

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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

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 Alan G. Levin’s Statement of Undisputed Material Facts.

A. Parties

1. Plaintiffs

1. Undisputed.

2. Alan Levin

2. Undisputed.

3. Undisputed.

4. Undisputed.

5. Undisputed.

6. Undisputed.

7. Undisputed.

8. Undisputed.

B. The Bextra Investigation

9. Undisputed.

10. Disputed. Pfizer did not adequately disclose the Bextra Investigation.¹ From 2003-2009 the investigation included blatant off-label promotion of Bextra for unapproved uses and doses.

¹ “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 Pfizer’s outside counsel, Covington & Burling LLP (“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. The “Government” refers to the U.S. Department of Justice (“DOJ”) and/or the U.S. Department of Health & Human Services Office of Inspector General (“OIG”). 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.

11. Undisputed.

12. Disputed. Pfizer met with the DOJ in 2004 and began a dialogue about Bextra off-label marketing.

“In February 2004, the Department of Justice alerted the [C]ompany that it and the HHS, OIG are investigating allegations that the company promoted Bextra for generalized acute pain in possible violation of federal criminal law.”²

On July 15, 2004, Covington presented “a pretty extensive slide deck” relating to the marketing and sale of Bextra to the DOJ and OIG.³ The slide deck noted that a *qui tam* complaint had been filed alleging the promotion of “Bextra for ‘Acute Pain’” through “Improper Comparison to Vioxx,” “Improper Dissemination of Medical Literature,” “Protocols and Standing Orders,” “Use of Physician Consultants” and for “Pre- and Post-Operative Use” as well as the promotion of Bextra “20 Mg for Uses Other Than Primary Dysmenorrhea.”⁴ The slide deck also noted Pfizer’s “Review of Headquarters Bextra Sales Marketing Practices” and its “Ongoing Review of Select Geographic Areas,” which included a finding from a “Physician Recall Report March 2004” that “acute pain/inflammation now [wa]s the leading Bextra usage discussion” between sales representatives and physicians.⁵

On November 16-17, 2004, Covington met with the DOJ and OIG and presented a slide deck entitled “Pfizer Inc. Review and Voluntary Disclosure Relating to Bextra Allegations.”⁶ The slide

² Ex. 153 at KPMG-PFIZ-DS 053290; *see also* Ex. 195 at PFE-JONES 00005227.

³ Ex. 437 at PFE-JONES 00002299-300; Ex. 211 at PFE-JONES 00006992-93.

⁴ Ex. 247 at PFE DERIV 00066670.

⁵ Ex. 247 at PFE DERIV 00066698, 706.

⁶ Ex. 211 at PFE-JONES 00006993-94; Ex. 397 at PFE DERIV 00066448-667.

deck noted that after “Hundreds of Thousands of Documents Reviewed” and “Over 70 Interviews Conducted,” Pfizer found that it was a “Senior Management Decision to Make Available Under WLF” a Bextra reprint on “Dental Pain (vs. Tylox)” and that surveys of the sales force and the physicians they detailed revealed “many [sales representatives] communicat[ing] 10 mg. is for OA and RA and 20 mg. is for acute pain states” and that “[t]he most common positioning is . . . ‘Bextra for acute pain’” although “[s]everal . . . mention[ed] their discomfort in delivering the desired positioning [because] it is Celebrex that has the acute pain data vs. narcotics that they can show to physicians, yet they are being asked to position Bextra for the acute patient.”⁷

In December 2004, Pfizer received a subpoena from the U.S. Attorney’s Office for the District of Massachusetts requesting documents concerning, *inter alia*, clinical studies, sales, promotion and marketing of Bextra,⁸ further outlining the Government’s areas of investigation.

In September 2005, Pfizer noted that while the Bextra investigation was at an early stage and the issues are still being defined, the “government is *still outlining its theories*,” implying that the Government’s initial views had already been communicated to Pfizer or its agents.⁹ At that time, Pfizer also noted that “we are likely to be forced to reach some form of settlement of this matter.”¹⁰ Although defendants shielded discovery of their Investigations Counsel,¹¹ by August 2006,

⁷ Ex. 397 at PFE DERIV 00066490, 512, 529, 599.

⁸ Ex. 435 at PFE DERIV A 00008540; Ex. 153 at KPMG-PFIZ-DS 053290.

⁹ Declaration of Joseph G. Petrosinelli in Support of Pfizer’s Motion for Summary Judgment (“Petrosinelli Decl.”), Ex. P-5 at PFE-JONES 00043524.

¹⁰ Petrosinelli Decl., Ex. P-5 at PFE-JONES 00043524.

¹¹ “Investigations Counsel” refers to Pfizer’s counsel who were involved in the Bextra Investigation, including, but not limited to, Covington and in-house counsel Douglas Lankler (“Lankler”), Carlton Wessel (“Wessel”) and Gary Giampetruzzi (“Giampetruzzi”).

defendants' agents had met with the Government on seven separate occasions.¹² It is a ready inference that, although the Government was still "outlining its theories" in September 2005, Pfizer understood the Government's views by August 2006.

13. Disputed. Defendants rely on a summary of the meeting prepared by Pfizer's attorneys in connection with litigation sometime after July 2010.¹³ This evidence is inadmissible if offered by defendants.¹⁴

14. Undisputed.

15. Disputed. Levin cites the Petrosinelli Decl, Ex. Y-6 in support of his purported fact. The exhibit does not prove his purported fact. In fact, the letter dated April 4, 2008 states: "As you know, this proposal was within neither the structure nor the financial range *we previously communicated to you as being necessary for us to recommend the resolution of this matter.*"¹⁵ The April 4, 2008 letter does not indicate the timing of those "previous communications."

16. Disputed. Pfizer commenced discussions with the DOJ. See plaintiffs' response to Levin Undisputed Fact No. 12.

On August 17, 2006, the DOJ presented to Pfizer several slide decks and hundreds of supporting documents "concerning contentions about alleged off-label promotion" of Bextra.¹⁶ The slide deck entitled "Preliminary Statement: Investigation Continuing" noted: (1) the "FDA Rejection of Bextra for: Acute and Peri-Operative Pain . . . [and] 20 mg outside PD"; (2) that the "Off-Label

¹² Ex. 167 at PFE-JONES 00006988.

¹³ Declaration of Alexander C. Drylewski in Support of Alan G. Levin's Motion for Summary Judgment ("Drylewski Decl."), Ex. B-L.

¹⁴ Fed. R. Evid. 801(c), 802.

¹⁵ Petrosinelli Decl., Ex. Y-6.

¹⁶ Ex. 211 at PFE-JONES 00006996-7014.

Promotion Continue[d] after Launch” into 2004; (3) that “Unapproved, False and/or Misleading Claims Made For Bextra” included “Acute Pain generally,” “Safer or More Effective Than Vioxx,” “Pre and Post Op Pain” and “Doses above 10 mg (Outside PD)”; (4) that the Company’s “Tactics Used” included the “Hospital Selling Campaign,” “Protocols, Standing Orders and Pain Pathways,” “Sampling 20 mg to doctors with no on label use,” “\$\$ Remuneration to Influence doctors” at “Consultant Meetings/Advisory Boards,” “Control of purportedly independent CME,” and the “Publication Strategy”; and (5) that “HQ knowledge” was demonstrated by the “Bextra Positioning for Acute Pain” and “Headquarters knowledge of promotion for unapproved uses.”¹⁷ The slide deck entitled “Review of Key Events & Factors” noted: (1) that Bextra had “\$2.4 Billion in Revenues,” but the “Majority of Sales [were] for Unapproved Uses”; (2) the “Potential Criminal Charges” that the DOJ was considering bringing against Pfizer; and (3) the “Aggravating Factors,” including “Knowledge at the Top,” “A Deliberate Scheme,” “Pervasive Misconduct” and “The Conduct continued despite: Ongoing Neurontin criminal investigation, Two [Corporate Integrity Agreements], Two self-disclosures on other issues, Numerous internal complaints and red flags [and] Disclosure of the Bextra *qui tam* complaint and ongoing Bextra investigation.”¹⁸ The slide deck entitled “Summary of Bextra Call Note Evidence” presented call note excerpts by sales representatives all over the United States reflecting the promotion of Bextra for acute pain.¹⁹

On September 19, 2006, the DOJ presented to Pfizer slide decks that were substantially similar to the ones that had been presented on August 17, 2006 and dozens of additional supporting

¹⁷ Ex. 248 at DOJ000235-40.

¹⁸ Ex. 249 at DOJ000199, 205, 207-08.

¹⁹ Ex. 251.

documents “concerning certain contentions about the marketing of Bextra” for off-label uses.²⁰ Moreover, Levin cites Petrosinelli Decl., Ex. Y-6 in support of his purported fact. The exhibit does not prove his purported fact. In fact, the letter dated April 4, 2008 states: “As you know, this proposal was within neither the structure nor the financial range *we previously communicated to you as being necessary for us to recommend the resolution of this matter.*”²¹ The April 4, 2008 letter does not indicate the timing of those “previous communications.”

17. Disputed. The Form 10-K for 2006, filed on March 1, 2007, stated that Pfizer, as to the Bextra Investigation, was “considering various ways to resolve these matters.”²² In addition, defendants shielded from discovery communications between Levin, Pfizer and Pfizer’s Government Investigations Counsel.²³ Levin cannot now rely on such undisclosed alleged communications with Pfizer’s attorneys.

18. Disputed. In addition, defendants shielded from discovery communications between Levin, Pfizer and Pfizer’s Government Investigations Counsel.²⁴

19. Disputed. *See* plaintiffs’ responses to Levin Undisputed Facts Nos. 16, 17 and 18.

20. Disputed. The Government outlined its evidence to Pfizer in August and September 2006.²⁵ It appears that defendants were unquestionably working on methodologies no later than October 2007. In support of this purported fact, Levin points to a letter from Pfizer to KPMG LLP

²⁰ Ex. 211 at PFE-JONES 00007014-25; Ex. 250 (slide deck entitled “Preliminary Statement: Investigation Continuing”); Ex. 314 (slide deck entitled “Review of Key Events & Facts”).

²¹ Petrosinelli Decl., Ex. Y-6.

²² Petrosinelli Decl., Ex. D-1.

²³ Dkt. No. 172 at 25; July 19, 2013 Hearing Tr. at 12:1-2; Dkt. No. 246 at 1, 5.

²⁴ Dkt. No. 172 at 25; July 19, 2013 Hearing Tr. at 12:1-2; Dkt. No. 246 at 1, 5.

²⁵ *See* Exs. 250, 258, 314.

(“KPMG”) dated November 2, 2007.²⁶ The letter does not state that the September 2007 meeting was “the first time” that the Government made such a request. Moreover, defendants shielded from discovery communications between Pfizer and its Government Investigations Counsel, thereby potentially preventing plaintiffs from obtaining further evidence with which to dispute this purported fact.²⁷

21. Disputed. This is not the first time the Government gave Pfizer the statutory framework which laid out Pfizer’s criminal exposure and the statutes violated. *See* Plaintiffs’ Response to Levin Undisputed Fact No. 22. Pfizer never shared this with KPMG.

The DOJ had set forth the potential criminal charges at least as far back as August 17, 2006.²⁸ Pfizer already knew of the loss theory used in other cases, including Neurontin and Genotropin.²⁹ In addition, defendants shielded from discovery communications between Levin, Pfizer and Pfizer’s Government Investigations Counsel potentially preventing plaintiffs from obtaining further evidence with which to dispute this purported fact.³⁰

22. Disputed. Covington, in addition to contesting the DOJ’s intended loss theory, also set forth a methodology to calculate damages in “analogous cases” such as Neurontin. This response was not shared with KPMG.³¹

²⁶ Petrosinelli Decl., Ex. K-4.

²⁷ Dkt. No. 172 at 25; July 19, 2013 Hearing Tr. at 12:1-2; Dkt. No. 246 at 1, 5; Petrosinelli Decl., Ex. N-6.

²⁸ *See* Ex. 258.

²⁹ Petrosinelli Decl., Ex. B-6.

³⁰ Dkt. No. 172 at 25; July 19, 2013 Hearing Tr. at 12:1-2; Dkt. No. 246 at 1, 5.

³¹ Petrosinelli Decl., Ex. B-6.

23. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 15. Moreover, on February 5, 2008, Sara Bloom stated that she was willing to recommend figures substantially below \$4 billion.³²

24. Undisputed.

25. Undisputed. The Board of Directors' Minutes reflect its approval on that date.

26. Disputed. Pfizer was prosecuted for this crime. As part of the agreement between Pfizer and the Government, a wholly owned subsidiary of Pfizer that did not even exist at the time the charged conduct with respect to Bextra was undertaken, entered the plea.

27. Undisputed.

28. Undisputed.

29. Undisputed.

C. The Geodon, Lyrica and Zyvox Investigations

30. Undisputed.

31. Undisputed.

32. Undisputed.

D. Pfizer's Disclosures Regarding Legal Proceedings and Contingencies During Levin's Tenure as CFO

33. Undisputed. However, in fairness, other portions of the Pfizer 2005 Form 10-K must be considered contemporaneously with the language cited by Levin to prevent this excerpt from being misleading.

³² Ex. 104.

34. Undisputed. However, in fairness, other portions of the Pfizer 2005 Form 10-K must be considered contemporaneously with the language cited by Levin to prevent this excerpt from being misleading.

35. Undisputed. Disputed to the extent the disclosure fails to say future judgments could have a material adverse effect on Pfizer's results of operations in more than one "particular period." If Pfizer were to be debarred as a result of its illegal off-label promotion of drugs, that could have a material adverse effect in perpetuity. Therefore, in fairness, other portions of the Pfizer 1Q06 Form 10-Q must be considered contemporaneously with the language cited by Levin to prevent this excerpt from being misleading.

36. Undisputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 35.

37. Undisputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 35.

38. Undisputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 35.

39. Undisputed. Disputed to the extent the disclosure fails to say future judgments could have a material adverse effect on Pfizer's results of operations in more than one "particular period." If Pfizer were to be debarred as a result of its illegal off-label promotion of drugs, that could have a material adverse effect in perpetuity. Therefore, in fairness, other portions of the Pfizer 2006 Form 10-K must be considered contemporaneously with the language cited by Levin to prevent this excerpt from being misleading.

E. Levin's Role as CFO

40. Disputed. Plaintiffs agree that Levin attended monthly executive litigation review meetings, met with KPMG, participated in Disclosure Committee meetings, reviewed drafts of both earnings press releases and U.S. Securities and Exchange Commission ("SEC") filings and met with other Pfizer executives as part of executing certifications. However, to the extent that Levin lists this conduct to demonstrate his good faith, he fails to do so.

Defendants have expressly denied relying on any counsel other than Dennis Block ("Block") or Lawrence Fox ("Fox") for their defense in this case³³ (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 on Defendants' Release 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 case³⁴ or Pfizer's defenses,³⁵ whether a loss or conviction was probable, or whether such loss was reasonably estimable.³⁶

³³ Dkt. No. 172 at 25; July 19, 2013 Hearing Transcript at 12:1-2; Dkt. No. 246 at 1, 5.

³⁴ 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.

³⁵ Ex. 37 (Block Depo.) at 104:6-23; Ex. 49 (Fox Depo.) at 86:13-19, 90:12-20.

³⁶ 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.

Moreover, defendants withheld from Block and Fox critical evidence concerning the Bextra Investigation, including call notes,³⁷ documents that corroborated a *qui tam* relator's claims,³⁸ Bextra-related documents that Pfizer employees had attempted to delete or alter,³⁹ sales force survey results⁴⁰ and employee interview memoranda.⁴¹ Instead, all information and input regarding the Bextra Investigation came from Investigations Counsel.⁴² 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.⁴³

Block never personally and professionally assessed nor advised defendants that Pfizer had substantial defenses to the Bextra Investigation.⁴⁴

Fox never independently determined or advised defendants that Pfizer had substantial defenses to the Bextra Investigation.⁴⁵

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

³⁸ 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 59:14-60:6, 230:21-231:8; Ex. 49 (Fox Depo.) at 49:9-23.

⁴⁰ Ex. 37 (Block Depo.) at 54:8-22, 56:2-11; Ex. 49 (Fox Depo.) at 97:11-18, 211:16-212:1.

⁴¹ 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.

⁴² 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.

⁴³ Ex. 55 (Lankler Depo.) at 92:23-97:21.

⁴⁴ Ex. 37 (Block Depo.) at 104:6-23.

⁴⁵ Ex. 49 (Fox Depo.) at 86:13-19, 90:12-20.

Neither Block nor Fox made an assessment or advised defendants as to the strengths and weaknesses of Pfizer's defenses or of the Government's case.⁴⁶

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.⁴⁷

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.⁴⁸

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.⁴⁹

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

⁴⁶ 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.

⁴⁷ 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.

⁴⁸ 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.

⁴⁹ 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.

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.⁵⁰

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.⁵¹

⁵⁰ 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.

⁵¹ Ex. 49 (Fox Depo.) at 90:12-20; Ex. 55 (Lankler Depo.) at 107:22-108:1; Ex. 58 (9/23/14 Levin Depo.) at 39:25-40:24, 43:11-44:1, 99:19-100:4, 113:10-114:10, 115:6-116:2; Ex. 54 (10/10/14 Kindler Depo.) at 31:10-32:8; Ex. 68 (10/16/14 Waxman Depo.) at 16:2-14, 20:15-21.

Neither Block nor Fox has ever worked as a criminal law prosecutor or a criminal defense attorney.⁵²

Neither Block nor Fox was familiar with the elements of a misbranding offense.⁵³

Neither Block nor Fox was familiar with elements or application of *respondeat superior* liability.⁵⁴

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.⁵⁵

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.⁵⁶

Fox incorrectly understood the terms grand jury "target" and grand jury "subject" to be interchangeable.⁵⁷

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.⁵⁸

⁵² Ex. 37 (Block Depo.) at 13:12-14:6, 14:13-15:10; Ex. 49 (Fox Depo.) at 35:21-36:12.

⁵³ Ex. 37 (Block Depo.) at 16:6-17:8; Ex. 49 (Fox Depo.) at 37:17.

⁵⁴ Ex. 37 (Block Depo.) at 232:20-233:12; Ex. 49 (Fox Depo.) at 36:13-37:9.

⁵⁵ 42 U.S.C. §1320a-7.

⁵⁶ Ex. 49 (Fox Depo.) at 130:7-15, 218:21-219:5.

⁵⁷ Ex. 49 (Fox Depo.) at 106:3-23.

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

Pfizer and its Investigations Counsel always represented to Block that Pfizer's sales representatives had not promoted Bextra off-label.⁵⁹ In fact, from February 2002 through April 2005: Pfizer promoted Bextra for uses that were not within Bextra's FDA-approved label, including (a) for general acute pain, (b) for pre-operative and post-operative surgical pain and (c) as opioid-sparing in the context of surgery;⁶⁰ 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");⁶¹ Pfizer introduced Bextra into interstate commerce for the treatment of acute pain, surgical pain and other unapproved uses and at unapproved dosages, even though it lacked adequate directions for such uses and dosages;⁶² Pfizer promoted Bextra with an intent to defraud or mislead;⁶³ 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;⁶⁴ 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.⁶⁵

⁵⁹ Ex. 37 (Block Depo.) at 50:5-20, 232:3-12.

⁶⁰ Ex. 240 at 51:10-17.

⁶¹ Ex. 240 at 51:17-18.

⁶² Ex. 240 at 51:19-21.

⁶³ Ex. 240 at 51:22-23.

⁶⁴ Ex. 240 at 52:1-4.

⁶⁵ Ex. 240 at 52:5-9.

No one provided Block a copy of Kopchinski's Complaint or any of the internal Pfizer documents that were exhibits to it.⁶⁶ The same appears to be true as to Fox, as the record does not indicate that he received those documents either.⁶⁷

No one ever provided Block or Fox the internal documents that Pfizer's sales representatives had attempted to delete or alter.⁶⁸

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.⁶⁹

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.⁷⁰

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.⁷¹

No one provided Block or Fox copies of any of the interview memoranda from the Bextra Investigation.⁷²

⁶⁶ Ex. 37 (Block Depo.) at 54:8-22; Ex. 60 (9/19/14 McKinnell Depo.) at 60:7-10; *see also* Ex. 54 (10/10/14 Kindler Depo.) at 34:19-24.

⁶⁷ Ex. 49 (Fox Depo.) at 211:5-212:1; *see also* Ex. 54 (10/10/14 Kindler Depo.) at 35:18-36:10.

⁶⁸ Ex. 37 (Block Depo.) at 59:14-60:1, 230:21-231:8; Ex. 49 (Fox Depo.) at 49:9-23.

⁶⁹ 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.

⁷⁰ *See* Ex. 37 (Block Depo.) at 54:8-22, 56:2-11; Ex. 49 (Fox Depo.) at 97:11-18, 211:16-212:1.

⁷¹ Ex. 37 (Block Depo.) at 76:5-23, 144:21-145:4; Ex. 49 (Fox Depo.) at 60:3-22, 61:3-11.

⁷² Ex. 37 (Block Depo.) at 54:8-22, 56:2-11, 105:3-13; Ex. 49 (Fox Depo.) at 13:2-8, 53:23-54:14, 211:16-212:1.

Neither Block nor Fox received access to any of Pfizer's Investigations Counsel's written work product concerning the Bextra Investigation.⁷³

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.⁷⁴

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. 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.⁷⁵ 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.⁷⁶ 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.⁷⁷ The DOJ also set forth the criminal charges based on Federal Food, Drug, and Cosmetic Act ("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. The

⁷³ Ex. 55 (Lankler Depo.) at 101:1-11; Ex. 37 (Block Depo.) at 54:8-22; Ex. 49 (Fox Depo.) at 97:11-18.

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

⁷⁵ Ex. 256 at DOJ000237.

⁷⁶ Ex. 256 at DOJ000238.

⁷⁷ Ex. 256 at DOJ000239.

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.⁷⁸ Instead, KPMG was repeatedly told that the DOJ was still outlining the theories of liability.⁷⁹ 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.⁸⁰ 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 Health Care Compliance ("HCC") function could have a material impact on Pfizer's financial results.⁸¹ 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.⁸² This presentation set forth the complete lack of controls over the Review Committee and, thus, Pfizer's HCC function.⁸³ These failures are particularly glaring given: (1) Pfizer considered Review Committee procedures to be one

⁷⁸ Ex. 258 at DOJ000207-08.

⁷⁹ Petrosinelli Decl., Ex. C-6.

⁸⁰ Ex. 258 at DOJ000205.

⁸¹ Ex. 161.

⁸² Ex. 203.

⁸³ Ex. 203.

of the top ten areas of greatest risk;⁸⁴ (2) KPMG's concern that Pfizer's controls over sales and marketing practices were impaired;⁸⁵ and (3) KPMG had recently been informed by Pfizer that the significant deficiency with regard to HCC had been remediated by the end of 2Q07.⁸⁶

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.⁸⁷

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 that the fine in the Bextra Investigation should be calculated as it was in "analogous" cases such as Neurontin, Schering, Serono and Genotropin.⁸⁸

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

⁸⁴ Ex.120.

⁸⁵ Exs.149-150.

⁸⁶ Ex. 346 at KPMG PFIZ-DS 0003257 (2Q07 Interim Completion Document).

⁸⁷ Ex. 310.

⁸⁸ Petrosinelli Decl., Ex. B-6.

Bextra Investigation was “probable.”⁸⁹ 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.⁹⁰ 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.⁹¹

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.⁹² 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.⁹³

Again, instead, Block repeatedly told KPMG at least as early as October 2007 and 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.⁹⁴

KPMG relied on representations of Pfizer management in the form of quarterly management representation letters signed by the Chief Financial Officer (“CFO”) and Controller, quarterly in-

⁸⁹ 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).

⁹⁰ Ex. 44 (Chapman Depo.) at 122:19-123:16.

⁹¹ Ex. 38 (Bradley Depo.) at 239:9-20.

⁹² Petrosinelli Decl., Ex. N-6.

⁹³ Petrosinelli Decl., Ex. N-6; Ex. 44 (Chapman Depo.) at 130:12-18.

⁹⁴ Petrosinelli Decl., Exs. B-6, C-6.

house legal representation letters signed by defendants Allen Waxman (“Waxman”) and Jeffrey B. Kindler (“Kindler”), and annual legal representation letters from Pfizer’s outside counsel. The quarterly management representation letters confirmed that management was responsible for the fair presentation of the financial statements in conformity with Generally Accepted Accounting Principles (“GAAP”) and confirmed certain material matters, including a representation that all relevant information relating to certain compliance matters subject to the investigation of alleged 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.⁹⁵ 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.⁹⁶ Fees paid to KPMG by Pfizer

⁹⁵ *E.g.*, Ex. 134 at KPMG-PFIZ-DS 017125.

⁹⁶ Exs. 10, 14, 17-18.

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.⁹⁷

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.”⁹⁸ 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.”⁹⁹ In addition, she never received warning letters from the FDA,¹⁰⁰ letters to the OIG from Investigations Counsel regarding reportable events pursuant to Pfizer’s Corporate Integrity Agreements,¹⁰¹ documents concerning methodologies to evaluate damages for the Government investigation,¹⁰² or documents relating to the review committee process or reforms or initiatives concerning it.¹⁰³

41. Undisputed.

⁹⁷ Exs. 19-23.

⁹⁸ Statement of Undisputed Facts in Support of Pfizer’s Motion for Summary Judgment, ¶31.

⁹⁹ Petrosinelli Decl., Ex. N-6

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

¹⁰¹ Ex. 43 (Cangialosi Depo.) at 181:6-184:20.

¹⁰² Ex. 43 (Cangialosi Depo.) at 294:13-295:6.

¹⁰³ Ex. 43 (Cangialosi Depo.) at 96:15-98:7, 112:23-119:4, 124:24-128:13.

42. Disputed. Plaintiffs agree that Levin executed certifications for every Form 10-Q and 10-K. However, to the extent that Levin is suggesting that he operated in good faith, plaintiffs dispute this fact. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 40.

43. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 40.

44. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 40.

45. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 40.

46. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 40.

47. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 40.

48. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 40.

49. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 40.

50. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 40.

51. Undisputed.

52. Undisputed. However, the Litigation Report contained information supplied by Pfizer's Government Investigations Counsel. Defendants may not assert an advice of counsel

defense for the reasons set forth in plaintiffs' Motion for Partial Summary Judgment, which is incorporated by reference herein.

53. Disputed. Defendants have expressly denied relying on any counsel other than Block or Fox for their defense in this case¹⁰⁴ (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. Neither Block nor Fox assessed critical portions of Pfizer's legal proceedings disclosure and the FAS reserve decisions: the strengths or weaknesses of the Government's case¹⁰⁵ or Pfizer's defenses,¹⁰⁶ whether a loss or conviction was probable or whether such loss was reasonably estimable.¹⁰⁷ Moreover, defendants withheld from Block and Fox critical evidence concerning the Bextra Investigation, including call notes,¹⁰⁸ documents that corroborated a *qui tam* relator's claims,¹⁰⁹ Bextra-related documents that Pfizer employees had attempted to delete or alter,¹¹⁰ sales force survey results¹¹¹ and employee interview

¹⁰⁴ Dkt. No. 172 at 25; July 19, 2013 Hearing Transcript at 12:1-2; Dkt. No. 246 at 1, 5.

¹⁰⁵ 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.

¹⁰⁶ Ex. 37 (Block Depo.) at 104:6-23; Ex. 49 (Fox Depo.) at 86:13-19, 90:12-20.

¹⁰⁷ 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.

¹⁰⁸ Ex. 37 (Block Depo.) at 76:5-23, 144:21-145:4; Ex. 49 (Fox Depo.) at 60:3-22, 61:3-11.

¹⁰⁹ 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.

¹¹⁰ Ex. 37 (Block Depo.) at 59:14-60:6, 230:21-231:8; Ex. 49 (Fox Depo.) at 49:9-23.

¹¹¹ Ex. 37 (Block Depo.) at 54:8-22, 56:2-11; Ex. 49 (Fox Depo.) at 97:11-18, 211:16-212:1.

memoranda.¹¹² Instead, all information and input regarding the Bextra Investigation came from Investigations Counsel.¹¹³ 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.¹¹⁴

Block never personally and professionally assessed nor advised defendants that Pfizer had substantial defenses to the Bextra Investigation.¹¹⁵

Fox never independently determined or advised defendants that Pfizer had substantial defenses to the Bextra Investigation.¹¹⁶

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.¹¹⁷

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.¹¹⁸

¹¹² 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.

¹¹³ 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.

¹¹⁴ Ex. 55 (Lankler Depo.) at 92:23-97:21.

¹¹⁵ Ex. 37 (Block Depo.) at 104:6-23.

¹¹⁶ Ex. 49 (Fox Depo.) at 86:13-19, 90:12-20.

¹¹⁷ 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.

¹¹⁸ 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.¹¹⁹

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.¹²⁰

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

¹¹⁹ 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.

¹²⁰ 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.

Investigations Counsel; or the Bextra-related call notes quoted, summarized and/or analyzed in the Government's presentations to Pfizer and its Investigations Counsel.¹²¹

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.¹²²

Neither Block nor Fox has ever worked as a criminal law prosecutor or a criminal defense attorney.¹²³

Neither Block nor Fox was familiar with the elements of a misbranding offense.¹²⁴

¹²¹ 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.

¹²² 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.

¹²³ Ex. 37 (Block Depo.) at 13:12-14:6, 14:13-15:10; Ex. 49 (Fox Depo.) at 35:21-36:12.

¹²⁴ 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.¹²⁵

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.¹²⁶

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.¹²⁷

Fox incorrectly understood the terms grand jury "target" and grand jury "subject" to be interchangeable.¹²⁸

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.¹²⁹

Pfizer and its Investigations Counsel always represented to Block that Pfizer's sales representatives had not promoted Bextra off-label.¹³⁰ In fact, from February 2002 through April 2005: Pfizer promoted Bextra for uses that were not within Bextra's FDA-approved label, including (a) for general acute pain, (b) for pre-operative and post-operative surgical pain and (c) as opioid-

¹²⁵ Ex. 37 (Block Depo.) at 232:20-233:12; Ex. 49 (Fox Depo.) at 36:13-37:9.

¹²⁶ 42 U.S.C. §1320a-7.

¹²⁷ Ex. 49 (Fox Depo.) at 130:7-15, 218:21-219:5.

¹²⁸ Ex. 49 (Fox Depo.) at 106:3-23.

¹²⁹ 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.

¹³⁰ Ex. 37 (Block Depo.) at 50:5-20, 232:3-12.

sparing in the context of surgery;¹³¹ 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;¹³² Pfizer introduced Bextra into interstate commerce for the treatment of acute pain, surgical pain and other unapproved uses and at unapproved dosages, even though it lacked adequate directions for such uses and dosages;¹³³ Pfizer promoted Bextra with an intent to defraud or mislead;¹³⁴ 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;¹³⁵ 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.¹³⁶

No one provided Block a copy of Kopchinski's Complaint or any of the internal Pfizer documents that were exhibits to it.¹³⁷ The same appears to be true as to Fox, as the record does not indicate that he received those documents either.¹³⁸

No one ever provided Block or Fox the internal documents that Pfizer's sales representatives had attempted to delete or alter.¹³⁹

¹³¹ Ex. 240 at 51:10-17.

¹³² Ex. 240 at 51:17-18.

¹³³ Ex. 240 at 51:19-21.

¹³⁴ Ex. 240 at 51:22-23.

¹³⁵ Ex. 240 at 52:1-4.

¹³⁶ Ex. 240 at 52:5-9.

¹³⁷ Ex. 37 (Block Depo.) at 54:8-22; Ex. 60 (9/19/14 McKinnell Depo.) at 60:7-10; *see also* Ex. 54 (10/10/14 Kindler Depo.) at 34:19-24.

¹³⁸ Ex. 49 (Fox Depo.) at 211:5-212:1; *see also* Ex. 54 (10/10/14 Kindler Depo.) at 35:18-36:10.

No one provided Block or Fox with redacted or unredacted copies of the interview memoranda of the Pfizer employees involved in the attempted deletion and alteration of Bextra-related documents.¹⁴⁰

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.¹⁴¹

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.¹⁴²

No one provided Block or Fox copies of any of the interview memoranda from the Bextra Investigation.¹⁴³

Neither Block nor Fox received access to any of Pfizer's Investigations Counsel's written work product concerning the Bextra Investigation.¹⁴⁴

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.¹⁴⁵

¹³⁹ Ex. 37 (Block Depo.) at 59:14-60:1, 230:21-231:8; Ex. 49 (Fox Depo.) at 49:9-23.

¹⁴⁰ 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.

¹⁴¹ See Ex. 37 (Block Depo.) at 54:8-22, 56:2-11; Ex. 49 (Fox Depo.) at 97:11-18, 211:16-212:1.

¹⁴² Ex. 37 (Block Depo.) at 76:5-23, 144:21-145:4; Ex. 49 (Fox Depo.) at 60:3-22, 61:3-11.

¹⁴³ 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.

¹⁴⁴ Ex. 55 (Lankler Depo.) at 101:1-11; Ex. 37 (Block Depo.) at 54:8-22; Ex. 49 (Fox Depo.) at 97:11-18.

¹⁴⁵ Ex. 37 (Block Depo.) at 69:6-15, 73:21-74:16; Ex. 49 (Fox Depo.) at 74:22-80:1.

Moreover, the investigation was not “still in the early stages.” *See* plaintiffs’ responses to Levin Undisputed Facts Nos. 12 and 16.

54. Disputed. Plaintiffs agree that Levin received the referenced Litigation Report. However, to the extent that Levin attempts to demonstrate his reliance on counsel, he fails to do so. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 54.

F. Levin’s Reliance on the Advice of Internal and External Disclosure Counsel in Connection with the Company’s Disclosures

55. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 40.

56. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 53.

57. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 40.

58. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 40.

59. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 40.

60. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 53.

61. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 53.

62. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 53.

63. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 40.

64. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 53.

65. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 53.

G. Pfizer's Process for Setting Litigation Reserves

66. Disputed. Defendants cannot assert a reliance on auditors defense for the reasons set forth in plaintiffs' Motion for Partial Summary Judgment, incorporated by reference herein. Moreover, 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. 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.¹⁴⁶ 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.¹⁴⁷ 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.¹⁴⁸ The DOJ also set forth the criminal charges based on Food & Drug Act

¹⁴⁶ Ex. 256 at DOJ000237.

¹⁴⁷ Ex. 256 at DOJ000238.

¹⁴⁸ Ex. 256 at DOJ000239.

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. 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.¹⁴⁹ Instead, KPMG was repeatedly told that the DOJ was still outlining the theories of liability.¹⁵⁰ 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.¹⁵¹ 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 results.¹⁵² 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.¹⁵³ This presentation set forth the complete lack of controls over the Review Committee and,

¹⁴⁹ Ex. 258 at DOJ000207-08.

¹⁵⁰ Petrosinelli Decl., Ex. C-6.

¹⁵¹ Ex. 258 at DOJ000205.

¹⁵² Ex. 161.

¹⁵³ Ex. 203.

thus, Pfizer's HCC function.¹⁵⁴ These failures are particularly glaring given: (1) Pfizer considered Review Committee procedures to be one of the top ten areas of greatest risk;¹⁵⁵ (2) KPMG's concern that Pfizer's controls over sales and marketing practices were impaired;¹⁵⁶ and (3) KPMG had recently been informed by Pfizer that the significant deficiency with regard to HCC had been remediated by the end of 2Q07.¹⁵⁷

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.¹⁵⁸ Similarly, KPMG was never informed that Pfizer received a target letter from the DOJ on February 5, 2008.¹⁵⁹ 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.¹⁶⁰

¹⁵⁴ Ex.203.

¹⁵⁵ Ex. 120.

¹⁵⁶ Exs. 149-150.

¹⁵⁷ Ex. 346 at KPMG PFIZ-DS 0003257 (2Q07 Interim Completion Document).

¹⁵⁸ Ex. 310.

¹⁵⁹ Ex. 131; Ex. 39 (Bradley Depo.) at 242:13-16.

¹⁶⁰ Petrosinelli Decl, Es. Y-6.

KPMG was misled by Lankler regarding the Zyvox and Geodon investigations in June and July 2008 during compliance meetings. Lankler told KPMG that off-label marketing of Zyvox was identified in isolated cases and not linked to senior management back at Pfizer headquarters.¹⁶¹ 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.¹⁶² 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.”¹⁶³ Similarly, Lankler told KPMG that the off-label marketing of Geodon had not been linked back to senior management at corporate headquarters.¹⁶⁴

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 the fine in the Bextra Investigation should be calculated as it was in “analogous” cases such as Neurontin, Schering, Serono and Genotropin.¹⁶⁵

¹⁶¹ Ex.159.

¹⁶² Exs. 138-139.

¹⁶³ Ex. 204.

¹⁶⁴ Ex. 204.

¹⁶⁵ Petrosinelli Decl., Ex. B-6.

More glaring, is that KPMG was never informed that on October 9, 2007, Pfizer's disclosure counsel and Pfizer's in-house accountants and attorneys again concluded that a loss from the DOJ Bextra Investigation was "probable."¹⁶⁶ KPMG audit partner Chapman testified he had not been informed by November 3, 2007 that the probable "pillar" of FAS 5 had been met.¹⁶⁷ Similarly, KPMG audit partner Bradley 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.¹⁶⁸

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.¹⁶⁹ 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.¹⁷⁰ After becoming the engagement partner in early 2008, Bradley did not know that Lankler and Wessel were working on methodologies to calculate potential losses.¹⁷¹

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

¹⁶⁶ 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).

¹⁶⁷ Ex. 44 (Chapman Depo.) at 122:19-123:16.

¹⁶⁸ Ex. 38 (Bradley Depo.) at 239:9-20.

¹⁶⁹ Petrosinelli Decl., Ex. N-6.

¹⁷⁰ Petrosinelli Decl., Ex. N-6; Ex. 44 (Chapman Depo.) at 130:12-18.

¹⁷¹ Ex. 38 (Bradley Depo.) at 234:1-236:2.

continued to falsely assure KPMG that the loss was neither probable nor estimable even though Posner's response to the DOJ set forth a methodology to calculate the loss.¹⁷²

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.¹⁷³ 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.¹⁷⁴ KPMG was never informed in or around June 2008 that Covington offered \$750 million to settle the DOJ Bextra Investigation.¹⁷⁵ 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.¹⁷⁶ In fact, KPMG workpapers from June and July 2008 show that Pfizer told KPMG that no offers to settle to date had been made.¹⁷⁷

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

¹⁷² Petrosinelli Decl., Ex. B-6, C-6.

¹⁷³ Ex. 104; Ex. 38 (Bradley Depo.) at 236:3-11.

¹⁷⁴ Petrosinelli Decl., Ex. Y-6; Ex. 38 (Bradley Depo.) at 247:22-248:5.

¹⁷⁵ 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.").

¹⁷⁶ Ex. 158.

¹⁷⁷ Ex. 159.

GAAP and confirmed certain material matters, including a representation that all relevant information relating to certain compliance matters subject to the investigation of alleged fraud or potential illegal acts conducted by the Government Investigations Section and the Office of Corporate Compliance were disclosed by Pfizer to the Audit Committee, to the investigating team and to KPMG.¹⁷⁸ 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.¹⁷⁹ 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.¹⁸⁰

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

¹⁷⁸ *E.g.*, Ex. 134 at KPMG-PFIZ-DS 017125.

¹⁷⁹ Exs. 14, 17-18.

¹⁸⁰ Exs. 19-23.

complied with Generally Accepted Accounting Principles (GAAP), particularly FAS 5.”¹⁸¹ 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.”¹⁸² In addition, she never received warning letters from the FDA,¹⁸³ letters to the OIG from Investigations Counsel regarding reportable events pursuant to Pfizer’s Corporate Integrity Agreements,¹⁸⁴ documents concerning methodologies to evaluate damages for the Government investigation,¹⁸⁵ the February 5, 2008 target letter from the Government,¹⁸⁶ the April 4, 2008 letter in which Investigations Counsel made a \$250 million offer to the Government to settle its investigation,¹⁸⁷ or documents relating to the review committee process or reforms or initiatives concerning it.¹⁸⁸

67. Undisputed.

68. Disputed. Levin, as CFO, certified that Pfizer’s Forms 10-Q and 10-K did “not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report” and that to his knowledge “the financial

¹⁸¹ Statement of Undisputed Facts in Support of Pfizer’s Motion for Summary Judgment, ¶31.

¹⁸² Petrosinelli Decl., Ex. N-6.

¹⁸³ Ex. 43 (Cangialosi Depo.) at 100:20-101:20.

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

¹⁸⁵ Ex. 43 (Cangialosi Depo.) at 294:13-295:6.

¹⁸⁶ Ex. 43 (Cangialosi Depo.) at 253:19-254:5.

¹⁸⁷ Ex. 43 (Cangialosi Depo.) at 260:5-8, 321:20-322:4.

¹⁸⁸ Ex. 43 (Cangialosi Depo.) at 96:15-98:7, 112:23-119:4, 124:24-128:13.

statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.”¹⁸⁹ Further, Levin testified that part of his job as CFO included determining whether or not a reserve related to the Bextra Investigation should be taken.¹⁹⁰ Similarly, Levin admitted: “The determination of whether or not we had a probable and estimable liability against which we would have a reserve was a decision that I would make in consultation with our controller.”¹⁹¹

69. Disputed. Plaintiffs agree that Levin attended monthly executive litigation review meetings. However, to the extent that Levin refers to these meetings to demonstrate his good faith, he fails to do so. Plaintiffs incorporate their response to Levin Undisputed Fact No. 40.

70. Disputed. Plaintiffs agree that Levin attended monthly executive litigation review meetings. However, to the extent that Levin refers to these meetings to demonstrate his good faith, he fails to do so. Plaintiffs incorporate their response to Levin Undisputed Fact No. 40.

71. Disputed. Plaintiffs agree that Levin attended monthly executive litigation review meetings. However, to the extent that Levin refers to these meetings to demonstrate his good faith, he fails to do so. Plaintiffs incorporate their response to Levin Undisputed Fact No. 40.

72. Disputed. Defendants have expressly denied relying on any counsel other than Block or Fox for their defense in this case¹⁹² (consistent with that denial, defendants successfully shielded Investigations Counsel from discovery), so defendants may not invoke or rely on Investigations

¹⁸⁹ See, e.g., Petrosinelli Decl., Ex. B-1.

¹⁹⁰ Ex. 57 (12/10/13 Levin Depo.) at 97:1-6.

¹⁹¹ Ex. 57 (12/10/13 Levin Depo.) at 100:3-8.

¹⁹² Dkt. No. 172 at 25; July 19, 2013 Hearing Transcript at 12:1-2; Dkt. No. 246 at 1, 5.

Counsel, including relying on anyone who relied on Investigations Counsel. Defendants cannot assert an advice of counsel or reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment, and Plaintiffs' Memorandum. 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 case¹⁹³ or Pfizer's defenses,¹⁹⁴ whether a loss or conviction was probable, or whether such loss was reasonably estimable.¹⁹⁵ Moreover, defendants withheld from Block and Fox critical evidence concerning the Bextra Investigation, including call notes,¹⁹⁶ documents that corroborated a *qui tam* relator's claims,¹⁹⁷ Bextra-related documents that Pfizer employees had attempted to delete or alter,¹⁹⁸ sales force survey results¹⁹⁹ and employee interview memoranda.²⁰⁰ Instead, all information and input regarding the Bextra Investigation came from Investigations Counsel.²⁰¹ For example:

¹⁹³ 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.

¹⁹⁴ Ex. 37 (Block Depo.) at 104:6-23; Ex. 49 (Fox Depo.) at 86:13-19, 90:12-20.

¹⁹⁵ 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.

¹⁹⁶ Ex. 37 (Block Depo.) at 76:5-23, 144:21-145:4; Ex. 49 (Fox Depo.) at 60:3-22, 61:3-11.

¹⁹⁷ 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.

¹⁹⁸ Ex. 37 (Block Depo.) at 59:14-60:6, 230:21-231:8; Ex. 49 (Fox Depo.) at 49:9-23.

¹⁹⁹ Ex. 37 (Block Depo.) at 54:8-22, 56:2-11; Ex. 49 (Fox Depo.) at 97:11-18, 211:16-212:1.

²⁰⁰ 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.

²⁰¹ Ex. 37 (Block Depo.) at 36:15-24, 104:15-23, 168:18-169:15; Ex. 49 (Fox Depo.) at 44:24-45:7, 47:2-7, 60:17-22, 61:25-62:7, 87:11-88:14, 222:21-225:6; Ex. 68 (10/16/14 Waxman Depo.) at 20:15-21.

Block and Fox were never among Pfizer's most informed attorneys as to the facts concerning the Bextra Investigation, nor as to assessing such facts legally.²⁰²

Block never personally and professionally assessed nor advised defendants that Pfizer had substantial defenses to the Bextra Investigation.²⁰³

Fox never independently determined or advised defendants that Pfizer had substantial defenses to the Bextra Investigation.²⁰⁴

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.²⁰⁵

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.²⁰⁶

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.²⁰⁷

²⁰² Ex. 55 (Lankler Depo.) at 92:23-97:21.

²⁰³ Ex. 37 (Block Depo.) at 104:6-23.

²⁰⁴ Ex. 49 (Fox Depo.) at 86:13-19, 90:12-20.

²⁰⁵ 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.

²⁰⁶ 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.

²⁰⁷ 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.²⁰⁸

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.²⁰⁹

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

²⁰⁸ 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.

²⁰⁹ 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.²¹⁰

Neither Block nor Fox has ever worked as a criminal law prosecutor or a criminal defense attorney.²¹¹

Neither Block nor Fox was familiar with the elements of a misbranding offense.²¹²

Neither Block nor Fox was familiar with elements or application of *respondeat superior* liability.²¹³

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.²¹⁴

²¹⁰ 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.

²¹¹ Ex. 37 (Block Depo.) at 13:12-14:6, 14:13-15:10; Ex. 49 (Fox Depo.) at 35:21-36:12.

²¹² Ex. 37 (Block Depo.) at 16:6-17:8; Ex. 49 (Fox Depo.) at 37:17.

²¹³ Ex. 37 (Block Depo.) at 232:20-233:12; Ex. 49 (Fox Depo.) at 36:13-37:9.

²¹⁴ 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.²¹⁵

Fox incorrectly understood the terms grand jury “target” and grand jury “subject” to be interchangeable.²¹⁶

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.²¹⁷

Pfizer and its Investigations Counsel always represented to Block that Pfizer’s sales representatives had not promoted Bextra off-label.²¹⁸ In fact, from February 2002 through April 2005: Pfizer promoted Bextra for uses that were not within Bextra’s FDA-approved label, including (a) for general acute pain, (b) for pre-operative and post-operative surgical pain and (c) as opioid-sparing in the context of surgery;²¹⁹ 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;²²⁰ Pfizer introduced Bextra into interstate commerce for the treatment of acute pain and surgical pain, other unapproved uses and at unapproved dosages, even though it lacked adequate directions for such uses and dosages;²²¹ Pfizer promoted Bextra with an intent to defraud or mislead;²²² certain

²¹⁵ Ex. 49 (Fox Depo.) at 130:7-15, 218:21-219:5.

²¹⁶ Ex. 49 (Fox Depo.) at 106:3-23.

²¹⁷ 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.

²¹⁸ Ex. 37 (Block Depo.) at 50:5-20, 232:3-12.

²¹⁹ Ex. 240 at 51:10-17.

²²⁰ Ex. 240 at 51:17-18.

²²¹ Ex. 240 at 51:19-21.

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,²²³ 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.²²⁴

No one provided Block a copy of Kopchinski's Complaint or any of the internal Pfizer documents that were exhibits to it.²²⁵ The same appears to be true as to Fox, as the record does not indicate that he received those documents either.²²⁶

No one ever provided Block or Fox the internal documents that Pfizer's sales representatives had attempted to delete or alter.²²⁷

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.²²⁸

²²² Ex. 240 at 51:22-23.

²²³ Ex. 240 at 52:1-4.

²²⁴ Ex. 240 at 52:5-9.

²²⁵ Ex. 37 (Block Depo.) at 54:8-22; Ex. 60 (9/19/14 McKinnell Depo.) at 60:7-10; *see also* Ex. 54 (10/10/14 Kindler Depo.) at 34:19-24.

²²⁶ Ex. 49 (Fox Depo.) at 211:5-212:1; *see also* Ex. 54 (10/10/14 Kindler Depo.) at 35:18-36:10.

²²⁷ Ex. 37 (Block Depo.) at 59:14-60:1, 230:21-231:8; Ex. 49 (Fox Depo.) at 49:9-23.

²²⁸ Ex. 37 (Block Depo.) at 54:8-22, 56:2-11, 105:3-13, 230:25-231:6; Ex. 49 (Fox Depo.) at 13:2-8, 49:9-50:16, 66:3-6.

No one provided Block or Fox copies of the results of Bextra-related surveys of Pfizer's sales force, nor any of the revelations from the surveys.²²⁹

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.²³⁰

No one provided Block or Fox copies of any of the interview memoranda from the Bextra Investigation.²³¹

Neither Block nor Fox received access to any of Pfizer's Investigations Counsel's written work product concerning the Bextra Investigation.²³²

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.²³³

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."²³⁴ For example, she was not included in the October 9, 2007 meeting during which Pfizer's Investigations

²²⁹ See Ex. 37 (Block Depo.) at 54:8-22, 56:2-11; Ex. 49 (Fox Depo.) at 97:11-18, 211:16-212:1.

²³⁰ Ex. 37 (Block Depo.) at 76:5-23, 144:21-145:4; Ex. 49 (Fox Depo.) at 60:3-22, 61:3-11.

²³¹ 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.

²³² Ex. 55 (Lankler Depo.) at 101:1-11; Ex. 37 (Block Depo.) at 54:8-22; Ex. 49 (Fox Depo.) at 97:11-18.

²³³ Ex. 37 (Block Depo.) at 69:6-15, 73:21-74:16; Ex. 49 (Fox Depo.) at 74:22-80:1.

²³⁴ Statement of Undisputed Facts in Support of Pfizer's Motion for Summary Judgment, ¶31.

Counsel, disclosures counsel and Legal Finance confirmed “that the ‘probable’ criteria of FAS5 ha[d] been met.”²³⁵ In addition, she never received warning letters from the FDA,²³⁶ letters to the OIG from Investigations Counsel regarding reportable events pursuant to Pfizer’s Corporate Integrity Agreements,²³⁷ documents concerning methodologies to evaluate damages for the Government investigation,²³⁸ the February 5, 2008 target letter from the Government,²³⁹ the April 4, 2008 letter in which Investigations Counsel made a \$250 million offer to the Government to settle its investigation,²⁴⁰ or documents relating to the review committee process or reforms or initiatives concerning it.²⁴¹

73. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 53.

74. Disputed. Defendants have expressly denied relying on any counsel other than Block or Fox for their defense in this case²⁴² (consistent with that denial, defendants successfully shielded Investigations Counsel from discovery), so defendants may not invoke or rely on Investigations Counsel, including relying on anyone who relied on Investigations Counsel. Defendants cannot

²³⁵ Petrosinelli Decl., Ex. N-6.

²³⁶ Ex. 43 (Cangialosi Depo.) at 100:20-101:20.

²³⁷ Ex. 43 (Cangialosi Depo.) at 181:6-184:20.

²³⁸ Ex. 43 (Cangialosi Depo.) at 294:13-295:6.

²³⁹ Ex. 43 (Cangialosi Depo.) at 253:19-254:5.

²⁴⁰ Ex. 43 (Cangialosi Depo.) at 260:5-8, 321:20-322:4.

²⁴¹ Ex. 43 (Cangialosi Depo.) at 96:15-98:7, 112:23-119:4, 124:24-128:13.

²⁴² Dkt. No. 172 at 25; July 19, 2013 Hearing Transcript at 12:1-2; Dkt. No. 246 at 1, 5.

assert an advice of counsel or reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment, and Plaintiffs' Memorandum.

75. Disputed. Plaintiffs agree that Levin accurately reports his testimony. However, defendants have expressly denied relying on any counsel other than Block or Fox for their defense in this case²⁴³ (consistent with that denial, defendants successfully shielded Investigations Counsel from discovery), so defendants may not invoke or rely on Investigations Counsel, including relying on anyone who relied on Investigations Counsel. Defendants cannot assert an advice of counsel or reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment, and Plaintiffs' Memorandum.

76. Disputed. Plaintiffs incorporate by reference their Response to Levin Undisputed Fact No. 72.

(a) The Company's Outside Auditor

77. Undisputed.

78. 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. 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

²⁴³ Dkt. No. 172 at 25; July 19, 2013 Hearing Transcript at 12:1-2; Dkt. No. 246 at 1, 5.

surgery.²⁴⁴ 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.²⁴⁵ 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.²⁴⁶ 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. 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.²⁴⁷ Instead, KPMG was repeatedly told that the DOJ was still outlining the theories of liability.²⁴⁸ 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.²⁴⁹ 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

²⁴⁴ Ex. 256 at DOJ000237.

²⁴⁵ Ex. 256 at DOJ000238.

²⁴⁶ Ex. 256 at DOJ000239.

²⁴⁷ Ex. 258 at DOJ000207-08.

²⁴⁸ Petrosinelli Decl., Ex. C-6.

²⁴⁹ Ex. 258 at DOJ000205.

results.²⁵⁰ 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.²⁵¹ This presentation set forth the complete lack of controls over the Review Committee and, thus, Pfizer's HCC function.²⁵² These failures are particularly glaring given: (1) Pfizer considered Review Committee procedures to be one of the top ten areas of greatest risk;²⁵³ (2) KPMG's concern that Pfizer's controls over sales and marketing practices were impaired;²⁵⁴ and (3) KPMG had recently been informed by Pfizer that the significant deficiency with regard to HCC had been remediated by the end of 2Q07.²⁵⁵

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.²⁵⁶ Similarly, KPMG was never informed that Pfizer received a target letter from the DOJ on February

²⁵⁰ Ex. 161.

²⁵¹ Ex. 203.

²⁵² Ex. 203.

²⁵³ Ex. 120.

²⁵⁴ Exs. 149-150.

²⁵⁵ Ex. 346 at KPMG PFIZ-DS 0003257 (2Q07 Interim Completion Document).

²⁵⁶ Ex. 310.

5, 2008.²⁵⁷ 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.²⁵⁸

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.²⁵⁹ 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.²⁶⁰ 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.”²⁶¹ Similarly, Lankler told KPMG that the off-label marketing of Geodon had not been linked back to senior management at corporate headquarters.²⁶²

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

²⁵⁷ Ex. 131; Ex. 38 (Bradley Depo.) at 242:13-16.

²⁵⁸ Petrosinelli Decl., Ex. Y-6.

²⁵⁹ Ex. 159.

²⁶⁰ Exs. 138-139.

²⁶¹ Ex. 204.

²⁶² 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.²⁶³

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.”²⁶⁴ KPMG audit partner Chapman testified he had not been informed by November 3, 2007 that the probable “pillar” of FAS 5 had been met.²⁶⁵ Similarly, KPMG audit partner Bradley 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.²⁶⁶

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.²⁶⁷ Additionally, Chapman testified he did not know Pfizer was working with methodologies to estimate the loss and

²⁶³ Petrosinelli Decl., Ex. B-6.

²⁶⁴ 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).

²⁶⁵ Ex. 44 (Chapman Depo.) at 122:19-123:16.

²⁶⁶ Ex. 38 (Bradley Depo.) at 239:9-20.

²⁶⁷ Petrosinelli Decl., Ex. N-6

that the Company had discussed an estimate range.²⁶⁸ After becoming the engagement partner in early 2008, Bradley did not know that Lankler and Wessel were working on methodologies to calculate potential losses.²⁶⁹

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.²⁷⁰

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.²⁷¹ 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.²⁷² KPMG was never informed in or around June 2008 that Covington offered \$750 million to settle the DOJ Bextra Investigation.²⁷³ 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

²⁶⁸ Petrosinelli Decl., Ex. N-6; Ex. 44 (Chapman Depo.) at 130:12-18.

²⁶⁹ Ex. 38 (Bradley Depo.) at 234:1-236:2.

²⁷⁰ Petrosinelli Decl., Exs. B-6, C-6.

²⁷¹ Ex. 104; Ex. 38 (Bradley Depo.) at 236:3-11.

²⁷² Petrosinelli Decl., Ex. Y-6; Ex. 38 (Bradley Depo.) at 247:22-248:5.

²⁷³ Ex. 158; Ex. 39 (8/9/13Bradley 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.").

rejected Pfizer's recent \$750 million offer to settle.²⁷⁴ In fact, KPMG workpapers from June and July 2008 show that Pfizer told KPMG that no offers to settle to date had been made.²⁷⁵

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.²⁷⁶ 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.

²⁷⁴ Ex. 158.

²⁷⁵ Ex. 159.

²⁷⁶ *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.²⁷⁷ 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.²⁷⁸

79. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 78.

80. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 78. Moreover, Levin misstates KPMG's responsibility. KPMG's responsibility is to plan and perform the audit to obtain reasonable, not absolute, assurance about whether Pfizer's financial statements were free of material misstatements. The financial statements are management's responsibility.²⁷⁹

81. Disputed. Petrosinelli Decl., Ex. H-4 does not contain the quotation set forth in Levin's purported fact.

82. Disputed. Plaintiffs object to Petrosinelli Decl., Exs. J-4 and U-4 for the reasons set forth in Plaintiffs' Objections to Exhibits Submitted in Support of Defendants' Motions for Summary Judgment, which is incorporated by reference herein. In addition, plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 78.

83. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 40.

²⁷⁷ Exs. 14, 17-18.

²⁷⁸ Exs. 19-23.

²⁷⁹ AU §110.02-.03.

H. Pfizer's Internal Controls

84. Undisputed.

85. Disputed. Plaintiffs agree that Levin provided this testimony, after testifying in the same answer that he was “ultimately” responsible for “the internal controls over financial reporting.”²⁸⁰ Regarding KPMG, Chapman testified that KPMG did not perform audits of healthcare compliance controls.²⁸¹ 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 results.²⁸² 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.²⁸³ Additionally, Pfizer and KPMG employed a reliance model where KPMG relied on Pfizer’s Internal Audit department to the maximum extent possible.²⁸⁴

86. Disputed. Although Pfizer characterized the monitoring controls over healthcare compliance as a “significant deficiency,” the control deficiencies at Pfizer actually constituted a material weakness.²⁸⁵

²⁸⁰ Ex. 57 (12/10/13 Levin Depo.) at 42:24-43:4.

²⁸¹ Ex. 44 (Chapman Depo.) at 117:8-24.

²⁸² Ex. 161.

²⁸³ Ex. 203.

²⁸⁴ Ex. 44 (Chapman Depo.) at 170:8-171:1; Ex. 327.

²⁸⁵ Ex. 7 (Regan Supp. Report) at 67-94.

87. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Facts No. 85.

88. Disputed. KPMG did not audit Pfizer's Healthcare Compliance controls.²⁸⁶ Moreover, Levin misstates KPMG's responsibility. KPMG's responsibility is to plan and perform the audit to obtain reasonable, not absolute, assurance about whether Pfizer's financial statements were free of material misstatements. The financial statements are management's responsibility.²⁸⁷ Levin testified that he is ultimately responsible for internal controls.²⁸⁸ Chuck Mooney, Internal Audit, testified that Levin, along with the CEO and Controller were ultimately responsible for determining whether the Company had a significant deficiency.²⁸⁹ Further, the control deficiencies at Pfizer actually constituted a material weakness.²⁹⁰

89. Disputed. Plaintiffs incorporate by reference their response to Levin Undisputed Fact No. 88.

I. The First Amended Complaint

90. Undisputed.

91. Undisputed.

92. Undisputed.

93. Disputed. Levin served as CFO from March 2005 until September 2007 and remained employed by the Company until November 2007. Levin was CFO for approximately 600

²⁸⁶ See Ex. 44 (Chapman Depo.) at 114:20-115:4, 117:20-24.

²⁸⁷ AU §110.02-.03.

²⁸⁸ Ex. 57 (12/10/13 Levin Depo.) at 42:24-43:1.

²⁸⁹ Ex. 61 (Mooney Depo.) at 21:22-22:6.

²⁹⁰ Ex. 7 (Regan Supp. Report) at 67-94.

days during the Class Period on which Pfizer's stock was trading at prices artificially inflated by defendants' false and misleading statements.

94. Undisputed.

95. Undisputed.

96. Disputed. Levin is responsible for the statements attributed to him in the chart of Defendants' False and Misleading Statements, attached to Plaintiffs' Memorandum of Law in Opposition to Defendants' Motions for Summary Judgment.

97. Disputed. Levin has made a representation with respect to his "understanding" of his ownership of Pfizer common stock. He has not affirmed under oath that the numbers set forth in this purported fact are correct. Plaintiffs object to his statement for its evident lack of foundation and lack of personal knowledge.²⁹¹ Finally, plaintiffs did not receive discovery of Levin's personal financial statements.

98. Disputed. Levin has made a representation with respect to his "understanding" of his ownership of Pfizer common stock. He has not affirmed under oath that the numbers set forth in this purported fact are correct. Plaintiffs object to his statement for its evident lack of foundation and lack of personal knowledge.²⁹² Finally, plaintiffs did not receive discovery of Levin's personal financial statements.

²⁹¹ Fed. R. Evid. 601, 602.

²⁹² Fed. R. Evid. 601, 602.

99. Disputed. Levin has made a representation with respect to his “understanding” of his ownership of Pfizer common stock. He has not affirmed under oath that the numbers set forth in this purported fact are correct. Plaintiffs object to his statement for its evident lack of foundation and lack of personal knowledge.²⁹³ Finally, plaintiffs did not receive discovery of Levin’s personal financial statements.

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²⁹³ Fed. R. Evid. 601, 602.

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CERTIFICATE OF SERVICE

I hereby certify that on November 26, 2014, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the attached Electronic Mail Notice List, and I hereby certify that I caused to be mailed the foregoing document or paper via the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on November 26, 2014.

s/ HENRY ROSEN

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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: [312](#)

Docket Text:

RESPONSE re: [259] 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:

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