities disclosure issues, or pharmaceutical company compliance programs.

Separately, the three additional experts Plaintiffs claim are overlapping with regard to the opinions of their econometric modeling and pharmaceutical marketing experts, Meredith Rosenthal and Jerry Avorn, are:

- *Sean Nicholson (Econometrics)*: Dr. Nicholson is a Professor in the Department of Policy Analysis and Management at Cornell University. He specializes in the economics of healthcare, including econometric analysis.⁹ He will offer opinions regarding, *inter alia*, the econometric analyses used by Ms. Rosenthal and Plaintiffs' expert Christopher

⁵ Llorens Decl. Ex. 18 (Coates Rep.) ¶ 2.

⁶ Llorens Decl. Ex. 12 (Expert Report of Jack T. Tanselle, dated July 15, 2014) ("Tanselle Rep.") ¶ 2, App. 1.

⁷ Llorens Decl. Ex. 12 (Tanselle Rep.) ¶ 2, App. 1.

⁸ December 10, 2014 Declaration of Trig R. Smith in Support of Plaintiffs' Motion *in Limine* to Exclude Defendants' Cumulative Expert Testimony ("Smith Decl.") Ex. 3 (Expert Report of Nicholas C. Theodorou, Esq., dated July 15, 2014) ("Theodorou Rep.") at 3.

⁹ Smith Decl. Ex. 5 (Expert Report of Dr. Sean Nicholson, dated July 22, 2014) ("Nicholson Rep.") ¶¶ 1-2, App. 1.

Baum in attempting to describe the relationship between Pfizer's alleged off-label promotion and its sale of pharmaceuticals.¹⁰

- *David Feigal (FDA)*: Dr. Feigal is a medical doctor and a consultant on regulatory matters under the jurisdiction of the Food and Drug Administration, where he held a number of senior positions between 1992 and 2004.¹¹ He will offer opinions on a variety of matters regarding the FDA's regulation of pharmaceutical marketing, the prescribing behavior of physicians, and the "challenged" medical specialties included in Ms. Rosenthal's analysis.¹² Unlike Dr. Nicholson, he offers no opinions on econometric models.
- *Sunil Panchal (anesthesiologist)*: Dr. Panchal is a Board-certified anesthesiologist with subspecialty training in interventional pain medicine.¹³ He will offer opinions regarding, *inter alia*, how and why doctors prescribe medications, including for off-label uses. In addition, he will rebut Ms. Rosenthal's unsupported opinion that anesthesiologists and other physicians specializing in pain management would typically prescribe Bextra and Lyrica only for off-label conditions.¹⁴

As is plain from their backgrounds, reports and deposition transcripts, each of these experts offers opinions in different areas, based on their own expertise in different subjects. Plaintiffs' attempt to conflate them is improper and, in any event, totally at odds with their opinions.

¹⁰ Smith Decl. Ex. 5 (Nicholson Report) ¶¶ 10–19.

¹¹ Llorens Decl. Ex. 5 (Expert Report of David Feigal, M.D., M.P.H., dated July 15, 2014) ("Feigal Rep.") ¶¶ 1, 3, Ex. A.

¹² Declaration of Amanda A. MacDonald in Support of Defendants' Responses to Plaintiffs' Motions *in Limine*, dated Dec. 22, 2014 ("Dec. 22, 2014 MacDonald Decl.") Ex. RR-4 (Feigal (Oct. 21, 2014) Dep. 18:22-20:21; 26:1-8; 92:21-24; 111:4-114:4; 127:7-128:11).

¹³ Llorens Decl. Ex. 2 (Expert Report of Dr. Sunil Panchal, dated July 15, 2014) ("Panchal Rep.") at 1–2, Ex. A.

¹⁴ Llorens Decl. Ex. 2 (Panchal Rep.) at 5–9.

ARGUMENT

I. MESSRS. COATES, TANSELLE, THEODOROU, AND HOLDER HAVE DIFFERENT AREAS OF EXPERTISE AND, ACCORDINGLY, OFFER DISCRETE OPINIONS IN RESPONSE TO PLAINTIFFS' ALLEGATIONS.

To the extent Plaintiffs' expert Paul Regan actually restricts his opinions to his own area of purported expertise—accounting—the only one of Defendants' experts who will address his opinions is Defendants' accounting expert, Professor Holder. However, in his report and his deposition, Mr. Regan purports to offer a wide range of opinions across a number of different areas of expertise—including several in which he has no experience whatsoever—which would require rebuttal from experts in multiple fields. For example, Mr. Regan opines, without any experience or background on the subject, that certain facts uncovered in the government investigations “increased the probability . . . that the Government would take action against Pfizer,” and that it would have been a “simple” process for Pfizer to determine the criminal multiplier under the US Sentencing Guidelines that the federal government would apply in the future whenever the parties ultimately resolved the Bextra investigation.¹⁵ If these particular “opinions” were offered, Defendants would rebut them with the testimony of Mr. Theodorou, who (unlike Mr. Regan), is an expert in government investigations.¹⁶ Similarly, to respond to Mr. Regan's opinion—also offered without any expertise or specialization on his part—that Pfizer's compliance programs were inadequate,¹⁷ Defendants may offer the testimony of Mr.

¹⁵ December 10, 2014 Amanda M. MacDonald in Support of Defendants' Motions *in Limine* WW-2 (Supplemental Expert Report of D. Paul Regan, dated July 31, 2014) (“Regan Rep.”) 18; *see also id.* at 35 (“the only remaining variable to make a reasonable estimate of the contingent loss was the multiplier, which itself was relatively simple to analyze”).

¹⁶ Smith Decl. Ex. 3 (Theodorou Rep.) at 3.

¹⁷ Dec. 10, 2014 MacDonald Decl. WW-2 (Regan Rep. at 1-2, 69-71).

Tanselle, who specializes in assessing pharmaceutical healthcare compliance programs.¹⁸ Mr. Regan also opines, without any background to do so, that Pfizer's securities disclosures were inadequate;¹⁹ if he does so at trial, Defendants would rebut this view with the opinions of Professor Coates, a well-recognized expert in corporate law and governance.²⁰ Accordingly, the fact that multiple of Defendants' experts criticize Mr. Regan's opinions is not evidence that these experts' opinions are cumulative, but rather that Mr. Regan overstepped in offering such varied opinions.²¹

The differences in education and specialization among Messrs. Holder, Coates, Tanselle, and Theodorou result in their critiques of Mr. Regan (and several of Plaintiffs' other experts, including Mr. Buthusiem, their proffered securities disclosure process expert, and Mr. O'Brien) having different significance. To take an example cited by Plaintiffs in their Motion, when Professor Coates opines that from a securities disclosure perspective, Mr. Regan did not identify "any material misstatement in or omission from" Pfizer's disclosures, Mot. 3, that conclusion is substantively very different from Mr. Holder's finding, based on his accounting expertise, that Mr. Regan failed to adduce evidence that Pfizer's FAS 5 reserves or related disclosures were false or misleading under the Generally Accepted Accounting Principles ("GAAP"). *Id.* at 3-4. Similarly, that Mr. Theodorou's government investigations experience led him to conclude,

¹⁸ Llorens Decl. Ex. 12 (Tanselle Rep.) ¶ 2.

¹⁹ Dec. 10, 2014 MacDonald Decl. WW-2 (Regan Rep. at 1-2).

²⁰ Llorens Decl. Ex. 18 (Expert Report of Professor John C. Coates IV, dated July 15, 2014) ("Coates Rep.") ¶ 2.

²¹ The fact that multiple, disparate experts agree that the opinions offered by Plaintiffs' purported expert are flawed is not grounds to exclude those opinions. That experts address the same subject area or come to the same conclusions using different analyses does not render those opinions inadmissible. *See Johnson v. United States*, 780 F.2d 902, 906 (11th Cir. 1986) (district court abused discretion in excluding third medical expert witness where witness had different credentials and would have offered different evidence and analysis).

contrary to Mr. Regan, that it would have been improper for Pfizer to use a damages analysis from a different government investigation to estimate the potential loss from the government's investigation of Bextra, *id.* at 4, is entirely distinct from Mr. Holder's opinion that, from an accounting perspective in apply Financial Accounting Standard No. 5, Mr. Regan's opinion that Pfizer could and should have estimated the potential contingent loss associated with the government's Bextra investigation earlier than it did is "flawed."²²

Even if Plaintiffs could demonstrate that Defendants' experts were offering "identical and cumulative opinions" concerning Pfizer's disclosures and the faulty opinions of Mr. Regan (which they have not), the vastly different backgrounds of these experts allows them to assist the jury in distinct ways. Plaintiffs' reliance on *United States v. Mermelstein*, 487 F. Supp. 2d 242 (E.D.N.Y. 2007), to support their claim that "only one" of Defendants' experts "should be permitted to testify at trial" regarding certain subjects, Mot. 3, is misplaced. The court in that case—which *denied* a motion to exclude expert testimony as cumulative, *id.* at 266—held merely that "some courts permit each side to put up only one expert witness *in any particular area of expertise.*" *Id.* (emphasis added) (internal quotation marks omitted). Here, as discussed, Messrs. Holder, Coates, Tanselle, and Theodorou represent distinct areas of expertise. Accordingly, their opinions are proper, non-cumulative, and admissible.

II. DR. NICHOLSON, DR. FEIGAL, AND DR. PANCHAL HAVE DIFFERENT AREAS OF EXPERTISE AND OFFER DISCRETE OPINIONS IN RESPONSE TO PLAINTIFFS' ALLEGATIONS.

Plaintiffs argue that Defendants' experts Sean Nicholson, David Feigal, and Sunil Panchal offer "cumulative attack[s]" on Plaintiffs' experts Meredith Rosenthal and Jerry Avorn. Mot. 5–7. However, as with Defendants' other experts, Drs. Nicholson, Feigal and Panchal have

²² Llorens Decl. Ex. 8 (Holder Rep.) ¶¶ 160–164.

different backgrounds and areas of expertise, and therefore their critiques of Ms. Rosenthal and Dr. Avorn are different.

As an initial matter, alleged off-label promotion of Bextra, Geodon, Zyvox, and Lyrica—the sole subject matter of the Avorn/Rosenthal opinions—is entirely irrelevant to Plaintiffs’ securities law claims. For that and other reasons, Defendants have moved to exclude this evidence. *See* Defendants’ Motions *In Limine* Nos. 1, 2, 3, 5, and 10. If those motions are granted, Defendants will have no need to present the testimony of Dr. Nicholson, Dr. Feigal, or Dr. Panchal, as these witnesses were designated solely to respond to Plaintiffs’ drug-related experts.

In any event, the variety of training and specialties possessed by Drs. Nicholson, Feigal, and Panchal allows them to review and critique the opinions of Ms. Rosenthal and Dr. Avorn in different ways. For example, Plaintiffs claim that Dr. Feigal and Dr. Nicholson “offer cumulative testimony in their disagreement with Rosenthal’s use of” ICD-9²³ codes. Mot. 6. But Dr. Nicholson’s critique of Ms. Rosenthal stems from his opinion, based on his econometric expertise, that Ms. Rosenthal’s failure to “follow any recognized economic methodology” in using the codes to select competitor drugs as part of her analysis renders her analysis unreliable.²⁴ Dr. Feigal’s critique, on the other hand, is based on his medical experience with the codes in health services research and pharmacoepidemiology. As he explained, Ms. Rosenthal did not check the validity of the coding by pulling sample medical charts, and she failed to

²³ ICD-9 codes are part of the International Statistical Classification of Diseases and Related Health Problems. These codes are used for a variety of epidemiological, clinical, and health-related purposes to identify different health conditions.

²⁴ Smith Decl. Ex. 5 (Nicholson Rep.) ¶¶ 92–94.

account for the differences between the inpatient and outpatient codes in her analysis.²⁵ The fact that both Dr. Nicholson and Dr. Feigal conclude that Ms. Rosenthal's use of the ICD-9 codes was deficient does not make their individual opinions, based on entirely separate areas of expertise, cumulative.

Similarly, Plaintiffs contend that Drs. Panchal and Feigal offer overlapping opinions criticizing the classification of physician specialties Ms. Rosenthal used. Mot. 6. But what Plaintiffs ignore is that Dr. Panchal is a practicing anesthesiologist who frequently prescribed Bextra and continues to prescribe Lyrica for on-label conditions,²⁶ despite Ms. Rosenthal's assertion (upon which her entire analysis as to these two drugs is based) that anesthesiologists do not typically treat such conditions.²⁷ His opinions relate solely to Bextra and Lyrica and are based on areas in which he practices and/or has professional experience as a pain medicine specialist.²⁸ By contrast, Dr. Feigal's opinions concern all of the pharmaceutical products considered by Ms. Rosenthal and stem from his broad training as an internist and his general medical knowledge²⁹—exactly like the previously undisclosed internist, Dr. Stan Finkelstein, whose “expert” specialty classification opinions Ms. Rosenthal adopts.³⁰ *See* Memorandum in

²⁵ Dec. 22, 2014 MacDonald Decl. Ex. RR-4 (Feigal (Oct. 21, 2014) Dep. 138:18–142:10).

²⁶ Llorens Decl. Ex. 2 (Panchal Rep.) 5–8.

²⁷ Smith Decl. Ex. 1 (Expert Report of Dr. Meredith Rosenthal, dated June 10, 2014) Attach. E.1 (“[An anesthesiology] specialist would typically treat acute pain relating to surgery, which is not a labeled indication for Bextra.”), E.3 (“[An anesthesiology] specialist would typically treat acute pain relating to surgery, which is not a labeled indication for Lyrica.”).

²⁸ Dec. 22, 2014 MacDonald Decl. Ex. TT-4 (Panchal (Aug. 22, 2014) Dep. 24:10–22, 228:8–21 (describing specialties that practice pain medicine)).

²⁹ Dec. 22, 2014 MacDonald Decl. Ex. RR-4 (Feigal (Oct. 21, 2014) Dep. 145:21–149:18 (describing critique of classifications used by Dr. Finkelstein)).

³⁰ Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 25:8–19 (“Dr. Finkelstein helped me in two particular sets of decisions that I made. He provided clinical input when I was

Support of Defendants' Motion *in Limine* No. 2 to Exclude Plaintiffs' Designated Experts Meredith Rosenthal and Christopher Baum (moving to exclude testimony of Ms. Rosenthal for relying on expert opinions of undisclosed expert). Like Mr. Regan, Ms. Rosenthal offers opinions not just in her area of specialization, but also concerning areas in which she has no background, forcing her to rely on another expert's conclusions. As discussed in Defendants' motion to exclude Ms. Rosenthal, Defendants had no opportunity to review the opinions of Dr. Finkelstein or the bases for his classification opinions, despite the fact that the conclusions of Ms. Rosenthal and Plaintiffs' designated expert Christopher Baum are based entirely on these classifications. *Id.* at 5–11. Accordingly, not knowing the reasons for Dr. Finkelstein's classifications or how these opinions will be presented at trial, Defendants have prepared multiple experts to opine that they are incorrect, based on different areas of expertise, in order to defend themselves against Dr. Finkelstein's *ipse dixit* views. Such testimony is not cumulative.

III. EXPERTS WITH DIFFERENT AREAS OF EXPERTISE ARE PERMITTED TO OFFER COMPLEMENTARY OPINIONS.

Even if Plaintiffs were correct that there are areas of overlap between certain of Defendants' expert reports, "[t]he mere presence of overlap, reference to another expert's report, or a similar conclusion, however, does not render an expert report unnecessarily 'cumulative' pursuant to FRE 403." *Banks v. United States*, 93 Fed. Cl. 41, 51 (2010); *see also Rodriguez v. Cnty. of Stanislaus*, No. 1:08-CV-00856 OWW, 2010 WL 2720940, at *2 (E.D. Cal. July 8, 2010) (same). Even similar opinions can add meaningfully to the evidence at trial when the experts providing them have differing expertise, backgrounds, and perspectives. As explained

reviewing the diagnosis codes and alternative therapies in constructing the list of competitor drugs for each of the drugs that Dr. Baum used regression models to estimate impact. He also helped me review the specialties in the promotional data with regard to the appropriateness of including or excluding those specialists in my measure of off-label detailing.").

by the court in *Rodriguez*, in deciding to admit opinions challenged as cumulative, “[t]he qualifications of these two experts alone is sufficient reason to permit the designation and testimony of each.” 2010 WL 2720940, at *2 (noting that experts held different degrees in different areas of study). Accordingly, all of Defendants’ experts, who bring to bear entirely different backgrounds and perspectives in critiquing Plaintiffs’ purported experts, should be permitted to testify.

IV. EXCLUSION OF DEFENDANTS’ EXPERTS’ TESTIMONY IS PREMATURE.

Plaintiffs have failed to identify any testimony from any of Defendants’ experts that is duplicative. However, even if Defendants’ experts had expressed overlapping opinions in their expert reports or during deposition testimony, that testimony only becomes “needlessly cumulative” in the context of trial, if Defendants seek to introduce it in a context that does not add to the jury’s understanding of the evidence. At this point, given the broad expanse of Plaintiffs’ allegations and the variety of forms their case may take, it is unclear which experts will be testifying and as to what. The proper time for such an objection is at trial, when Defendants seek to offer expert opinions, such that the court can weigh the relevance of the proposed testimony “against cumulativeness and delay.” *United States v. Rubin/Chambers, Dunhill Ins. Servs.*, 828 F. Supp. 2d 698, 715 (S.D.N.Y. 2011) (denying motion to strike cumulative evidence because “required balancing of relevance . . . against cumulativeness and delay cannot be performed properly in the abstract prior to trial”).

CONCLUSION

For the above reasons, Plaintiffs' motion *in limine* to exclude cumulative testimony should be denied.

Date: Washington, D.C.
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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on this 22nd day of December, 2014, the foregoing Defendants' Memorandum of Law in Opposition to Plaintiffs' *Motion In Limine* to Exclude Defendants' Cumulative Expert Testimony was filed with the Court through the CM/ECF system and thereby served to all parties of record.

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