UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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

Plaintiffs Stichting Philips Pensioenfonds and Mary K. Jones, on behalf of Pfizer Inc. ("Pfizer" or the "Company") investors, respectfully submit the following Response to Defendant Allen Waxman's Statement of Undisputed Material Facts.

1. Undisputed.

2. Undisputed.

3. Undisputed.

4. Disputed. Allen Waxman ("Waxman") refused to answer basic questions concerning his departure from Pfizer when asked at his depositions. Waxman was asked if he departed Pfizer due to violating a Company policy. Waxman was asked if he ever violated a Company policy. Waxman was asked if his departure was related to anyone who was mentioned in the documents he reviewed at his deposition. Waxman was asked if his departure had anything to do with a relationship with anyone at Pfizer. Waxman refused to answer any of these relevant questions concerning his departure.[1]

5. Disputed. Defendants have expressly denied relying on any counsel other than Dennis Block ("Block") or Lawrence Fox ("Fox") for their defense in this case[2] (consistent with that denial, defendants successfully shielded Investigations Counsel[3] from discovery), so defendants may

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[1] Ex. 67 (11/14/13 Waxman Depo.) at 216:2-219:12. 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] Dkt. No. 172 at 25; July 19, 2013 Hearing Transcript at 12:1-2; Dkt. No. 246 at 1, 5.

[3] "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").

not invoke or rely on Investigations Counsel, including relying on anyone who relied on Investigations Counsel. Plaintiffs incorporate by reference Plaintiffs' Motion for Partial Summary Judgment on Defendants' Reliance on Advice of Counsel and Good Faith Defenses ("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's[4] case[5] or Pfizer's defenses,[6] whether a loss or conviction was probable or whether such loss was reasonably estimable.[7] Moreover, defendants withheld from Block and Fox critical evidence concerning the Bextra Investigation,[8] including call notes,[9] documents that corroborated a *qui tam* relator's claims,[10] Bextra-related documents that Pfizer employees had attempted to delete or alter,[11]

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

[5] 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.

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

[7] 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.

[8] "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 Depo.) at 20:19-21:4; Ex. 68 (10/16/14 Waxman Depo.) at 32:18-20.

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

[10] 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.

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

sales force survey results[12] and employee interview memoranda.[13] Instead, all information and input regarding the Bextra Investigation came from Investigations Counsel.[14] 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.[15]

Block never personally and professionally assessed nor advised defendants that Pfizer had substantial defenses to the Bextra Investigation.[16]

Fox never independently determined nor advised defendants that Pfizer had substantial defenses to the Bextra Investigation.[17]

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.[18]

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.[19]

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

[13] 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.

[14] 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.

[15] Ex. 55 (Lankler Depo.) at 92:23-97:21.

[16] Ex. 37 (Block Depo.) at 104:6-23.

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

[18] 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.

[19] 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.

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.[20]

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.[21]

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 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

[20] 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.

[21] 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.

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.[22]

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.[23]

Neither Block nor Fox has ever worked as a criminal law prosecutor or a criminal defense attorney.[24]

Neither Block nor Fox was familiar with the elements of a misbranding offense.[25]

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[22] 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.

[23] 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.

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

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

Neither Block nor Fox was familiar with elements or application of *respondeat superior* liability.[26]

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.[27]

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.[28]

Fox incorrectly understood the terms grand jury "target" and grand jury "subject" to be interchangeable.[29]

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.[30]

Pfizer and its Investigations Counsel always represented to Block that Pfizer's sales representatives had not promoted Bextra off-label.[31] 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

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

[27] 42 U.S.C. §1320a-7.

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

[29] Ex. 49 (Fox Depo.) at 106:3-23.

[30] 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.

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

and post-operative surgical pain and (c) as opiod-sparing in the context of surgery;[32] 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");[33] 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;[34] Pfizer promoted Bextra with an intent to defraud or mislead;[35] 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;[36] 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.[37]

No one provided Block or Fox a copy of Kopchinski's Complaint or any of the internal Pfizer documents that were exhibits to it.[38]

No one ever provided Block or Fox the internal documents that Pfizer's sales representatives had attempted to delete or alter.[39]

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[32] Ex. 240 at 51:10-17.

[33] Ex. 240 at 51:17-18.

[34] Ex. 240 at 51:19-21.

[35] Ex. 240 at 51:22-23.

[36] Ex. 240 at 52:1-4.

[37] Ex. 240 at 52:5-9.

[38] *See* 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.

[39] 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 with redacted or unredacted copies of the interview memoranda of the Pfizer employees involved in the attempted deletion and alteration of Bextra-related documents.[40]

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.[41]

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.[42]

No one provided Block or Fox copies of any of the interview memoranda from the Bextra Investigation.[43]

Neither Block nor Fox received access to any of Pfizer's Investigations Counsel's written work product concerning the Bextra Investigation.[44]

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.[45]

6. Disputed. Plaintiffs dispute this asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 5, which is incorporated herein by reference.

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[40] 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.

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

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

[43] 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.

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

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

7. Disputed. Mr. Block is not currently associated with Cadwalader Wickersham & Taft, and his prominence as a securities lawyer is a matter of opinion.

8. Undisputed.

9. Disputed. Exhibit C-2 to the Declaration of Joseph G. Petrosinelli in Support of Pfizer's Motion for Summary Judgment ("Petrosinelli Decl.") does not include Ex. 54 (10/10/14 Kindler Depo.) at 117:1-19 and Ex. 54 (10/10/14 Kindler Depo.) at 116:25 and does not support the asserted fact.

10. Disputed. Plaintiffs dispute this asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 5, which is incorporated by reference herein.

11. Disputed. Plaintiffs dispute this asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 5, which is incorporated by reference herein.

12. Disputed. Plaintiffs dispute this asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 5, which is incorporated by reference herein.

13. Disputed. Plaintiffs dispute this asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 5, which is incorporated by reference herein.

14. Disputed. Plaintiffs dispute this asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 5, which is incorporated by reference herein.

15. Disputed. Waxman's reliance on documents indicating that three discussions of Pfizer's legal proceeding disclosures occurred during the 20-month period Waxman was Pfizer's General Counsel does not qualify as it being "not uncommon for Waxman to meet with Fox, Block and others" to discuss "the detail" of the disclosures. Moreover, Waxman's request to know what else was considered was not specific to the Bextra Investigation, and as a result, this litigation.

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

16. Disputed. Plaintiffs dispute this asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 5, which is incorporated by reference herein.

17. Undisputed.

18. Undisputed.

19. Disputed. Defendants have expressly denied relying on any counsel other than Block or Fox for their defense in this case[46] (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. Plaintiffs incorporate by reference 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 case[47] or Pfizer's defenses,[48] whether a loss or conviction was probable, or whether such loss was reasonably estimable.[49] Moreover, defendants withheld from Block and Fox critical evidence concerning the Bextra Investigation,[50] including call notes,[51] documents that corroborated a *qui tam* relator's claims,[52]

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

[47] 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.

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

[49] 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.

[50] 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 Depo.) at 32:18-20.

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

Bextra-related documents that Pfizer employees had attempted to delete or alter,[53] sales force survey results[54] and employee interview memoranda.[55] Instead, all information and input regarding the Bextra Investigation came from Investigations Counsel.[56] 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.[57]

Block never personally and professionally assessed nor advised defendants that Pfizer had substantial defenses to the Bextra Investigation.[58]

Fox never independently determined or advised defendants that Pfizer had substantial defenses to the Bextra Investigation.[59]

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.[60]

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[52] 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.

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

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

[55] 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.

[56] 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.

[57] Ex. 55 (Lankler Depo.) at 92:23-97:21.

[58] Ex. 37 (Block Depo.) at 104:6-23.

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

[60] 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.[61]

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.[62]

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.[63]

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

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[61] 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.

[62] 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.

[63] 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.

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.[64]

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.[65]

Neither Block nor Fox has ever worked as a criminal law prosecutor or a criminal defense attorney.[66]

Neither Block nor Fox was familiar with the elements of a misbranding offense.[67]

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[64] 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.

[65] 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.

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

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

Neither Block nor Fox was familiar with elements or application of *respondeat superior* liability.[68]

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.[69]

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.[70]

Fox incorrectly understood the terms grand jury "target" and grand jury "subject" to be interchangeable.[71]

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.[72]

Pfizer and its Investigations Counsel always represented to Block that Pfizer's sales representatives had not promoted Bextra off-label.[73] 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 opiod-

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

[69] 42 U.S.C. §1320a-7.

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

[71] Ex. 49 (Fox Depo.) at 106:3-23.

[72] 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.

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

sparing in the context of surgery;[74] 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;[75] 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;[76] Pfizer promoted Bextra with an intent to defraud or mislead;[77] 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;[78] 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.[79]

No one provided Block or Fox a copy of Kopchinski's Complaint or any of the internal Pfizer documents that were exhibits to it.[80]

No one ever provided Block or Fox the internal documents that Pfizer's sales representatives had attempted to delete or alter.[81]

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[74] Ex. 240 at 51:10-17.

[75] Ex. 240 at 51:17-18.

[76] Ex. 240 at 51:19-21.

[77] Ex. 240 at 51:22-23.

[78] Ex. 240 at 52:1-4.

[79] Ex. 240 at 52:5-9.

[80] *See* 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.

[81] 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 with redacted or unredacted copies of the interview memoranda of the Pfizer employees involved in the attempted deletion and alteration of Bextra-related documents.[82]

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.[83]

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.[84]

No one provided Block or Fox copies of any of the interview memoranda from the Bextra Investigation.[85]

Neither Block nor Fox received access to any of Pfizer's Investigations Counsel's written work product concerning the Bextra Investigation.[86]

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.[87]

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

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[82] 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.

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

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

[85] 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.

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

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

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.[88] 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.[89] The DOJ further told Pfizer how the Company paid physicians to attend consultant meetings, advisory boards and speaker events, and used a publication strategy all to promote Bextra off-label.[90] 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 about the illegal marketing of Bextra and that it was a deliberate scheme with pervasive misconduct and knowledge at the top.[91] Instead, KPMG was repeatedly told that the DOJ was still outlining the theories of liability.[92] 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.[93] Pfizer also misled

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[88] Ex. 256 at DOJ000237.

[89] Ex. 256 at DOJ000238.

[90] Ex. 256 at DOJ000239.

[91] Ex. 258 at DOJ000207-08.

[92] Petrosinelli Decl., Ex. C-6.

[93] Ex. 258 at DOJ000205.

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, Pfizer's director of Corporate Internal Audit who headed up the healthcare compliance audit function, which explained how problems with Pfizer's Health Care Compliance ("HCC") function could have a material impact on Pfizer's financial results.[94] 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.[95] This presentation set forth the complete lack of controls over the Review Committee and, thus, Pfizer's HCC function.[96] These failures are particularly glaring given: (1) Pfizer considered Review Committee procedures to be one of the top ten areas of greatest risk;[97] (2) KPMG's concern that Pfizer's controls over sales and marketing practices were impaired;[98] 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.[99]

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,

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[94] Ex.161.

[95] Ex. 203.

[96] Ex. 203.

[97] Ex. 120.

[98] Exs. 149-150.

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

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.[100] Similarly, KPMG was never informed that Pfizer received a target letter from the DOJ on February 5, 2008.[101] 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.[102]

KPMG was misled by Douglas Lankler ("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.[103] 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.[104] 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."[105] Similarly,

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[100] Ex. 310.

[101] Ex. 131; Ex. 39 (Bradley Depo.) at 242:13-16.

[102] Petrosinelli Decl., Ex. Y-6.

[103] Ex. 159.

[104] Exs. 138-139.

[105] Ex. 204.

Lankler told KPMG that the off-label marketing of Geodon had not been linked back to senior management at corporate headquarters.[106]

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.[107]

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."[108] 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.[109] 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.[110]

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[106] Ex. 204.

[107] Petrosinelli Decl., Ex. B-6.

[108] Petrosinelli Decl., Ex. N-6. (October 17, 2007 e-mail 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).

[109] Ex. 44 (Chapman Depo.) at 122:19-123:16.

[110] Ex. 38 (Bradley Depo.) at 239:9-20.

Nor was it revealed to KPMG that as a result of the Government asking them to propose a number, Lankler and Carlton Wessel ("Wessel") were working on calculating potential losses.[111] 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.[112] After becoming the engagement partner in early 2008, Bradley did not know that Lankler and Wessel were working on methodologies to calculate potential losses.[113]

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.[114]

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.[115] 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.[116] KPMG was never informed in or around June 2008, that Covington offered $750 million to settle the DOJ Bextra

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[111] Petrosinelli Decl., Ex. N-6.

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

[113] Ex. 38 (Bradley Depo.) at 234:1-236:2.

[114] Petrosinelli Decl., Exs. B-6, C-6.

[115] Ex. 104; Ex. 38 (Bradley Depo.) at 236:3-11.

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

Investigation.[117] 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.[118] In fact, KPMG workpapers from June and July 2008 show that Pfizer told KPMG that no offers to settle to date had been made.[119]

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 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 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.[120] 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,

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[117] 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.").

[118] Ex. 158.

[119] Ex. 159.

[120] *E.g.*, Ex. 134 at KPMG-PFIZ-DS 017125.

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.[121] 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.[122]

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), particularly FAS 5."[123] 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."[124] In addition, she never received warning letters from the FDA,[125] letters to the OIG from Investigations Counsel regarding reportable events pursuant to Pfizer's CIA,[126] documents concerning methodologies to evaluate damages for the Government

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[121] Exs. 14, 17-18.

[122] Exs 19-23.

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

[124] Petrosinelli Decl., Ex. N-6.

[125] Ex. 43 (Cangialosi Depo.) at 100:20-101:20.

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

investigation,[127] the February 5, 2008 target letter from the Government,[128] the April 4, 2008, letter in which Investigations Counsel made a $250 million offer to the Government to settle its investigation[129] or documents relating to the review committee process or reforms or initiatives concerning it.[130]

20. Disputed. Plaintiffs dispute this asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 5, which is incorporated by reference herein.

21. Disputed. Plaintiffs dispute this asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 5, which is incorporated by reference herein.

22. Disputed. Plaintiffs dispute this asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 5, which is incorporated by reference herein.

23. Disputed. Plaintiffs dispute this asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 5, which is incorporated herein by reference.

24. Disputed. Defendants have expressly denied relying on any counsel other than Block or Fox for their defense in this case[131] (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. Plaintiffs incorporate by reference 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

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[127] Ex. 43 (Cangialosi Depo.) at 294:13-295:6.

[128] Ex. 43 (Cangialosi Depo.) at 253:19-254:5.

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

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

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

5 reserve decisions, the strengths or weaknesses of the Government's case[132] or Pfizer's defenses,[133] whether a loss or conviction was probable or whether such loss was reasonably estimable.[134] Moreover, defendants withheld from Block and Fox critical evidence concerning the Bextra Investigation,[135] including call notes,[136] documents that corroborated a *qui tam* relator's claims,[137] Bextra-related documents that Pfizer employees had attempted to delete or alter,[138] sales force survey results[139] and employee interview memoranda.[140] Instead, all information and input regarding the Bextra Investigation came from Investigations Counsel.[141] 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.[142]

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[132] 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.

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

[134] 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.

[135] 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 Depo.) at 32:18-20.

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

[137] 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.

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

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

[140] 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.

[141] 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.

[142] Ex. 55 (Lankler Depo.) at 92:23-97:21.

Block never personally and professionally assessed nor advised defendants that Pfizer had substantial defenses to the Bextra Investigation.[143]

Fox never independently determined or advised defendants that Pfizer had substantial defenses to the Bextra Investigation.[144]

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.[145]

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.[146]

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.[147]

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[143] Ex. 37 (Block Depo.) at 104:6-23.

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

[145] 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.

[146] 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.

[147] 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.[148]

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 John 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.[149]

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

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[148] 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.

[149] 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.[150]

Neither Block nor Fox has ever worked as a criminal law prosecutor or a criminal defense attorney.[151]

Neither Block nor Fox was familiar with the elements of a misbranding offense.[152]

Neither Block nor Fox was familiar with elements or application of *respondeat superior* liability.[153]

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.[154]

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[150] 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.

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

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

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

[154] 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.[155]

Fox incorrectly understood the terms grand jury "target" and grand jury "subject" to be interchangeable.[156]

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.[157]

Pfizer and its Investigations Counsel always represented to Block that Pfizer's sales representatives had not promoted Bextra off-label.[158] 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 opiod-sparing in the context of surgery;[159] 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;[160] 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;[161] Pfizer promoted Bextra with an intent to defraud or mislead;[162] certain members of

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

[156] Ex. 49 (Fox Depo.) at 106:3-23.

[157] 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.

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

[159] Ex. 240 at 51:10-17.

[160] Ex. 240 at 51:17-18.

[161] 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;[163] 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.[164]

No one provided Block or Fox a copy of Kopchinski's Complaint or any of the internal Pfizer documents that were exhibits to it.[165]

No one ever provided Block or Fox the internal documents that Pfizer's sales representatives had attempted to delete or alter.[166]

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.[167]

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.[168]

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[162] Ex. 240 at 51:22-23.

[163] Ex. 240 at 52:1-4.

[164] Ex. 240 at 52:5-9.

[165] *See* 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.

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

[167] 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.

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

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.[169]

No one provided Block or Fox copies of any of the interview memoranda from the Bextra Investigation.[170]

Neither Block nor Fox received access to any of Pfizer's Investigations Counsel's written work product concerning the Bextra Investigation.[171]

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.[172]

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.[173] 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

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

[170] 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.

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

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

[173] 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 Depo.) at 32:18-20.

surgery.[174] 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.[175] The DOJ further told Pfizer how the Company paid physicians to attend consultant meetings, advisory boards and speaker events, and used a publication strategy all to promote Bextra off-label.[176] 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 CIA's. 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.[177] Instead, KPMG was repeatedly told that the DOJ was still outlining the theories of liability.[178] 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.[179] 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, Pfizer's director of Corporate Internal Audit who headed up the healthcare compliance audit function, which explained how problems with Pfizer's HCC function could have a material impact on Pfizer's financial

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[174] Ex. 256 at DOJ000237.

[175] Ex. 256 at DOJ000238.

[176] Ex. 256 at DOJ000239.

[177] Ex. 258 at DOJ000207-08.

[178] Petrosinelli Decl., Ex. C-6

[179] Ex. 258 at DOJ000205.

results.[180] 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.[181] This presentation set forth the complete lack of controls over the Review Committee and, thus, Pfizer's HCC function.[182] These failures are particularly glaring given: (1) Pfizer considered Review Committee procedures to be one of the top ten areas of greatest risk;[183] (2) KPMG's concern that Pfizer's controls over sales and marketing practices were impaired;[184] 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.[185]

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.[186] Similarly, KPMG was never informed that Pfizer received a target letter from the DOJ on February

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[180] Ex. 161.

[181] Ex. 203.

[182] Ex. 203.

[183] Ex. 120.

[184] Exs. 149-150.

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

[186] Ex. 310.

5, 2008.[187] 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.[188]

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.[189] 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.[190] 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."[191] Similarly, Lankler told KPMG that the off-label marketing of Geodon had not been linked back to senior management at corporate headquarters.[192]

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

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[187] Ex. 131; Ex. 38 (Bradley Depo.) at 242:13-16.

[188] Petrosinelli Decl., Ex. Y-6.

[189] Ex. 159.

[190] Exs. 138-139.

[191] Ex. 204.

[192] Ex. 204.

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 that the fine in the Bextra Investigation should be calculated as it was in "analogous" cases such as Neurontin, Schering, Serono and Genotropin.[193]

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."[194] Chapman, KPMG audit partner, testified he had not been informed by November 3, 2007, that the probable "pillar" of FAS 5 had been met.[195] 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.[196]

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.[197] Additionally, Chapman testified he did not know Pfizer was working with methodologies to estimate the loss and

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[193] Petrosinelli Decl., Ex. B-6.

[194] Petrosinelli Decl., Ex. N-6. (October 17, 2007 e-mail 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).

[195] Ex. 44 (Chapman Depo.) at 122:19-123:16.

[196] Ex. 38 (Bradley Depo.) at 239:9-20.

[197] Petrosinelli Decl., Ex. N-6.

that the Company had discussed an estimate range.[198] After becoming the engagement partner in early 2008, Bradley did not know that Lankler and Wessel were working on methodologies to calculate potential losses.[199]

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.[200]

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.[201] 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.[202] KPMG was never informed in or around June 2008, that Covington offered $750 million to settle the DOJ Bextra Investigation.[203] 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

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

[199] Ex. 38 (Bradley Depo.) at 234:1-236:2.

[200] Petrosinelli Decl., Exs. B-6, C-6.

[201] Ex.104; Ex. 38 (BradleyDepo.) at 236:3-11.

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

[203] 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.").

recent $750 million offer to settle.[204] In fact, KPMG workpapers from June and July 2008 show that Pfizer told KPMG that no offers to settle to date had been made.[205]

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.[206] 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.

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[204] Ex. 158.

[205] Ex. 159.

[206] *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.[207] 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.[208]

25. Disputed. Waxman's testimony suggests that he was not aware of intricacies of the disclosure committee process.[209] For example, Waxman could not recall the review process that Pfizer's April 2, 2007, press release went through to determine the accuracy of the information disclosed.[210] According to Waxman, press releases were not reviewed by the disclosure committee.[211] Moreover, Waxman does not recall being a member of the Disclosure Committee.[212]

26. Disputed. Plaintiffs dispute this asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 5 which is incorporated by reference herein.

27. Disputed. The cited exhibits and deposition testimony do not reveal the reasons or purposes the certification meetings were designed and created. Moreover, the minutes cited do not reveal the questions that were asked, or the responses to the questions asked, at the certification meetings.

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[207] Exs. 14, 17-18.

[208] Exs. 19-23.

[209] Ex. 67 (11/14/13 Waxman Depo.) at 143:11-19.

[210] Ex. 67 (11/14/13 Waxman Depo.) at 158:6-159:20.

[211] Ex. 67 (11/14/13 Waxman Depo.) at 143:11-19.

[212] Ex. 67 (11/14/13 Waxman Depo.) at 27:6-21.

28. Disputed. It is not disputed that Kindler made the quoted statement at his deposition, but plaintiffs dispute any assertion that the statement suggests Pfizer's Class Period Sarbanes-Oxley Act of 2002 ("SOX") certificates and securities filings were true and accurate.

29. Disputed. The materials cited to support the purported fact do not reflect any discussions amongst the CEO, CFO and Block. Moreover, the materials cited do not reflect discussions including Kindler or Frank D'Amelio ("D'Amelio"). Plaintiffs dispute this asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 5, which is incorporated by reference herein.

30. Disputed. The cited certification meeting minutes note that the certificates were attached, however, the documents cited do not attach any certificates. 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 Generally Accepted Accounting Principles (GAAP), particularly FAS 5."[213] 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."[214] In addition, she never received warning letters from the FDA,[215] letters to the OIG from Investigations Counsel regarding reportable events pursuant to Pfizer's CIA,[216] documents concerning

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

[214] Petrosinelli Decl., Ex. N-6.

[215] Ex. 43 (Cangialosi Depo.) at 100:20-101:20.

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

methodologies to evaluate damages for the Government investigation,[217] the February 5, 2008, target letter from the Government,[218] the April 4, 2008, letter in which Investigations Counsel made a $250 million offer to the Government to settle its investigation[219] or documents relating to the review committee process or reforms or initiatives concerning it.[220]

31. Disputed. The cited certification meeting minutes note that the certificates were attached, however, the documents cited do not attach any certificates.

32. Disputed. Plaintiffs do not dispute that the sub-certifications included this information. Plaintiffs do not dispute that while General Counsel at Pfizer, Waxman certified every quarter and year end that the disclosures contained all required information, did not contain any untrue statement of material fact, and did not contain any material omissions. However, Waxman's certifications do not indicate that he was certifying to this information in reliance on the advice of counsel. Moreover, the certifications Waxman signed do not qualify his knowledge based on any advice from counsel or a "process."

33. Disputed. Plaintiffs dispute this asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 5, which is incorporated by reference herein.

34. Disputed. Plaintiffs dispute this characterization of the case. Plaintiffs also dispute Waxman's assertion that the disclosures in Pfizer's securities filings are the only misleading statements that are at issue. Plaintiffs further dispute that those are the only misleading statements in

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[217] Ex. 43 (Cangialosi Depo.) at 294:13-295:6.

[218] Ex. 43 (Cangialosi Depo.) at 253:19-254:5.

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

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

Pfizer's legal proceeding disclosures and financial statements during the Class Period.[221] Plaintiffs have alleged that defendants' statements that Pfizer complied with healthcare laws, that Pfizer did not off-label promote, and that Geodon, Lyrica, and Zyvox were growing were all false and misleading. Moreover, the failure to take a FAS 5 reserve associated with the Bextra Investigation was also false and misleading.

35. Disputed. It is not clear what "challenged statements" Waxman is referring to. Moreover, the assertion that statements were accurate and believed is a legal conclusion, not a fact. Defendants were aware that Bextra, Geodon, Zyvox and Lyrica were promoted off-label, that Pfizer employees destroyed or attempted to destroy documents indicating the off-label promotion of Bextra, that the Government showed Pfizer hundreds of call-notes indicating Bextra was off-label promoted, that Kopchinski's Complaint alleged that Bextra was off-label promoted, and that interviews of Pfizer employees revealed Bextra was off-label promoted.[222] Further, the testimony cited does not support the fact asserted.

36. Disputed. Waxman understood that the focus of the Bextra Investigation was a criminal investigation into off-label promotion as early as December 1, 2005.[223] In September 2006 he described the investigation as follows:

> The Department of Justice, spearheaded by the U.S. Attorney's Office in Boston, is investigating whether Company personnel promoted Bextra for non-arthritic "actuate pain" after Bextra was launched in April 2002, potentially in violation of the Food Drug and Cosmetic Act and the False Claims Act. When Bextra was approved in late 2001, the FDA explicitly did not approve Bextra for

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

[222] Plaintiffs' Statement of Material Facts Requiring Denial of Defendants' Motion for Summary Judgment ("PSMF") §IV, submitted herewith.

[223] Ex. 85 at PFE-JONES 00006635.

> more generalized acute pain, asserting that its safety had not been established in the perioperative setting based largely on the findings of a study of Bextra in patients undergoing coronary artery bypass graft (CABG surgery). The DOJ investigation focuses on whether Pharmacia (before the merger) and Pfizer promoted Bextra outside of the approved indications by encouraging sales representatives to make affirmative reference, when speaking with doctors, to Bextra's efficacy in various unapproved acute pain indications.
>
> This investigation has been very active, with subpoenas served on the Company and several employees being interviewed by the government and testifying before a federal grand jury in Boston. The DOJ is currently conducting interviews of managers and other leaders in Marketing and Medical, as well as members of the sales force that detailed Bextra, with a view towards having those employees testify before the grand jury. The DOJ has also interviewed third party physicians who have served as consultants for the Company. We have been engaged in extensive discussions with the government on these issues and will continue our efforts to pursue the most favorable outcome possible for the company.[224]

The February 5, 2008, letter from the DOJ to Pfizer makes it clear that the Government's focus was on off-label promotion, also known as misbranding.

> The purpose of this letter is to formally advise you that your client, Pfizer, Inc. and its subsidiaries and divisions (collectively "Pfizer"), is the target of a federal grand jury investigation in this District. The investigation of Pfizer concerns the introduction of misbranded and unapproved drugs, including specifically Bextra, into interstate commerce in violation of the Food Drug & Cosmetic Act ("FD&C Act"), 21 U.S.C. §301 *et seq.*, and related crimes, including among other statutes, conspiracy to violate the FD&C Act in violation of 18 U.S.C. §371; and the payment of remuneration, directly and indirectly, to induce others to purchase or order, or to recommend purchasing or ordering, Pfizer's pharmaceutical products, including for unapproved uses, for products for which payment was made in whole or in part through federal health care programs, and conspiracy to make such payments of remuneration in violation of, among other things statutes, 42 U.S.C. §1320a-7b(b) (kickbacks) and 18 U.S.C. §371 (conspiracy).[225]

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[224] Ex. 196 at PFE DERIV 00004070-71.

[225] Ex. 169 at PFE DERIV 00066088.

Also, on September 22, 2005, Waxman informed Pfizer employees at the Quarterly Reserve Review Meeting that the Bextra Investigation "includes the DOJ which is focused on the off-label use of Bextra."[226]

37. Disputed. Plaintiffs do not dispute the content of the April 4, 2008, letter. Plaintiffs do dispute, however, any assertion that a phrase used in the DOJ settlement proposal on April 4, 2008, supports defendants' use of the phrase "marketing and safety" to describe the Bextra Investigation. Further, the April 4, 2008, DOJ letter uses the phrase "sales and marketing" while Pfizer used the phrase "safety and marketing."

38. Disputed. Plaintiffs dispute the asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Fact Nos. 24 and 36, which are incorporated by reference herein.

39. Disputed. Waxman's factual assertion is a legal conclusion. Further plaintiffs dispute the asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Material Fact Nos. 5 and 36, which are incorporated herein by reference.

Moreover, Pfizer did not intend to go to trial. Pfizer's Government investigation counsel, Brien O'Conner, admitted:

> Now, did we ever say, you know, we think it would be terrific if you indicted Pfizer and we had a trial? No. That's the problem.
>
> The problem is that if there is – it's not prudent for, you know, people, all of us, who are acting as fiduciaries for all these shareholders and employees and all, given the way the exclusion rules work to roll the dice and hope that you can get a not guilty on every and any individual count that might be brought based on the conduct of any one of our employees. I mean, that's a tough thing to do. And so, no. We didn't want to be in that position, because, you know, it's just not a prudent thing to do.
>
> So we were saying, We'd love to find common ground with you by talking through the issues – you know, the facts, the laws, the equities – and trying to come

[226] Ex. 129 at KPMG PFIZ DS 0002181.

> to a fair and reasonable result. That's what we were saying. And they were saying, okay, great. Then the fair and reasonable result is, you know, this and, you know, we didn't agree with them for a long, long time. We never agreed with them, but we reached a compromise with them.
>
> Q. I take it, you expressed to the government the sentiment that it wouldn't be prudent for you to defend Pfizer or Pharmacia against these charges?
>
> A. That's something that they knew to their core to begin with, because they weren't born yesterday and they've been doing these cases for a long time. But, yeah, I mean, in word, substance, you know, yeah. I mean, that was always either assumed because it's so obvious, or part to some extent of what we were trying – you know, what we were expressing to them.[227]

40. Disputed. Plaintiffs dispute the asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 5, which is incorporated by reference herein.

41. Disputed. The portions of the deposition transcript cited do not support an assertion of what Fox or Block relied on in signing off on the reference to "substantial defenses" in Pfizer's disclosures. The deposition transcript cited simply acknowledges that there was a White Paper. In no way do those citations support a fact that Block or Fox even received the White Paper, let alone relied on it.

42. Disputed. The statements Waxman is responsible for are set forth in FMS.

43. Disputed. The statements Waxman is responsible for are set forth in FMS. The statement by Waxman in Pfizer's April 2, 2007, press release announced more than the settlement of Genotropin.[228] The press release discussed the off-label promotion of Genotropin, and concludes with Waxman stating that Pfizer had internal controls to prevent those activities.[229] As such, the

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[227] Ex. 62 (O'Connor Depo.) at 122:1-123:15.

[228] *See* Ex. 351.

[229] *See* Ex. 351.

press release concerned the promotion of all of Pfizer's drugs and Pfizer's healthcare compliance controls.

44. Disputed. The announcement of the Genotropin investigation and subsequent settlement are certainly at issue in this case. The statement by Waxman in Pfizer's April 2, 2007, press release announced more than the settlement of Genotropin.[230] The press release discussed the off-label promotion of Genotropin, and concludes with Waxman stating that Pfizer had internal controls to prevent those activities.[231] As such, the press release concerned the promotion of all of Pfizer's drugs and Pfizer's healthcare compliance controls.

45. Disputed. The testimony cited does not confirm who at Pfizer other than Waxman reviewed the April 2, 2007, press release. The testimony does not confirm the process of review press releases went through at Pfizer during the Class Period, either. Plaintiffs agree that Waxman stated: "'As the Department of Justice has acknowledged, Pfizer voluntarily and fully self-disclosed the off-label promotion of Genotropin by a Pharmacia subsidiary before Pharmacia was acquired by Pfizer. . . . Pfizer's marketing and promotion practices are not involved in the settlement. The company has internal controls to guard against these types of practices.'"[232]

46. Disputed. Waxman's statements in Pfizer's April 2, 2007, disclosure of the Genotropin settlement caused and/or maintained the artificial inflation in Pfizer's stock price.

47. Disputed. Waxman's statements in the April 2, 2007, press release were not truthful. Waxman stated that Pfizer had internal controls to guard against off-label promotion practices while knowing Pfizer off-label promoted other drugs; Pfizer's healthcare compliance controls were

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[230] *See* Ex. 351.

[231] Ex. 351.

[232] Ex. 351.

significantly deficient; and Pfizer had an ineffective regulatory compliance function at least in the US.[233]

48. Disputed. Plaintiffs dispute the asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 47, which is incorporated by reference herein.

49. Disputed. Pfizer's healthcare compliance controls did not ensure compliance in healthcare laws as reflected by the wide-spread off-label marketing and the significant deficiencies in the Company's health care compliance controls and an "ineffective regulatory compliance function" in the United States. Pfizer had detected numerous violations of Pfizer's compliance policies and had self-reported a number of them to the OIG.[234] Defendants were also aware of a number of *qui tam* complaints that alleged off-label promotion.[235] Defendant Read admitted in a memo to the Audit Committee that when he became WPO President in 2006, "the status of Healthcare Compliance in the US Pharmaceuticals organization was not where it needed to be," and seven of the top ten areas considered to be greatest risk were unsatisfactory until at least mid-2007.[236] Even Pfizer's Audit Committee was questioning in 2006 whether there were certain activities that the Company should continue to engage in given the potential impact on Pfizer's reputation and whether compliance was embedded in the fabric of the organization to the extent that it needed to be.[237] Prior to and throughout the forepart of the Class Period, there were a multitude of internal audits that were rated unsatisfactory as a result of healthcare compliance violations due to

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[233] PSMF, §IV.C.

[234] *E.g.*, Ex. 214 (9/25/06 letter); Ex. 110 (10/2/06 letter); Ex. 111 (10/3/06 letter); Ex. 112 (11/30/06 letter); Ex. 398 (2/28/07 letter); Ex. 401 (3/16/07 letter); Ex. 400 (3/16/07 letter).

[235] Ex. 523 (5/6/05 legal rep letter); Ex. 524 (5/5/06 legal rep letter).

[236] Exs. 120, 203.

[237] Ex. 120.

weaknesses in controls and an overall ineffective regulatory compliance function in the US.[238] The same or similar issues were found in numerous healthcare compliance areas and persisted for several years despite the obvious awareness of management.[239] Pfizer admitted that although guidelines existed, standard operating procedures had often not been developed to implement the guidelines and there were generally inadequate monitoring controls to ensure the guidelines or standard operating procedures were being followed.[240] Further, the evidence demonstrates that in September 2007, WPO Compliance reported Pfizer's review committees suffered from control weaknesses.[241] Nor was monitoring of the sales force or the training sufficient to ensure compliance.[242]

50. Disputed. The document cited does not support an assertion that the Company acted aggressively to further strengthen controls to guard against marketing and other misconduct. As noted in the email, at that time it was not clear to everyone on the email chain why there was a significant deficiency. Because the Company had not yet even communicated the reasons for the significant deficiency, it could not have been aggressively remediating it at the time of the email.[243] Plaintiffs' further dispute the assertion that the November 2006 memo only reported that there was a significant deficiency within some of Pfizer's compliance controls. The November 2006 memo concluded that Pfizer did "not have an effective healthcare law regulatory compliance function." Moreover, the "ineffective HCC Compliance function in USP [did constitute] a significant

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[238] Exs. 116, 155, 161; Ex. 345 at KPMG-PFIZ-DS 00001110.

[239] Ex. 161.

[240] Exs. 151, 161.

[241] Ex. 203.

[242] *E.g.*, Ex. 192 at PFE DERIV 00075598.

[243] Declaration of Ross Galin in Support of Defendant Allen Waxman's Motion for Summary Judgment, Ex. S-W; Ex. 439.

deficiency for SOX purposes." Plaintiffs also dispute the asserted fact set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 49, which is incorporated by reference herein.

51. Disputed. Plaintiffs also dispute the asserted fact set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 49, which is incorporated by reference herein. At the time each cited document was drafted, the significant deficiency continued to exist. Moreover, reacting to an identified healthcare compliance issue is not remediation.[244] The holistic remediation plan was not even finalized until July 13, 2007.[245]

52. Disputed. Plaintiffs dispute the asserted fact set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 49, which is incorporated by reference herein.

53. Disputed. The CFO would make reserving decision in consultation with the controller.[246] 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."[247] 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."[248] In addition, she never received warning letters from the FDA,[249] letters to the OIG from Investigations Counsel

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[244] Ex. 64 (Riso Depo.) at 57:4-15.

[245] Ex. 163.

[246] Ex. 57 (Levin Depo.) at 100:3-8; Ex. 46 (D'Amelio Depo.) at 33:14-20.

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

[248] Petrosinelli Decl, Ex. N-6.

[249] Ex. 43 (Cangialosi Depo.) at 100:20-101:20.

regarding reportable events pursuant to Pfizer's CIA,[250] documents concerning methodologies to evaluate damages for the Government investigation,[251] the February 5, 2008, target letter from the Government,[252] the April 4, 2008, letter in which Investigations Counsel made a $250 million offer to the Government to settle its investigation[253] or documents relating to the review committee process or reforms or initiatives concerning it.[254]

54. 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.[255] 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.[256] 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

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

[251] Ex. 43 (Cangialosi Depo.) at 294:13-295:6.

[252] Ex. 43 (Cangialosi Depo.) at 253:19-254:5.

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

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

[255] 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 Depo.) at 32:18-20.

[256] Ex. 256 at DOJ000237.

not treat on-label use.[257] The DOJ further told Pfizer how the Company paid physicians to attend consultant meetings, advisory boards and speaker events, and used a publication strategy all to promote Bextra off-label.[258] 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.[259] Instead, KPMG was repeatedly told that the DOJ was still outlining the theories of liability.[260] 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.[261] 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, 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.[262] 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"

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[257] Ex. 256 at DOJ000238.

[258] Ex. 256 at DOJ000239.

[259] Ex. 258 at DOJ000207-08.

[260] Petrosinelli Decl., Ex. C-6.

[261] Ex. 258 at DOJ000205.

[262] Ex. 161.

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.[263] This presentation set forth the complete lack of controls over the Review Committee and, thus, Pfizer's HCC function.[264] These failures are particularly glaring given: (1) Pfizer considered Review Committee procedures to be one of the top ten areas of greatest risk;[265] (2) KPMG's concern that Pfizer's controls over sales and marketing practices were impaired;[266] 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.[267]

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.[268] Similarly, KPMG was never informed that Pfizer received a target letter from the DOJ on February 5, 2008.[269] 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

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[263] Ex. 203.

[264] Ex. 203.

[265] Ex. 120.

[266] Exs. 149-150.

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

[268] Ex. 310.

[269] Ex. 161; Ex. 38 (Bradley Depo.) at 242:13-16.

Investigation in that the DOJ intended to pursue criminal charges against Pfizer and offered a settlement of approximately $5 billion.[270]

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.[271] 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.[272] 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."[273] Similarly, Lankler told KPMG that the off-label marketing of Geodon had not been linked back to senior management at corporate headquarters.[274]

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 that

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[270] Petrosinelli Decl., Ex. Y-6.

[271] Ex. 159.

[272] Exs. 138-139.

[273] Ex. 204.

[274] Ex. 204.

the fine in the Bextra Investigation should be calculated as it was in "analogous" cases such as Neurontin, Schering, Serono and Genotropin.[275]

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."[276] Chapman, KPMG audit partner, testified he had not been informed by November 3, 2007, that the probable "pillar" of FAS 5 had been met.[277] 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.[278]

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.[279] 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.[280] After becoming the engagement partner in early 2008, Bradley did not know that Lankler and Wessel were working on methodologies to calculate potential losses.[281]

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[275] Petrosinelli Decl., Ex. B-6.

[276] Petrosinelli Decl., Ex. N-6 (October 17, 2007 e-mail 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).

[277] Ex. 44 (Chapman Depo.) at 122:19-123:16.

[278] Ex. 38 (Bradley Depo.) at 239:9-20.

[279] Petrosinelli Decl., Ex. N-6.

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

[281] Ex. 38 (Bradley Depo.) at 234:1-236:2.

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.[282]

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.[283] 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.[284] KPMG was never informed in or around June 2008, that Covington offered $750 million to settle the DOJ Bextra investigation.[285] 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.[286] In fact, KPMG workpapers from June and July 2008 show that Pfizer told KPMG that no offers to settle to date had been made.[287]

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

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[282] Petrosinelli Decl., Exs. B-6, C-6

[283] Ex. 104; Ex. 38 (BradleyDepo.) at 236:3-11.

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

[285] 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.").

[286] Ex. 158.

[287] Ex. 159.

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.[288] 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.[289] 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.[290]

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[288] *E.g.*, Ex. 134 at KPMG-PFIZ-DS 017125.

[289] Exs. 14, 17-18.

[290] Exs. 19-23.

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."[291] 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."[292] In addition, she never received warning letters from the FDA,[293] letters to the OIG from Investigations Counsel regarding reportable events pursuant to Pfizer's CIA,[294] documents concerning methodologies to evaluate damages for the Government investigation,[295] the February 5, 2008, target letter from the Government,[296] the April 4, 2008, letter in which Investigations Counsel made a $250 million offer to the Government to settle its investigation[297] or documents relating to the review committee process or reforms or initiatives concerning it.[298]

55. Disputed. Plaintiffs dispute this asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 24, which is incorporated by reference herein.

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

[292] Petrosinelli Decl., Ex. N-6.

[293] Ex. 43 (Cangialosi Depo.) at 100:20-101:20.

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

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

[296] Ex. 43 (Cangialosi Depo.) at 253:19-254:5.

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

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

56. Disputed. Plaintiffs dispute this asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 5, which is incorporated by reference herein.

57. Disputed. Plaintiffs dispute this asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 5, which is incorporated by reference herein.

58. Disputed. Plaintiffs dispute this asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 19, which is incorporated by reference herein.

59. Disputed. The document cited also demonstrates that Pfizer knew of the methodology to be used to reasonably estimate losses as was done in the Neurontin case.[299]

60. Undisputed.

61. Undisputed.

62. Disputed. Plaintiffs dispute this asserted fact for the reasons set forth in Plaintiffs' Response to Waxman's Undisputed Fact No. 54, which is incorporated by reference herein.

DATED: November 26, 2014

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

s/ HENRY ROSEN
HENRY ROSEN

[299] Petrosinelli Decl., Ex. B-6.

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

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

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

Lead Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on 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

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

E-mail: henryr@rgrdlaw.com

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

Electronic Mail Notice List

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

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

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

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

Manual Notice List

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

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

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

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

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

Francisco Mendoza

From: NYSD_ECF_Pool@nysd.uscourts.gov
Sent: Monday, December 01, 2014 9:55 AM
To: CourtMail@nysd.uscourts.gov
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U.S. District Court

Southern District of New York

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Case Number: 1:10-cv-03864-AKH
Filer: Mary K. Jones
Stichting Philips Pensioenfonds
Document Number: 314

Docket Text:
RESPONSE re: [261] Rule 56.1 Statement . Document filed by Mary K. Jones(Individually), Stichting Philips Pensioenfonds. (Rosen, Henry)

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

Alexander C Drylewski alexander.drylewski@skadden.com

Amanda M. MacDonald amacdonald@wc.com

Brant Duncan Kuehn brantkuehn@quinnemanuel.com

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

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

Daniel Prugh Roeser droeser@goodwinprocter.com

Danielle Suzanne Myers dmyers@rgrdlaw.com

Darren J. Robbins e_file_sd@rgrdlaw.com

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

Donald Alan Migliori dmigliori@motleyrice.com

Eugene Mikolajczyk genem@rgrdlaw.com

Gary John Hacker ghacker@skadden.com

George Anthony Borden gborden@wc.com

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

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

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

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

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

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

James R. Harper coljamesrharper@me.com

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

Jay B. Kasner jkasner@skadden.com

Jennifer Lynn Spaziano jen.spaziano@skadden.com

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

John K. Villa jvilla@wc.com

Joseph F. Rice jrice@motleyrice.com

Joseph G. Petrosinelli jpetrosinelli@wc.com

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

Keir Nicholas Dougall kdougall@dougallpc.com

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

Lauren Kristina Collogan lcollogan@wc.com

Leigh R. Lasky lasky@laskyrifkind.com

Lori McGill lorialvinomcgill@quinnemanuel.com

Matthew Melamed mmelamed@rgrdlaw.com

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

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

Michael Scott Bailey michael.bailey@skadden.com

Mitchell M.Z. Twersky mtwersky@aftlaw.com

Paul T. Hourihan phourihan@wc.com

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

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

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

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

Scott D. Musoff smusoff@skadden.com, david.carney@skadden.com

Seema Mittal smittal@wc.com

Sheila L. Birnbaum sheilabirnbaum@quinnemanuel.com

Sidney Bashago sidney.bashago@dpw.com

Steven M.. Farina sfarina@wc.com

Stuart Michael Sarnoff ssarnoff@omm.com

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

William E. Schurmann wschurmann@wc.com

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

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

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

Catherine J. Kowalewski

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

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

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

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

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