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

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANTS' MOTION *IN LIMINE* NO. 13 TO EXCLUDE THE OPINIONS OF D. PAUL REGAN

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Defendants respectfully submit this reply memorandum of law in further support of their motion to exclude the opinions of D. Paul Regan pursuant to Federal Rule of Evidence 702.

PRELIMINARY STATEMENT

Plaintiffs' Opposition[1] confirms that Plaintiffs do not and cannot carry their burden of establishing that Mr. Regan's opinions are relevant and reliable under Rule 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Plaintiffs try to mask their failure with bluster but, once the rhetoric is stripped away, their arguments all lead to one conclusion: This Court should exclude the opinions of Mr. Regan.

First, this Court should exclude Mr. Regan's opinions that Pfizer did not properly account for, or disclose, a contingent loss associated with the Government Investigations for the following separate and independent reasons:[2]

- Plaintiffs do not dispute that they must first demonstrate that Mr. Regan has the necessary experience and expertise to qualify as an expert in establishing and evaluating a pharmaceutical company's contingent liabilities under FAS 5 for a government investigation into alleged off-label marketing. Mr. Regan himself

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[1] Unless otherwise noted, capitalized terms have the same meanings as in the Memorandum of Law in Support of Defendants' Motion to Exclude the Opinions of D. Paul Regan ("Br."). "Opposition" or "Opp." refers to Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion *in Limine* No. 13 to Exclude the Opinions of D. Paul Regan.

[2] Plaintiffs assert that "defendants are silent concerning Mr. Regan's opinion of the adequacy of Pfizer's legal proceedings disclosures under FAS 5, ¶10" and, therefore, "concede that opinion is admissible at trial." (Opp. at 2.) That is demonstrably incorrect. Defendants expressly argued that this Court should exclude Mr. Regan's opinion concerning the adequacy of Pfizer's legal proceedings disclosures under FAS 5:

> Mr. Regan opines that "Pfizer failed to accrue for the contingent loss associated with the Government's Off-Label Promotion Investigation [*i.e.*, the Government Investigations] as of December 31, 2005 and continuing thereafter through the Class Period" and that "Pfizer failed to provide adequate disclosure associated with the Government's Off-Label Promotion Investigation as of December 31, 2005 and continuing thereafter." Mr. Regan bases his opinions on an analysis of Pfizer's reserve and disclosures under Statement of Financial Accounting Standards No. 5, Accounting for Contingencies ("FAS 5"). Mr. Regan's opinions should be excluded under Rule 702 and *Daubert* . . .

(Br. at 3 (citations omitted); *see also id.* at 4-6.) Defendants have not conceded anything.

admits that he has never established or audited a loss contingency reserve for a pharmaceutical (or other) company and has less experience in the relevant subject matter than Pfizer's management and independent auditor whom he now criticizes more than five years after the fact. Plaintiffs present no evidence to the contrary.

- Plaintiffs do not dispute that they must also establish that Mr. Regan has applied a methodology that is generally accepted in the field. If Mr. Regan's "recipe"[3] were generally accepted, then pharmaceutical companies would have accurately established reserves or disclosed ranges of possible loss before resolving government investigations – and Pfizer would have been an outlier in failing to do so. In fact, exactly the opposite is true.

- Plaintiffs do not dispute that they must further establish that Mr. Regan uses the same level of intellectual rigor as Pfizer's management and independent auditor. Plaintiffs do not challenge Mr. Regan's testimony that one "very important" component of his "recipe" is the extent to which off-label marketing actually resulted in sales revenue, and Mr. Regan's own concessions make clear that his methodology and the data are wholly inadequate to answer that question.

Second, this Court should exclude Mr. Regan's opinions that certain control deficiencies at Pfizer constituted a material weakness in internal controls over financial reporting from September 2006 through September 2007. Although Plaintiffs have abandoned any claims alleging a false or misleading statement about a material weakness in Pfizer's internal controls, they seek to offer Mr. Regan's expert testimony on the subject. That testimony should be excluded for the following separate and independent reasons:

- Mr. Regan's opinions concerning Pfizer's internal controls are irrelevant. He admits that Pfizer never disclosed a material weakness in internal controls from September 2006 through September 2007 (or at any other time during the Class Period). As a result, Plaintiffs may not recover on any allegedly false or misleading statement concerning internal controls, and Mr. Regan's opinions are irrelevant and inadmissible.

- Mr. Regan lacks the requisite experience and expertise to evaluate whether the collective judgments of Pfizer's management and independent auditor were erroneous. He admits that he has never audited a company's internal controls

[3] Plaintiffs accuse Defendants of "mischaracterizing" the actual gain model as Mr. Regan's "recipe." Yet Mr. Regan repeatedly accepted and used that term during his deposition. *See* January 2, 2015 Declaration of Amanda M. MacDonald in Support of Replies in Support of Defendants' Motions *in Limine* ("Jan. 2, 2015 MacDonald Decl.") Ex. GG-5 (Regan Dep. 46:12, 88:9, 89:22-23, 90:21-25, 91:9-10, 108:9-22, 109:4-11, 169:18-19.)

over financial reporting under the applicable standard (or, in fact, under any standard) and has less experience in the relevant subject matter than Pfizer's management and independent auditor with whom he disagrees.

For all of these reasons and those below, this Court should exclude the opinions of Mr. Regan.

ARGUMENT

I. THIS COURT SHOULD EXCLUDE MR. REGAN'S OPINIONS THAT PFIZER DID NOT PROPERLY ACCOUNT FOR, OR DISCLOSE, A CONTINGENT LOSS ASSOCIATED WITH THE GOVERNMENT INVESTIGATIONS.

A. Mr. Regan Lacks the Requisite Experience and Expertise.

Plaintiffs do not dispute that, for Mr. Regan's opinions to be admissible, they must first demonstrate that he has the necessary experience and expertise to qualify as an expert in establishing and evaluating a pharmaceutical company's contingent liabilities under FAS 5 for a government investigation into alleged off-label marketing. (Br. at 4.) Unable to carry their burden, Plaintiffs mislead both by overstating the qualifications of Mr. Regan and understating the experience of Pfizer's independent auditor.

First, Plaintiffs take issue with the facts that (1) Mr. Regan has ***never*** been involved in establishing a loss contingency reserve for a pharmaceutical (or other) company and (2) Mr. Regan has ***never*** audited or contemporaneously evaluated a loss contingency reserve for a pharmaceutical (or other) company, including Pfizer's loss contingency reserve in this case. (Opp. at 4.) Yet those are Mr. Regan's own admissions, and Plaintiffs' statements to the contrary are refuted by Mr. Regan himself. Specifically:

- Plaintiffs assert: "Mr. Regan has participated in establishing FAS 5 loss reserves for numerous companies, both public and private." (Opp. at 4.) Mr. Regan testified: "[Q.] Have you ever been involved in calculating the loss contingency reserves for a pharmaceutical company, in other words, actually helping to establish the reserve in the first instance? A. Not in the first instance. The work that I've done has all been subsequent to the establishment of the reserves and

working with the company and/or counsel in connection with legal disputes that arose as a result of an argument of whether those reserves were adequate."[4]

- Plaintiffs assert: "Mr. Regan testified that he had experience analyzing and auditing loss contingency reserves of pharmaceutical companies, including in support of a PCAOB investigation." (Opp. at 5.) Mr. Regan testified: "Q. Sir, do you have any experience auditing the loss contingency reserves of a pharmaceutical company? A. I don't believe so, as an audit in accordance with Generally Accepted Auditing Standards. My work in that area is only in connection with my reviewing and analyzing those reserves in connection with either litigation or what might become litigation."[5]

As Mr. Regan's own testimony makes clear, he lacks the requisite experience and expertise to qualify as an expert in establishing and evaluating a pharmaceutical company's contingent liabilities under FAS 5 for a government investigation into alleged off-label marketing.[6]

Second, Plaintiffs take issue with the fact that the auditors leading KPMG had more experience auditing large public companies, and particularly pharmaceutical companies, than Mr. Regan has. (Opp. at 6.) According to Plaintiffs, Mr. Regan's experience "is equally as compelling as the backgrounds of Messrs. Chapman, Bradley and Riso." (*Id.*) Once again, however, Plaintiffs' claims are refuted by Mr. Regan himself. Specifically:

- With respect to John Chapman – the lead signing partner on the 2006 and 2007 audits and global chairman of KPMG's pharmaceutical practice prior to his transition onto the Pfizer engagement – Mr. Regan testified: "Q. And would you

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4 Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 16:7-15.)

5 Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 12:23-13:4.)

6 Plaintiffs contend that Mr. Regan "has audited and/or evaluated loss reserves for numerous companies, including in support of the PCAOB, in the context of litigation and/or under circumstances that may ripen into legal disputes" and that "the expert services Mr. Regan provided to the PCAOB included the auditing and analysis of a pharmaceutical company's loss reserves related to Medicare and Medicaid." (Opp. at 5.) Mr. Regan has not audited loss contingency reserves for any company (*see supra* at 3) and conceded that "[t]he work that I've done has all been subsequent to the establishment of the reserves and working with the company and/or counsel in connection with legal disputes that arose as a result of an argument of whether those reserves were adequate." Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 16:11-15; *see also id.* 13:1-4, 13:8-13.) As Defendants have explained, such work does not give Mr. Regan the necessary experience or expertise to second-guess the judgments of Pfizer management and its independent auditor in the field. (Br. at 6 n.19.) Moreover, Mr. Regan's work for the PCAOB involved a pharmaceutical company's revenue recognition and return reserve – not a loss contingency reserve. Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 13:11-14:16.)

agree with me that John Chapman of KPMG has more experience than you do auditing pharmaceutical companies? . . . THE WITNESS: I would have that expectation, yes."[7]

- With respect to Larry Bradley – the lead signing partner on the 2008 audit, the engagement signing partner for several publicly traded companies, and an SEC reviewing partner for more than 30 publicly traded companies, Mr. Regan testified: "Q. Do you believe that Mr. Bradley has more experience than you do auditing pharmaceutical companies? A. Yes."[8]

- With respect to Eric Riso – the second partner on the 2006, 2007, and 2008 audits – Mr. Regan testified: "Q. And same question: You would agree that Mr. Riso has more experience than you do auditing pharmaceutical companies? . . . THE WITNESS: Yes."[9]

As Mr. Regan's own admissions establish, he lacks the experience that Pfizer's independent auditors, whom he now criticizes, have.[10]

Plaintiffs have not established that Mr. Regan has the requisite experience and expertise to render reliable opinions on the collective judgments of Pfizer management and KPMG concerning whether and when to reserve for, or disclose, a contingent loss associated with the Government Investigations. Therefore, this Court should exclude Mr. Regan's opinions.

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7 Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 16:25-17:5.)

8 Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 17:21-23.)

9 Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 19:4-8.)

10 Plaintiffs also take issue with the fact that – unlike Mr. Regan – KPMG actually performed an audit of Pfizer's loss contingency reserves and disclosures, including its reserves and disclosures specifically associated with off-label marketing. (Opp. at 6 n.3.) Plaintiffs assert that "Defendants mislead this Court" in pointing out this fact (*id.*), but Mr. Regan testified: (1) "[KPMG] audited the financial statements of Pfizer with the objective of rendering an opinion on the financial statements taken as a whole"; (2) the reserves are a component of the financial statements; and (3) "[a]s part of that audit, [KPMG] performed certain procedures . . . including gaining an understanding of the process that Pfizer used to determine its reserves" by "ma[king] inquiries about the state of the investigation and the judgments of Pfizer, as to whether it was probable and reasonably estimable" and by "sen[ding] the standard attorneys' letters that went out to attorneys, including attorneys that were working on this investigation." Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 76:14-77:19.) And Plaintiffs do not dispute that (1) every KPMG witness has testified that Pfizer was not required to take a reserve or disclose a range of possible loss before reaching an agreement in principle with the government or (2) KPMG stands by its judgment to this day. (*See* Opp. at 7 n.4.) Defendants did not mislead this Court about anything.

B. Mr. Regan Applies a Methodology That Is Not Generally Accepted.

Plaintiffs do not dispute that, for Mr. Regan's opinion to be admissible, they must also establish that he has applied a methodology that is generally accepted in the field and that "a known technique which has been able to attract only minimal support within the community may properly be viewed with skepticism." *Daubert*, 509 U.S. at 594 (citation and internal quotation marks omitted). (*See also* Br. at 2-3.) Try as they might, Plaintiffs cannot legitimize Mr. Regan's "recipe."

First, Plaintiffs argue that Mr. Regan's "actual gain" methodology is "well-accepted" because it was used by the Boston U.S. Attorney's Office "to estimate damages" in several investigations. (Opp. at 7-8.) As an initial matter, Plaintiffs offer no support for their claim that Mr. Regan's "recipe" was used by the Boston U.S. Attorney's office; do not even suggest that Mr. Regan had any involvement with the Boston U.S. Attorney's office; and have no answer to the undisputed fact that the Boston U.S. Attorney's office sought damages wholly unconnected to any alleged "recipe." Moreover, Plaintiffs' argument is a *non sequitur* on multiple levels. Mr. Regan purports to opine on whether and when Pfizer should have reserved for, and provided disclosures concerning, the Government Investigations in accordance with FAS 5.[11] Plaintiffs must show that Mr. Regan has applied a methodology that has been used to make such reserve and disclosure decisions, not a methodology that has been used to estimate damages in a litigation; and Plaintiffs must also show that Mr. Regan's methodology is generally accepted in the accounting field, not just by a U.S. Attorney's Office in several of its litigation matters. In any event, Mr. Regan's methodology is not generally accepted even by U.S. Attorney's Offices. For example, Plaintiffs do not claim that U.S. Attorney's Offices – ***including the Boston U.S.***

[11] December 10, 2014 Declaration of Amanda M. MacDonald in Support of Defendants' Motions *in Limine* ("Dec. 10, 2014 MacDonald Declaration") Ex. WW-2 (Regan Report at 11-56.)

Attorney's Office – used that methodology in their investigations of Eli Lilly, Allergan, Elan, Merck, and Amgen. (*See* Br. at 8-11.)

Second, Plaintiffs concede that "a series of other public companies . . . reserved for off-label investigations at or around the time each company announced it had settled with the government, just like Pfizer did" (Opp. at 8; *see also* Br. at 8-11), but seek to distinguish them all by arguing that "[t]here is absolutely nothing in the record evidencing the facts and circumstances of Eli Lilly, Allergan, Elan, Merck, Abbott Labs and Amgen's accounting judgments and why they reserved when they did" (Opp. at 9). Plaintiffs simply ignore the fact that, although ***Mr. Regan could not identify any information that any of these companies lacked in order to use his five-part "recipe" to estimate a settlement***, their judgments were all similar to Pfizer's concerning whether and when to establish a loss contingency reserve or disclose a range of possible loss.[12] And Plaintiffs do not even attempt to explain Mr. Regan's remarkable admission that ***he did not consider any of this conflicting evidence***.[13]

Third, Plaintiffs concede that Mr. Regan has identified ***no*** "peer companies" that used his "recipe." Plaintiffs offer no evidence that the actual gain methodology was used by

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[12] Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 72:24-73:24, 86:15-88:9, 152:11-156:13) and Dec. 10, 2014 MacDonald Declaration Ex. OO-3 (Ex. 2268), Dec. 10, 2014 MacDonald Declaration Ex. RR-1 (Ex 2269), Dec. 10, 2014 MacDonald Declaration Ex. VV-3 (Ex 2280) (Eli Lilly); Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 115:10-124:10, 162:5-164:12) and Dec. 10, 2014 MacDonald Declaration Ex. QQ-3 (Ex. 2271), Dec. 10, 2014 MacDonald Declaration Ex. EE-1 (Ex. 2272), Dec. 10, 2014 MacDonald Declaration Ex. XX-3 (Ex. 2282) (Allergan); Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 39:11-20, 44:20-50:14, 157:5-158:15) and Dec. 10, 2014 MacDonald Declaration Ex. LL-3 (Ex. 2263), Dec. 10, 2014 MacDonald Declaration Ex. SS-1 (Ex. 2264), Dec. 10, 2014 MacDonald Declaration Ex. WW-3 (Ex. 2281) (Elan); Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 132:9-134:25) and Dec. 10, 2014 MacDonald Declaration Ex. UU-3 (Ex. 2278), Dec. 10, 2014 MacDonald Declaration Ex. JJ-1 (Ex. 2279) (Merck); Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 168:11-173:6) and Dec. 10, 2014 MacDonald Declaration Ex. YY-3 (Ex. 2283), Dec. 10, 2014 MacDonald Declaration Ex. CC-1 (Ex. 2284) (Abbott); Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 54:16-55:2, 60:11-63:10, 158:18-162:4) and Dec. 10, 2014 MacDonald Declaration Ex. MM-3 (Ex. 2265), Dec. 10, 2014 MacDonald Declaration Ex. TT-1 (Ex. 2266), Dec. 10, 2014 MacDonald Declaration Ex. NN-3 (Ex. 2267) (Amgen).)

[13] Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 63:18-64:10 (Eli Lilly), 94:25-95:2 (Allergan), 50:15-50:18 (Elan), 130:6-14 (Merck), 53:11-13 (Amgen).)

GlaxoSmithKline and Schering-Plough, the only two "peer companies" cited by Mr. Regan, in estimating a reserve and instead misdirect this Court by trying to shift the burden to Defendants to prove a negative (*i.e.*, "that the actual gain methodology was not used"). (Opp. at 11.) Plaintiffs next contend that "Mr. Regan did not identify GlaxoSmithKline ("Glaxo") and Schering Plough ("Schering") to support an argument about how a reserve is to be calculated, rather he identified these companies merely to support his argument that Pfizer should have booked a reserve much earlier than it did." (*Id.*) Plaintiffs' contention makes no sense. If Mr. Regan cannot show that GlaxoSmithKline and Schering-Plough followed his recipe, those companies do not "support his argument." Finally, Plaintiffs criticize "Defendants' descriptions of the timing of the Glaxo and Schering reserves" (*id.*), but that criticism proves Defendants' point. According to Plaintiffs, GlaxoSmithKline "established an initial reserve in 4Q08" (almost five years into an ongoing government investigation) and then "added a few billion dollars to the reserve in 4Q10"; likewise, "Schering established an initial reserve in 4Q02" (almost two years into an ongoing government investigation) but then "virtually fully reserved for the government investigation by 3Q03." (*Id.* at 11-12.) That the "peer companies" held up as examples by Mr. Regan established their loss contingency reserves only after years of government investigation and, even then, were wrong by hundreds of millions (or billions) of dollars confirms that Mr. Regan's "recipe" does not work.

Fourth, Plaintiffs dispute Mr. Regan's admission that the SEC has refused to follow his "recipe" and instead accepted the judgment of companies (Eli Lilly and Allergan) that did not take a loss contingency reserve for government investigations into sales and marketing practices before reaching an agreement in principle ***for the very reasons that Pfizer chose not to do so***. (Opp. at 7 n.5.) Plaintiffs claim that "Defendants cite to nothing in the record to support that

baseless assertion" (*id.*), but there is no "baseless assertion" here: Defendants cited to (1) the SEC's inquiries into the timing of the Eli Lilly and Allergan reserves, (2) the explanations from those companies that tracked Pfizer's reasoning, (3) the SEC's decision not to take further action, and (4) Mr. Regan's testimony that Pfizer followed the same practice for the same reasons. (Br. at 13-14.) As a fallback, Plaintiffs argue that "defendants have provided no legal authority supporting an argument that the SEC must bless a reserve estimation methodology before it may be utilized by an accounting expert in a securities fraud case." (Opp. at 7 n.5.) Plaintiffs' argument smacks of hypocrisy where Plaintiffs' primary support (such as it is) for Mr. Regan's "recipe" is its alleged use by the government (specifically, the Boston U.S. Attorney's Office) to estimate damages in several investigations. (*See supra* at 6.)

Plaintiffs have not established that Mr. Regan's methodology is generally accepted in the field by pharmaceutical companies, Big Four accounting firms, or the government (either the SEC or U.S. Attorney's Offices). Accordingly, this Court should exclude Mr. Regan's opinions.

C. Mr. Regan Offers Opinions That Lack the Necessary Intellectual Rigor.

Plaintiffs do not dispute that, for Mr. Regan's opinions to be admissible, they must further establish that he uses the same level of intellectual rigor as Pfizer's management and independent auditor. (Br. at 14-15.) Nor do they dispute Mr. Regan's testimony that "one component of the recipe that's very important" to establish a loss contingency reserve or disclose a range of possible loss is: "To what extent did the off-label marketing behavior actually result in revenue to the company?"[14] Since Mr. Regan's own concessions make clear that his methodology and the data are wholly inadequate to answer that question, Plaintiffs obfuscate.

First, although Mr. Regan concedes that "[t]he recipe doesn't work" if there is a dispute about the extent to which off-label marketing resulted in sales revenue, Plaintiffs claim that

[14] Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 109:8-11; *see also id.* 106:9-13.)

"defendants have cherry-picked a sound-bite regarding the methodology and omit necessary contextual testimony." (Opp. at 12.) Not so. Mr. Regan testified as follows:

> Q. So if it's a matter of dispute between the Government and the company as to the extent to which any off-label promotion actually caused physicians to prescribe medications for off-label uses, then the recipe isn't applicable?
>
> [Objection.]
>
> THE WITNESS: ***The recipe doesn't work in – in that circumstance***. There may be other reasons why the recipe doesn't work for purposes of this company based upon its totality of the mix of things, which it needs to consider. But that's an example of – of one component of the recipe that's very important, which is: To what extent did the off-label marketing behavior actually result in revenue to the company?
>
> Q. BY MR. FARINA: Sir, ***do you not understand that that was one of the critical areas of dispute in the Pfizer/Bextra investigation? The company contested the extent to which off-label promotion caused off-label use by physicians. Do you not understand that that was an item in dispute?***
>
> [Objection.]
>
> THE WITNESS: ***I know that that was -- that that percentage was negotiated and discussed and disputed between Pfizer and the Government.*** The Government had a -- initially had a much higher percentage than what was eventually included in the settlement. ***The settlement was 37 percent. And it started at a higher level. And I believe Pfizer had a much lower level.***[15]

Plaintiffs rely on Mr. Regan's "clarification" that, if a company concludes that there are no revenues generated as a result of the off-label activity, the calculation of the loss would be zero. (Opp. at 12.) That non-responsive testimony merely states the obvious: no revenues from off-label marketing results in no losses. Unlike Mr. Regan's answers above, it does not speak to what happens when the amount of revenues is in dispute.

[15] Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 108:23-110:2.)

Second, Plaintiffs do not dispute Mr. Regan's concession that the data required to determine the sales revenue or profit from Pfizer's alleged off-label marketing do not exist. (Br. at 16-17.) Nor could they. Mr. Regan admits that (1) physicians are permitted to, and do, prescribe medications for off-label uses; (2) no publicly available data record the reasons that a particular doctor prescribed a particular drug to a particular patient (*e.g.*, as a result of off-label marketing or otherwise); and (3) therefore, there are no data on the revenue or profit caused by off-label marketing. (*Id.*) Since there are no data to support this component of Mr. Regan's "recipe," this Court should exclude his opinions.

To distract the Court from this straightforward result, Plaintiffs instead dispute that Mr. Regan's estimate of profits from off-label marketing relies entirely on government presentations to Pfizer. (Opp. at 14-15.) Plaintiffs once again ignore Mr. Regan's testimony. He was asked directly by Defendants' counsel how he made a reasonable estimate of the amount of revenue that Pfizer generated from off-label marketing, and the ***only*** source that he identified as the basis of that estimate was government presentations to Pfizer.[16] In Mr. Regan's words:

> In this instance, what we've got is, you know, looking at the Government's PowerPoints that were made in August of 2006 and again in September of 2006, you've got the Government that has analyzed and determined that of approximately $2.4 billion of Bextra revenue, there's 1,257,000,000 of 20 milligram dosages.
>
> And there is – my understanding is that there is some on-label use of 20-milligram dosages, but that that should be a small number, not 52 percent of the total sales. And so the Government appeared to take the position that that's a strong indication that a substantial amount of revenue was at a dosage which exceeded the on-label dosage for the indication that it was used.[17]

Moreover, Plaintiffs do not and cannot dispute that (1) Mr. Regan concedes that those government presentations did not adjust for off-label uses unrelated to any alleged off-label

[16] Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 140:24-146:20.)
[17] Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 141:10-23.)

marketing, and (2) Mr. Regan identifies no information from which one can differentiate between off-label uses caused by off-label marketing and all other off-label uses (or even between off-label and on-label uses for the drugs at issue here). (Br. at 17.)

Plaintiffs have not established that Mr. Regan applies the intellectual rigor required under Rule 702 and *Daubert*. Consequently, this Court should exclude his opinions.

II. THIS COURT SHOULD EXCLUDE MR. REGAN'S OPINIONS THAT CERTAIN CONTROL DEFICIENCIES AT PFIZER CONSTITUTED A MATERIAL WEAKNESS IN INTERNAL CONTROLS OVER FINANCIAL REPORTING FROM SEPTEMBER 2006 THROUGH SEPTEMBER 2007.

Mr. Regan opines that "Pfizer's internal control over financial reporting was ineffective due to a material weakness in its Healthcare Compliance process from September 30, 2006 through September 30, 2007" and that "Pfizer's SOX 404 reports as well as its SOX 302 reports in these periods were false and misleading" because "[t]he opinions and certifications expressed by Pfizer and its management regarding the effectiveness of its internal control failed to disclose the existence of a material weakness from September 30, 2006 to September 30, 2007."[18] Mr. Regan bases his opinions on an analysis of Pfizer's internal controls under Auditing Standard No. 2, An Audit of Internal Control Over Financial Reporting Performed In Conjunction With an Audit of Financial Statements ("AS 2").[19]

Plaintiffs assert that Defendants "have not challenged Mr. Regan's opinion concerning the status of the Company's internal controls" and, therefore, "concede Mr. Regan's internal control opinion is admissible at trial." (Opp. at 2.) That is wrong. Defendants argued that (1) "Mr. Regan's opinions concerning Pfizer's internal controls should be excluded because (*inter alia*) Plaintiffs have abandoned any claims alleging a false or misleading statement about those internal controls" and (2) "Plaintiffs have failed to establish that Mr. Regan has the

[18] Dec. 10, 2014 MacDonald Declaration Ex. WW-2 (Regan Report at 2.)
[19] Dec. 10, 2014 MacDonald Declaration Ex. WW-2 (Regan Report at 68-69.)

requisite experience and expertise to render reliable opinions concerning Pfizer's internal controls." (Br. at 2 n.1.) Indeed, Mr. Regan's opinions should be excluded because his admissions establish that (1) those opinions are legally irrelevant and (2) he lacks the requisite experience and expertise to render reliable opinions.

A. Mr. Regan's Opinions Concerning Pfizer's Internal Controls Are Irrelevant.

Even if Plaintiffs have not abandoned their claims alleging a false or misleading statement about Pfizer's internal controls over financial reporting (and they have), Mr. Regan's opinions concerning a purported material weakness in those internal controls are inadmissible because such opinions do not relate to a false or misleading statement for which Plaintiffs may recover – as Mr. Regan's own admissions make clear.

Even assuming that a material weakness existed when Plaintiffs' expert says it did—and it didn't, according to Pfizer, KPMG, and every single witness with personal knowledge deposed by Plaintiffs—Pfizer ***never*** disclosed a material weakness in its internal controls from September 2006 through September 2007 (or at any other time during the Class Period). Mr. Regan admits as much:

> Q. So there's never been any disclosure made by Pfizer, KPMG or anyone else indicating that the company had a material weakness during the period when you said that they had a material weakness; correct?
>
> A. Correct. The company has not made that disclosure.[20]

Plaintiffs may not recover on any alleged omission with respect to Pfizer's internal controls over financial reporting because there was no disclosure concerning those controls that "purported to reveal some then-undisclosed fact with regard to the specific misrepresentations alleged in the complaint." *In re Omnicom Grp., Inc. Sec. Litig.*, 597 F.3d 501, 511 (2d Cir.

[20] Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 264:15-20.)

2010). The absence of such a disclosure is "fatal under Second Circuit precedent." *In re Omnicom Grp., Inc. Sec. Litig.*, 541 F. Supp. 2d 546, 551 (S.D.N.Y. 2008).

Since Mr. Regan's opinions do not relate to any disclosure for which Plaintiffs may recover, they are not relevant and consequently not helpful to the jury. *See Daubert*, 509 U.S. at 591-92. Accordingly, they are inadmissible under Rule 702 and should be excluded.[21]

B. Mr. Regan Lacks the Requisite Experience and Expertise.

For Mr. Regan's opinions to be admissible, Plaintiffs must also establish that he qualifies as an expert in evaluating and auditing pharmaceutical companies' internal controls under AS 2. Mr. Regan admits that he lacks the necessary qualifications:

- Mr. Regan has ***never*** audited or contemporaneously evaluated a company's internal controls over financial reporting under any standard.[22]
- Mr. Regan has ***never*** audited or contemporaneously evaluated a pharmaceutical company's internal controls over financial reporting under AS 2.[23] As Mr. Regan conceded: "[M]y last audit in accordance with Generally Accepted Auditing Standards was, I believe, in 1995 or 1996. And AS 2 arose later than that."[24]
- Mr. Regan has ***never*** audited or contemporaneously evaluated Pfizer's internal controls over financial reporting in this case.[25]

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[21] Plaintiffs assert that "Mr. Regan's opinion that Pfizer's internal controls suffered a material weakness is directly relevant to, *inter alia*, the falsity of defendant Waxman's April 2, 2007 statement that Pfizer has internal controls to guard against these types of [illegal off-label] practices." (Opp. at 2 (internal quotation marks omitted).) That is plainly wrong. Mr. Regan's after-the-fact opinions on Pfizer's internal controls are not relevant to Mr. Waxman's state of mind as to those internal controls more than seven years earlier. Indeed, Plaintiffs make no reference to Mr. Regan's opinions in arguing that, "[a]t the time he made this statement, Waxman was well aware of the overwhelming evidence of massive undisclosed off-label promotion at Pfizer, as well as the near certainty that Pfizer would have to pay over $1 billion in penalties due to its off-label-promotion activities." (Plaintiffs' Memorandum of Law in Opposition to Pfizer Inc.'s and the Individual Defendants' Motions for Summary Judgment at 42 (emphasis omitted); *see also id.* at 42-44.) In any event, ***it does not matter*** because Mr. Regan's admissions establish that his opinions on Pfizer's internal controls do not relate to a false or misleading statement for which Plaintiffs may recover.

[22] Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 15:19-16:6.)

[23] Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 15:5-14, 256:2-7.)

[24] Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 15:5-14.)

[25] Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 255:21-256:1.)

In contrast, Pfizer's management and KPMG have extensive experience and expertise with such issues. For example, the KPMG teams were led by Mr. Chapman, Mr. Bradley, and Mr. Riso, who together had more than 65 years of experience performing audits – including many years performing audits of pharmaceutical companies. (Br. at 4-5.) Those audits necessarily covered internal controls.[26] Mr. Regan admits that Mr. Chapman, Mr. Bradley, and Mr. Riso all have more experience auditing internal controls than he does:

- "Q. Would you agree that Mr. Chapman has more experience auditing companies under AS 2 than you do? . . . THE WITNESS: Yes, I would agree with that."[27]
- "Q. Do you believe that Mr. Bradley has more experience than you do auditing companies under AS 2, their internal controls? A. I would expect so, yes."[28]
- "Q. . . . And he [*i.e.*, Mr. Riso] has more experience than you do auditing internal controls under AS 2? . . . THE WITNESS: Yes, for – defining 'audit' as audits in accordance with Generally Accepted . . . Auditing Standards."[29]

Mr. Regan also admits that (unlike him) KPMG actually performed an audit of Pfizer's internal controls over financial reporting and that every KPMG witness has testified that, as a result of its audit procedures, KPMG concluded that Pfizer did not have a material weakness in those internal controls.[30] For example, Mr. Chapman and Mr. Riso both concluded that any control deficiency at Pfizer from September 2006 through September 2007 (or at any other time during the Class Period) did ***not*** constitute a material weakness:

- Mr. Chapman testified that KPMG evaluated whether any control deficiency constituted a material weakness as part of its review of Pfizer's internal controls; KPMG concluded that any control deficiency "was not a material weakness"; and he was personally comfortable with that conclusion.[31]

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[26] Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 250:8-15; 251:13-252:13.)
[27] Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 17:11-14.)
[28] Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 17:24-18:2.)
[29] Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 19:4-14.)
[30] Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 254:25-255:20.)
[31] Dec. 10, 2014 MacDonald Declaration Ex. CC-2 (Chapman Dep. 96:8-97:22; *see also id.* 23:11-15; 25:10-26:9.)

- Mr. Riso testified that KPMG evaluated whether there were any material weaknesses in Pfizer's internal controls as part of its audits; found "[t]hat there were none"; and instead concluded that those controls were well-designed and operating effectively.[32]

Plaintiffs have not established that Mr. Regan has the requisite experience and expertise to render reliable opinions concerning Pfizer's internal controls under AS 2. Therefore, this Court should also exclude Mr. Regan's opinions on that basis.[33]

CONCLUSION

For the foregoing reasons and those in Defendants' opening brief, this Court should grant Defendants' motion to exclude the opinions of Mr. Regan.

[32] Dec. 10, 2014 MacDonald Declaration Ex. NN-2 (Riso Dep. 139:3-140:17.)

[33] Mr. Regan admits that "I don't recall ever participating in an audit where I rendered an opinion. I would render letters describing internal control systems that were in place and, I think, identified deficiencies or material weaknesses, but that would be not in connection with giving an opinion on those deficiencies, but merely describing them and describing what the deficiencies were." Jan. 2, 2015 MacDonald Decl. Ex. GG-5 (Regan Dep. 15:24-16:6; *see also id.* 255:21-256:1.) Such work does not give Mr. Regan the necessary experience or expertise to second-guess the judgments of Pfizer's management and independent auditor. (*See* Br. at 6 n.19.)

Date: January 2, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on this 2nd day of January, 2015, the foregoing Reply Memorandum of Law in Further Support of Defendants' Motion *in Limine* No. 13 to Exclude the Opinions of D. Paul Regan was filed with the Court through the CM/ECF system and thereby served on all parties of record.

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