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 TO EXCLUDE CERTAIN TESTIMONY OF DEFENDANTS' EXPERTS SUNIL PANCHAL, WILLIAM W. HOLDER, JACK T. TANSELLE AND JOHN C. COATES IV

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Plaintiffs' motion to exclude certain opinions of Defendants' experts Sunil Panchal, William Holder, Jack Tanselle, and John Coates fails to identify any testimony or opinions that are inadmissible under Rule 702. Defendants' experts are highly qualified, and offer opinions that are consistent with their expertise and reflect the reliable application of principles and methods to the facts of this case. In the absence of any ground to exclude these opinions, Plaintiffs quibble over, for example, whether an expert cites to peer-reviewed literature or was able to recall certain names and events during his deposition. These "objections" to Defendants' experts are relevant, if at all, only to the weight of their opinions, not their qualifications and admissibility. Plaintiffs' motion should be denied.

ARGUMENT

I. DR. PANCHAL HAS THE REQUISITE EXPERIENCE TO TESTIFY REGARDING PHYSICIAN PRESCRIBING BEHAVIOR.

Plaintiffs assert that Dr. Panchal, a seasoned surgeon and teacher who has treated thousands of patients and trained numerous physicians over 20 years, lacks the "qualifications" necessary to offer testimony about physician prescribing behavior because his "experience" alone is insufficient. 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 ("Mot.") at 3–5. Their support for this assertion is that Dr. Panchal has not participated in any formal research or studies regarding the impact of pharmaceutical company marketing on prescribing behavior. *Id.* at 4. Plaintiffs are simply incorrect. As the advisory committee notes to Rule 702 make clear, "experience alone . . . may . . . provide a sufficient foundation for expert testimony." Fed. R. Evid. 702 advisory committee's note ("[T]he text of Rule 702 expressly contemplates that an expert may be qualified on the basis of experience."); *see also SR Int'l Bus. Ins. Co. v. World Trade Ctr.*

Properties, LLC, 467 F.3d 107, 132-34 (2d Cir. 2006) (over 30 years of experience in and familiarity with insurance industry qualified expert to offer opinion); *Reach Music Pub., Inc. v. Warner Chappell Music, Inc.*, 988 F. Supp. 2d 395, 404–05 (S.D.N.Y. 2013) (expert's experience qualified him to opine on "custom and practice" in music industry).

Here, Dr. Panchal testified that the bases for his opinions as to the impact of promotional activities in the "decision-making for therapy choice by physicians" are

> my training, my experience in practice for almost 20 years in being at several large academic institutions where I was involved with the training of medical students, residents, fellows, educating people at other institutions when I was a visiting professor or educating other physicians by involvement in lecturing at the national society conferences and the research, interactions with other colleagues and feedback I get from patients as well.[1]

Dr. Panchal's experience includes *teaching other doctors* about how to choose medications in the treatment of patients, including the various factors a physician should consider in prescribing medications.[2] He is therefore eminently qualified to offer opinions on physician prescribing behavior and the influence (or lack thereof) of commercial marketing.

Plaintiffs' complaint that Dr. Panchal cannot speak to physician prescribing behavior because he has never personally experienced off-label (as opposed to on-label) detailing, Mot. at 4–8, is immaterial. Dr. Panchal will testify as to the relative effects of pharmaceutical

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[1] December 22, 2014 Declaration of Amanda M. MacDonald in Support of Defendants' Responses to Plaintiff's Motions in Limine (hereinafter "Dec. 22, 2014 MacDonald Decl.") Ex. TT-4 (Panchal (Aug. 22, 2014) Dep. 225:20–227:6); *see also id.* at 164:17–165:22 (describing "ongoing process" of how physicians make treatment decisions).

[2] Dec. 22, 2014 MacDonald Decl. Ex. TT-4 (Panchal (Aug. 22, 2014) Dep. 164:17–165:22 (describing "experience being on faculty at several major university institutions, teaching there, participating in grand rounds, listening to discussion from other colleagues there, seeing the methodology that we use to train our residents and fellows to make decisions, our medical students, how to evaluate the scientific literature"); *see also id.* at 100:16–101:4 (describing "discussions" with colleagues and trainees about how decide among various approaches to treating conditions), 101:21–102:4.

marketing, whether on- or off-label, on physician prescribing behavior and that the influence of such marketing pales in comparison with the influence of other factors, such as scientific literature, experience, recommendations of colleagues, and patient feedback.[3] That Dr. Panchal has not experienced a specific type of detailing does not disqualify him from opining on the activity generally. *See SR Int'l Bus. Ins. Co.*, 467 F.3d at 132–33 (that expert in insurance industry custom and practice was "not aware of any instance where his understanding of custom and practice had been applied to a terrorism case" did not affect his expertise). Similarly, Plaintiffs' claim that Dr. Panchal "cannot point to peer reviewed literature to buttress his opinion" and did not provide enough detail in supporting his opinion, Mot. at 5–8, does not go to Dr. Panchal's qualifications as an expert in this area. If anything, Plaintiffs' objections "go to the weight of [Dr. Panchal's] expert testimony, not its admissibility in the first instance." *Emig v. Electrolux Home Prods. Inc.*, No. 06-CV-4791 (KMK), 2008 WL 4200988, at *9 (S.D.N.Y. Sept. 11, 2008); *see also Figueroa v. Boston Scientific Corp.*, 254 F. Supp. 2d 361, 367–69 (S.D.N.Y. 2003) (arguments about the lack of testing or data or textual support for experts' opinions implicate weight, and not admissibility, of testimony).

Plaintiffs argue that Dr. Panchal's testimony as to the "safety and efficacy of Lyrica and Bextra is irrelevant to the issues in this case." Mot. at 7. Defendants wholeheartedly agree that evidence concerning marketing practices is irrelevant. For that reason, Defendants have sought to have all testimony and evidence regarding the development, use, and marketing of these and other products excluded. *See* Defs.' Mot. *in Limine* No. 5. Defendants would not offer Dr. Panchal's testimony on this topic but for Plaintiffs' insistence in dragging these issues into the case. For example, Plaintiffs' designated expert Jerry Avorn—whom Dr. Panchal was retained

[3] Dec. 22, 2014 MacDonald Decl. Ex. TT-4 (Panchal (Aug. 22, 2014) Dep. 102:19-103:15, 162:25-164:16).

to rebut, among others—has offered multiple opinions as to his doubts about the safety and efficacy of Bextra and other products, presumably hoping that the insinuation of patient harm will persuade the jury that Pfizer violated securities laws.[4] Accordingly, if Dr. Avorn's testimony is admissible, testimony from another expert (who, unlike Dr. Avorn, has extensive experience prescribing these products for patients) that contradicts Dr. Avorn's views on this subject is relevant and admissible. If, on the other hand, Dr. Avorn (and Plaintiffs' other experts on marketing issues) are precluded from appearing at trial, Defendants will not call Dr. Panchal.

II. DR. PANCHAL IS NOT A FACT WITNESS AND DOES NOT OFFER FACT-BASED TESTIMONY.

Plaintiffs next contend that Dr. Panchal's testimony is a fact witness. Mot. at 8. This argument is without merit for at least two reasons. First, Plaintiffs support their claim by alleging that Dr. Panchal "was a highly paid speaker on the benefits of Bextra for Pfizer . . . during the period January 19, 2006 to January 23, 2009." Mot. at 1. This assertion is demonstrably false; it is undisputed that Bextra was taken off of the market in April 2005.[5] Accordingly, Pfizer did not market Bextra after 2005, and it retained no one to speak on the "benefits" of Bextra after that time. There is nothing in the record to suggest that Dr. Panchal had any involvement with Bextra or received any payments from Pfizer related to Bextra during the Class Period.

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[4] Dec. 22, 2014 MacDonald Decl. Ex. NN-4 (Avorn (Aug. 7, 2014) Dep. 23:3–16 (stating that "we had a fair amount of skepticism about all the selective COX-2 drugs" and that he had "concerns about [Bextra's] safety"); Dec. 10, 2014 Declaration of Amanda M. MacDonald in Support of Defendants' Motions *In Limine* (Expert Report of Dr. Jerry Avorn ¶ 4 (Pfizer marketed Bextra, Lyrica, Geodon, and Zyvox at the "expense of patient safety"), ¶ 22 (opining about lack of "acceptable benefit-risk relationship" for purposes for which Pfizer marketed Bextra and other drugs), ¶ 26 (describing "safety problem [with Bextra] that proved to be lethal for many patients" and describing FDA findings regarding safety and efficacy of Bextra), ¶ 40 (describing "unacceptable safety risks" of Bextra), ¶ 41 (referring to Bextra's "capacity to cause potentially fatal side effects")), ECF No. 384 (hereinafter "Avorn Rep.").

[5] Pls.' Statement of Material Facts Requiring Denial of Defs.' Mots. For Summ. J. ¶ 55 (Pfizer "took [Bextra] off the market in April 2005"), ECF No. 303.

Second, Dr. Panchal is not a fact witness in this case, and Defendants do not intend to offer his testimony as a fact witness at trial. Dr. Panchal was a member of a Bextra advisory board in 2001, conducted research into the medication's effectiveness, and participated in conferences and presentations relating to Bextra and Lyrica.[6] But Defendants do not intend to offer testimony from Dr. Panchal on these topics. Dr. Panchal was not identified by either party as an individual likely to have discoverable information, and he was not deposed as a fact witness. As support for their claim that Defendants seek to introduce factual testimony from Dr. Panchal, Plaintiffs cite a sentence from Dr. Panchal's expert deposition in which he was ***asked by Plaintiffs' counsel*** whether he would be offering "opinions about whether Pfizer sales reps marketed Bextra on or off-label."[7] Dr. Panchal responded that

> I will be able to answer questions regarding my interactions with Pfizer personnel and anything that I had discussions with other physicians, *but I would not be able to give you a discussion of every single individual that works for Pfizer*.[8]

In other words, Dr. Panchal agreed that he does not have the knowledge or experience necessary to offer opinions about whether Pfizer sales representatives marketed Bextra off-label. His statement that he would be able to answer questions about his personal interactions with Pfizer personnel was simply a truthful response to *Plaintiffs'* question. Defendants have no intention of asking Dr. Panchal about his interactions with Pfizer personnel or whether he experienced off-label detailing.

Plaintiffs' claim that Dr. Panchal's testimony about the safety and efficacy of Bextra and Lyrica is not "expert-based" is similarly misguided. Mot. at 9. Dr. Panchal has extensive training and experience in the use of Bextra and Lyrica. In addition to his attendance and

[6] Dec. 22, 2014 MacDonald Decl. Ex. TT-4 (Panchal (Aug. 22, 2014) Dep. 105:23–112:16).

[7] Dec. 22, 2014 MacDonald Decl. Ex. TT-4 (Panchal (Aug. 22, 2014) Dep. 122:7–9).

[8] Dec. 22, 2014 MacDonald Decl. Ex. TT-4 (Panchal (Aug. 22, 2014) Dep. 122:10–16).

participation in various medical conferences, lectures, and presentations related to Bextra and Lyrica,[9] he is the author of two peer-reviewed articles and five abstracts relating to the use and efficacy of Bextra in its oral and injectable forms.[10] He was the principal investigator in a clinical trial examining the narcotic sparing activities of Bextra as compared to a placebo.[11] He also developed and executed a protocol using Bextra and Lyrica in treating thoracotomy patients at a cancer center.[12] He routinely uses Lyrica to treat a variety of types of pain in his patients.[13] Dr. Panchal is much more qualified to testify about Bextra and Lyrica than Dr. Avorn, who stopped treating patients 15 years ago, never prescribed Bextra, has prescribed Lyrica "under a hundred times," and has no published research on these products.[14] Accordingly, Dr. Panchal is a qualified expert and should be permitted to testify.

III. MR. HOLDER'S OPINIONS REGARDING LEGAL LETTERS TO KPMG IS ADMISSIBLE.

Plaintiffs seek to exclude Mr. Holder's opinion regarding the annual audit response letter ("Legal Letters") sent to KPMG by Pfizer's counsel (as required by the Generally Accepted Auditing Standards ("GAAS")) to assist KPMG in its evaluation of Pfizer's compliance. Mot. at 10. Specifically, Mr. Holder states that Plaintiffs' designated expert Paul Regan failed to consider the Legal Letters in rendering his opinion, and that these letters appear to contradict Mr. Regan's opinion that Pfizer did not consult with outside counsel in evaluating its loss

[9] December 10, 2014 Declaration of Ryan Llorens Ex. 2 (Expert Report of Dr. Sunil Panchal at 5, 7), ECF No. 387 (hereinafter "Panchal Rep.").

[10] Dec. 10, 2014 Llorens Decl. Ex. 2 (Panchal Rep. Ex. A at 19–20, 22 (curriculum vitae)).

[11] Dec. 10, 2014 Llorens Decl. Ex. 2 (Panchal Rep. Ex. A at 24).

[12] Dec. 22, 2014 MacDonald Decl. Ex. TT-4 (Panchal (Aug. 22, 2014) Dep. 83:9-88:6, 154:5–11).

[13] Dec. 10, 2014 Llorens Decl. Ex. 2 (Panchal Rep. 7-9).

[14] Dec. 22, 2014 MacDonald Decl. Ex. NN-4 (Avorn (Aug. 7, 2014) Dep. 21:4-5, 24:19-25:3).

contingencies.[15] Mr. Holder also interprets the letters, based on his experience and understanding of GAAS, as saying, *inter alia*, that Pfizer's outside counsel "concluded that a litigation loss contingencies related to Government Investigation was not 'probable.'"[16] Plaintiffs dispute Mr. Holder's reading of the letters, arguing that he did not "identify any additional factual support for his attenuated interpretation" of certain language in the documents. Mot. at 11. They further contend that he is "an accountant, not a lawyer," and that his analysis of the "legal assessments and opinions" in the letters is therefore not admissible. *Id.* at 12. Finally, they argue that Mr. Holder should not be able to testify as to what Pfizer's lawyer "was thinking" when he wrote the letter. *Id.*

Plaintiffs misunderstand both the bases for Mr. Holder's opinions and the function of Rule 702. As explained in Mr. Holder's report, GAAS "contain[s] a specific section related to Legal Letters" and provides for auditors "a standard on how to request and evaluate" those letters.[17] That these letters are written by lawyers is irrelevant to the ability of accountants to read and interpret them—indeed, they are written for, and to be used by, accountants. What matters here is how a reasonable accountant, relying on GAAS standards, would interpret the Legal Letters Mr. Regan failed to consider in rendering his opinions—not what Pfizer's lawyer "was thinking" when he drafted them or how non-accountants (like Plaintiffs' counsel) might construe them. Accordingly, Mr. Holder, an accountant well-versed in GAAS, is well within his area of expertise in reviewing and interpreting the Legal Letters that KPMG (an accounting firm) requested and relied on in auditing Pfizer. That Plaintiffs' counsel have a different view of the

[15] Dec. 10, 2014 Llorens Decl. Ex. 8 (Expert Report of William Holder ¶¶ 89–97) (hereinafter "Holder Rep.").

[16] Dec. 10, 2014 Llorens Decl. Ex. 8 (Holder Rep. ¶ 97).

[17] Dec. 10, 2014 Llorens Decl. Ex. 8 (Holder Rep. ¶ 89).

meaning of the language used in the Legal Letters is of no consequence in assessing the admissibility of Mr. Holder's opinions. The "lack of textual authority for [an expert's] opinion[ ] go[es] to the weight, not the admissibility, of his testimony." *Figueroa*, 254 F. Supp. 2d at 368 (internal quotation marks omitted). Plaintiffs will be able to question Mr. Holder on the "factual support" for his opinions when he testifies at trial, but these questions are irrelevant to the admissibility of his testimony.

IV. MR. TANSELLE'S OPINIONS REGARDING HEALTHCARE COMPLIANCE PROGRAMS ARE ADMISSIBLE.

Plaintiffs continue to misapply Rule 702 in attacking the opinion of Mr. Tanselle. As with Dr. Panchal, Plaintiffs criticize Mr. Tanselle for failing to "rely on academic research regarding the relative strengths and weaknesses of pharmaceutical companies' compliance programs." Mot. at 13. But as discussed, Rule 702 explicitly allows experts to base their opinions on their "experience." Fed. R. Evid. 702; *see also SR Int'l Bus. Ins. Co.*, 467 F.3d at 132–33. Mr. Tanselle currently serves as a Board Advisor for a large pharmaceutical company operating under a Corporate Integrity Agreement, advises a Chief Compliance Officer for another major pharmaceutical company on compliance initiatives, and has assisted numerous clients in the industry with developing healthcare compliance programs.[18] Here, Mr. Tanselle testified that his evaluation of Pfizer's healthcare compliance programs as "one of the most robust and sophisticated compliance programs in the industry" was based on his

> experience, which was a combination of seeing other compliance programs, what [he] understood about Pfizer's program through that time period, based on industry conferences that [he] would attend, and then in looking at the materials provided in this matter.[19]

[18] Dec. 10, 2014 Llorens Decl. Ex. 12 (Expert Report of Jack T. Tanselle ¶ 2 & App. 1 (curriculum vitae)) (hereinafter "Tanselle Rep.").

[19] Dec. 22, 2014 MacDonald Decl. Ex. VV-4 (Tanselle (Aug. 28, 2014) Dep. 58:16–59:7).

He further explained that his opinion is "based on both having reviewed the compliance programs of some of the companies—all the companies I've mentioned at some point or another, but the projects are all different; as well as discussions at industry conferences and other forums."[20] He also supports "multiple pharmaceutical and medical device companies" with the development and implementation of physician payment compliance programs and has worked with dozens of companies on compliance-related issues in his consulting role.[21] Mr. Tanselle's extensive experience in the area of healthcare compliance qualifies him to offer opinions as to the relative effectiveness of Pfizer's programs.

Plaintiffs complain that Mr. Tanselle "did not cite to a single academic research article, industry survey or other reliable data to support his opinion," was unable to supply certain information about other pharmaceutical companies, and was "factually inaccurate" in his assumption that Pfizer's first speaker cap was instituted in 2005, rather than 2006. Mot. at 15–16. These quibbles do not go to Mr. Tanselle's expert qualifications or the admissibility of his opinions, but rather to their weight. *See, e.g.*, *Reach Music Pub., Inc.*, 988 F. Supp. 2d at 404-05. If Plaintiffs wish to argue at trial that Mr. Tanselle's inability to recall the head of compliance at GlaxoSmithKline between 2006 and 2009, Mot. at 15, somehow lessens the weight the jury should give his opinions, they are free to do so.

V. THE OPINIONS OF PROFESSOR COATES RESPOND TO THOSE OFFERED BY PLAINTIFFS' EXPERTS AND ARE ADMISSIBLE.

Plaintiffs' final argument is that Professor Coates's opinions are inadmissible "legal conclusions" about the adequacy of Pfizer's securities disclosures. As is plain from his report, however, Professor Coates does ***not*** opine on whether Pfizer's legal proceeding disclosures

[20] Dec. 22, 2014 MacDonald Decl. Ex. VV-4 (Tanselle (Aug. 28, 2014) Dep. 61:10–15).

[21] Dec. 10, 2014 Llorens Decl. Ex. 12 (Tanselle Rep. App. 1).

complied with securities laws. Rather, Professor Coates relies on his extensive experience in corporate disclosures to offer the following opinions:

- Pfizer "used a well-designed process for producing litigation proceeding disclosures" and it "followed [that] process in producing" the disclosures at issue in this case;[22]

- Neither Plaintiffs nor Plaintiffs' experts Messrs. Buthusiem or Regan identified any material misstatement in or omission from the disclosures at issue in this case;[23] and

- Plaintiffs' experts materially misstate the customs and practices of disclosure processes and materially misstate the record, disclosures of government investigations in other cases, and offer mistaken legal opinions.[24]

None of these opinions constitute "legal conclusions" regarding the adequacy of Pfizer's disclosures. Moreover, nearly all of these opinions are directly responsive to the opinions offered by ***Plaintiffs'*** experts. Indeed, as Professor Coates explained during his deposition in an exchange mentioned, but not quoted, by Plaintiffs, Mot. at 18:

> Q. Mr. Coates, are you offering an opinion on whether Pfizer's disclosure of the off-label marketing investigation in its SEC filings complied with the securities laws?
>
> A. Well, that sounds like a legal opinion which I don't consider myself offering. The only qualification to that is that I have been asked to rebut opinions by your experts, Mr. Buthusiem and Mr. Regan. And I think fairly understood, some of their opinions are about the adequacy of the disclosures, and to that extent I'm going to offer rebuttal opinion, if that's permitted. But I'm—I didn't in the first instance imagine I was going to be asked to give a legal opinion.
>
> Q. So other than your rebuttal of plaintiffs' experts, you are not offering an opinion on the adequacy of Pfizer's disclosure of its off-label marketing investigation; correct?

[22] Dec. 10, 2014 Llorens Decl. Ex. 18 (Expert Report of John C. Coates, IV ¶ 2) (hereinafter "Coates Rep.").

[23] Dec. 10, 2014 Llorens Decl. Ex. 18 (Coates Rep. ¶ 2).

[24] Dec. 10, 2014 Llorens Decl. Ex. 18 (Coates Rep. ¶ 2).

> [Form objection]
>
> A. In general terms I think that's right. If what you mean is I'm asking—I'm being asked a legal opinion about it, no, I don't think that's what I was understood to be doing.
>
> Q. And you're not offering an opinion on whether or not Pfizer's off-label marketing investigation disclosure violated Rule 10(b)(5), are you?
>
> A. Again, except insofar as it is implicit in rebuttal testimony that I would offer to Mr. Buthusiem, I'm not expecting to give an opinion about compliance with Rule 10(b)(5), no.[25]

By way of comparison, ***Plaintiffs'*** expert Mr. Buthusiem devoted half of his report to the "evaluation" Pfizer's disclosures in this case, assessing the disclosures against the requirements of Rule 10b-5 and other regulations and concluding that "Pfizer's legal proceedings disclosures during the Class Period contained material misstatements and omissions regarding the content and the magnitude of the DOJ investigation into Pfizer's off-label promotion."[26] For his part, ***Plaintiffs'*** expert Mr. Regan similarly opined that Pfizer "failed to properly . . . disclose the contingent losses" associated with the government's investigation of Bextra under GAAP.[27] In other words, ***Mr. Buthusiem and Mr. Regan***, not Professor Coates, are the ones who impermissibly attempt to offer legal conclusions regarding the adequacy of Pfizer's disclosures. If any of Professor Coates' opinions are inadmissible, so too are those of Plaintiffs' experts to whom Professor Coates responds.

CONCLUSION

For the above reasons, Plaintiffs' motion to exclude certain testimony of Dr. Panchal and Messrs. Holder and Tanselle, and Prof. Coates should be denied.

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[25] Dec. 22, 2014 MacDonald Decl. Ex. QQ-4 (Coates (Oct. 3, 2014) Dep. 28:6–29:12).

[26] November 27, 2014 Declaration of Henry Rosen Ex. 3 (Expert Report of Edward J. Buthusiem ¶ 47), ECF No. 305.

[27] Dec. 10, 2014 MacDonald Decl. Ex. WW-2 (Expert Report of D. Paul Regan 11–51).

Date: Washington, D.C.
December 22, 2014

Respectfully submitted,

WILLIAMS & CONNOLLY LLP

By: /s/ Joseph G. Petrosinelli

Joseph G. Petrosinelli (admitted *pro hac vice*)
Steven M. Farina (admitted *pro hac vice*)
George A. Borden
Amanda M. MacDonald (admitted *pro hac vice*)
725 Twelfth Street, N.W.
Washington, D.C. 20005
Telephone: (202) 434-5000
Facsimile: (202) 434-5029
sfarina@wc.com
jpetrosinelli@wc.com
gborden@wc.com
amacdonald@wc.com

Counsel for Defendant Pfizer Inc.

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP

By: /s/ Scott D. Musoff

Scott D. Musoff
Four Times Square
New York, New York 10036
Telephone: (212) 735-3000
Facsimile: (212) 735-2000
scott.musoff@skadden.com

Jennifer L. Spaziano (*pro hac vice* pending)
Michael S. Bailey (*pro hac vice* pending)
1440 New York Avenue NW
Washington, DC 20005
Telephone: (202) 371-7000
Facsimile: (202) 393-5760
Email: Jen.Spaziano@skadden.com
Email: Michael.Bailey@skadden.com

Counsel for Henry A. McKinnell

DAVIS POLK & WARDWELL LLP

By: /s/ James P. Rouhandeh
James P. Rouhandeh
Charles S. Duggan
450 Lexington Avenue
New York, New York 10017
Telephone: (212) 450-4000
james.rouhandeh@davispolk.com
charles.duggan@davispolk.com

Counsel for Defendant Jeffrey B. Kindler

GOODWIN PROCTER LLP

By: /s/ Richard M. Strassberg
Richard M. Strassberg
Daniel Roeser
The New York Times Building
620 Eighth Avenue
New York, NY 10018
Tel.: 212.813.8800
Fax: 212.355.3333
rstrassberg@goodwinprocter.com
droeser@goodwinprocter.com

Counsel for Defendant Frank D'Amelio

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP

By: /s/ Jay B. Kasner
Jay B. Kasner
Gary J. Hacker
Alexander C. Drylewski
Four Times Square

New York, New York 10036
Telephone: (212) 735-3000
Facsimile: (212) 735-2000
jay.kasner@skadden.com
gary.hacker@skadden.com
alexander.drylewski@skadden.com

Counsel for Defendant Alan G. Levin

QUINN EMANUEL URQUHART & SULLIVAN, LLP

By: /s/ Michael B. Carlinsky
Michael B. Carlinsky
Sheila Birnbaum
Brant Duncan Kuehn (*pro hac vice* pending)
51 Madison Avenue
New York, New York 10010
(212) 849-7000

Lori Alvino McGill
777 6th Street, NW
Washington, DC 20001
(202) 538-8000

Counsel for Defendant Ian C. Read

O'MELVENY & MYERS LLP

By: /s/ Ross B. Galin
Ross B. Galin
Stuart Sarnoff
Howard E. Heiss
7 Times Square
New York, New York 10036
Telephone: (212) 326-2000
Facsimile: (212) 326-2061
rgalin@omm.com
ssarnoff@omm.com
hheiss@omm.com

Counsel for Defendant Allen Waxman

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 To Exclude Certain Testimony of Defendants' Experts Sunil Panchal, William W. Holder, Jack T. Tanselle, and John C. Coates IV was filed with the Court through the CM/ECF system and thereby served to all parties of record.

/s/ Lauren K. Collogan

Lauren K. Collogan
Williams & Connolly LLP
725 Twelfth Street, N.W.
Washington, D.C. 20005
Telephone: (202) 434-5000
Facsimile: (202) 434-5029
lcollogan@wc.com

Regan Karstrand

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Alexander C Drylewski alexander.drylewski@skadden.com

Amanda M. MacDonald amacdonald@wc.com

Brant Duncan Kuehn brantkuehn@quinnemanuel.com

Charles S. Duggan charles.duggan@dpw.com, ecf.ct.papers@davispolk.com

Cynthia Margaret Monaco cmonaco@cynthiamonacolaw.com, cmmonaco@gmail.com

Daniel Prugh Roeser droeser@goodwinprocter.com

Danielle Suzanne Myers dmyers@rgrdlaw.com

Darren J. Robbins e_file_sd@rgrdlaw.com

David Avi Rosenfeld drosenfeld@rgrdlaw.com, e_file_ny@rgrdlaw.com, e_file_sd@rgrdlaw.com

Donald Alan Migliori dmigliori@motleyrice.com

Eugene Mikolajczyk genem@rgrdlaw.com

Gary John Hacker ghacker@skadden.com

George Anthony Borden gborden@wc.com

Hamilton Philip Lindley hlindley@deanslyons.com, mgoens@deanslyons.com

Henry Rosen henryr@rgrdlaw.com, dianah@rgrdlaw.com

Howard E. Heiss hheiss@omm.com, #nymanagingattorney@omm.com

Ivy T. Ngo ingo@rgrdlaw.com, e_file_sd@rgrdlaw.com

James M. Hughes jhughes@motleyrice.com, erichards@motleyrice.com, kweil@motleyrice.com, kweil@pacernotice.com, mgruetzmacher@motleyrice.com

James P. Rouhandeh james.rouhandeh@dpw.com, ecf.ct.papers@davispolk.com

James R. Harper coljamesrharper@me.com

Jason A. Forge jforge@rgrdlaw.com, e_file_SD@rgrdlaw.com, tholindrake@rgrdlaw.com

Jay B. Kasner jkasner@skadden.com

Jennifer Lynn Spaziano jen.spaziano@skadden.com

Joe Kendall administrator@kendalllawgroup.com, hlindley@kendalllawgroup.com, jkendall@kendalllawgroup.com

John K. Villa jvilla@wc.com

Joseph F. Rice jrice@motleyrice.com

Joseph G. Petrosinelli jpetrosinelli@wc.com

Juliana Newcomb Murray juliana.murray@davispolk.com, ecf.ct.papers@davispolk.com, lisa.hirakawa@davispolk.com

Keir Nicholas Dougall kdougall@dougallpc.com

Kevin Anthony Burke kaburke@sidley.com, efilingnotice@sidley.com, nyefiling@sidley.com

Lauren Kristina Collogan lcollogan@wc.com

Leigh R. Lasky lasky@laskyrifkind.com

Lori McGill lorialvinomcgill@quinnemanuel.com

Matthew Melamed mmelamed@rgrdlaw.com

Michael Barry Carlinsky michaelcarlinsky@quinnemanuel.com, brantkuehn@quinnemanuel.com, jomairecrawford@quinnemanuel.com

Michael Joseph Dowd miked@rgrdlaw.com, e_file_sd@rgrdlaw.com, e_file_sf@rgrdlaw.com, tome@rgrdlaw.com

Michael Scott Bailey michael.bailey@skadden.com

Mitchell M.Z. Twersky mtwersky@aftlaw.com

Paul T. Hourihan phourihan@wc.com

Richard Mark Strassberg rstrassberg@goodwinprocter.com, nymanagingclerk@goodwinprocter.com

Ross Bradley Galin rgalin@omm.com, lisachen@omm.com, mochoa@omm.com, neverhart@omm.com

Ryan A. Llorens ryanl@rgrdlaw.com, kirstenb@rgrdlaw.com, nbear@rgrdlaw.com

Samuel Howard Rudman srudman@rgrdlaw.com, e_file_ny@rgrdlaw.com, e_file_sd@rgrdlaw.com, mblasy@rgrdlaw.com

Scott D. Musoff smusoff@skadden.com

Seema Mittal smittal@wc.com

Sheila L. Birnbaum sheilabirnbaum@quinnemanuel.com

Sidney Bashago sidney.bashago@dpw.com, ecf.ct.papers@davispolk.com, jennifer.kan@davispolk.com

Steven M.. Farina sfarina@wc.com

Stuart Michael Sarnoff ssarnoff@omm.com

Trig Randall Smith trigs@rgrdlaw.com, e_file_sd@rgrdlaw.com, nhorstman@rgrdlaw.com

William E. Schurmann wschurmann@wc.com

William H. Narwold bnarwold@motleyrice.com, ajanelle@motleyrice.com, vlepine@motleyrice.com

Willow E. Radcliffe willowr@rgrdlaw.com, ptiffith@rgrdlaw.com

1:10-cv-03864-AKH Notice has been delivered by other means to:

Catherine J. Kowalewski
Robbins Geller Rudman & Dowd LLP (San Diego)
655 West Broadway
Suite 1900
San Diego, CA 92101

Daniel E. Hill
Kendall Law Group, LLP
3232 McKinney Avenue
Suite 700
Dallas, TX 75204

David C. Walton
Robbins Geller Rudman & Dowd LLP (SANDIEGO)
655 West Broadway
Suite 1900
San Diego, CA 92101

Jamie J. McKey
Kendall Law Group, LLP
3232 McKinney Avenue
Suite 700
Dallas, TX 75204

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