

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 JEFFREY B.
PFIZER INC., et al.,	:	KINDLER'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 Jeffrey B. Kindler’s Statement of Undisputed Material Facts.

1. Undisputed.
2. Disputed. Defendants’ advice of counsel defense should be precluded, as set forth in 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. Further, Jeffrey B. Kindler (“Kindler”) testified that he did not look to Lawrence Fox (“Fox”) for advice regarding the strengths and weaknesses of the Government’s¹ Bextra Investigation,² and the defenses to that investigation.³ Kindler, in support of this fact, fails to cite to any deposition testimony that actually supports his claim of Fox’s advice. Additionally, the Minutes of the Disclosure Committee Meeting cited by Kindler Declaration of Joseph G. Petrosinelli in Support of Pfizer’s Motion for Summary Judgment (“Petrosinelli Decl.”) Ex. V-6 at PFE-JONES 00036383-685) for February 22, 2006, April 18, 2006, May 1, 2006, July 18, 2006 and August 1, 2006 do not prove his contention that Fox advised him

¹ “Government” refers to the Department of Justice (“DOJ”) and/or the Health & Human Services Office of Inspector General (“OIG”).

² “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 & Burling LLP (“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. 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.

³ Ex. 54 (10/10/14 Kindler Depo.) at 31:10-32:5.

that “the disclosures were accurate and complied with the federal securities laws.”⁴ In reality, the referenced minutes demonstrate that the Committee, chaired by Kindler, determined that Kindler should sign the Certification and deliver it to the Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”). In addition, defendants rely on exhibits which are objectionable as set forth in Plaintiffs’ objections to Exhibits Submitted in Support of Defendants’ Motion for Summary Judgment (“Plaintiffs’ Objections”), which is filed concurrently herewith. In particular, plaintiffs object to Petrosinelli Decl., Ex. V-6.

Defendants have expressly denied relying on any counsel other than Dennis Block (“Block”) or Fox for their defense in this case⁵ (consistent with that denial, defendants successfully shielded Investigations Counsel⁶ 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 and Plaintiffs’ Memorandum. 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’s case⁷ or Pfizer’s defenses,⁸ whether a loss or conviction was probable or whether

⁴ Dkt. No. 275 at 2.

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

⁶ “Investigations Counsel” refers to Pfizer’s counsel who were involved in the Bextra Investigation, including, but not limited to, Covington and in-house counsel Douglas Lankler (“Lankler”), Carlton Wessel (“Wessel”) and Gary Giampetruzzi (“Giampetruzzi”).

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.

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 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

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.

¹⁰ 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.

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

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

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

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.

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 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

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.

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

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

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.

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.

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

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

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.

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.

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

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

³⁹ Ex. 240 at 52:5-9.

⁴⁰ See 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.

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

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

3. Disputed. Plaintiffs incorporate by reference their Response to Kindler's Undisputed Fact No. 2.

4. Disputed. Defendants' contention that the quarterly certification meetings establish their good faith reliance on counsel is unfounded. First, defendants rely on exhibits which are objectionable as set forth in Plaintiffs' Objections. In particular, plaintiffs object to Petrosinelli Decl., Ex. B-4 and Exs. G-K, E-K to the Declaration of James P. Rouhandeh in Support of Defendant Jeffrey B. Kindler's Motion for Summary Judgment (Dkt. No. 276) ("Rouhandeh Decl."). Moreover, as to the Bextra Investigation and defendants' purported reliance on the sub-certification process for the accuracy of their SEC filings.

Defendants have expressly denied relying on any counsel other than Block or Fox for their defense in this case⁴⁹ (consistent with that denial, defendants successfully shielded Investigations Counsel from discovery), so defendants may not invoke or rely on Investigations Counsel, including

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.

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

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. Neither 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 case⁵⁰ or Pfizer's defenses,⁵¹ whether a loss or conviction was probable or whether such loss was reasonably estimable.⁵² Moreover, defendants withheld from Block and Fox critical evidence concerning the Bextra Investigation,⁵³ including call notes,⁵⁴ documents that corroborated a *qui tam* relator's claims,⁵⁵ Bextra-related documents that Pfizer employees had attempted to delete or alter,⁵⁶ sales force survey results⁵⁷ and employee interview memoranda.⁵⁸

⁵⁰ 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.

⁵¹ Ex. 37 (Block Depo.) at 104:6-23; Ex. 49 (Fox Depo.) at 86:13-19, 90:12-20.

⁵² 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.

⁵³ 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.

⁵⁴ Ex. 37 (Block Depo.) at 76:5-23, 144:21-145:4; Ex. 49 (Fox Depo.) at 60:3-22, 61:3-11.

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⁵⁶ Ex. 37 (Block Depo.) at 59:14-60:6, 230:21-231:8; Ex. 49 (Fox Depo.) at 49:9-23.

⁵⁷ Ex. 37 (Block Depo.) at 54:8-22, 56:2-11; Ex. 49 (Fox Depo.) at 97:11-18, 211:16-212:1.

⁵⁸ 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.

Instead, all information and input regarding the Bextra Investigation came from Investigations Counsel.⁵⁹ 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.⁶⁰

Block never personally and professionally assessed nor advised defendants that Pfizer had substantial defenses to the Bextra Investigation.⁶¹

Fox never independently determined or advised defendants that Pfizer had substantial defenses to the Bextra Investigation.⁶²

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.⁶³

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.⁶⁴

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

⁵⁹ 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.

⁶⁰ Ex. 55 (Lankler Depo.) at 92:23-97:21.

⁶¹ Ex. 37 (Block Depo.) at 104:6-23.

⁶² Ex. 49 (Fox Depo.) at 86:13-19, 90:12-20.

⁶³ 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.

⁶⁴ 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.

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.⁶⁵

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.⁶⁶

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 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.⁶⁷

⁶⁵ 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.

⁶⁶ 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.

⁶⁷ 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.

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.⁶⁸

Neither Block nor Fox has ever worked as a criminal law prosecutor or a criminal defense attorney.⁶⁹

Neither Block nor Fox was familiar with the elements of a misbranding offense.⁷⁰

Neither Block nor Fox was familiar with elements or application of *respondeat superior* liability.⁷¹

⁶⁸ 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.

⁶⁹ Ex. 37 (Block Depo.) at 13:12-14:6, 14:13-15:10; Ex. 49 (Fox Depo.) at 35:21-36:12.

⁷⁰ Ex. 37 (Block Depo.) at 16:6-17:8; Ex. 49 (Fox Depo.) at 37:17.

⁷¹ Ex. 37 (Block Depo.) at 232:20-233:12; Ex. 49 (Fox Depo.) at 36:13-37:9.

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.⁷²

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.⁷³

Fox incorrectly understood the terms grand jury "target" and grand jury "subject" to be interchangeable.⁷⁴

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.⁷⁵

Pfizer and its Investigations Counsel always represented to Block that Pfizer's sales representatives had not promoted Bextra off-label.⁷⁶ 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-sparing in the context of surgery;⁷⁷ 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;⁷⁸ Pfizer

⁷² 42 U.S.C. §1320a-7.

⁷³ Ex. 49 (Fox Depo.) at 130:7-15, 218:21-219:5.

⁷⁴ Ex. 49 (Fox Depo.) at 106:3-23.

⁷⁵ 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.

⁷⁶ Ex. 37 (Block Depo.) at 50:5-20, 232:3-12.

⁷⁷ Ex. 240 at 51:10-17.

⁷⁸ Ex. 240 at 51:17-18.

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;⁷⁹ Pfizer promoted Bextra with an intent to defraud or mislead;⁸⁰ 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;⁸¹ 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.⁸²

No one provided Block a copy of Kopchinski's Complaint or any of the internal Pfizer documents that were exhibits to it.⁸³ The same appears to be true as to Fox, as the record does not indicate that he received those documents either.⁸⁴

No one ever provided Block or Fox the internal documents that Pfizer's sales representatives had attempted to delete or alter.⁸⁵

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.⁸⁶

⁷⁹ Ex. 240 at 51:19-21.

⁸⁰ Ex. 240 at 51:22-23.

⁸¹ Ex. 240 at 52:1-4.

⁸² Ex. 240 at 52:5-9.

⁸³ *See also* Ex. 37 (Block Depo.) at 54:8-22; Ex. 60 (9/19/14 McKinnell Depo.) at 60:7-10; Ex. 54 (10/10/14 Kindler Depo.) at 34:19-24.

⁸⁴ Ex. 49 (Fox Depo.) at 211:5-212:1; *see also* Ex. 54 (10/10/14 Kindler Depo.) at 35:18-36:10.

⁸⁵ Ex. 37 (Block Depo.) at 59:14-60:1, 230:21-231:8; Ex. 49 (Fox Depo.) at 49:9-23.

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.⁸⁷

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.⁸⁸

No one provided Block or Fox copies of any of the interview memoranda from the Bextra Investigation.⁸⁹

Neither Block nor Fox received access to any of Pfizer's Investigations Counsel's written work product concerning the Bextra Investigation.⁹⁰

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.⁹¹

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 company's reserves complied with Generally Accepted Accounting Principles ["GAAP"],

⁸⁶ 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.

⁸⁷ See Ex. 37 (Block Depo.) at 54:8-22, 56:2-11; Ex. 49 (Fox Depo.) at 97:11-18, 211:16-212:1.

⁸⁸ Ex. 37 (Block Depo.) at 76:5-23, 144:21-145:4; Ex. 49 (Fox Depo.) at 60:3-22, 61:3-11.

⁸⁹ 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.

⁹⁰ Ex. 55 (Lankler Depo.) at 101:1-11; Ex. 37 (Block Depo.) at 54:8-22; Ex. 49 (Fox Depo.) at 97:11-18.

⁹¹ Ex. 37 (Block Depo.) at 69:6-15, 73:21-74:16; Ex. 49 (Fox Depo.) at 74:22-80:1.

particularly FAS 5.”⁹² 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.”⁹³ In addition, she never received warning letters from the FDA,⁹⁴ letters to the OIG from Investigations Counsel regarding reportable events pursuant to Pfizer’s Corporate Integrity Agreement (“CIA”),⁹⁵ documents concerning methodologies to evaluate damages for the Government investigation,⁹⁶ the February 5, 2008 target letter from the Government,⁹⁷ the April 4, 2008 letter in which Investigations Counsel made a \$250 million offer to the Government to settle its investigation⁹⁸ or documents relating to the review committee process or reforms or initiatives concerning it.⁹⁹

5. Disputed. Defendants have expressly denied relying on any counsel other than Block or Fox for their defense in this case¹⁰⁰ (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’

⁹² Statement of Undisputed Facts in Support of Pfizer’s Motion for Summary Judgment, ¶31.

⁹³ Petrosinelli Decl., Ex. N-6.

⁹⁴ Ex. 43 (Cangialosi Depo.) at 100:20-101:20.

⁹⁵ Ex. 43 (Cangialosi Depo.) at 181:6-184:20.

⁹⁶ Ex. 43 (Cangialosi Depo.) at 294:13-295:6.

⁹⁷ Ex. 43 (Cangialosi Depo.) at 253:19-254:5.

⁹⁸ Ex. 43 (Cangialosi Depo.) at 260:5-8, 321:20-322:4.

⁹⁹ Ex. 43 (Cangialosi Depo.) at 96:15-98:7, 112:23-119:4, 124:24-128:13.

¹⁰⁰ Dkt. No. 172 at 25; July 19, 2013 Hearing Transcript at 12:1-2; Dkt. No. 246 at 1, 5.

Motion for Partial Summary Judgment, and Plaintiffs' Memorandum. Neither 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 case¹⁰¹ or Pfizer's defenses,¹⁰² whether a loss or conviction was probable or whether such loss was reasonably estimable.¹⁰³ Moreover, defendants withheld from Block and Fox critical evidence concerning the Bextra Investigation,¹⁰⁴ including call notes,¹⁰⁵ documents that corroborated a *qui tam* relator's claims,¹⁰⁶ Bextra-related documents that Pfizer employees had attempted to delete or alter,¹⁰⁷ sales force survey results¹⁰⁸ and employee interview memoranda.¹⁰⁹ Instead, all information and input regarding the Bextra Investigation came from Investigations Counsel.¹¹⁰ For example:

¹⁰¹ 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.

¹⁰² Ex. 37 (Block Depo.) at 104:6-23; Ex. 49 (Fox Depo.) at 86:13-19, 90:12-20.

¹⁰³ 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.

¹⁰⁴ Ex. 57 (12/10/13 Levin Depo.) at 231:9-16; Ex. 54 (10/10/14 Kindler Depo.) at 20:19-21:4; Ex. 68 (10/16/14 Waxman) at 32:18-20.

¹⁰⁵ Ex. 37 (Block Depo.) at 76:5-23, 144:21-145:4; Ex. 49 (Fox Depo.) at 60:3-22, 61:3-11.

¹⁰⁶ 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.

¹⁰⁷ Ex. 37 (Block Depo.) at 59:14-60:6, 230:21-231:8; Ex. 49 (Fox Depo.) at 49:9-23.

¹⁰⁸ Ex. 37 (Block Depo.) at 54:8-22, 56:2-11; Ex. 49 (Fox Depo.) at 97:11-18, 211:16-212:1.

¹⁰⁹ 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.

¹¹⁰ 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.

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.¹¹¹

Block never personally and professionally assessed nor advised defendants that Pfizer had substantial defenses to the Bextra Investigation.¹¹²

Fox never independently determined or advised defendants that Pfizer had substantial defenses to the Bextra Investigation.¹¹³

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.¹¹⁴

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.¹¹⁵

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.¹¹⁶

¹¹¹ Ex. 55 (Lankler Depo.) at 92:23-97:21.

¹¹² Ex. 37 (Block Depo.) at 104:6-23.

¹¹³ Ex. 49 (Fox Depo.) at 86:13-19, 90:12-20.

¹¹⁴ 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.

¹¹⁵ 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.

¹¹⁶ 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.

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.¹¹⁷

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 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.¹¹⁸

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

¹¹⁷ 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.

¹¹⁸ 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.

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.¹¹⁹

Neither Block nor Fox has ever worked as a criminal law prosecutor or a criminal defense attorney.¹²⁰

Neither Block nor Fox was familiar with the elements of a misbranding offense.¹²¹

Neither Block nor Fox was familiar with elements or application of *respondeat superior* liability.¹²²

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.¹²³

¹¹⁹ 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.

¹²⁰ Ex. 37 (Block Depo.) at 13:12-14:6, 14:13-15:10; Ex. 49 (Fox Depo.) at 35:21-36:12.

¹²¹ Ex. 37 (Block Depo.) at 16:6-17:8; Ex. 49 (Fox Depo.) at 37:17.

¹²² Ex. 37 (Block Depo.) at 232:20-233:12; Ex. 49 (Fox Depo.) at 36:13-37:9.

¹²³ 42 U.S.C. §1320a-7.

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.¹²⁴

Fox incorrectly understood the terms grand jury “target” and grand jury “subject” to be interchangeable.¹²⁵

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.¹²⁶

Pfizer and its Investigations Counsel always represented to Block that Pfizer’s sales representatives had not promoted Bextra off-label.¹²⁷ 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-sparing in the context of surgery;¹²⁸ 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;¹²⁹ 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;¹³⁰ Pfizer promoted Bextra with an intent to defraud or mislead;¹³¹ certain members of

¹²⁴ Ex. 49 (Fox Depo.) at 130:7-15, 218:21-219:5.

¹²⁵ Ex. 49 (Fox Depo.) at 106:3-23.

¹²⁶ 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.

¹²⁷ Ex. 37 (Block Depo.) at 50:5-20, 232:3-12.

¹²⁸ Ex. 240 at 51:10-17.

¹²⁹ Ex. 240 at 51:17-18.

¹³⁰ Ex. 240 at 51:19-21.

Pfizer's sales force promoted Bextra with false and misleading claims, including that Bextra had no dose proportional increase in hypertension and edema;¹³² 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.¹³³

No one provided Block a copy of Kopchinski's Complaint or any of the internal Pfizer documents that were exhibits to it.¹³⁴ The same appears to be true as to Fox, as the record does not indicate that he received those documents either.¹³⁵

No one ever provided Block or Fox the internal documents that Pfizer's sales representatives had attempted to delete or alter.¹³⁶

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.¹³⁷

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.¹³⁸

¹³¹ Ex. 240 at 51:22-23.

¹³² Ex. 240 at 52:1-4.

¹³³ Ex. 240 at 52:5-9.

¹³⁴ *See also* Ex. 37 (Block Depo.) at 54:8-22; Ex. 60 (9/19/14 McKinnell Depo.) at 60:7-10; *see* Ex. 54 (10/10/14 Kindler Depo.) at 34:19-24.

¹³⁵ Ex. 49 (Fox Depo.) at 211:5-212:1; *see also* Ex. 54 (10/10/14 Kindler Depo.) at 35:18-36:10.

¹³⁶ Ex. 37 (Block Depo.) at 59:14-60:1, 230:21-231:8; Ex. 49 (Fox Depo.) at 49:9-23.

¹³⁷ 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.

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.¹³⁹

No one provided Block or Fox copies of any of the interview memoranda from the Bextra Investigation.¹⁴⁰

Neither Block nor Fox received access to any of Pfizer's Investigations Counsel's written work product concerning the Bextra Investigation.¹⁴¹

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.¹⁴²

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.¹⁴³ The DOJ also presented to Pfizer the tactics Pfizer used to market

¹³⁸ See Ex. 37 (Block Depo.) at 54:8-22, 56:2-11; Ex. 49 (Fox Depo.) at 97:11-18, 211:16-212:1.

¹³⁹ Ex. 37 (Block Depo.) at 76:5-23, 144:21-145:4; Ex. 49 (Fox Depo.) at 60:3-22, 61:3-11.

¹⁴⁰ 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.

¹⁴¹ Ex. 55 (Lankler Depo.) at 101:1-11; Ex. 37 (Block Depo.) at 54:8-22; Ex. 49 (Fox Depo.) at 97:11-18.

¹⁴² Ex. 37 (Block Depo.) at 69:6-15, 73:21-74:16; Ex. 49 (Fox Depo.) at 74:22-80:1.

¹⁴³ Ex. 256 at DOJ000237.

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.¹⁴⁴ 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.¹⁴⁵ 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.¹⁴⁶ Instead, KPMG was repeatedly told that the DOJ was still outlining the theories of liability.¹⁴⁷ 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.¹⁴⁸ 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.¹⁴⁹ KPMG never received the presentation reviewed by Pfizer's

¹⁴⁴ Ex. 256 at DOJ000238.

¹⁴⁵ Ex. 256 at DOJ000239.

¹⁴⁶ Ex. 258 at DOJ000207-08.

¹⁴⁷ Petrosinelli Decl., Ex. C-6.

¹⁴⁸ Ex. 258 at DOJ000205.

¹⁴⁹ Ex. 161.

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.¹⁵⁰ This presentation set forth the complete lack of controls over the Review Committee and, thus, Pfizer’s HCC function.¹⁵¹ These failures are particularly glaring given: (1) Pfizer considered Review Committee procedures to be one of the top ten areas of greatest risk;¹⁵² (2) KPMG’s concern that Pfizer’s controls over sales and marketing practices were impaired;¹⁵³ and (3) KPMG had recently been informed by Pfizer that the significant deficiency with regard to HCC had been remediated by the end of 2Q07.¹⁵⁴

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.¹⁵⁵ Similarly, KPMG was never informed that Pfizer received a target letter from the DOJ on February 5, 2008.¹⁵⁶ 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

¹⁵⁰ Ex. 203.

¹⁵¹ Ex. 203.

¹⁵² Ex. 120.

¹⁵³ Exs. 149-150.

¹⁵⁴ Ex. 346 at KPMG PFIZ-DS 0003257 (2Q07 Interim Completion Document).

¹⁵⁵ Ex. 310.

¹⁵⁶ Ex. 131; Ex. 38 (Bradley Depo.) at 242:13-16.

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.¹⁵⁷

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.¹⁵⁸ 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.¹⁵⁹ 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.”¹⁶⁰ Similarly, Lankler told KPMG that the off-label marketing of Geodon had not been linked back to senior management at corporate headquarters.¹⁶¹

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

¹⁵⁷ Petrosinelli Decl., Ex. Y-6.

¹⁵⁸ Ex. 159.

¹⁵⁹ Exs. 138-139.

¹⁶⁰ Ex. 204.

¹⁶¹ Ex. 204.

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.¹⁶²

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.”¹⁶³ 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.¹⁶⁴ 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.¹⁶⁵

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.¹⁶⁶ 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.¹⁶⁷ After becoming the engagement partner in

¹⁶² Petrosinelli Decl., Ex. B-6.

¹⁶³ Petrosinelli Decl., Ex. N-6 (October 17, 2007, email summarizing the October 9, 2007, meeting attended by Block, Lankler, Wessel, Kim Dadlani (“Dadlani”) and Paul Brockie (“Brockie”)); Ex. 265 (3Q07 Interim Completion Document showing as of November 3, 2007, KPMG had been told loss not probable).

¹⁶⁴ Ex. 44 (Chapman Depo.) at 122:19-123:16.

¹⁶⁵ Ex. 38 (Bradley Depo.) at 239:9-20.

¹⁶⁶ Petrosinelli Decl., Ex. N-6

¹⁶⁷ Petrosinelli Decl., Ex. N-6; Ex. 44 (Chapman Depo.) at 130:12-18.

early 2008, Bradley did not know that Lankler and Wessel were working on methodologies to calculate potential losses.¹⁶⁸

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.¹⁶⁹

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.¹⁷⁰ 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.¹⁷¹ KPMG was never informed in or around June 2008, that Covington offered \$750 million to settle the DOJ Bextra Investigation.¹⁷² 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.¹⁷³ In fact, KPMG workpapers from June and July 2008 show that Pfizer told KPMG that no offers to settle to date had been made.¹⁷⁴

¹⁶⁸ Ex. 38 (Bradley Depo.) at 234:1-236:2.

¹⁶⁹ Petrosinelli Decl., Exs. B-6, C-6.

¹⁷⁰ Ex. 286; Ex. 38 (Bradley Depo.) at 236:3-11.

¹⁷¹ Petrosinelli Decl., Ex. Y-6; Ex. 38 (Bradley Depo.) at 247:22-248:5.

¹⁷² Ex. 158; Ex. 38 (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.").

¹⁷³ Ex. 158.

¹⁷⁴ Ex. 159.

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 Allen Waxman (“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 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.¹⁷⁵ 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.¹⁷⁶ Fees paid to KPMG by Pfizer for services rendered after the Class Period (January 19, 2006 to January 23, 2009) were

¹⁷⁵ *E.g.*, Ex. 134 at KPMG-PFIZ-DS 017125.

¹⁷⁶ Exs. 14, 17-18.

\$37,353,000, \$38,993,000, \$38,999,000, \$50,267,000 and \$32,014,200 for 2009, 2010, 2011, 2012 and 2013, respectively.¹⁷⁷

Moreover, to the extent defendants seek to rely on 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 company's reserves complied with GAAP, particularly FAS 5."¹⁷⁸ 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."¹⁷⁹ In addition, she never received warning letters from the FDA,¹⁸⁰ letters to the OIG from Investigations Counsel regarding reportable events pursuant to Pfizer's CIA,¹⁸¹ documents concerning methodologies to evaluate damages for the Government investigation,¹⁸² the February 5, 2008 target letter from the Government,¹⁸³ the April 4, 2008 letter in which Investigations Counsel made a \$250 million offer to the Government to settle its investigation¹⁸⁴ or documents relating to the review committee process or reforms or initiatives concerning it.¹⁸⁵

¹⁷⁷ Exs. 19-23.

¹⁷⁸ Statement of Undisputed Facts in Support of Pfizer's Motion for Summary Judgment, ¶31.

¹⁷⁹ Petrosinelli Decl., Ex. N-6.

¹⁸⁰ Ex. 43 (Cangialosi Depo.) at 100:20-101:20.

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

¹⁸² Ex. 43 (Cangialosi Depo.) at 294:13-295:6.

¹⁸³ Ex. 43 (Cangialosi Depo.) at 253:19-254:5.

¹⁸⁴ Ex. 43 (Cangialosi Depo.) at 260:5-8, 321:20-322:4.

¹⁸⁵ Ex. 43 (Cangialosi Depo.) at 96:15-98:7, 112:23-119:4, 124:24-128:13.

The exhibits defendants cite do not prove this purported undisputed fact. Moreover, the following exhibits are objectionable: Petrosinelli Decl., Exs. A-6, I-5 and Rouhandeh Decl., Ex. C-K, as more fully set forth in Plaintiffs' Objections.

6. Disputed. Plaintiffs incorporate by reference their Response to Kindler's Undisputed Fact No. 2.

7. Disputed. Plaintiffs incorporate by reference their Response to Kindler's Undisputed Fact No. 2.

8. Disputed. Plaintiffs incorporate by reference their Response to Kindler's Undisputed Fact No. 2.

Moreover, plaintiffs object to Petrosinelli Decl., Ex. O-7, which contains certification memoranda signed by Block, for the reasons set forth in Plaintiffs' Objections.

9. Disputed. Plaintiffs incorporate by reference their Response to Kindler's Undisputed Fact No. 2.

10. Disputed. Plaintiffs incorporate by reference their Response to Kindler's Undisputed Fact No. 2.

11. 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, and Plaintiffs' Memorandum.

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.¹⁸⁶ During

¹⁸⁶ 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.

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.¹⁸⁷ 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.¹⁸⁸ 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.¹⁸⁹ 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.¹⁹⁰ Instead, KPMG was repeatedly told that the DOJ was still outlining the theories of liability.¹⁹¹ 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.¹⁹² 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.

¹⁸⁷ Ex. 256 at DOJ000237.

¹⁸⁸ Ex. 256 at DOJ000238.

¹⁸⁹ Ex. 256 at DOJ000239.

¹⁹⁰ Ex. 258 at DOJ000207-08.

¹⁹¹ Petrosinelli Decl., Ex. C-6.

¹⁹² Ex. 258 at DOJ000205.

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.¹⁹³ 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.¹⁹⁴ This presentation set forth the complete lack of controls over the Review Committee and, thus, Pfizer's HCC function.¹⁹⁵ These failures are particularly glaring given: (1) Pfizer considered Review Committee procedures to be one of the top ten areas of greatest risk;¹⁹⁶ (2) KPMG's concern that Pfizer's controls over sales and marketing practices were impaired;¹⁹⁷ and (3) KPMG had recently been informed by Pfizer that the significant deficiency with regard to HCC had been remediated by the end of 2Q07.¹⁹⁸

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.¹⁹⁹

¹⁹³ Ex. 161.

¹⁹⁴ Ex. 203.

¹⁹⁵ Ex. 203.

¹⁹⁶ Ex. 120.

¹⁹⁷ Exs. 149-150

¹⁹⁸ Ex. 346 at KPMG PFIZ-DS 0003257 (2Q07 Interim Completion Document).

¹⁹⁹ Ex. 310.

Similarly, KPMG was never informed that Pfizer received a target letter from the DOJ on February 5, 2008.²⁰⁰ 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.²⁰¹

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.²⁰² 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.²⁰³ 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.”²⁰⁴ Similarly, Lankler told KPMG that the off-label marketing of Geodon had not been linked back to senior management at corporate headquarters.²⁰⁵

²⁰⁰ Ex. 131; Ex. 38 (Bradley Depo.) at 242:13-16.

²⁰¹ Petrosinelli Decl., Ex. Y-6.

²⁰² Ex. 159.

²⁰³ Exs. 138-139.

²⁰⁴ Ex. 204.

²⁰⁵ Ex. 204.

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.²⁰⁶

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.”²⁰⁷ Chapman, KPMG audit partner, testified he had not been informed by November 3, 2007 that the probable “pillar” of FAS 5 had been met.²⁰⁸ 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.²⁰⁹

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.²¹⁰ Additionally,

²⁰⁶ Petrosinelli Decl., Ex. B-6.

²⁰⁷ Petrosinelli Decl., Ex. N-6 (October 17, 2007, email summarizing the October 9, 2007, meeting attended by Block, Lankler, Wessel, Dadlani and Brockie); Ex. 265 (3Q07 Interim Completion Document showing as of November 3, 2007, KPMG had been told loss not probable).

²⁰⁸ Ex. 44 (Chapman Depo.) at 122:19-123:16.

²⁰⁹ Ex. 38 (Bradley Depo.) at 239:9-20.

²¹⁰ Petrosinelli Decl., Ex. N-6

Chapman testified he did not know Pfizer was working with methodologies to estimate the loss and that the Company had discussed an estimate range.²¹¹ After becoming the engagement partner in early 2008, Bradley did not know that Lankler and Wessel were working on methodologies to calculate potential losses.²¹²

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.²¹³

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.²¹⁴ 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.²¹⁵ KPMG was never informed in or around June 2008, that Covington offered \$750 million to settle the DOJ Bextra Investigation.²¹⁶ 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

²¹¹ Petrosinelli Decl., Ex. N-6; Ex. 44 (Chapman Depo.) at 130:12-18.

²¹² Ex. 38 (Bradley Depo.) at 234:1-236:2.

²¹³ Petrosinelli Decl., Exs. B-6, C-6.

²¹⁴ Ex. 286; Ex. 38 (Bradley Depo.) at 236:3-11.

²¹⁵ Ex. 349; Ex. 38 (Bradley Depo.) at 247:22-248:5.

²¹⁶ Ex. 476; Ex. 38 (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.").

recent \$750 million offer to settle.²¹⁷ In fact, KPMG workpapers from June and July 2008 show that Pfizer told KPMG that no offers to settle to date had been made.²¹⁸

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 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.²¹⁹ 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.

²¹⁷ Ex. 158.

²¹⁸ Ex. 159.

²¹⁹ *E.g.*, Ex. 134 at KPMG-PFIZ-DS 017125.

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.²²⁰ 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.²²¹

Moreover, to the extent defendants seek to rely on 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 company's reserves complied with [GAAP], particularly FAS 5."²²² 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."²²³ In addition, she never received warning letters from the FDA,²²⁴ letters to the OIG from Investigations Counsel regarding reportable events pursuant to Pfizer's CIA,²²⁵ documents concerning methodologies to evaluate damages for the Government investigation,²²⁶ the February 5, 2008 target letter from the Government,²²⁷ the April 4, 2008 letter in which Investigations Counsel made a \$250 million offer to the Government to settle its

²²⁰ Exs. 14, 17-18.

²²¹ Exs. 19-22.

²²² Statement of Undisputed Facts in Support of Pfizer's Motion for Summary Judgment, ¶31.

²²³ Petrosinelli Decl., Ex. N-6.

²²⁴ Ex. 43 (Cangialosi Depo.) at 100:20-101:20.

²²⁵ Ex. 43 (Cangialosi Depo.) at 181:6-184:20.

²²⁶ Ex. 43 (Cangialosi Depo.) at 294:13-295:6.

²²⁷ Ex. 43 (Cangialosi Depo.) at 253:19-254:5.

investigation²²⁸ or documents relating to the review committee process or reforms or initiatives concerning it.²²⁹

12. Disputed. During the Class Period, KPMG never performed an audit of Pfizer's internal controls over HCC, which suffered from a material weakness.²³⁰ Further, 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.²³¹ 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.²³² This presentation set forth the complete lack of controls over the Review Committee and, thus, Pfizer's HCC function.²³³ These failures are particularly glaring given: (1) Pfizer considered Review Committee procedures to be one of the top ten areas of greatest risk;²³⁴ (2) KPMG's concern that Pfizer's controls over sales and

²²⁸ Ex. 43 (Cangialosi Depo.) at 260:5-8, 321:20-322:4.

²²⁹ Ex. 43 (Cangialosi Depo.) at 96:15-98:7, 112:23-119:4, 124:24-128:13.

²³⁰ Ex. 44 (Chapman Depo.) at 117:8-24; Ex. 161; Ex. 7 (Supplemental Expert Report of D. Paul Regan) at 56-94.

²³¹ Ex. 161.

²³² Ex. 203.

²³³ Ex. 203.

²³⁴ Ex. 120.

marketing practices were impaired;²³⁵ and (3) KPMG had recently been informed by Pfizer that the significant deficiency with regard to HCC had been remediated by the end of 2Q07.²³⁶

Additionally, Pfizer and KPMG employed a reliance model where KPMG relied on Pfizer's Internal Audit department to the maximum extent possible.²³⁷

13. Disputed. Kindler could not have believed in good faith that Pfizer maintained effective internal controls over financial reporting because he was aware Pfizer's internal controls over HCC suffered from a material weakness. Kindler was aware that Pfizer suffered from an ineffective regulatory compliance function.²³⁸

14. Disputed. Plaintiffs incorporate by reference their Response to Kindler's Undisputed Fact No. 5. Defendants' citations to deposition testimony do not prove their purported undisputed material fact. Finally, plaintiffs object to Petrosinelli Decl., Ex. V-4 and Rouhandeh Decl., Ex. J-K for the reasons set forth in Plaintiffs' Objections.

15. Disputed. Moreover, to the extent defendants seek to rely on 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 company's reserves complied with [GAAP], particularly FAS 5."²³⁹ For example, she was not included in the October 9, 2007 meeting during which Pfizer's Investigations Counsel, disclosures

²³⁵ Exs. 149-150.

²³⁶ Ex. 346 at KPMG PFIZ-DS 0003257 (2Q07 Interim Completion Document).

²³⁷ Ex. 44 (Chapman Depo.) at 170:8-171:1; KPMG-PFIZ-DS 014392.

²³⁸ See Ex. 161; Ex. 7 (Supplemental Expert Report of D. Paul Regan) at 56-94.

²³⁹ Statement of Undisputed Facts in Support of Pfizer's Motion for Summary Judgment, ¶31.

counsel and Legal Finance confirmed “that the ‘probable’ criteria of FAS5 ha[d] been met.”²⁴⁰ In addition, she never received warning letters from the FDA,²⁴¹ letters to the OIG from Investigations Counsel regarding reportable events pursuant to Pfizer’s CIA,²⁴² documents concerning methodologies to evaluate damages for the Government investigation,²⁴³ the February 5, 2008 target letter from the Government,²⁴⁴ the April 4, 2008 letter in which Investigations Counsel made a \$250 million offer to the Government to settle its investigation²⁴⁵ or documents relating to the review committee process or reforms or initiatives concerning it.²⁴⁶ Cangialosi’s determinations did not reflect that in September 2005, Pfizer concluded it would be forced to settle the Bextra investigation.²⁴⁷ Based on the 2004 Neurontin settlement, the Company already had the tools to calculate the loss.²⁴⁸ Additionally, even though Pfizer continued throughout the Class Period to claim the loss was not estimable, Posner’s October 1, 2007, letter acknowledged the methodology for calculating the fine in a manner similar to those used in analogous cases like Neurontin.²⁴⁹ Further, even Pfizer’s auditor admitted that the Neurontin settlement was the benchmark.²⁵⁰

²⁴⁰ Petrosinelli Decl., Ex. N-6.

²⁴¹ Ex. 43 (Cangialosi Depo.) at 100:20-101:20.

²⁴² Ex. 43 (Cangialosi Depo.) at 181:6-184:20.

²⁴³ Ex. 43 (Cangialosi Depo.) at 294:13-295:6.

²⁴⁴ Ex. 43 (Cangialosi Depo.) at 253:19-254:5.

²⁴⁵ Ex. 43 (Cangialosi Depo.) at 260:5-8, 321:20-322:4.

²⁴⁶ Ex. 43 (Cangialosi Depo.) at 96:15-98:7, 112:23-119:4, 124:24-128:13.

²⁴⁷ Petrosinelli Decl., Ex. C-6.

²⁴⁸ Ex. 7 (Supplemental Expert Report of D. Paul Regan) at 30-35.

²⁴⁹ Petrosinelli Decl., Ex. B-6.

Cangialosi testified that she was not included on relevant emails or at meetings regarding FAS 5.²⁵¹ Regarding the Bextra Investigation, Cangialosi did not have the ability to assess the sufficiency of the FAS 5 contingency reserves, the legal proceedings disclosure, the strengths or weaknesses of the Government's case, Pfizer's defenses, whether a loss or conviction was probable or whether such loss was reasonably estimable. Instead, all information and input regarding the Bextra Investigation came from Investigations Counsel (counsel involved in the Bextra Investigation, including Covington, Lankler and Wessel), and defendants have expressly denied relying on any counsel other than Block or Fox. As a result, and for reasons explained more fully in Plaintiffs' Motion for Partial Summary Judgment, defendants are precluded from invoking or relying on Investigations Counsel. Because input from Investigations Counsel was the most integral aspect of the FAS 5 determination, defendants cannot in good faith rely on Cangialosi.

16. Disputed. Plaintiffs incorporate by reference their Response to Kindler's Undisputed Fact No. 11.

17. Disputed. Plaintiffs incorporate by reference their Response to Kindler's Undisputed Fact No. 15.

18. Disputed. Plaintiffs incorporate by reference their Response to Kindler's Undisputed Fact No. 11.

²⁵⁰ Ex. 44 (Chapman Depo.) at 129:16-22.

²⁵¹ Ex. 43 (Cangialosi Depo.) at 281:5-18.

19. Disputed. Plaintiffs incorporate by reference their Response to Kindler's Undisputed Fact No. 5. Further, defendants' citation, to deposition testimony does not prove their purported undisputed material fact.

DATED: November 26, 2014

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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/ HENRY ROSEN

HENRY ROSEN

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Case Number: [1:10-cv-03864-AKH](#)
Filer: Mary K. Jones
Stichting Philips Pensioenfonds

Document Number: [310](#)

Docket Text:

RESPONSE re: [275] Rule 56.1 Statement . Document filed by Mary K. Jones(Individually), Stichting Philips Pensioenfonds. (Rosen, Henry)

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