

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

_____	X	
MARY K. JONES, Individually and on Behalf	:	Civil Action No. 1:10-cv-03864-AKH
of All Others Similarly Situated,	:	
	:	<u>CLASS ACTION</u>
Plaintiff	:	
vs.	:	PLAINTIFFS' LOCAL RULE 56.1
	:	RESPONSE TO DEFENDANT FRANK
PFIZER INC., et al.,	:	D'AMELIO'S STATEMENT OF
	:	UNDISPUTED MATERIAL FACTS
Defendants.	:	
_____	X	

Plaintiffs Stichting Philips Pensioenfond and Mary K. Jones, on behalf of Pfizer Inc. (“Pfizer” or the “Company”) investors, respectfully submit the following Response to Defendant Frank D’Amelio’s Statement of Undisputed Material Facts.

1. Undisputed.
2. Undisputed.
3. Undisputed.
4. Disputed. Defendant Frank D’Amelio (“D’Amelio”) mischaracterizes Edward Buthusiem’s testimony. Mr. Buthusiem testified that Pfizer had a disclosure committee for year-end 2006, which went through the process and he recognized the process as one that he used.¹ He also testified that while it “appeared” the Company had proper controls over financial reporting, he concluded that the process, as applied, demonstrated that Pfizer did not have proper internal controls over financial reporting.² Mr. Buthusiem also opined that Pfizer’s legal proceedings disclosure process was flawed because it did not enable Pfizer and its counsel to make informed decisions about its legal disclosure requirements regarding the off-label promotion investigations. According to Mr. Buthusiem, Lawrence Fox (“Fox”) and Dennis Block (“Block”) lacked appropriate expertise in off-label marketing investigations; there was a failure to share marketing information concerning the off-label marketing investigation; and there was a lack of independent verification of material facts.³

¹ Ex. 42 (Buthusiem Depo.) at 319:6-12. All “Ex. ____” references herein are exhibits attached to the Declaration of Henry Rosen in Support of Plaintiffs’ Memorandum of Law in Opposition to Pfizer, Inc.’s and the Individual Defendants’ Motions for Summary Judgment, submitted herewith, unless otherwise noted. Unless otherwise noted, all emphasis is added and citations are omitted.

² Ex. 42 (Buthusiem Depo.) at 319:6-16.

³ Ex. 3 (Buthusiem Report) at 5.

5. Disputed. Defendants have expressly denied relying on any counsel other than Block or Fox for their defense in this case⁴ (consistent with that denial, defendants successfully shielded Investigations Counsel⁵ from discovery), so defendants may not invoke or rely on Investigations Counsel, including relying on anyone who relied on Investigations Counsel. Plaintiffs incorporate by reference Plaintiffs' Motion to Partial Summary Judgment ("Plaintiffs' Motion for Partial Summary Judgment"), filed November 14, 2014, and Plaintiffs' Memorandum of Law in Opposition to Pfizer Inc.'s and the Individual Defendants' Motions for Summary Judgment ("Plaintiffs' Memorandum"), filed concurrently herewith. Neither Block nor Fox assessed critical portions of Pfizer's legal proceedings disclosure and the Statement of Financial Accounting Standards No. 5 ("FAS 5") reserve decisions: the strengths or weaknesses of the Government's⁶ case⁷ or Pfizer's defenses,⁸ whether a loss or conviction was probable, or whether such loss was reasonably estimable.⁹ Moreover, defendants withheld from Block and Fox critical evidence concerning the Bextra Investigation,¹⁰ including call notes,¹¹ documents that corroborated a *qui tam* relator's

⁴ Dkt. No. 172 at 25; July 19, 2013 Hearing Transcript at 12:1-2; Dkt. No. 246 at 1, 5.

⁵ "Investigations Counsel" refers to Pfizer's counsel who were involved in the Bextra Investigation, including, but not limited to, Covington & Burling LLP ("Covington") and in-house counsel Douglas Lankler ("Lankler"), Carlton Wessel ("Wessel") and Gary Giampetruzzi ("Giampetruzzi").

⁶ "Government" refers to the Department of Justice ("DOJ") and/or the Health & Human Services Office of Inspector General ("OIG").

⁷ Ex. 37 (Block Depo.) at 34:1-22, 104:15-23; Ex. 49 (Fox Depo.) at 32:11-18, 60:17-22, 90:12-20, 224:22-225:6.

⁸ Ex. 37 (Block Depo.) at 104:6-23; Ex. 49 (Fox Depo.) at 86:13-19, 90:12-20.

⁹ Ex. 37 (Block Depo.) at 33:7-25, 34:1-22, 35:4-11, 36:15-24, 39:3-41:12, 71:13-25, 142:18-143:2; Ex. 49 (Fox Depo.) at 43:17-45:7, 76:15-19, 80:5-21, 90:21-91:8.

claims,¹² Bextra-related documents that Pfizer employees had attempted to delete or alter,¹³ sales force survey results¹⁴ and employee interview memoranda.¹⁵ Instead, all information and input regarding the Bextra Investigation came from Investigations Counsel.¹⁶ For example:

Block and Fox were never among Pfizer's most informed attorneys as to the facts concerning the Bextra Investigation, nor as to assessing such facts legally.¹⁷

Block never personally and professionally assessed nor advised defendants that Pfizer had substantial defenses to the Bextra Investigation.¹⁸

Fox never independently determined or advised defendants that Pfizer had substantial defenses to the Bextra Investigation.¹⁹

¹⁰ "Bextra Investigation" refers to the Government's investigation concerning Pfizer's misbranding (*i.e.*, off-label) promotion of Bextra, which was paralleled by Pfizer's internal investigation, led by Covington. Ex. 57 (12/10/13 Levin Depo.) at 231:9-16; Ex. 54 (10/10/14 Kindler) at 20:19-21:4; Ex. 68 (10/16/14 Waxman) at 32:18-20.

¹¹ Ex. 37 (Block Depo.) at 76:5-23, 144:21-145:4; Ex. 49 (Fox Depo.) at 60:3-22, 61:3-11.

¹² Ex. 54 (10/10/14 Kindler Depo.) at 34:19-24, 35:18-36:10; Ex. 60 (9/19/14 McKinnell Depo.) at 60:7-10; Ex. 37 (Block Depo.) at 128:14-21.

¹³ Ex. 37 (Block Depo.) at 59:14-60:6, 230:21-231:8; Ex. 49 (Fox Depo.) at 49:9-23.

¹⁴ Ex. 37 (Block Depo.) at 54:8-22, 56:2-11; Ex. 49 (Fox Depo.) at 97:11-18, 211:16-212:1.

¹⁵ Ex. 37 (Block Depo.) at 54:8-22, 56:2-11, 105:3-13, 230:21-231:8; Ex. 49 (Fox Depo.) at 13:2-8, 49:9-50:16, 66:3-6.

¹⁶ Ex. 37 (Block Depo.) at 36:15-24, 104:15-23, 168:18-169:15; Ex. 49 (Fox Depo.) at 44:24-45:7, 47:2-7, 60:17-22, 61:25-62:7, 87:11-88:14, 222:21-225:6; Ex. 68 (10/16/14 Waxman Depo.) at 20:15-21.

¹⁷ Ex. 55 (Lankler Depo.) at 92:23-97:21.

¹⁸ Ex. 37 (Block Depo.) at 104:6-23.

¹⁹ Ex. 49 (Fox Depo.) at 86:13-19, 90:12-20.

Neither Block nor Fox made an assessment or advised defendants as to the strengths and weaknesses of Pfizer's defenses or of the Government's case.²⁰

Neither Block nor Fox made an assessment or advised defendants as to the probability of a criminal conviction in or losses from the Bextra Investigation, or whether the loss from the Bextra Investigation was reasonably estimable.²¹

Block and Fox deferred to, and relied upon, Pfizer's Investigations Counsel to assess the Bextra Investigation including the strengths and weaknesses of Pfizer's defenses or of the Government's case, the probability of a criminal conviction in or losses from the Bextra Investigation or whether the loss from the Bextra Investigation was reasonably estimable.²²

Neither Block nor Fox made an assessment or advised defendants as to the facts and circumstances surrounding the Bextra Investigation in connection to Pfizer's FAS 5 determination.²³

Defendants did not seek or receive advice from Block regarding the propriety of representing that Pfizer had "substantial defenses" to the Bextra Investigation while omitting reference to any, let alone all, of the following in their Securities and Exchange Commission ("SEC") filings: Pfizer's awareness that its sales representatives had, in fact, promoted Bextra off-label; the internal Bextra-related documents that were exhibits to John Kopchinski's ("Kopchinski") Complaint; the results from Pfizer's Bextra-related sales force surveys; the internal Bextra-related documents that Pfizer's

²⁰ Ex. 37 (Block Depo.) at 104:15-23, 168:18-169:15; Ex. 49 (Fox Depo.) at 32:11-18, 60:17-22, 90:12-20, 224:22-225:6.

²¹ Ex. 37 (Block Depo.) at 32:16-34:22, 35:4-11, 36:15-24, 37:14-24, 39:3-41:12, 71:13-25, 142:18-143:2; Ex. 49 (Fox Depo.) at 44:24-45:7, 76:15-19, 80:5-21, 90:21-91:8.

²² Ex. 37 (Block Depo.) at 36:15-24, 39:10-41:5, 104:15-23, 168:18-169:15; Ex. 49 (Fox Depo.) at 44:24-45:7, 47:2-7, 60:17-22, 61:25-62:7, 87:11-88:14, 222:21-225:6; Ex. 68 (10/16/14 Waxman Depo.) at 20:15-21.

²³ Ex. 37 (Block Depo.) at 33:7-25, 36:15-24, 40:16-41:5; Ex. 49 (Fox Depo.) at 43:17-45:7, 80:5-21, 90:21-91:8.

District Manager instructed Pfizer's sales representatives to alter or delete; the Bextra-related call notes of the Pfizer sales representatives who were involved in the attempted alteration and destruction of internal Bextra-related documents; the admissions of the Pfizer sales representatives who were involved in the attempted alteration and destruction of internal Bextra-related documents; the admissions of other Pfizer employees interviewed by Pfizer's Investigations Counsel; or the Bextra-related call notes quoted, summarized and/or analyzed in the Government's presentations to Pfizer and its Investigations Counsel.²⁴

Defendants did not seek or receive advice from Fox regarding the propriety of representing that Pfizer had "substantial defenses" to the Bextra Investigation while omitting reference to any, let alone all, of the following in their SEC filings: the internal Bextra-related documents that were exhibits to Kopchinski's Complaint; the results from Pfizer's Bextra-related sales force surveys; the internal Bextra-related documents that Pfizer's District Manager instructed Pfizer's sales representatives to alter or delete; the Bextra-related call notes of the Pfizer sales representatives who were involved in the attempted alteration and destruction of internal Bextra-related documents; the admissions of the Pfizer sales representatives who were involved in the attempted alteration and destruction of internal Bextra-related documents; the admissions of other Pfizer employees interviewed by Pfizer's Investigations Counsel; or the Bextra-related call notes quoted, summarized and/or analyzed in the Government's presentations to Pfizer and its Investigations Counsel.²⁵

²⁴ Ex. 37 (Block Depo.) at 104:15-23; Ex. 55 (Lankler Depo.) at 108:2-10; Ex. 58 (9/23/14 Levin Depo.) at 39:25-40:24, 43:11-44:1, 99:19-100:4, 113:10-114:10, 115:6-116:2; Ex. 54 (10/10/14 Kindler Depo.) at 31:10-32:8; Ex. 68 (10/16/14 Waxman Depo.) at 16:2-14, 20:15-21, 38:13-23.

²⁵ Ex. 49 (Fox Depo.) at 90:12-20; Ex. 55 (Lankler Depo.) at 107:22-108:1; Ex. 58 (9/23/14 Levin Depo.) at 39:25-40:24, 43:11-44:1, 99:19-100:4, 113:10-114:10, 115:6-116:2; Ex. 54 (10/10/14 Kindler Depo.) at 31:10-32:8; Ex. 68 (10/16/14 Waxman Depo.) at 16:2-14, 20:15-21.

Neither Block nor Fox has ever worked as a criminal law prosecutor or a criminal defense attorney.²⁶

Neither Block nor Fox was familiar with the elements of a misbranding offense.²⁷

Neither Block nor Fox was familiar with elements or application of *respondeat superior* liability.²⁸

Debarment from participation in any federal health care program is mandatory if a company is convicted of a felony relating to health care fraud or controlled substances, and any such debarment would apply to all of the company's products.²⁹

Fox incorrectly believed that debarment was not automatic for a felony conviction and that even if a company is debarred from federal health benefits programs, such debarment would be limited to the product that triggered the debarment.³⁰

Fox incorrectly understood the terms grand jury "target" and grand jury "subject" to be interchangeable.³¹

No one ever informed Block that certain Pfizer sales representatives promoted Bextra for general acute and surgical pain, both of which were off-label indications.³²

²⁶ Ex. 37 (Block Depo.) at 13:12-14:6, 14:13-15:10; Ex. 49 (Fox Depo.) at 35:21-36:12.

²⁷ Ex. 37 (Block Depo.) at 16:6-17:8; Ex. 49 (Fox Depo.) at 37:17.

²⁸ Ex. 37 (Block Depo.) at 232:20-233:12; Ex. 49 (Fox Depo.) at 36:13-37:9.

²⁹ 42 U.S.C. §1320a-7.

³⁰ Ex. 49 (Fox Depo.) at 130:7-15, 218:21-219:5.

³¹ Ex. 49 (Fox Depo.) at 106:3-23.

³² Ex. 37 (Block Depo.) at 49:16-50:20, 56:21-58:9, 63:25-64:4; Ex. 58 (9/23/14 Levin Depo.) at 24:12-16.

Pfizer and its Investigations Counsel always represented to Block that Pfizer's sales representatives had not promoted Bextra off-label.³³ In fact, from February 2002 through April 2005: Pfizer promoted Bextra for uses that were not within Bextra's U.S. Food and Drug Administration ("FDA") approved label, including (a) for general acute pain, (b) for pre-operative and post-operative surgical pain and (c) as opioid-sparing in the context of surgery;³⁴ Pfizer promoted Bextra at dosages higher than the FDA-approved dosages of 10 mg once a day for osteoarthritis ("OA") and rheumatoid arthritis ("RA") and 20 mg twice daily as needed for primary dysmenorrhea ("PD");³⁵ Pfizer introduced Bextra into interstate commerce for the treatment of acute pain, surgical pain, other unapproved uses and at unapproved dosages even though it lacked adequate directions for such uses and dosages;³⁶ Pfizer promoted Bextra with an intent to defraud or mislead;³⁷ certain members of Pfizer's sales force promoted Bextra with false and misleading claims, including that Bextra had no dose proportional increase in hypertension and edema;³⁸ and certain members of Pfizer's sales force submitted to their supervisors false, fake medical requests indicating that physicians had requested off-label information when, in fact, they had not, and medical information letters regarding such off-label uses and/or dosages were sent to those physicians.³⁹

³³ Ex. 37 (Block Depo.) at 50:5-20, 232:3-12.

³⁴ Ex. 240 at 51:10-17.

³⁵ Ex. 240 at 51:17-18.

³⁶ Ex. 240 at 51:19-21.

³⁷ Ex. 240 at 51:22-23.

³⁸ Ex. 240 at 52:1-4.

³⁹ Ex. 240 at 52:5-9.

No one provided Block a copy of Kopchinski's Complaint or any of the internal Pfizer documents that were exhibits to it.⁴⁰ The same appears to be true as to Fox, as the record does not indicate that he received those documents either.⁴¹

No one ever provided Block or Fox the internal documents that Pfizer's sales representatives had attempted to delete or alter.⁴²

No one provided Block or Fox with redacted or unredacted copies of the interview memoranda of the Pfizer employees involved in the attempted deletion and alteration of Bextra-related documents.⁴³

No one provided Block or Fox copies of the results of Bextra-related surveys of Pfizer's sales force, nor any of the revelations from the surveys.⁴⁴

No one provided Block or Fox copies of any call notes, or summaries or analyses of any call notes, including the call notes that the Government quoted, referenced, summarized and/or analyzed in its August and September 2006 presentations to Pfizer and its Investigations Counsel.⁴⁵

No one provided Block or Fox copies of any of the interview memoranda from the Bextra Investigation.⁴⁶

⁴⁰ Ex. 37 (Block Depo.) at 54:8-22; Ex. 60 (9/19/14 McKinnell Depo.) at 60:7-10; *see also* Ex. 54 (10/10/14 Kindler Depo.) at 34:19-24.

⁴¹ Ex. 49 (Fox Depo.) at 211:5-212:1; *see also* Ex. 54 (10/10/14 Kindler Depo.) 35:18-36:10.

⁴² Ex. 37 (Block Depo.) at 59:14-60:1, 230:21-231:8; Ex. 49 (Fox Depo.) at 49:9-23.

⁴³ Ex. 37 (Block Depo.) at 54:8-22, 56:2-11, 105:3-13, 230:25-231:6; Ex. 49 (Fox Depo.) at 13:2-8, 49:9-50:16, 66:3-6.

⁴⁴ *See* Ex. 37 (Block Depo.) at 54:8-22, 56:2-11; Ex. 49 (Fox Depo.) at 97:11-18, 211:16-212:1.

⁴⁵ Ex. 37 (Block Depo.) at 76:5-23, 144:21-145:4; Ex. 49 (Fox Depo.) at 60:3-22, 61:3-11.

⁴⁶ Ex. 37 (Block Depo.) at 54:8-22, 56:2-11, 105:3-13; Ex. 49 (Fox Depo.) at 13:2-8, 53:23-54:14, 211:16-212:1.

Neither Block nor Fox received access to any of Pfizer's Investigations Counsel's written work product concerning the Bextra Investigation.⁴⁷

No one disclosed to Block or Fox any estimates of the number of Bextra prescriptions written for off-label uses or the amount of Pfizer's gain from the off-label promotion of Bextra.⁴⁸

Defendants have failed to adduce admissible evidence that they shared all pertinent information with KPMG LLP ("KPMG"). For example, KPMG was never told the specifics from the August and September 2006 meetings Pfizer had with the DOJ regarding the Bextra investigation. During those meetings, the DOJ presented to Pfizer, in detail, the unapproved, false and/or misleading claims Pfizer used to market Bextra. These off-label claims included marketing Bextra for acute pain generally, marketing Bextra as safer and more effective than Vioxx and marketing it for use in surgery.⁴⁹ The DOJ also presented to Pfizer the tactics Pfizer used to market Bextra for these off-label indications to hospitals via protocols, standing orders and 20 mg samples to physicians who did not treat on-label use.⁵⁰ The DOJ further told Pfizer how the Company paid physicians to attend consultant meetings, advisory boards, speaker events and used a publication strategy all to promote Bextra off-label.⁵¹ The DOJ also set forth the criminal charges based on Food & Drug Act and False Claims Act violations Pfizer would face and the aggravating factors including that the illegal promotion of Bextra continued despite the on-going Neurontin investigation and Pfizer was subject to two Corporate Integrity Agreements ("CIA"). The DOJ also told Pfizer

⁴⁷ Ex. 55 (Lankler Depo.) at 101:1-11; Ex. 37 (Block Depo.) at 54:8-22; Ex. 49 (Fox Depo.) at 97:11-18.

⁴⁸ Ex. 37 (Block Depo.) at 69:6-15, 73:21-74:16; Ex. 49 (Fox Depo.) at 74:22-80:1.

⁴⁹ Ex. 256 at DOJ000237.

⁵⁰ Ex. 256 at DOJ000238.

⁵¹ Ex. 256 at DOJ000239.

about the illegal marketing of Bextra and that it was a deliberate scheme with pervasive misconduct and knowledge at the top.⁵² Instead, KPMG was repeatedly told that the DOJ was still outlining the theories of liability.⁵³ This was misleading because the DOJ told Pfizer exactly how the off-label marketing of Bextra violated the Food & Drug Act and the False Claims Act.⁵⁴ Pfizer also misled KPMG by claiming not to know how to calculate the potential fine despite possessing the methodology based on the Company's prior experience with the Neurontin settlement.

KPMG never received the November 2006 memo by Chuck Mooney ("Mooney"), Pfizer's director of Corporate Internal Audit who headed up the healthcare compliance ("HCC") audit function, which explained how problems with Pfizer's HCC function could have a material impact on Pfizer's financial results.⁵⁵ KPMG never received the presentation reviewed by Pfizer's Worldwide Pharmaceutical Operations Compliance Committee in October 2007 entitled "'RC Reform'-Why, What, When, How & Who" which summarized the findings of the "deep dive" initiated by defendant Ian C. Read ("Read") in March 2007 in response to the existence of the significant deficiency in the sales and marketing compliance area.⁵⁶ This presentation set forth the complete lack of controls over the Review Committee and, thus, Pfizer's HCC function.⁵⁷ These failures are particularly glaring given: (1) Pfizer considered Review Committee procedures to be one

⁵² Ex. 258 at DOJ000207-08.

⁵³ Declaration of Joseph G. Petrosinelli in Support of Pfizer's Motion for Summary Judgment ("Petrosinelli Decl."), Ex. C-6.

⁵⁴ Ex. 258 at DOJ000205.

⁵⁵ Ex. 161.

⁵⁶ Ex. 203.

⁵⁷ Ex. 203.

of the top ten areas of greatest risk;⁵⁸ (2) KPMG's concern that Pfizer's controls over sales and marketing practices were impaired;⁵⁹ and (3) KPMG had recently been informed by Pfizer that the significant deficiency with regard to HCC had been remediated by the end of 2Q07.⁶⁰

KPMG was also kept in the dark regarding the DOJ's escalation of the off-label marketing investigation. For example, KPMG was not informed that Pfizer's investigation counsel, Covington, received a letter from the DOJ on June 19, 2007, confirming that Pfizer and Pharmacia wished to resolve the outstanding investigations of Bextra and other Pfizer drugs as a package deal.⁶¹ Similarly, KPMG was never informed that Pfizer received a target letter from the DOJ on February 5, 2008.⁶² KPMG was never informed that the DOJ wrote Covington on April 4, 2008, and confirmed key elements of the proposed Bextra Investigation resolution, mentioned the structure and financial range previously communicated by the DOJ, indicated a severe escalation of the Bextra Investigation in that the DOJ intended to pursue criminal charges against Pfizer and offered a settlement of approximately \$5 billion.⁶³

KPMG was misled by Lankler regarding the Zyvox and Geodon investigations in June and July 2008 during compliance meetings. Lankler told KPMG that off-label marketing of Zyvox was identified in isolated cases and not linked to senior management back at Pfizer headquarters.⁶⁴ Yet,

⁵⁸ Ex. 120.

⁵⁹ Exs. 149-150.

⁶⁰ Ex. 346 at KPMG-PFIZ-DS 0003257 (2Q07 Interim Completion Document).

⁶¹ Ex. 310.

⁶² Ex. 131; Ex. 38 (Bradley Depo.) at 242:13-16.

⁶³ Petrosinelli Decl., Ex. Y-6.

⁶⁴ Ex. 159.

KPMG was never told that immediately after Pfizer received the July 2005 Warning Letter from the FDA, Pfizer upper management continued to instruct the sales force to use the core marketing message that Zyvox was superior to vancomycin.⁶⁵ Also, on September 10, 2008, Lankler told the Pfizer Audit Committee that the internal investigation revealed that “unsubstantiated superiority claims” were made about Zyvox “on a fairly broad basis.”⁶⁶ Similarly, Lankler told KPMG that the off-label marketing of Geodon had not been linked back to senior management at corporate headquarters.⁶⁷

Pfizer also misled KPMG about whether the probable criteria had been met and whether the range of loss could be estimated. For example, KPMG was never informed that during a meeting on September 14, 2007, the DOJ proposed to use the “intended loss” theory to calculate the fine Pfizer would pay in connection with the Government’s investigation of Bextra. Similarly, KPMG never received Pfizer’s investigation counsel Ethan Posner’s (“Posner”) response to the DOJ’s “intended loss” proposal on October 1, 2007, which acknowledged a methodology for calculating the fine and argued that the fine in the Bextra Investigation should be calculated as it was in “analogous” cases such as Neurontin, Schering, Serono and Genotropin.⁶⁸

More glaring, is that KPMG was never informed that on October 9, 2007, Pfizer’s disclosure counsel and Pfizer’s in-house accountants and attorneys again concluded that a loss from the DOJ

⁶⁵ Exs. 138-139.

⁶⁶ Ex. 204.

⁶⁷ Ex. 204.

⁶⁸ Petrosinelli Decl., Ex. B-6.

Bextra Investigation was “probable.”⁶⁹ John Chapman (“Chapman”), KPMG audit partner, testified he had not been informed by November 3, 2007 that the probable “pillar” of FAS 5 had been met.⁷⁰ Similarly, Larry Bradley (“Bradley”), KPMG audit partner, testified no one informed him in 2007 that Pfizer had concluded that the loss associated with the Government’s investigation of the off-label promotion of Bextra was probable.⁷¹

Nor was it revealed to KPMG that as a result of the Government asking them to propose a number, Lankler and Wessel were working on calculating potential losses.⁷² Additionally, Chapman testified he did not know Pfizer was working with methodologies to estimate the loss and that the Company had discussed an estimate range.⁷³ After becoming the engagement partner in early 2008, Bradley did not know that Lankler and Wessel were working on methodologies to calculate potential losses.⁷⁴

Again, instead, Block repeatedly told KPMG through the FY 2007 audit that the Government had neither spelled out statutory remedies nor the types of damages it would seek. Block also continued to falsely assure KPMG that the loss was neither probable nor estimable even though Posner’s response to the DOJ set forth a methodology to calculate the loss.⁷⁵

⁶⁹ Petrosinelli Decl., Ex. N-6 (October 17, 2007, email summarizing the October 9, 2007, meeting attended by Block, Lankler, Wessel, Kim Dadlani and Paul Brockie); Ex. 265 (3Q07 Interim Completion Document showing as of November 3, 2007, KPMG had been told loss not probable).

⁷⁰ Ex. 44 (Chapman Depo.) at 122:19-123:16.

⁷¹ Ex. 38 (Bradley Depo.) at 239:9-20.

⁷² Petrosinelli Decl., Ex. N-6.

⁷³ Petrosinelli Decl., Ex. N-6; Ex. 44 (Chapman Depo.) at 130:12-18.

⁷⁴ Ex. 38 (Bradley Depo.) at 234:1-236:2.

⁷⁵ Petrosinelli Decl., Exs. B-6, C-6.

Pfizer also concealed from KPMG the settlement negotiations with the DOJ to resolve the Bextra investigation. KPMG was never informed in February 2008 that Covington made a \$50-\$70 million offer to settle the Bextra investigation to the DOJ, which the government rejected.⁷⁶ KPMG was never informed that on March 28, 2008, Covington made a \$250 million offer to settle the Bextra Investigation to the DOJ which the Government rejected.⁷⁷ KPMG was never informed in or around June 2008, that Covington offered \$750 million to settle the DOJ Bextra Investigation.⁷⁸ Lastly, KPMG was never told that King & Spalding sent a letter dated September 11, 2008, to the DOJ and several states attorney generals that the Government had rejected Pfizer's recent \$750 million offer to settle.⁷⁹ In fact, KPMG workpapers from June and July 2008 show that Pfizer told KPMG that no offers to settle to date had been made.⁸⁰

KPMG relied on representations of Pfizer management in the form of quarterly management representation letters signed by the Chief Financial Officer ("CFO") and Controller, quarterly in-house legal representation letters signed by defendants Allen Waxman ("Waxman") and Jeffrey B. Kindler ("Kindler") and annual legal representation letters from Pfizer's outside counsel. The quarterly management representation letters confirmed that management was responsible for the fair presentation of the financial statements in conformity with Generally Accepted Accounting Principles ("GAAP") and confirmed certain material matters, including a representation that all relevant information relating to certain compliance matters subject to the investigation of alleged

⁷⁶ Ex. 104; Ex. 38 (Bradley Depo.) at 236:3-11.

⁷⁷ Petrosinelli Decl., Ex. Y-6; Ex. 38 (Bradley Depo.) at 247:22-248:5.

⁷⁸ Ex. 158; Ex. 39 (Bradley Depo.) at 268:4-18, 276:16-21, 278:3-8 ("I was not aware of a specific dollar amount that had been proposed by or prepared to recommend by Pfizer counsel.").

⁷⁹ Ex. 158.

⁸⁰ Ex. 159.

fraud or potential illegal acts conducted by the Government Investigations Section and the Office of Corporate Compliance were disclosed by Pfizer to the Audit Committee, to the investigating team and to KPMG.⁸¹ The quarterly in-house legal representation letters were to provide KPMG with an update of significant pending litigation, and the annual legal letters from outside counsel were to provide KPMG with the following information pertaining to material pending or threatened litigation: the nature of the litigation; the progress of the case to date; how management is responding or intends to respond to the litigation; and an evaluation of the likelihood of an unfavorable outcome and an estimate, if one can be made, of the amount or range of potential loss. The representations KPMG received failed to disclose information, as set forth above, necessary for KPMG to render advice regarding Pfizer's contingency reserves and disclosures regarding the Government's off-label marketing investigation.

Fees paid to KPMG by Pfizer were \$30,285,000, \$32,410,000, \$28,220,000 and \$27,735,000 for services rendered in 2005, 2006, 2007 and 2008, respectively.⁸² Fees paid to KPMG by Pfizer for services rendered after the Class Period (January 19, 2006 to January 23, 2009) were \$37,353,000, \$38,993,000, \$38,999,000, \$50,267,000 and \$32,014,200 for 2009, 2010, 2011, 2012 and 2013, respectively.⁸³

Moreover, to the extent defendants seek to rely on Loretta Cangialosi ("Cangialosi") and her team, Pfizer's process for creating a reserve related to the Government Investigation did not always include Cangialosi even though she claimed to be "primarily responsible for determining that the

⁸¹ *E.g.*, Ex. 134 at KPMG-PFIZ-DS 017125.

⁸² Exs. 14, 17-18.

⁸³ Exs. 19-23.

company's reserves complied with [GAAP], particularly FAS 5."⁸⁴ For example, she was not included in the October 9, 2007 meeting during which Pfizer's Investigations Counsel, disclosures counsel and Legal Finance confirmed "that the 'probable' criteria of FAS5 ha[d] been met."⁸⁵ In addition, she never received warning letters from the FDA,⁸⁶ letters to the OIG from Investigations Counsel regarding reportable events pursuant to Pfizer's CIA,⁸⁷ documents concerning methodologies to evaluate damages for the Government investigation,⁸⁸ the February 5, 2008 target letter from the Government,⁸⁹ the April 4, 2008 letter in which Investigations Counsel made a \$250 million offer to the Government to settle its investigation⁹⁰ or documents relating to the review committee process or reforms or initiatives concerning it.⁹¹

Finally, upon becoming the CFO of Pfizer in September 2007, D'Amelio was advised by Pfizer's inside and outside counsel of the details of the Government investigations into the Company's drug products.⁹²

6. Disputed. The deposition testimony cited by D'Amelio in support of this purported fact does not support it. Fox did not testify that he or Block "led" Pfizer's disclosure process. Fox

⁸⁴ Statement of Undisputed Facts in Support of Pfizer's Motion for Summary Judgment (Dkt. No. 248 ("Pfizer's SUF"), ¶31.

⁸⁵ Petrosinelli Decl., Ex. N-6.

⁸⁶ Ex. 43 (Cangialosi Depo.) at 100:20-101:20.

⁸⁷ Ex. 43 (Cangialosi Depo.) at 181:6-184:20.

⁸⁸ Ex. 43 (Cangialosi Depo.) at 294:13-295:6.

⁸⁹ Ex. 43 (Cangialosi Depo.) at 253:19-254:5.

⁹⁰ Ex. 43 (Cangialosi Depo.) at 260:5-8, 321:20-322:4.

⁹¹ Ex. 43 (Cangialosi Depo.) at 96:15-98:7, 112:23-119:4, 124:24-128:13.

⁹² Ex. 46 (D'Amelio Depo.) at 182:17-184:4; Ex. 210 at PFE-JONES 00042253-54.

testified regarding the disclosure process, but noted that he was not even a member of the Disclosure Committee during the Class Period, serving as the quasi-Secretary for that Committee. The testimony cited by D'Amelio regarding Block's purported leadership of Pfizer's disclosure process is even less compelling.⁹³ Block testified that he did not give an opinion on the disclosures, he simply commented "on what I understood was a fair disclosure of what they were trying to disclose."

Defendants have expressly denied relying on any counsel other than Block or Fox for their defense in this case⁹⁴ (consistent with that denial, defendants successfully shielded Investigations Counsel from discovery), so defendants may not invoke or rely on Investigations Counsel, including relying on anyone who relied on Investigations Counsel). Defendants cannot assert an advice of counsel or reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment, and Plaintiffs' Memorandum. Block nor Fox assessed critical portions of Pfizer's legal proceedings disclosure and the FAS 5 reserve decisions: the strengths or weaknesses of the Government's case⁹⁵ or Pfizer's defenses,⁹⁶ whether a loss or conviction was probable or whether such loss was reasonably estimable.⁹⁷ Moreover, defendants withheld from Block and Fox critical evidence concerning the Bextra Investigation,⁹⁸ including call notes,⁹⁹ documents that corroborated a

⁹³ Ex. 37 (Block Depo.) at 44:6-16.

⁹⁴ Dkt. No. 172 at 25; July 19, 2013 Hearing Transcript at 12:1-2; Dkt. No. 246 at 1, 5.

⁹⁵ Ex. 37 (Block Depo.) at 34:1-22, 104:15-23; Ex. 49 (Fox Depo.) at 32:11-18, 60:17-22, 90:12-20, 224:22-225:6.

⁹⁶ Ex. 37 (Block Depo.) at 104:6-23; Ex. 49 (Fox Depo.) at 86:13-19, 90:12-20.

⁹⁷ Ex. 37 (Block Depo.) at 33:7-25, 34:1-22, 35:4-11, 36:15-24, 39:3-41:12, 71:13-25, 142:18-143:2; Ex. 49 (Fox Depo.) at 43:17-45:7, 76:15-19, 80:5-21, 90:21-91:8.

⁹⁸ Ex. 57 (12/10/13 Levin Depo.) at 231:9-16; Ex. 54 (10/10/14 Kindler) at 20:19-21:4; Ex. 68 (10/16/14 Waxman) at 32:18-20.

⁹⁹ Ex. 37 (Block Depo.) at 76:5-23, 144:21-145:4; Ex. 49 (Fox Depo.) at 60:3-22, 61:3-11.

qui tam relator's claims,¹⁰⁰ Bextra-related documents that Pfizer employees had attempted to delete or alter,¹⁰¹ sales force survey results¹⁰² and employee interview memoranda.¹⁰³ Instead, all information and input regarding the Bextra Investigation came from Investigations Counsel.¹⁰⁴ For example:

Block and Fox were never among Pfizer's most informed attorneys as to the facts concerning the Bextra Investigation, nor as to assessing such facts legally.¹⁰⁵

Block never personally and professionally assessed nor advised defendants that Pfizer had substantial defenses to the Bextra Investigation.¹⁰⁶

Fox never independently determined or advised defendants that Pfizer had substantial defenses to the Bextra Investigation.¹⁰⁷

Neither Block nor Fox made an assessment or advised defendants as to the strengths and weaknesses of Pfizer's defenses or of the Government's case.¹⁰⁸

¹⁰⁰ Ex. 54 (10/10/14 Kindler Depo.) at 34:19-24, 35:18-36:10; Ex. 60 (9/19/14 McKinnell Depo.) at 60:7-10; Ex. 37 (Block Depo.) at 128:14-21.

¹⁰¹ Ex. 37 (Block Depo.) at 59:14-60:6, 230:21-231:8; Ex. 49 (Fox Depo.) at 49:9-23.

¹⁰² Ex. 37 (Block Depo.) at 54:8-22, 56:2-11; Ex. 49 (Fox Depo.) at 97:11-18, 211:16-212:1.

¹⁰³ Ex. 37 (Block Depo.) at 54:8-22, 56:2-11, 105:3-13, 230:21-231:8; Ex. 49 (Fox Depo.) at 13:2-8, 49:9-50:16, 66:3-6.

¹⁰⁴ Ex. 37 (Block Depo.) at 36:15-24, 104:15-23, 168:18-169:15; Ex. 49 (Fox Depo.) at 44:24-45:7, 47:2-7, 60:17-22, 61:25-62:7, 87:11-88:14, 222:21-225:6; Ex. 68 (10/16/14 Waxman Depo.) at 20:15-21.

¹⁰⁵ Ex. 55 (Lankler Depo.) at 92:23-97:21.

¹⁰⁶ Ex. 37 (Block Depo.) at 104:6-23.

¹⁰⁷ Ex. 49 (Fox Depo.) at 86:13-19, 90:12-20.

¹⁰⁸ Ex. 37 (Block Depo.) at 104:15-23, 168:18-169:15; Ex. 49 (Fox Depo.) at 32:11-18, 60:17-22, 90:12-20, 224:22-225:6.

Neither Block nor Fox made an assessment or advised defendants as to the probability of a criminal conviction in or losses from the Bextra Investigation, or whether the loss from the Bextra Investigation was reasonably estimable.¹⁰⁹

Block and Fox deferred to, and relied upon, Pfizer's Investigations Counsel to assess the Bextra Investigation including the strengths and weaknesses of Pfizer's defenses or of the Government's case, the probability of a criminal conviction in or losses from the Bextra Investigation or whether the loss from the Bextra Investigation was reasonably estimable.¹¹⁰

Neither Block nor Fox made an assessment or advised defendants as to the facts and circumstances surrounding the Bextra Investigation in connection to Pfizer's FAS 5 determination.¹¹¹

Defendants did not seek or receive advice from Block regarding the propriety of representing that Pfizer had "substantial defenses" to the Bextra Investigation while omitting reference to any, let alone all, of the following in their SEC filings: Pfizer's awareness that its sales representatives had, in fact, promoted Bextra off-label; the internal Bextra-related documents that were exhibits to Kopchinski's Complaint; the results from Pfizer's Bextra-related sales force surveys; the internal Bextra-related documents that Pfizer's District Manager instructed Pfizer's sales representatives to alter or delete; the Bextra-related call notes of the Pfizer sales representatives who were involved in the attempted alteration and destruction of internal Bextra-related documents; the admissions of the

¹⁰⁹ Ex. 37 (Block Depo.) at 32:16-34:22, 35:4-11, 36:15-24, 37:14-24, 39:3-41:12, 71:13-25, 142:18-143:2; Ex. 49 (Fox Depo.) at 44:24-45:7, 76:15-19, 80:5-21, 90:21-91:8.

¹¹⁰ Ex. 37 (Block Depo.) at 36:15-24, 39:10-41:5, 104:15-23, 168:18-169:15; Ex. 49 (Fox Depo.) at 44:24-45:7, 47:2-7, 60:17-22, 61:25-62:7, 87:11-88:14, 222:21-225:6; Ex. 68 (10/16/14 Waxman Depo.) at 20:15-21.

¹¹¹ Ex. 37 (Block Depo.) at 33:7-25, 36:15-24, 40:16-41:5; Ex. 49 (Fox Depo.) at 43:17-45:7, 80:5-21, 90:21-91:8.

Pfizer sales representatives who were involved in the attempted alteration and destruction of internal Bextra-related documents; the admissions of other Pfizer employees interviewed by Pfizer's Investigations Counsel; or the Bextra-related call notes quoted, summarized and/or analyzed in the Government's presentations to Pfizer and its Investigations Counsel.¹¹²

Defendants did not seek or receive advice from Fox regarding the propriety of representing that Pfizer had "substantial defenses" to the Bextra Investigation while omitting reference to any, let alone all, of the following in their SEC filings: the internal Bextra-related documents that were exhibits to Kopchinski's Complaint; the results from Pfizer's Bextra-related sales force surveys; the internal Bextra-related documents that Pfizer's District Manager instructed Pfizer's sales representatives to alter or delete; the Bextra-related call notes of the Pfizer sales representatives who were involved in the attempted alteration and destruction of internal Bextra-related documents; the admissions of the Pfizer sales representatives who were involved in the attempted alteration and destruction of internal Bextra-related documents; the admissions of other Pfizer employees interviewed by Pfizer's Investigations Counsel; or the Bextra-related call notes quoted, summarized and/or analyzed in the Government's presentations to Pfizer and its Investigations Counsel.¹¹³

Neither Block nor Fox has ever worked as a criminal law prosecutor or a criminal defense attorney.¹¹⁴

Neither Block nor Fox was familiar with the elements of a misbranding offense.¹¹⁵

¹¹² Ex. 37 (Block Depo.) at 104:15-23; Ex. 55 (Lankler Depo.) at 108:2-10; Ex. 58 (9/23/14 Levin Depo.) at 39:25-40:24, 43:11-44:1, 99:19-100:4, 113:10-114:10, 115:6-116:2; Ex. 54 (10/10/14 Kindler Depo.) at 31:10-32:8; Ex. 68 (10/16/14 Waxman Depo.) at 16:2-14, 20:15-21, 38:13-23.

¹¹³ Ex. 49 (Fox Depo.) at 90:12-20; Ex. 55 (Lankler Depo.) at 107:22-108:1; Ex. 58 (9/23/14 Levin Depo.) at 39:25-40:24, 43:11-44:1, 99:19-100:4, 113:10-114:10, 115:6-116:2; Ex. 54 (10/10/14 Kindler Depo.) at 31:10-32:8; Ex. 68 (10/16/14 Waxman Depo.) at 16:2-14, 20:15-21.

¹¹⁴ Ex. 37 (Block Depo.) at 13:12-14:6, 14:13-15:10; Ex. 49 (Fox Depo.) at 35:21-36:12.

Neither Block nor Fox was familiar with elements or application of *respondeat superior* liability.¹¹⁶

Debarment from participation in any federal health care program is mandatory if a company is convicted of a felony relating to health care fraud or controlled substances, and any such debarment would apply to all of the company's products.¹¹⁷

Fox incorrectly believed that debarment was not automatic for a felony conviction and that even if a company is debarred from federal health benefits programs, such debarment would be limited to the product that triggered the debarment.¹¹⁸

Fox incorrectly understood the terms grand jury "target" and grand jury "subject" to be interchangeable.¹¹⁹

No one ever informed Block that certain Pfizer sales representatives promoted Bextra for general acute and surgical pain, both of which were off-label indications.¹²⁰

Pfizer and its Investigations Counsel always represented to Block that Pfizer's sales representatives had not promoted Bextra off-label.¹²¹ In fact, from February 2002 through April 2005: Pfizer promoted Bextra for uses that were not within Bextra's FDA-approved label, including (a) for general acute pain, (b) for pre-operative and post-operative surgical pain and (c) as opioid-

¹¹⁵ Ex. 37 (Block Depo.) at 16:6-17:8; Ex. 49 (Fox Depo.) at 37:17.

¹¹⁶ Ex. 37 (Block Depo.) at 232:20-233:12; Ex. 49 (Fox Depo.) at 36:13-37:9.

¹¹⁷ 42 U.S.C. §1320a-7.

¹¹⁸ Ex. 49 (Fox Depo.) at 130:7-15, 218:21-219:5.

¹¹⁹ Ex. 49 (Fox Depo.) at 106:3-23.

¹²⁰ Ex. 37 (Block Depo.) at 49:16-50:20, 56:21-58:9, 63:25-64:4; Ex. 58 (9/23/14 Levin Depo.) at 24:12-16.

¹²¹ Ex. 37 (Block Depo.) at 50:5-20, 232:3-12.

sparing in the context of surgery;¹²² Pfizer promoted Bextra at dosages higher than the FDA-approved dosages of 10 mg once a day for OA and RA and 20 mg twice daily as needed for PD;¹²³ Pfizer introduced Bextra into interstate commerce for the treatment of acute pain, surgical pain, other unapproved uses and at unapproved dosages even though it lacked adequate directions for such uses and dosages;¹²⁴ Pfizer promoted Bextra with an intent to defraud or mislead;¹²⁵ certain members of Pfizer's sales force promoted Bextra with false and misleading claims, including that Bextra had no dose proportional increase in hypertension and edema;¹²⁶ and certain members of Pfizer's sales force submitted to their supervisors false, fake medical requests indicating that physicians had requested off-label information when, in fact, they had not, and medical information letters regarding such off-label uses and/or dosages were sent to those physicians.¹²⁷

No one provided Block a copy of Kopchinski's Complaint or any of the internal Pfizer documents that were exhibits to it.¹²⁸ The same appears to be true as to Fox, as the record does not indicate that he received those documents either.¹²⁹

No one ever provided Block or Fox the internal documents that Pfizer's sales representatives had attempted to delete or alter.¹³⁰

¹²² Ex. 240 at 51:10-17.

¹²³ Ex. 240 at 51:17-18.

¹²⁴ Ex. 240 at 51:19-21.

¹²⁵ Ex. 240 at 51:22-23.

¹²⁶ Ex. 240 at 52:1-4.

¹²⁷ Ex. 240 at 52:5-9.

¹²⁸ Ex. 37 (Block Depo.) at 54:8-22; Ex. 60 (9/19/14 McKinnell Depo.) at 60:7-10; *see also* Ex. 54 (10/10/14 Kindler Depo.) at 34:19-24.

¹²⁹ Ex. 49 (Fox Depo.) at 211:5-212:1; *see also* Ex. 54 (10/10/14 Kindler Depo.) at 35:18-36:10.

No one provided Block or Fox with redacted or unredacted copies of the interview memoranda of the Pfizer employees involved in the attempted deletion and alteration of Bextra-related documents.¹³¹

No one provided Block or Fox copies of the results of Bextra-related surveys of Pfizer's sales force, nor any of the revelations from the surveys.¹³²

No one provided Block or Fox copies of any call notes, or summaries or analyses of any call notes, including the call notes that the Government quoted, referenced, summarized and/or analyzed in its August and September 2006 presentations to Pfizer and its Investigations Counsel.¹³³

No one provided Block or Fox copies of any of the interview memoranda from the Bextra Investigation.¹³⁴

Neither Block nor Fox received access to any of Pfizer's Investigations Counsel's written work product concerning the Bextra Investigation.¹³⁵

No one disclosed to Block or Fox any estimates of the number of Bextra prescriptions written for off-label uses or the amount of Pfizer's gain from the off-label promotion of Bextra.¹³⁶

¹³⁰ Ex. 37 (Block Depo.) at 59:14-60:1, 230:21-231:8; Ex. 49 (Fox Depo.) at 49:9-23.

¹³¹ Ex. 37 (Block Depo.) at 54:8-22, 56:2-11, 105:3-13, 230:25-231:6; Ex. 49 (Fox Depo.) at 13:2-8, 49:9-50:16, 66:3-6.

¹³² See Ex. 37 (Block Depo.) at 54:8-22, 56:2-11; Ex. 49 (Fox Depo.) at 97:11-18, 211:16-212:1.

¹³³ Ex. 37 (Block Depo.) at 76:5-23, 144:21-145:4; Ex. 49 (Fox Depo.) at 60:3-22, 61:3-11.

¹³⁴ Ex. 37 (Block Depo.) at 54:8-22, 56:2-11, 105:3-13; Ex. 49 (Fox Depo.) at 13:2-8, 53:23-54:14, 211:16-212:1.

¹³⁵ Ex. 55 (Lankler Depo.) at 101:1-11; Ex. 37 (Block Depo.) at 54:8-22; Ex. 49 (Fox Depo.) at 97:11-18.

¹³⁶ Ex. 37 (Block Depo.) at 69:6-15, 73:21-74:16; Ex. 49 (Fox Depo.) at 74:22-80:1.

7. Disputed. Defendants cannot assert an advice of counsel defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated by reference herein. Plaintiffs also object to Ex. R-D to the Declaration of Richard M. Strassberg in Support of Defendant Frank D'Amelio's Motion for Summary Judgment (Dkt. No. 277) ("Strassberg Decl.") and Petrosinelli Decl., Exs. Y-1, O-1, E-2, K-5, A-6 for the reasons set forth in Plaintiffs' Objections to Exhibits Submitted in Support of Defendants' Motions for Summary Judgment ("Plaintiffs' Objections"), which is incorporated by reference herein.

8. Undisputed. D'Amelio mistakenly cites to memoranda regarding certification meetings.¹³⁷ However, plaintiffs agree that D'Amelio attended Disclosure Committee meetings between September 2007 and the end of the Class Period.

9. Disputed. Regardless of the Disclosure Committee's aims, Pfizer's disclosures to the investment community were not accurate and complete and did not fairly present the Company's financial condition and results of operations in all material respects.¹³⁸ In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated by reference herein.

10. Disputed. Defendants cannot assert an advice of counsel or reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 6, which is incorporated by reference herein. To the extent D'Amelio's attempts to point to Cangialosi in support of this purported fact. Pfizer's process for creating a reserve related to the

¹³⁷ Petrosinelli Decl., Ex. B-4.

¹³⁸ See Ex. 7 (Supplemental Expert Report of D. Paul Regan) at 11-47.

Government investigation did not always include Cangialosi even though she claimed to be “primarily responsible for determining that the company’s reserves complied with [GAAP], particularly FAS 5.”¹³⁹ For example, she was not included in the October 9, 2007 meeting during which Pfizer’s Investigations Counsel, disclosures counsel and Legal Finance confirmed “that the ‘probable’ criteria of FAS5 ha[d] been met.”¹⁴⁰ In addition, she never received warning letters from the FDA,¹⁴¹ letters to the OIG from Investigations Counsel regarding reportable events pursuant to Pfizer’s CIA,¹⁴² documents concerning methodologies to evaluate damages for the Government investigation,¹⁴³ the February 5, 2008 target letter from the Government,¹⁴⁴ the April 4, 2008 letter in which Investigations Counsel made a \$250 million offer to the Government to settle its investigation¹⁴⁵ or documents relating to the review committee process or reforms or initiatives concerning to it.¹⁴⁶ Plaintiffs also object to Strassberg Decl., Ex. T-D for the reasons set forth in Plaintiffs’ Objections, which is incorporated by reference herein.

11. Disputed. Defendants cannot assert an advice of counsel defense for the reasons set forth in Plaintiffs’ Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs’ Response to D’Amelio’s Undisputed Fact No. 6, which is

¹³⁹ Pfizer’s SUF, ¶31.

¹⁴⁰ Petrosinelli Decl., Ex. N-6.

¹⁴¹ Ex. 43 (Cangialosi Depo.) at 100:20-101:20.

¹⁴² Ex. 43 (Cangialosi Depo.) at 181:6-184:20.

¹⁴³ Ex. 43 (Cangialosi Depo.) at 294:13-295:6.

¹⁴⁴ Ex. 43 (Cangialosi Depo.) at 253:19-254:5.

¹⁴⁵ Ex. 43 (Cangialosi Depo.) at 260:5-8; 321:20-322:4.

¹⁴⁶ Ex. 43 (Cangialosi Depo.) at 96:15-98:7, 112:23-119:4, 124:24-128:13.

incorporated by reference herein. To the extent D'Amelio's attempts to point to Cangialosi in support of this purported fact, plaintiffs dispute it for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 10.

12. Undisputed.

13. Disputed. D'Amelio's role was not "the same as anybody else." Upon becoming the CFO of Pfizer in September 2007, D'Amelio was advised by Pfizer's inside and outside counsel of the details of the Government investigations into the Company's drug products.¹⁴⁷ In addition, D'Amelio was a member of Pfizer's Executive Leadership Team ("ELT") and regularly attended ELT meetings with Kindler, Read and Waxman.¹⁴⁸ In his capacity as a member of the ELT, D'Amelio was responsible for approving the settlements of legal cases in amounts greater than \$100 million or involving issues of unusual significance, such as the Government investigations.¹⁴⁹ Moreover, D'Amelio was Pfizer's CFO and signed the Company's SEC filings, thereby certifying their accuracy.

14. Disputed. Defendants cannot assert an advice of counsel or reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated by reference herein. Further, Block and KPMG were not Pfizer employees, as such, they were not Pfizer decision-makers.

15. Disputed. Defendants cannot assert an advice of counsel or reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition,

¹⁴⁷ Ex. 46 (D'Amelio Depo.) at 182:17-184:4; Ex. 210 at PFE-JONES 00042253-54.

¹⁴⁸ *E.g.*, Ex. 342; Ex. 208.

¹⁴⁹ Ex. 202.

plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Responses to D'Amelio's Undisputed Fact Nos. 6 and 10, which are incorporated by reference herein. Further, both Cangialosi and Hugh Donnelly ("Donnelly") had received unsatisfactory Internal Audit Reports regarding the Company's internal controls over HCC 2005-2006.¹⁵⁰ In addition, plaintiffs object Petrosinelli Decl., Exs. B-4, O-7 and Strassberg Decl., Exs. BB-D, CC-D for the reasons set forth in Plaintiffs' Objections, which is incorporated by reference herein.

16. Disputed. Defendants cannot assert an advice of counsel or reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated by reference herein.

17. Disputed. Defendants cannot assert an advice of counsel or reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated by reference herein. Moreover, plaintiffs object to Petrosinelli Decl., Ex. B-4 for the reasons stated in Plaintiffs' Objections, which is incorporated by reference herein.

18. Disputed. Defendants cannot assert an advice of counsel or reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated by reference herein.

19. Disputed. Defendants cannot assert an advice of counsel or reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition,

¹⁵⁰ Ex. 7 (Supplemental Expert Report of D. Paul Regan) at 69-94.

plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated by reference herein.

20. Disputed. Defendants cannot assert an advice of counsel defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set for in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 6, which is incorporated by reference herein.

21. Disputed. Plaintiffs incorporate by reference their Response to D'Amelio's Undisputed Fact No. 6. Moreover, D'Amelio himself, upon becoming the CFO of Pfizer in September 2007, was advised by Pfizer's inside and outside counsel of the details of the Government investigations into the Company's drug products.¹⁵¹

22. Disputed. Plaintiffs incorporate by reference their Response to D'Amelio's Undisputed Fact No. 6. However, D'Amelio himself, upon becoming the CFO of Pfizer in September 2007, was advised by Pfizer's inside and outside counsel of the details of the Government investigations into the Company's drug products.¹⁵² Plaintiffs object to Petrosinelli Decl., Exs. B-4, V-6 for the reasons set forth in Plaintiffs' Objections, which is incorporated by reference herein.

23. Disputed. Plaintiffs incorporate by reference their Response to D'Amelio's Undisputed Fact No. 6. Plaintiffs object to Petrosinelli Decl., Exs. Z-5, Y-5 for the reasons set forth in Plaintiffs' Objections, which is incorporated by reference herein.

24. Disputed. Plaintiffs incorporate by reference their Response to D'Amelio's Undisputed Fact No. 6.

¹⁵¹ Ex. 46 (D'Amelio Depo.) at 182:17-184:4; Ex. 210 at PFE-JONES 00042253-54.

¹⁵² Ex. 46 (D'Amelio Depo.) at 182:17-184:4; Ex. 210 at PFE-JONES 00042253-54.

25. Disputed. Plaintiffs incorporate by reference their Response to D'Amelio's Undisputed Fact No. 6. Plaintiffs object to Petrosinelli Decl., Ex. B-4 for the reasons set forth in Plaintiffs' Objections, which is incorporated by reference herein.

26. Disputed. Plaintiffs incorporate by reference their Response to D'Amelio's Undisputed Fact No. 6. In addition, upon becoming the CFO of Pfizer in September 2007, D'Amelio was advised by Pfizer's inside and outside counsel of the details of the Government investigations into the Company's drug products.¹⁵³ Plaintiffs object to Petrosinelli Decl., Ex. O-7 and Strassberg Decl., Ex. JJ-D for the reasons set forth in Plaintiffs' Objections, which is incorporated by reference herein.

27. Disputed. D'Amelio could not have believed in good faith that Pfizer maintained effective internal controls over financial reporting. D'Amelio was aware of several on-going investigations into promotional activities and had been updated on the status of key compliance risk areas.¹⁵⁴

28. Disputed. Defendants cannot assert an advice of counsel or reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated by reference herein. Plaintiffs also object to Strassberg Decl., Ex. E-D for the reasons set forth in Plaintiffs' Objections, which is incorporated by reference herein.

29. Disputed. Defendants cannot assert an advice of counsel or reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition,

¹⁵³ Ex. 46 (D'Amelio Depo.) at 182:17-184:4; Ex. 210 at PFE-JONES 00042253-54.

¹⁵⁴ Ex. 525 at PFE DERIV A 00001349-50.

plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated by reference herein.

30. Disputed. Plaintiffs incorporate by reference their Response to D'Amelio Undisputed Fact No. 5. Plaintiffs object to Strassberg Decl., Ex. E-D for the reasons set forth in Plaintiffs' Objections, which is incorporated by reference herein.

31. Disputed. Defendants cannot assert a reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated by reference herein.

32. Disputed. Pfizer's plans to remediate the deficiencies with respect to the compliance controls had neither been finalized or tested.¹⁵⁵ In addition, KPMG never received the presentation reviewed by Pfizer's Worldwide Pharmaceutical Operations Compliance Committee in October 2007 entitled "'RC Reform'-Why, What, When, How & Who" which summarized the findings of the "deep dive" initiated by defendant Read in March 2007 in response to the existence of the significant deficiency in the sales and marketing compliance area.¹⁵⁶

33. Disputed. KPMG did not audit Pfizer's HCC controls.¹⁵⁷

34. Disputed. Defendants cannot assert an advice of counsel or reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated by reference herein.

¹⁵⁵ Exs. 117, 163.

¹⁵⁶ Ex. 203.

¹⁵⁷ See Ex. 44 (Chapman Depo.) at 114:20-115:4, 117:20-24.

35. Disputed. Defendants cannot assert an advice of counsel or reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated by reference herein. Further, D'Amelio testified that at Pfizer he was responsible for "what reserves get recorded and not recorded."¹⁵⁸

36. Disputed. Defendants cannot assert an advice of counsel or reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated by reference herein.

37. Disputed. Defendants cannot assert an advice of counsel or reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated by reference herein.

38. Disputed. Defendants cannot assert an advice of counsel or reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated by reference herein. Further, D'Amelio testified that at Pfizer he was responsible for "what reserves get recorded and not recorded."¹⁵⁹

39. Disputed. Defendants cannot assert a reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for

¹⁵⁸ Ex. 46 (D'Amelio Depo.) at 33:14-20.

¹⁵⁹ Ex. 46 (D'Amelio Depo.) at 33:14-20.

the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated herein by reference.

40. Disputed. Defendants cannot assert a reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated herein by reference.

41. Disputed. Defendants cannot assert a reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment.

Defendants have failed to adduce admissible evidence that they shared all pertinent information with KPMG. For example, KPMG was never told the specifics from the August and September 2006 meetings Pfizer had with the DOJ regarding the Bextra Investigation.¹⁶⁰ During those meetings, the DOJ presented to Pfizer, in detail, the unapproved, false and/or misleading claims Pfizer used to market Bextra. These off-label claims included marketing Bextra for acute pain generally, marketing Bextra as safer and more effective than Vioxx and marketing it for use in surgery.¹⁶¹ The DOJ also presented to Pfizer the tactics Pfizer used to market Bextra for these off-label indications to hospitals via protocols, standing orders and 20 mg samples to physicians who did not treat on-label use.¹⁶² The DOJ further told Pfizer how the Company paid physicians to attend consultant meetings, advisory boards, speaker events and used a publication strategy all to promote

¹⁶⁰ Ex. 57 (12/10/13 Levin Depo.) at 231:9-16; Ex. 54 (10/10/14 Kindler) at 20:19-21:4; Ex. 68 (10/16/14 Waxman) at 32:18-20.

¹⁶¹ Ex. 256 at DOJ000237.

¹⁶² Ex. 256 at DOJ000238.

Bextra off-label.¹⁶³ The DOJ also set forth the criminal charges based on Food & Drug Act and False Claims Act violations Pfizer would face and the aggravating factors including that the illegal promotion of Bextra continued despite the on-going Neurontin investigation and Pfizer was subject to two CIAs. The DOJ also told Pfizer about the illegal marketing of Bextra and that it was a deliberate scheme with pervasive misconduct and knowledge at the top.¹⁶⁴ Instead, KPMG was repeatedly told that the DOJ was still outlining the theories of liability.¹⁶⁵ This was misleading because the DOJ told Pfizer exactly how the off-label marketing of Bextra violated the Food & Drug Act and the False Claims Act.¹⁶⁶ Pfizer also misled KPMG by claiming not to know how to calculate the potential fine despite possessing the methodology based on the Company's prior experience with the Neurontin settlement.

KPMG never received the November 2006 memo by Mooney, Pfizer's director of Corporate Internal Audit who headed up the HCC audit function, which explained how problems with Pfizer's HCC function could have a material impact on Pfizer's financial results.¹⁶⁷ KPMG never received the presentation reviewed by Pfizer's Worldwide Pharmaceutical Operations Compliance Committee in October 2007 entitled "'RC Reform'-Why, What, When, How & Who" which summarized the findings of the "deep dive" initiated by defendant Read in March 2007 in response to the existence of the significant deficiency in the sales and marketing compliance area.¹⁶⁸ This presentation set

¹⁶³ Ex. 256 at DOJ000239.

¹⁶⁴ Ex. 258 at DOJ000207-08.

¹⁶⁵ Petrosinelli Decl., Ex. C-6.

¹⁶⁶ Ex. 258 at DOJ000205.

¹⁶⁷ Ex. 161.

¹⁶⁸ Ex. 203.

forth the complete lack of controls over the Review Committee and, thus, Pfizer's HCC function.¹⁶⁹ These failures are particularly glaring given: (1) Pfizer considered Review Committee procedures to be one of the top ten areas of greatest risk;¹⁷⁰ (2) KPMG's concern that Pfizer's controls over sales and marketing practices were impaired;¹⁷¹ and (3) KPMG had recently been informed by Pfizer that the significant deficiency with regard to HCC had been remediated by the end of 2Q07.¹⁷²

KPMG was also kept in the dark regarding the DOJ's escalation of the off-label marketing investigation. For example, KPMG was not informed that Pfizer's investigation counsel, Covington, received a letter from the DOJ on June 19, 2007, confirming that Pfizer and Pharmacia wished to resolve the outstanding investigations of Bextra and other Pfizer drugs as a package deal.¹⁷³ Similarly, KPMG was never informed that Pfizer received a target letter from the DOJ on February 5, 2008.¹⁷⁴ KPMG was never informed that the DOJ wrote Covington on April 4, 2008, and confirmed key elements of the proposed Bextra Investigation resolution, mentioned the structure and financial range previously communicated by the DOJ, indicated a severe escalation of the Bextra Investigation in that the DOJ intended to pursue criminal charges against Pfizer and offered a settlement of approximately \$5 billion.¹⁷⁵

¹⁶⁹ Ex. 203.

¹⁷⁰ Ex. 120.

¹⁷¹ Exs. 149-150.

¹⁷² Ex. 346 at KPMG PFIZ-DS 0003257 (2Q07 Interim Completion Document).

¹⁷³ Ex. 310.

¹⁷⁴ Ex. 131; Ex. 38 (Bradley Depo.) at 242:13-16.

¹⁷⁵ Petrosinelli Decl., Ex. Y-6.

KPMG was misled by Lankler regarding the Zyvox and Geodon investigations in June and July 2008 during compliance meetings. Lankler told KPMG that off-label marketing of Zyvox was identified in isolated cases and not linked to senior management back at Pfizer headquarters.¹⁷⁶ Yet, KPMG was never told that immediately after Pfizer received the July 2005 Warning Letter from the FDA, Pfizer upper management continued to instruct the sales force to use the core marketing message that Zyvox was superior to vancomycin.¹⁷⁷ Also, on September 10, 2008, Lankler told the Pfizer Audit Committee that the internal investigation revealed that “unsubstantiated superiority claims” were made about Zyvox “on a fairly broad basis.”¹⁷⁸ Similarly, Lankler told KPMG that the off-label marketing of Geodon had not been linked back to senior management at corporate headquarters.¹⁷⁹

Pfizer also misled KPMG about whether the probable criteria had been met and whether the range of loss could be estimated. For example, KPMG was never informed that during a meeting on September 14, 2007, the DOJ proposed to use the “intended loss” theory to calculate the fine Pfizer would pay in connection with the Government’s investigation of Bextra. Similarly, KPMG never received Pfizer’s investigation counsel Posner’s response to the DOJ’s “intended loss” proposal on October 1, 2007, which acknowledged a methodology for calculating the fine and argued that the fine in the Bextra Investigation should be calculated as it was in “analogous” cases such as Neurontin, Schering, Serono and Genotropin.¹⁸⁰

¹⁷⁶ Ex. 159.

¹⁷⁷ Exs. 138-139.

¹⁷⁸ Ex. 204.

¹⁷⁹ Ex. 204.

¹⁸⁰ Petrosinelli Decl., Ex. B-6.

More glaring, is that KPMG was never informed that on October 9, 2007, Pfizer's disclosure counsel and Pfizer's in-house accountants and attorneys again concluded that a loss from the DOJ Bextra Investigation was "probable."¹⁸¹ Chapman, KPMG audit partner, testified he had not been informed by November 3, 2007 that the probable "pillar" of FAS 5 had been met.¹⁸² Similarly, Bradley, KPMG audit partner, testified no one informed him in 2007 that Pfizer had concluded that the loss associated with the Government's investigation of the off-label promotion of Bextra was probable.¹⁸³

Nor was it revealed to KPMG that as a result of the government asking them to propose a number, Lankler and Wessel were working on calculating potential losses.¹⁸⁴ Additionally, Chapman testified he did not know Pfizer was working with methodologies to estimate the loss and that the Company had discussed an estimate range.¹⁸⁵ After becoming the engagement partner in early 2008, Bradley did not know that Lankler and Wessel were working on methodologies to calculate potential losses.¹⁸⁶

Again, instead, Block repeatedly told KPMG through the FY 2007 audit that the Government had neither spelled out statutory remedies nor the types of damages it would seek. Block also

¹⁸¹ Petrosinelli Decl., Ex. N-6 (October 17, 2007, email summarizing the October 9, 2007, meeting attended by Block, Lankler, Wessel, Kim Dadlani and Paul Brockie); Ex. 265 (3Q07 Interim Completion Document showing as of November 3, 2007, KPMG had been told loss not probable).

¹⁸² Ex. 44 (Chapman Depo.) at 122:19-123:16.

¹⁸³ Ex. 38 (Bradley Depo.) at 239:9-20.

¹⁸⁴ Petrosinelli Decl., Ex. N-6.

¹⁸⁵ Petrosinelli Decl., Ex. N-6; Ex. 44 (Chapman Depo.) at 130:12-18.

¹⁸⁶ Ex. 38 (Bradley Depo.) at 234:1-236:2.

continued to falsely assure KPMG that the loss was neither probable nor estimable even though Posner's response to the DOJ set forth a methodology to calculate the loss.¹⁸⁷

Pfizer also concealed from KPMG the settlement negotiations with the DOJ to resolve the Bextra Investigation. KPMG was never informed in February 2008 that Covington made a \$50-\$70 million offer to settle the Bextra Investigation to the DOJ, which the Government rejected.¹⁸⁸ KPMG was never informed that on March 28, 2008, Covington made a \$250 million offer to settle the Bextra Investigation to the DOJ which the government rejected.¹⁸⁹ KPMG was never informed in or around June 2008, that Covington offered \$750 million to settle the DOJ Bextra Investigation.¹⁹⁰ Lastly, KPMG was never told that King & Spalding sent a letter dated September 11, 2008, to the DOJ and several states attorney generals that the Government had rejected Pfizer's recent \$750 million offer to settle.¹⁹¹ In fact, KPMG workpapers from June and July 2008 show that Pfizer told KPMG that no offers to settle to date had been made.¹⁹²

KPMG relied on representations of Pfizer management in the form of quarterly management representation letters signed by the CFO and Controller, quarterly in-house legal representation letters signed by defendants Waxman and Kindler and annual legal representation letters from Pfizer's outside counsel. The quarterly management representation letters confirmed that management was responsible for the fair presentation of the financial statements in conformity with

¹⁸⁷ Petrosinelli Decl., Exs. B-6, C-6.

¹⁸⁸ Ex. 104; Ex. 38 (Bradley Depo.) at 236:3-11.

¹⁸⁹ Petrosinelli Decl., Ex. Y-6; Ex. 38 (Bradley Depo.) at 247:22-248:5.

¹⁹⁰ Ex. 158; Ex. 39 (Bradley Depo.) at 268:4-18, 276:16-21, 278:3-8 ("I was not aware of a specific dollar amount that had been proposed by or prepared to recommend by Pfizer counsel.").

¹⁹¹ Ex. 158.

¹⁹² Ex. 159.

GAAP and confirmed certain material matters, including a representation that all relevant information relating to certain compliance matters subject to the investigation of alleged fraud or potential illegal acts conducted by the Government Investigations Section and the Office of Corporate Compliance were disclosed by Pfizer to the Audit Committee, to the investigating team and to KPMG.¹⁹³ The quarterly in-house legal representation letters were to provide KPMG with an update of significant pending litigation, and the annual legal letters from outside counsel were to provide KPMG with the following information pertaining to material pending or threatened litigation: the nature of the litigation; the progress of the case to date; how management is responding or intends to respond to the litigation; and an evaluation of the likelihood of an unfavorable outcome and an estimate, if one can be made, of the amount or range of potential loss. The representations KPMG received failed to disclose information, as set forth above, necessary for KPMG to render advice regarding Pfizer's contingency reserves and disclosures regarding the Government's off-label marketing investigation.

Fees paid to KPMG by Pfizer were \$30,285,000, \$32,410,000, \$28,220,000 and \$27,735,000 for services rendered in 2005, 2006, 2007 and 2008, respectively.¹⁹⁴ Fees paid to KPMG by Pfizer for services rendered after the Class Period were \$37,353,000, \$38,993,000, \$38,999,000, \$50,267,000, and \$32,014,200 for 2009, 2010, 2011, 2012 and 2013, respectively.¹⁹⁵

42. Disputed. Defendants cannot assert a reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is

¹⁹³ *E.g.*, Ex. 134 at KPMG-PFIZ-DS 017125.

¹⁹⁴ Exs. 14, 17-18.

¹⁹⁵ Exs. 19-23.

incorporated herein by reference. Further, D'Amelio testified that at Pfizer he was responsible for "what reserves get recorded and not recorded."¹⁹⁶ It was Pfizer's determination, not KPMG.

43. Disputed. Defendants cannot assert a reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated herein by reference. Further, D'Amelio testified that at Pfizer he was responsible for "what reserves get recorded and not recorded."¹⁹⁷

44. Disputed. Defendants cannot assert a reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated herein by reference. Further, D'Amelio testified that at Pfizer he was responsible for "what reserves get recorded and not recorded."¹⁹⁸ Also, KPMG's unqualified audit opinions in the Forms 10-K do not state that Pfizer's financial statements were accurate, nor do they specify an opinion with regard to FAS 5 reserves.¹⁹⁹

45. Disputed. D'Amelio suggests that the fiscal year 2008 financial statements were the first time that Pfizer should have recorded an accrual for the Government investigations. D'Amelio's purported fact is incorrect.²⁰⁰ Further, defendants cannot assert a reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition,

¹⁹⁶ Ex. 46 (D'Amelio Depo.) at 33:14-20.

¹⁹⁷ Ex. 46 (D'Amelio Depo.) at 33:14-20.

¹⁹⁸ Ex. 46 (D'Amelio Depo.) at 33:14-20.

¹⁹⁹ Petrosinelli Decl., Ex. F-1 at 37.

²⁰⁰ Ex. 7 (Supplemental Expert Report of D. Paul Regan) at 11-47.

plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated herein by reference.

46. Disputed. Defendants cannot assert a reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated herein by reference. Further, D'Amelio testified that at Pfizer he was responsible for "what reserves get recorded and not recorded."²⁰¹

47. Disputed. Defendants cannot assert an advice of counsel or reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated by reference herein. In addition, plaintiffs object to Strassberg Decl., Ex. E-D for the reasons set forth in Plaintiffs' Objections, which is incorporated by reference herein.

48. Disputed. Defendants cannot assert a reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated herein by reference. Further, D'Amelio testified that at Pfizer he was responsible for "what reserves get recorded and not recorded."²⁰²

49. Disputed. Defendants cannot assert a reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is

²⁰¹ Ex. 46 (D'Amelio Depo.) at 33:14-20.

²⁰² Ex. 46 (D'Amelio Depo.) at 33:14-20.

incorporated herein by reference. Further, D'Amelio testified that at Pfizer he was responsible for "what reserves get recorded and not recorded."²⁰³

50. Disputed. Defendants cannot assert a reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 41. Further, D'Amelio testified that at Pfizer he was responsible for "what reserves get recorded and not recorded."²⁰⁴ Moreover, D'Amelio misstates KPMG's responsibility. KPMG's responsibility is to plan and perform the audit to obtain reasonable, not absolute, assurance about whether Pfizer's financial statements were free of material misstatement. The financial statements are management's responsibility.²⁰⁵

51. Disputed. Defendants cannot assert a reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 41.

52. Disputed. Defendants cannot assert a reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 41, which is incorporated herein by reference. Further, D'Amelio testified that at Pfizer he was responsible for "what reserves get recorded and not recorded."²⁰⁶ In addition, plaintiffs object to Strassberg Decl.

²⁰³ Ex. 46 (D'Amelio Depo.) at 33:14-20.

²⁰⁴ Ex. 46 (D'Amelio Depo.) at 33:14-20.

²⁰⁵ AU§110, ¶¶2-3.

²⁰⁶ Ex. 46 (D'Amelio Depo.) at 33:14-20.

Exs. U-D, AA-D for the reasons set forth in Plaintiffs' Objections, which is incorporated by reference herein.

53. Disputed. Defendants cannot assert a reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 41, which is incorporated herein by reference. Further, D'Amelio testified that at Pfizer he was responsible for "what reserves get recorded and not recorded."²⁰⁷

54. Undisputed.

55. Disputed. This purported undisputed fact is an opinion that calls for a legal conclusion.

56. Disputed. D'Amelio was the CFO of Pfizer in March 2008.²⁰⁸ As CFO, he had more information regarding the Company's financial position and dividend than employees in the Investor Relations group. For example, after becoming Pfizer's CFO in September 2007 D'Amelio was a member of Pfizer's ELT and regularly attended ELT meetings with Kindler, Read and Waxman.²⁰⁹ Moreover, in his capacity as a member of the Disclosure Committee, D'Amelio was responsible for reviewing the procedures relating to the preparation of the Company's communications to analysts and the investment community.²¹⁰ D'Amelio and Kindler reviewed and approved the statements before they were made.²¹¹

²⁰⁷ Ex. 46 (D'Amelio Depo.) at 33:14-20.

²⁰⁸ Strassberg Decl., Ex. G-D.

²⁰⁹ *E.g.*, Ex. 342; Ex. 208.

²¹⁰ Ex. 124.

²¹¹ *See* Strassberg Decl., Exs. DD-D and EE-D.

57. Disputed. Plaintiffs admit that Strassberg Decl., Ex. EE-D was widely distributed at Pfizer. To the extent that D'Amelio is suggesting that he relied on counsel for his statements, plaintiffs dispute that inference. Defendants cannot assert an advice of counsel defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 6, which is incorporated by reference herein. Further, in his capacity as a member of the ELT, D'Amelio was responsible for developing Pfizer's communication strategy to investors, including in SEC filings and press releases.²¹²

58. Disputed. Plaintiffs incorporate by reference their Response to D'Amelio's Undisputed Fact No. 6.

59. Undisputed.

60. Undisputed.

61. Undisputed.

62. Disputed. Pfizer had apparently been in discussions with Wyeth regarding the merger as early as June 2008.²¹³

63. Undisputed. The purported fact accurately reflects D'Amelio's testimony.

64. Undisputed. The purported fact accurately reflects D'Amelio's testimony.

65. Disputed. Pfizer's acquisition of Wyeth was being discussed as early as June 2008.²¹⁴ Further, as early as September 9, 2008, D'Amelio was requesting information regarding the dividend cut in light of the Wyeth acquisition. Strassberg Decl., Ex. GG-D.

²¹² Ex. 202.

²¹³ Ex. 37 (Block Depo.) at 217:17-25.

²¹⁴ Ex. 37 (Block Depo.) at 217:17-25.

66. Undisputed.

67. Disputed. Plaintiffs agree that D'Amelio made statements regarding sales revenue from Lyrica on October 18, 2007, January 23, 2008, April 17, 2008 and October 21, 2008. Plaintiffs agree that Investor Relations distributed materials to D'Amelio in advance of earnings calls. However, to the extent that D'Amelio implies that Investor Relations employees had more information regarding Pfizer's sales revenue and earnings than D'Amelio, the purported fact is inaccurate. D'Amelio was the Company's CFO. After becoming Pfizer's CFO in September 2007, D'Amelio was a member of Pfizer's ELT and regularly attended ELT meetings with Kindler, Read and Waxman.²¹⁵ In addition, to the extent that D'Amelio claims that earnings releases were vetted by inside and outside professionals, plaintiffs incorporate by reference their Response to D'Amelio's Undisputed Fact No. 5.

68. Disputed. Plaintiffs incorporate by reference their Response to D'Amelio's Undisputed Fact No. 5.

69. Disputed. Strassberg Decl., Ex. S-D was circulated to over 20 people within Pfizer. To the extent that D'Amelio asserts that the statements were vetted by counsel or Cangialosi, plaintiffs incorporate by reference their Response to D'Amelio's Undisputed Fact No. 5.

70. Disputed. Defendants cannot assert an advice of counsel or reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to D'Amelio's Undisputed Fact No. 5, which is incorporated by reference herein.

71. Undisputed.

²¹⁵ *E.g.*, Ex. 342; Ex. 208.

72. Disputed. D'Amelio's statements provided new information to the financial markets, even if D'Amelio's statements simply maintained the level of artificial inflation.²¹⁶

73. Disputed. Plaintiffs agree that the January 26, 2009 announcements did not contain the word "Lyrica." However, the announcements discuss the settlement of the Bextra Investigation and other open investigations. Lyrica was one of the other open investigations. The \$2.3 billion settlement in principle with the DOJ encompassed resolution of the Government's investigation into the off-label promotion of Geodon, Lyrica and Zyvox.²¹⁷ Pfizer's January 26, 2009 disclosure of the resolution of the DOJ investigation was a materialization of the concealed Class Period risks associated with Pfizer's illegal off-label promotion of the Company's pharmaceutical products, including Bextra, Geodon, Lyrica and Zyvox.²¹⁸ Prior to January 26, 2009, Pfizer knew the settlement encompassed Geodon, Lyrica and Zyvox, but chose not to name those drugs in its January 26, 2009 earnings press release.²¹⁹

74. Disputed. Plaintiffs incorporate by reference their Response to D'Amelio's Undisputed Fact No. 73.

75. Undisputed.

76. Disputed. Dr. Steven Feinstein has opined that each and every one of defendants' Class Period false and misleading statements caused plaintiffs' damages.

²¹⁶ Ex. 48 (Feinstein Depo.) at 108:16-116:4.

²¹⁷ See Pfizer's SUF, ¶113.

²¹⁸ See Ex. 4 (Report of Steven Feinstein), ¶¶29-32, 126.

²¹⁹ See Ex. 273.

77. Disputed. Dr. Feinstein has opined that defendants' Class Period statements created and maintained \$1.26 per share artificial inflation in the Company's stock price.²²⁰ For example, on January 19, 2006, defendants announced \$0.37 and \$1.09 earnings per share for 4Q05 and FY 2005, respectively.²²¹ By late September 2005, however, settlement of the DOJ's investigation into the off-label promotion of Bextra was virtually certain and the Company at that time could have estimated minimum reserve of at least \$1.0 billion.²²² Not only did Pfizer fail to book a charge to earnings on January 19, 2006, it also failed to disclose that the focus of the DOJ's investigation was the off-label promotion of Pfizer's pharmaceutical products.²²³

On January 19, 2006, defendants also touted the new-prescription and market growth of Geodon and Lyrica.²²⁴ At the time defendants made their January 19, 2006 statements concerning Geodon and Lyrica, the market share and new-prescription gains for those drugs in the U.S. were being fueled by Pfizer's unlawful off-label promotion.²²⁵ Defendants failed to disclose that fact to investors on January 19, 2006. As such, defendants' false and misleading statements created and maintained \$1.26 per share inflation in the Company's stock price throughout the Class Period.

²²⁰ See Ex. 4 (Report of Steven Feinstein), ¶¶18, 29-31, 126.

²²¹ See Plaintiffs' Statement of Material Facts Requiring Denial of Defendants' Motion for Summary Judgment, False and Misleading Statements Chart ("FMS"), ¶1.

²²² See Ex. 7 (Supplemental Expert Report of D. Paul Regan) at 18-35.

²²³ See Ex. 7 (Supplemental Expert Report of D. Paul Regan) at 48-55; Ex. 426 (December 12, 2005 Audit Committee minutes reflecting the DOJ's investigation concerned unlawful "off label promotion").

²²⁴ See Petrosinelli Decl., Ex. K-1.

²²⁵ See Ex. 8 (Expert Report of Meredith Rosenthal), ¶¶59-74 (Geodon), ¶¶75-87 (Lyrica).

78. Disputed. Dr. Feinstein testified that each one of defendants' Class Period false and misleading statements maintained the \$1.26 per share inflation in Pfizer's stock price.²²⁶ Indeed, Dr. Feinstein testified that had investors learned prior to January 26, 2009 that the Company had been, and currently was, unlawfully promoting its drugs, the Company's stock price would have dropped by \$1.26 per share.

79. Disputed. The evidence cited by defendants does not support their self-serving factual assertion. Dr. Feinstein twice disagreed with Pfizer's counsel's baseless assertions that he had not considered losses attributable to individual Class Period statements and concluded that individual statements were irrelevant to his loss causation and damages opinions.²²⁷

DATED: November 26, 2014

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²²⁶ See Ex. 48 (Feinstein Depo.) at 108:16-109:5; 126:11-127:2.

²²⁷ See Ex. 48 (Feinstein Depo.) at 183:18-185-10.

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CERTIFICATE OF SERVICE

I hereby certify that on November 26, 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 November 26, 2014.

s/ TRIG R. SMITH

TRIG R. SMITH

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Electronic Mail Notice List

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Southern District of New York

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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: [300](#)

Docket Text:

RESPONSE in Opposition to Motion re: [260] MOTION for Summary Judgment . Plaintiffs' Local Rule 56.1 Response to Defendant Frank DAmelio's Statement of Undisputed Material Facts. Document filed by Mary K. Jones(on behalf of all others similarly situated), Stichting Philips Pensioenfonds. (Smith, Trig)

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