UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MARY K. JONES, Individually and on Behalf of All Others Similarly Situated, Plaintiff vs. PFIZER INC., et al., Defendants.	Civil Action No. 1:10-cv-03864-AKH CLASS ACTION PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION *IN LIMINE* NO. 13 TO EXCLUDE THE OPINIONS OF D. PAUL REGAN

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

Plaintiffs Stichting Philips Pensioenfonds and Mary K. Jones, on behalf of the Class of Pfizer, Inc. ("Pfizer" or the "Company") investors, respectfully submit this memorandum of law in opposition to Defendants' Motion *in Limine* No. 13 to Exclude the Opinions of D. Paul Regan.

I. INTRODUCTION

D. Paul Regan ("Mr. Regan") is a Certified Public Accountant ("CPA") and Certified Fraud Examiner ("CFE") with over 40 years of accounting and auditing experience. He is a nationally recognized forensic accountant who has testified in his field of expertise on more than 100 occasions. Despite the overwhelming evidence that Mr. Regan is more than capable of assisting a jury to understand the various accounting and disclosure issues in this case, defendants make the incredible claim that Mr. Regan lacks the requisite experience and qualifications. *See* Memorandum of Law in Support of Defendants' Motion *in Limine* No. 13 to Exclude the Opinions of D. Paul Regan (Dkt. No. 378) ("Defs' Brf."). *See Fitzpatrick v. Teleflex, Inc.*, 763 F. Supp. 2d 224, 236 (D. Me. 2011) (noting "[i]t is ironic that the Court is being asked to rule that someone with roughly 30 years of CPA experience not be allowed to testify as an accounting expert"). In producing Mr. Regan's report to the Court, moreover, defendants stripped it of Mr. Regan's *curriculum vitae* and several critical exhibits in a desperate attempt to dent Mr. Regan's stellar qualifications and sound opinions. For this reason alone, the Court should deny defendants' motion in its entirety.

The main thrust of defendants' motion is that Mr. Regan erred in using what is known as the "actual gain" methodology to estimate what Pfizer should have reserved during the Class Period pursuant to Statement of Financial Accounting Standards No. 5 ("FAS 5"). *See* Defs' Brf. at 6-16. Specifically, defendants argue that Mr. Regan's FAS 5 reserve opinion should be excluded because the actual gain model is not generally accepted. *Id.* at 7. Defendants are wrong as the methodology was used three times by the same United States Attorney's Office ("USAO") office that accused

Pfizer of criminal off-label promotion in: (a) the Neurontin case; (b) the Genotropin case; and (3) yes, the Bextra case. During the Class Period, moreover, Pfizer admitted the model was the accepted standard to measure losses caused by illegal off-label promotion. Further, Pfizer insisted the model was the accepted standard because it had been consistently used in numerous cases prosecuted by the same USAO investigating the Bextra case. Even Pfizer's auditor, KPMG, professed that the model was the "benchmark" for estimating losses. Defendants' displeasure with Mr. Regan's use of the actual gain methodology, or their disagreement with the assumptions he used in applying the methodology, are not grounds for exclusion, but rather are more properly reserved for cross-examination at trial.

In a footnote, defendants notify the Court that they have not challenged Mr. Regan's opinion concerning the status of the Company's internal controls, claiming it is unnecessary. *See* Defs' Brf. at 2 n.1. They are mistaken. 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.'" *See* First Amended Consolidated Class Action Complaint for Violations of the Federal Securities Laws (Dkt. No. 71), ¶67.[1] By failing to raise a single argument here, they concede Mr. Regan's internal control opinion is admissible at trial. Further, defendants are silent concerning Mr. Regan's opinion of the adequacy of Pfizer's legal proceedings disclosures under FAS 5, ¶10. As such, defendants also concede that opinion is admissible at trial. The Court should deny defendants' motion in its entirety.

[1] Internal citations are omitted, unless otherwise noted.

II. MR. REGAN'S OPINIONS REGARDING DISCLOSURES, RESERVES AND INTERNAL CONTROLS

In Mr. Regan's July 31, 2014 Supplemental Expert Report ("Regan Report"), he details his opinions, and the basis for them, regarding Pfizer's Class Period: (a) failure to reserve for contingent losses associated with the Government Investigation into the unlawful off-label promotion of Bextra and other drugs; (b) inadequate legal proceedings disclosures of the Government Investigation into the unlawful off-label promotion of the Company's drugs; and (c) a material weakness in the Company's internal controls. *See* Declaration of Trig R. Smith in Support of Plaintiffs' Opposition to Defendants' Motion *in Limine* No. 13 to Exclude the Opinions of D. Paul Regan ("Smith Decl."), Ex. 1 ("Regan Report").

III. MR. REGAN'S QUALIFICATIONS

Mr. Regan's qualifications are impeccable. He is a CPA and CFE with over 40 years of accounting and auditing experience. *See id.* at 10-11 and Exhibit A (Mr. Regan's *curriculum vitae*). He received his B.S. in Accounting from the University of San Francisco and an M.S. in Accounting from Golden Gate University. *Id.*, Ex. A. The American Institute of Certified Public Accountants ("AICPA") designated Mr. Regan as Certified in Financial Forensics, and until October 2011, he served as a member of the AICPA's governing counsel. *Id.* In 2009, Mr. Regan received the Distinguished Service Award from the California Society of Certified Public Accountants, and he served on the organization's Board of Directors from 2001 to 2006. *Id.* In the past five years, Mr. Regan has served on the Board of Directors and Audit Committees of various organizations, including the public companies International Display Works, Inc. and Solar Power, Inc. *Id.* Mr. Regan is also Chairman of the Board of Hemming Morse, Inc., an accounting firm with over 100 employees. *Id.*

He has been retained as an accounting and disclosure expert in over 750 matters, including for large and small public and private companies, the SEC, Resolution Trust Corporation and Federal Deposit Insurance Corporation, and has provided testimony in more than 125 trials and arbitration proceedings. *See* Regan Report at 10. Mr. Regan has participated in establishing FAS 5 loss reserves for numerous companies, both public and private. In each of these matters Mr. Regan has applied the guidance of FAS 5 to inform his opinions. *See* Smith Decl., Ex. 2 ("Regan Depo.") at 12:23-14:25. His evaluation of loss contingency accruals and related disclosures has been done for a variety of public companies, including those in the pharmaceutical industry. *See id*. at 13:1-16. Mr. Regan has also been retained by the Public Company Accounting Oversight Board ("PCAOB"), the non-profit group established by Congress to oversee the accounting profession, to opine on FAS 5 loss reserves of a pharmaceutical company. *Id*. at 13:7-22.

IV. ARGUMENT

A. Mr. Regan Is Qualified to Opine Concerning the Accounting Issues in This Case

Defendants attack Mr. Regan's opinion regarding Pfizer's failure to timely reserve a loss relating to the Government Investigation, claiming "he lacks the requisite experience and expertise." Defs' Brf. at 3-6. Specifically, they criticize Mr. Regan because he has "***never*** been involved in establishing a loss contingency reserve" and has "***never*** audited or contemporaneously evaluated a loss contingency reserve." *Id.* at 4 (emphasis in original). Not only are defendants' arguments factually inaccurate, but they are unsupported by a single case in which a proposed accounting expert with Mr. Regan's credentials has been precluded from testifying at trial concerning accounting issues.[2]

[2] The only case defendants rely on in support of their argument is *Zaremba v. GMC*, 360 F.3d 355, 359-60 (2d Cir. 2004), which is distinguishable. First, it does not address accounting experts.

Mr. Regan has been a CPA for over 40 years (*see* Regan Report, Ex. A) and 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. *See* Regan Depo. at 12:23-14:25. For instance, 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. *Id.* 13:14-14:25. Certainly, Mr. Regan's decades of experience as a CPA and CFE, his extensive knowledge of generally accepted accounting principles ("GAAP"), his service to the PCAOB and experience as a testifying expert regarding FAS 5 loss reserves in numerous cases qualifies him here. *See, e.g.*, *Fitzpatrick*, 763 F. Supp. 2d at 236 ("It is ironic that the Court is being asked to rule that someone with roughly 30 years of CPA experience not be allowed to testify as an accounting expert.").

Defendants' argument regarding Mr. Regan's experience in the pharmaceutical industry is no less ironic or infirm. *See* Defs' Brf. at 4. Again, Mr. Regan testified that he had experience analyzing and auditing loss contingency reserves of pharmaceutical companies, including in support of a PCAOB investigation. *See* Regan Depo. at 13:14-14:25. In contrast, in early 2008, KPMG's new lead partner on the Pfizer engagement had no experience auditing pharmaceutical companies at all. *See* Smith Decl., Ex. 3. In fact, Mr. Bradley's primary experience stemmed from auditing candy bar and soda companies. *Id.* If Mr. Bradley had sufficient experience to audit Pfizer's Class Period FAS 5 legal proceeding disclosures and reserves, then Mr. Regan is certainly more qualified to provide accounting opinions regarding those matters. In any event, defendants' argument goes to the

---

Second, the expert in that case only had experience in designing air bag parts, not the structural components of an automobile (like the roof). *Id.* As such, the Second Circuit noted the expert had "meager qualifications to offer the opinions to automobile design [upon which] these plaintiffs rely." *Id*. Here, it is indisputable that Mr. Regan has ample experience with FAS 5 disclosure and loss contingency issues.

weight of Mr. Regan's testimony at trial, not its admissibility. *See, e.g.*, *Halterman v. Legato Software*, C 04-02660 JW, 2006 U.S. Dist. LEXIS 20136, at *3-*4 (N.D. Cal. Apr. 5, 2006) (qualifying plaintiff's accounting expert who held a CPA and CFE and had "twenty years of experience in accounting and related litigation services," even though the expert had no software industry experience).

Defendants next criticize Mr. Regan for not having as much auditing experience as members of KPMG.[3] *See* Defs' Brf. at 4-5. This argument is flawed for several reasons. First, defendants cite to no case law requiring an accounting expert opposing a public company in a securities fraud case to have as much or more auditing experience than the defendant company's auditors. Second, Mr. Regan's experience as a CPA and CFE, extensive knowledge of GAAP, his work for the PCAOB and his vast experience in explaining complex accounting issues to scores of fact finders is equally as compelling as the backgrounds of Messrs. Chapman, Bradley and Riso. Third, the argument is hypocritical. Defendants' accounting expert, Mr. Holder, has not performed a single audit procedure with regard to a single pharmaceutical company. *See* Smith Decl., Ex. 4 at 44:13-16. Yet, defendants found him sufficiently qualified to offer accounting opinions competing with those of Mr. Regan. Fourth, in just the last four years, Mr. Regan has testified in other matters where the proper implementation of FAS 5 was at issue at multiple companies, such as in *In re Paciocco & Anor v. Australia and New Zealand Banking Group Limited*, No. VID196 (Fed. Ct. of

[3] Defendants mislead this Court by claiming Mr. Regan "admits that . . . KPMG actually performed an audit of Pfizer's loss contingency reserves and disclosures." Defs' Brf. at 5. He made no such admission. *See* Regan Depo. at 76:13-21 (Mr. Regan retorting "[y]ou say that they audited the company's reserving decisions. They audited the financial statements of Pfizer with the objective of rendering an opinion on the financial statements taken as a whole. As part of that audit, they performed certain procedures [to] gain[] an understanding of the process that Pfizer used to determine its reserves. But they audited the financial statements."); 76:25-77:2 (KPMG does not "give separate opinions on . . . components of the financial statements.").

Austl.); *Livent Inc. Through Its Special Receiver and Manager, Roman Doroniuk*, No. 02-CV-225823 CM2 (Ontario Super. Ct. of Justice, Canada); *SEC v. Delphi Corp.et al*, No. 06-CV-14891 (E.D. Mich.); *In re Heller Ehrman LLP*, No. 08-32514 DM (Bankr. N.D. Cal.); and *SEC v. Morales, et. al*., No. 06 CIV 2435 (RJH) (S.D.N.Y.). *See* Regan Report, Ex. A. The KPMG engagement team on the other hand, only performed procedures on a single company, Pfizer. Clearly, Mr. Regan is sufficiently qualified to help a jury understand the accounting issues in this case.[4]

B. Mr. Regan's Opinion Concerning Pfizer's Failure to Timely Reserve a Loss Contingency Is Reliable and Admissible

Defendants contend that Mr. Regan's opinion regarding Pfizer's failure to timely reserve under FAS 5 is based on a methodology that is not generally accepted. *See* Defs' Brf. at 7-14. Not only is this argument false, but defendants attempt to legitimize it by mischaracterizing the well-accepted "actual gain" methodology as Mr. Regan's "'recipe.'" *Id.* at 7, 15-17.

The actual gain model is not Mr. Regan's recipe.[5] In 2004, the methodology was utilized by the Boston USAO and Pfizer to estimate damages associated with Pfizer's off-label promotion of Neurontin. *See* Smith Decl., Ex. 5. In 2005, it was utilized by the Boston USAO and Serono to estimate damages in the government's case against Serono. *See id*., Ex. 6. In 2007, the Boston USAO and Schering Sales Corp. used the methodology to estimate damages in the government's case against Schering Sales Corp. *See id.*, Ex. 7. In 2007, the methodology was utilized by the

[4] Defendants end their argument concerning Mr. Regan's qualifications by citing to KPMG standing by the judgments it made while working for Pfizer. *See* Defs' Brf. at 6. That testimony has nothing to do with Mr. Regan's qualifications as an expert, but certainly establishes there is a factual issue for a jury.

[5] Not only is the actual gain methodology not Mr. Regan's "'recipe,'" but Mr. Regan never conceded that the SEC "has refused to follow his 'recipe.'" Defs' Brf. at 13. Defendants cite to nothing in the record to support that baseless assertion. Further, 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.

Boston USAO and Pfizer to estimate damages associated with Pfizer's unlawful off-label promotion of Genotropin. *See id*., Ex. 8. And, yes, in 2009, the methodology was utilized by the Boston USAO and Pfizer to estimate damages associated with Pfizer's unlawful off-label promotion of Bextra. *See id*., Ex. 9. In October 2007, moreover, Pfizer admitted to the Boston USAO that the methodology was appropriate to calculate the ill-gotten gains from criminal off-label promotion of pharmaceutical products, including Bextra.[6] *See* Smith Decl., Ex. 10 at PF-JONES 00059190. Even Pfizer's auditor, KPMG, has acknowledged the actual gain methodology is the "benchmark." *See id*., Ex. 11 at 129:16-130:4. The actual gain methodology is well-accepted and that is precisely why Mr. Regan utilized it in forming his opinion concerning what Pfizer should have booked as a contingent loss during the Class Period.[7] *See* Regan Report at 36-37, Exs. 2 & 2.1.

Next, defendants parade a series of other public companies that reserved for off-label investigations at or around the time each company announced it had settled with the government, just like Pfizer did. *See* Defs.' Brf. at 8-11. Defendants then leap to the conclusion that because the

---

[6] In light of this fact, *Kass v. West Bend Co.*, 158 F. App'x 352, 353 (2d Cir. 2005) is of no avail to defendants. In *Kass*, the expert's opinion concerning "'a feasible alternative coffee maker design'" was precluded because it was based on conjecture and uninformative, cursory testing. *Id.* Here, Mr. Regan does not offer an alternative, but contends that defendants should have used the methodology the Boston USAO had utilized time-and-time again.

[7] Defendants cite to another one of their experts, who is not an accountant, for the proposition that there is no simple formula to estimate the amount of a settlement. *See* Defs' Brf. at 8. FAS 5, ¶8, however, holds that a company must take a charge to income when a loss contingency is probable and the amount of the loss can be ***reasonably estimated***. *See* Smith Decl., Ex. 12 at 5-6. Mr. Theodorou is confused – Mr. Regan is not opining on what the settlement amount should have been – Mr. Regan is opining on whether Pfizer had the tools and experience from which it could reasonably inform investors of the financial risks associated with the Bextra investigation. In Mr. Regan's opinion, the Company did have the tools and experience because, prior to the Class Period, it was aware of the actual gain methodology, it had admitted that it had engaged in illegal off-label promotion of Bextra and concluded it was likely it would be forced to settle with the government. In sum, Pfizer had the experience and the tools to take a reasonable charge at the beginning of the Class Period, it just decided not to.

other companies must have "made judgments similar to Pfizer's," the actual gain methodology of estimating a loss is unreliable. *Id*. at 8. This argument is as misguided as it is irrelevant.

As an initial matter, Pfizer used the actual gain methodology three times. Second, this is a case about Pfizer and its FAS 5 judgments, not some other company. There 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. There is no evidence in the record concerning the government's investigations of Eli Lilly, Allergan, Elan, Merck, Abbott Labs and Amgen, let alone the amounts and quality of evidence the government had compiled against those companies. Mr. Regan repeatedly reminded defense counsel of these realities during his deposition. *See, e.g.*, Regan Depo. at 91:15-19 (the parties "don't know the facts and circumstances . . . that Lilly [was] dealing with . . . it would take hundreds or a thousand hours to make that determination"); 116:13-18 (the parties do not know "the facts and circumstances that apply to Allergan"); 147:7-14 (the parties "don't know the facts and circumstances associated with the other cases [and the parties] don't know what the Government did in those cases").[8] Additionally, there is no evidence in the record concerning whether the government believed these other companies' conduct was accompanied by a multitude of "aggravating factors," as was the case for Pfizer, as discussed below. Defendants' argument concerning these other companies, therefore, is a mere diversionary tactic.

Again, the question before the jury will be whether Pfizer timely reserved for the Government Investigation into the criminal off-label promotion of Bextra and other drugs. In answering that question, the jury will have heard that in May 2004 Pfizer settled for $430 million

[8] Again, defendants falsely argue that Mr. Regan admitted that these other companies made reserving judgments similar to Pfizer. Defs' Brf. at 8. As indicated above, such a concession is impossible because those facts and circumstances are not known by the parties or Mr. Regan.

with the Boston USAO concerning the criminal off-label promotion of Neurontin. The jury will have heard that at the same time of the Neurontin settlement, Pfizer was engaged in the rampant off-label promotion of Bextra. The jury will have heard that Pfizer first disclosed evidence of the illegal off-label promotion of Bextra to the Boston USAO in November 2004. The jury will have heard that before the Class Period even began, Pfizer employees attempted to destroy evidence concerning the off-label promotion of Bextra. The jury will have heard that Pfizer concluded in September 2005 that it would likely be "forced to settle" with the Boston USAO (which then viewed Pfizer as a recidivist). The jury also will have heard that by August 2006, the Boston USAO had compiled compelling evidence of criminal conduct and enumerated several aggravating factors in its case against Pfizer, including:

- ***In November 2003, Pfizer stressed to the Boston USAO that it "emphasizes integrity and enforces compliance"***;
- ***Yet, in November 2003, Pfizer was engaged in the rampant, criminal off-label promotion of Bextra, including for acute pain***;
- ***The "FDA Said NO" to acute pain, but Pfizer ignored the FDA's mandate***;
- ***Pfizer's senior management was fully aware of the illegal conduct***;
- ***The criminal promotion of Bextra was a deliberate scheme***; and
- ***Pfizer's criminal conduct continued despite the USAO's ongoing criminal investigation into Neurontin***.

See Smith Decl., Ex. 13 at DOJ000194, 206-07.[9] Here, the parties are aware of these facts. Mr. Regan considered these facts in rendering his opinions. As such, defendants' suggestion that Mr.

[9] Defendants' expert, Mr. Holder, testified he had no knowledge of whether any such aggravating factors were present in the investigation of the other companies. *See* Smith Decl., Ex. 4 at 244:20-245:7. Further, there is no record even suggesting that the cases against the other companies defendants cite to in their brief were as damning as the USAO's case was against Pfizer.

Regan's opinions are flawed based on defendants' mere speculation of what other companies did is meaningless.

Next, defendants criticize Mr. Regan for identifying peer companies that had reserved for their government investigations well before a settlement in principle was publicly announced and suggest that those examples "do not support" the actual gain methodology. *See* Defs' Brf. at 11-12. Defendants, however, have failed to adduce any evidence suggesting that the actual gain methodology was not used by the other companies in estimating their reserve. Further, defendants' argument misses the point. 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. *See* Regan Report at 52-54.

Defendants' descriptions of the timing of the Glaxo and Schering reserves are also erroneous and, therefore, further undermine the credibility of their argument that using the actual gain methodology would produce an unreasonable estimate of loss. *See* Defs' Brf. at 11-12. While defendants admit that Glaxo established an initial reserve in 4Q08, they ignore the fact that Glaxo added a few billion dollars to the reserve in 4Q10 and, thus, had fully reserved for the government investigation – nearly a year prior to Glaxo announcing its settlement in principle in November 2011. *See* Smith Decl., Ex. 14. Likewise, defendants admit that Schering established an initial reserve in 4Q02, nearly four years before announcing a settlement in principle, but defendants ignore that Schering had virtually fully reserved for the government investigation by 3Q03 – three years

prior to the settlement in principle announced in August 2006.[10] *Id.*, Ex. 15. Unlike Pfizer, Glaxo and Schering timely informed investors of the financial risks associated with their unlawful conduct.

C. Mr. Regan's Opinions Possess the Necessary Intellectual Rigor

Defendants suggest Mr. Regan's opinions lack intellectual rigor based on hypothetical testimony that the actual gain methodology may not work if there is a dispute between the government and the defendant about the extent of illicit off-label sales. *See* Defs' Brf. at 15. Here, defendants have cherry-picked a sound-bite regarding the methodology and omit necessary contextual testimony.[11] Defendants ignored Mr. Regan's clarification on this point:

> [A]fter you assess or a company assesses all of the facts and circumstances and it is of the belief that there are no revenues that are generated as a result of the off-label activity, and [if] they honestly can put a percentage into the formula that is 0, the calculation of [the] loss would be 0.

Regan Depo. at 110:15-20.

Plaintiffs will prove that defendants were fully aware of the actual gain methodology as a result of its 2004 settlement with the Boston USAO for the illegal off-label promotions of Neurontin. Plaintiffs will prove defendants never honestly believed they could put a percentage of 0 into the actual gain methodology (unless, of course, they were willing to let Pfizer suffer the functional equivalent of the death penalty – *i.e.*, debarment). Plaintiffs will prove defendants did not believe

[10] Defendants further ignore the fact that Bristol-Myers Squibb started recording reserves three years prior to announcing a settlement in principle. *See* Smith Decl., Exs. 16, 17.

[11] The testimony defendants cite in support of their argument was set in the context of the hypothetical where Allergan did not believe it had engaged in off-label marketing and, thus, did not believe off-label promotion generated illegal profits. *See* Regan Depo. at 108:6-22. In contrast, Pfizer admitted to the USAO in November 2004 that its employees had, in fact, illegally promoted Bextra off-label. *See* Smith Decl., Ex. 13 at DOJ000197. Further, by March 1, 2006, Pfizer concluded that economic consequences of off-label marketing included greater than a $1.0 billion impact on profitability and, should that illegal conduct be publicly disclosed, the Company would suffer significant diminution to its reputation and a sustained reduction in market capitalization. *Id.*, Ex. 18. Accordingly, Mr. Regan's professional judgment to use the actual gain methodology to estimate a reserve was well-informed and reasonable under the facts of the Pfizer case.

that they would settle the Bextra case for less than $430 million, particularly after admitting to the illegal promotion of Bextra to the USAO in November 2004 (shortly after Pfizer executed the Corporate Integrity Agreement as a result of the criminal off-label promotion of Neurontin). Further, in August and September 2006, the DOJ confronted Pfizer with the fact that over half of Bextra's life-time revenue – *i.e.*, $1.8 billion out of $2.4 billion – was associated with off-label use and the Company had been engaged in deliberate criminal scheme of off-label promotion. *See* Smith Decl., Ex. 13 at DOJ000203, 207. Mr. Regan considered that evidence, as well as the full record, and reasonably concluded that at the outset of the Class Period, Pfizer possessed all necessary tools and experience to estimate and disclose a conservative loss – *i.e.*, $1.0 billion – associated with the Government Investigation. *See* Regan Report at 25-35.

Defendants next contend that Mr. Regan's opinion concerning the estimated loss should be rejected because he relied on Dr. Rosenthal's off-label revenue calculations. *See* Defs' Brf. at 15. This is just another false argument.[12] Pfizer admitted that $1.8 billion in profit was attributable to sales of Bextra between 2002 and 2005, and that is precisely the number Mr. Regan relied on to calculate his estimate of the loss caused by Pfizer's criminal conduct. *See* Regan Report at 36-37 &

[12] Indeed, defendants mislead this Court by asserting that "Mr. Regan effectively concedes that Dr. Rosenthal's methodology does not provide a reasonable estimate of sales profit." Defs' Brf. at 16. During Mr. Regan's deposition, defense counsel showed him an analysis performed by Dr. Rosenthal in another case with a class period that was nearly six years longer (*i.e.*, from November 1995 through December 2004) than the USAO's case against Pfizer for the off-label promotion of Neurontin (*i.e.*, from July 1995 through March 1999). *See* Regan Depo. at 196:21-198:4. Defendants' misdirection here is only made worse by the fact that between March 1999 and December 2004, ***after the end of the class period in the government's case against Pfizer***, total Neurontin prescription volume exploded. *See* Smith Decl., Ex. 19. That Dr. Rosenthal's estimate of sales profit for Neurontin between November 1995 and December 2004 is significantly higher than the sales profit estimated in the government case is not surprising and in no way impacts the reliability of Mr. Regan or Dr. Rosenthal's work in this case.

Exs. 2, 2.1. Further, Mr. Regan made clear to defendants that he did not rely on Dr. Rosenthal's calculations:

> I haven't used [Dr. Rosenthal's] information to calculate what I think the appropriate reserve for the criminal portion of the settlement would be. I've merely stated this as an indication of the reasonableness of my estimate in my calculation. I've not used this number in my calculation.

Regan Depo. at 186:1-10.[13]

Finally, defendants contend that Mr. Regan's estimate of ill-gotten gains attributable to off-label conduct "relies entirely on government presentations to Pfizer." Defs' Brf. at 17. Again, defendants advance another false argument in an effort to escape liability. As noted above, Pfizer admitted that the net gain for total Bextra sales (*i.e.*, $2.4 billion in sales less production and distribution costs) was $1.8 billion. *See* Regan Report, Exs. 2, 2.1. Clearly, defendants had access to information concerning the profitability of all of its drugs prior to and throughout the Class Period. Indeed, defendants publicly disclosed that information to investors between 2002 and 2005. Mr. Regan next explained why Pfizer should have used the 34% figure (which came into existence in 2004 as part of the actual gain methodology in connection with the Neurontin settlement) to derive the amount of losses caused by the criminal promotion of Bextra. *See* Regan Report at 36. Further, Mr. Regan explained why it would have been reasonable to use the 34% figure at the outset of the Class Period, including, the similarities of the unlawful conduct in the Neurontin and Bextra cases.

---

[13] Because Mr. Regan in no way relied on Dr. Rosenthal's calculations in reaching his reserve opinions (*see* Regan Depo. at 186:5-10), defendants' accusation that Mr. Regan does not know "the basis for the estimate of sales" is a baseless misrepresentation. Defs' Brf. at 15. Again, Mr. Regan's report made crystal clear that the basis for Bextra total profit (regardless of whether it was obtained illegally) used in his reserve calculation is what Pfizer, in fact, admitted it to have actually been between 2002 and 2005. *See* Regan Report, Ex. 2.1 (listing sources of information from table titled "Tickmark Legend"). ***It is telling that defendants stripped these key exhibits from Mr. Regan's Report when they produced it to this Court***.

See id. at 26-29. Accordingly, Mr. Regan has a sufficient factual basis upon which to base his opinion concerning what Pfizer should have reserved throughout the Class Period.

V. CONCLUSION

For the reasons stated herein, the Court should deny defendants' Motion *in Limine* No. 13 in its entirety.

DATED: December 22, 2014

Respectfully submitted,

ROBBINS GELLER RUDMAN
& DOWD LLP
MICHAEL J. DOWD
HENRY ROSEN
TRIG R. SMITH
JASON A. FORGE
RYAN A. LLORENS
IVY T. NGO

s/ TRIG R. SMITH
TRIG R. SMITH

655 West Broadway, Suite 1900
San Diego, CA 92101
Telephone: 619/231-1058
619/231-7423 (fax)
miked@rgrdlaw.com
henryr@rgrdlaw.com
trigs@rgrdlaw.com
jforge@rgrdlaw.com
ryanl@rgrdlaw.com
ingo@rgrdlaw.com

ROBBINS GELLER RUDMAN
& DOWD LLP
SAMUEL H. RUDMAN
58 South Service Road, Suite 200
Melville, NY 11747
Telephone: 631/367-7100
631/367-1173 (fax)
srudman@rgrdlaw.com

ROBBINS GELLER RUDMAN
& DOWD LLP
WILLOW E. RADCLIFFE
DANIEL J. PFEFFERBAUM
MATTHEW S. MELAMED
Post Montgomery Center
One Montgomery Street, Suite 1800
San Francisco, CA 94104
Telephone: 415/288-4545
415/288-4534 (fax)
willowr@rgrdlaw.com
dpfefferbaum@rgrdlaw.com
mmelamed@rgrdlaw.com

Lead Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on December 22, 2014, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the attached Electronic Mail Notice List, and I hereby certify that I caused to be mailed the foregoing document or paper via the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on December 22, 2014.

s/ TRIG R. SMITH
TRIG R. SMITH

ROBBINS GELLER RUDMAN
& DOWD LLP
655 West Broadway, Suite 1900
San Diego, CA 92101-8498
Telephone: 619/231-1058
619/231-7423 (fax)

E-mail: trigs@rgrdlaw.com

Mailing Information for a Case 1:10-cv-03864-AKH

Electronic Mail Notice List

The following are those who are currently on the list to receive e-mail notices for this case.

- **Michael Scott Bailey**
  michael.bailey@skadden.com
- **Sidney Bashago**
  sidney.bashago@dpw.com,jennifer.kan@davispolk.com,ecf.ct.papers@davispolk.com
- **Sheila L. Birnbaum**
  sheilabirnbaum@quinnemanuel.com
- **George Anthony Borden**
  gborden@wc.com
- **Kevin Anthony Burke**
  kaburke@sidley.com,nyefiling@sidley.com,efilingnotice@sidley.com
- **Michael Barry Carlinsky**
  michaelcarlinsky@quinnemanuel.com,brantkuehn@quinnemanuel.com,jomairecrawford@quinnemanuel.com
- **Lauren Kristina Collogan**
  lcollogan@wc.com
- **Keir Nicholas Dougall**
  kdougall@dougallpc.com
- **Michael Joseph Dowd**
  miked@rgrdlaw.com,e_file_sd@rgrdlaw.com,tome@rgrdlaw.com,e_file_sf@rgrdlaw.com
- **Alexander C Drylewski**
  alexander.drylewski@skadden.com
- **Charles S. Duggan**
  charles.duggan@dpw.com,ecf.ct.papers@davispolk.com
- **Steven M.. Farina**
  sfarina@wc.com
- **Jason A. Forge**
  jforge@rgrdlaw.com,tholindrake@rgrdlaw.com,e_file_SD@rgrdlaw.com
- **Ross Bradley Galin**
  rgalin@omm.com,mochoa@omm.com,neverhart@omm.com,lisachen@omm.com
- **Gary John Hacker**
  ghacker@skadden.com
- **James R. Harper**
  coljamesrharper@me.com
- **Howard E. Heiss**
  hheiss@omm.com,#nymanagingattorney@omm.com
- **Paul T. Hourihan**
  phourihan@wc.com
- **James M. Hughes**
  jhughes@motleyrice.com,kweil@pacernotice.com,mgruetzmacher@motleyrice.com,erichards@motleyrice.com,kweil@motleyrice.com
- **Jay B. Kasner**
  jkasner@skadden.com
- **Joe Kendall**
  administrator@kendalllawgroup.com,jkendall@kendalllawgroup.com,hlindley@kendalllawgroup.com

- **Brant Duncan Kuehn**
  brantkuehn@quinnemanuel.com
- **Leigh R. Lasky**
  lasky@laskyrifkind.com
- **Hamilton Philip Lindley**
  hlindley@deanslyons.com,mgoens@deanslyons.com
- **Ryan A. Llorens**
  ryanl@rgrdlaw.com,nbear@rgrdlaw.com,kirstenb@rgrdlaw.com
- **Amanda M. MacDonald**
  amacdonald@wc.com
- **Lori McGill**
  lorialvinomcgill@quinnemanuel.com
- **Matthew Melamed**
  mmelamed@rgrdlaw.com
- **Donald Alan Migliori**
  dmigliori@motleyrice.com
- **Eugene Mikolajczyk**
  genem@rgrdlaw.com
- **Seema Mittal**
  smittal@wc.com
- **Cynthia Margaret Monaco**
  cmonaco@cynthiamonacolaw.com,cmmonaco@gmail.com
- **Juliana Newcomb Murray**
  juliana.murray@davispolk.com,lisa.hirakawa@davispolk.com,ecf.ct.papers@davispolk.com
- **Scott D. Musoff**
  smusoff@skadden.com
- **Danielle Suzanne Myers**
  dmyers@rgrdlaw.com
- **William H. Narwold**
  bnarwold@motleyrice.com,vlepine@motleyrice.com,ajanelle@motleyrice.com
- **Ivy T. Ngo**
  ingo@rgrdlaw.com,e_file_sd@rgrdlaw.com
- **Joseph G. Petrosinelli**
  jpetrosinelli@wc.com
- **Willow E. Radcliffe**
  willowr@rgrdlaw.com,ptiffith@rgrdlaw.com
- **Joseph F. Rice**
  jrice@motleyrice.com
- **Darren J. Robbins**
  e_file_sd@rgrdlaw.com
- **Daniel Prugh Roeser**
  droeser@goodwinprocter.com
- **Henry Rosen**
  henryr@rgrdlaw.com,dianah@rgrdlaw.com
- **David Avi Rosenfeld**
  drosenfeld@rgrdlaw.com,e_file_ny@rgrdlaw.com,e_file_sd@rgrdlaw.com
- **James P. Rouhandeh**
  james.rouhandeh@dpw.com,ecf.ct.papers@davispolk.com

- **Samuel Howard Rudman**
  srudman@rgrdlaw.com,e_file_ny@rgrdlaw.com,mblasy@rgrdlaw.com,e_file_sd@rgrdlaw.com
- **Stuart Michael Sarnoff**
  ssarnoff@omm.com
- **William E. Schurmann**
  wschurmann@wc.com
- **Trig Randall Smith**
  trigs@rgrdlaw.com,e_file_sd@rgrdlaw.com,nhorstman@rgrdlaw.com
- **Jennifer Lynn Spaziano**
  jen.spaziano@skadden.com
- **Richard Mark Strassberg**
  rstrassberg@goodwinprocter.com,nymanagingclerk@goodwinprocter.com
- **Mitchell M.Z. Twersky**
  mtwersky@aftlaw.com
- **John K. Villa**
  jvilla@wc.com

Manual Notice List

The following is the list of attorneys who are **not** on the list to receive e-mail notices for this case (who therefore require manual noticing). You may wish to use your mouse to select and copy this list into your word processing program in order to create notices or labels for these recipients.

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

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

Jamie J. McKey
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

Regan Karstrand

From: NYSD_ECF_Pool@nysd.uscourts.gov
Sent: Monday, December 22, 2014 9:40 PM
To: CourtMail@nysd.uscourts.gov
Subject: Activity in Case 1:10-cv-03864-AKH Jones et al v. Pfizer, Inc. et al Memorandum of Law in Opposition to Motion

This is an automatic e-mail message generated by the CM/ECF system. Please DO NOT RESPOND to this e-mail because the mail box is unattended.
*****NOTE TO PUBLIC ACCESS USERS*** Judicial Conference of the United States policy permits attorneys of record and parties in a case (including pro se litigants) to receive one free electronic copy of all documents filed electronically, if receipt is required by law or directed by the filer. PACER access fees apply to all other users. To avoid later charges, download a copy of each document during this first viewing. However, if the referenced document is a transcript, the free copy and 30 page limit do not apply.**

U.S. District Court

Southern District of New York

Notice of Electronic Filing

The following transaction was entered by Smith, Trig on 12/22/2014 at 9:40 PM EST and filed on 12/22/2014
Case Name: Jones et al v. Pfizer, Inc. et al
Case Number: 1:10-cv-03864-AKH
Filer: Mary K. Jones
Stichting Philips Pensioenfonds
Document Number: 411

Docket Text:
MEMORANDUM OF LAW in Opposition re: [376] MOTION in Limine *No. 13 To Exclude the Opinions of D. Paul Regan*. . Document filed by Mary K. Jones(Individually), Stichting Philips Pensioenfonds. (Smith, Trig)

1:10-cv-03864-AKH Notice has been electronically mailed to:

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

The following document(s) are associated with this transaction:

Document description: Main Document
Original filename:n/a
Electronic document Stamp:
[STAMP dcecfStamp_ID=1008691343 [Date=12/22/2014] [FileNumber=14043113
-0] [5249cb44c59dfa0136c4918b343ded1cad6f462554008e29d4126e0d89be5d97d
0af390edf7fd7c0daceb2a1b014811ead1bdd6c655d5cea247ae66266b283a4]]