UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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

Pursuant to Rule 56.1 of the Local Rules of this Court, plaintiffs Stichting Philips Pensionfonds and Mary K. Jones, on behalf of Pfizer Inc. ("Pfizer" or the "Company") investors, hereby set forth their responses to defendant Henry A. McKinnell's ("McKinnell") Local Rule 56.1 Statement of Undisputed Facts in Support of Henry A. McKinnell's Motion for Summary Judgment.[1] These responses demonstrate that a reasonable jury could find defendant McKinnell liable for violations of the securities laws:

A.1. Undisputed.

A.2. Undisputed.

A.3. Undisputed.

A.4. Undisputed.

A.5. Disputed. The testimony cited does not support the statement that McKinnell continued to serve on Pfizer's Board of Directors "to ensure an orderly transition of responsibilities." McKinnell remained on Pfizer's Board until the end of February 2007 and was Chairman until the end of 2006.[2] He was a member of Pfizer's Board of Directors, and the Board "is the ultimate decision-making body of the Company except with respect to those matters reserved to the shareholders." Further, "the Board acts as an advisor and counselor to senior management and ultimately monitors its

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[1] Defendant McKinnell largely relies on his own inadmissible testimony as evidence for his undisputed facts. *See* Plaintiffs' Objections to Exhibits Submitted in Support of Defendants' Motion for Summary Judgment submitted herewith.

[2] Ex. 11 (Form 8-K filed 8/3/06 with 7/28/06 press release entitled "Kindler Succeeds Hank McKinnell, Who Will Remain Chairman of the Board . . . ."); Ex. 331 at KPMG-PFIZ-DS 037761; Ex. 338 at KPMG-PFIZ-DS 057263. 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. Emphasis is added and citations are omitted throughout unless otherwise indicated.

performance."[3] As a Board member he was also responsible for compliance and signed the 2006 Form 10-K.[4]

B.6 Disputed. McKinnell's self-serving testimony does not support the purported fact that "Pfizer implemented and maintained various controls to ensure that the Company's sales force complied with legal standards and Pfizer's policies." Pfizer's controls did not ensure compliance as reflected by not only the widespread off-label marketing at Pfizer but the significant control deficiencies over the Company's sales and marketing practices.[5] Pfizer detected numerous violations of Company compliance policies, including those it reported to the U.S. Department of Health & Human Services Office of Inspector General ("OIG") as reportable events (*i.e.*, a probable violation of criminal, civil or administrative laws – for which penalties or exclusions may be authorized).[6] These events were reported to the Audit Committee and the Board of Directors at meetings which McKinnell attended.[7] Additionally, at these meetings, defendant McKinnell was

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[3] Ex. 14 at 6.

[4] Declaration of Scott D. Musoff in Support of Henry A. McKinnell's Motion for Summary Judgment ("Musoff Decl.") (Dkt. No. 273), Ex. A-M (McKinnell Depo.) at 29:14-30:1; Plaintiffs' Statement of Material Facts Requiring Denial of Defendants' Motion for Summary Judgment, False and Misleading Statements Chart ("Plaintiffs' FMS") at Nos. 2, 3, 6-7.

[5] *See, e.g.*, Ex. 1 (Expert Report of Jerry Avorn) at 1-3, 9-53; Ex. 7 (Supplemental Expert Report of D. Paul Regan) at 67-93.

[6] Ex. 73 (2004 Corporate Integrity Agreement); *see also, e.g.*, Ex. 214 (9/25/06 letter); Ex. 110 (10/2/06 letter); Ex. 111 (10/3/06 letter); Ex. 112 (11/30/06 letter).

[7] Ex. 160 at PFE-JONES 00005331 (at the April 27, 2005 Audit Committee meeting "Mr. Lankler then discussed several other allegations under review and noted that these matters would also be brought to the government's attention"); Ex. 329 at KPMG-PFIZ-DS 017308 (During the Audit Committee report at the April 28, 2005 Board of Directors meeting it was noted that "The Committee was also advised of certain compliance issues that are 'reportable events' under the U.S. Corporate Integrity Agreement.").

made aware of a number of *qui tam* cases that alleged off-label promotion.[8] He also received unsatisfactory internal audit reports which highlighted numerous healthcare compliance violations.[9] Moreover, in 3Q06 Pfizer's Corporate Internal Audit ("IA") determined there was an overall ineffective regulatory compliance function in the United States.[10] For example, an executive summary of the unsatisfactory call notes and e-mails audit was e-mailed to defendant McKinnell on December 19, 2005, noting that this area was at issue in "federal government investigations."[11]

In 2005, KPMG LLP ("KPMG") reported that Pfizer had a "significant deficiency in the design and execution of the Company's monitoring controls (*i.e.*, those controls in place at the business unit level to monitor compliance with corporate policies and procedures) over its sales and marketing regulatory compliance activities."[12] Pfizer understood that it had "a perception problem fueled by various events and findings" including whistleblower lawsuits (regarding non-compliance with healthcare law), the Corporate Integrity Agreement with the government, document-retention violations and the unsatisfactory finding highlighted in the time and expense audit.[13] McKinnell

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[8] Ex. 243 at PFE DERIV 00003275 (4/27/05 Audit Committee pre-reading materials); Ex. 160 at PFE-JONES 00005332 (4/27/05 Audit Committee meeting minutes).

[9] Ex. 101 at PFE DERIV 00075592 (US Field Force Travel and Entertainment Audit received an unsatisfactory rating citing significant issues with compliance with PGP T&E policy); Ex. 103 at KPMG-PFIZ-DS 007294 (PGP U.S. Sales Force – Call Notes and E-mails: Audit received an unsatisfactory rating and recommended that "management develop strong capabilities to monitor, enforce, and report on compliance to policies and regulations that govern promotional activities"); Ex. 107 at PFE DERIV 00075210 (PGP Marketing Promotional Speaker Programs: Audit received an unsatisfactory rating citing issues in numerous areas including a lack of policies and procedures).

[10] Ex. 161 at PFE-JONES 00005991.

[11] Ex. 193 at PFE-JONES 00005356.

[12] Ex. 223 at PFE-JONES 00031267.

[13] Ex. 102 at Jenner-A 10000251929.

expressed anger and embarrassment over these findings.[14] Despite the 2005 findings, the same or similar issues were found in numerous healthcare compliance areas and persisted for several years. During the third quarter of 2006, IA reported another significant deficiency, which concluded, "the division does not have an effective healthcare law regulatory compliance function."[15] As a result, these "violations of laws and regulations resulting from this ineffective healthcare compliance ("HCC") function could be seen as having a material effect on the reliability of financial reporting and as a significant deficiency for Sarbanes Oxley Act of 2002 ("SOX") purposes."[16] The significant deficiency remained in place well after McKinnell's departure from Pfizer.[17]

B.7. Disputed. The controls that McKinnell references in his testimony did not ensure compliance with marketing laws and, in many cases, were deficient. Further, as to Bextra he was unaware of any specific activities that were undertaken at Pfizer to proactively determine whether Pfizer was promoting Bextra lawfully.[18] The 2004 Corporate Integrity Agreement entered into while McKinnell was Chief Executive Officer ("CEO"), obliged Pfizer to maintain compliance programs to ensure compliance with, among other things, "Federal health care program requirements."[19] Pfizer did not. For example, the review committee process was an ineffective control;[20] it was not

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[14] Ex. 102 at Jenner-A 10000251931.

[15] Ex. 161 at PFE-JONES 00005991.

[16] Ex. 161 at PFE-JONES 00005991.

[17] Ex. 163 at KPMG-PFIZ-DS 023093.

[18] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 90:7-15.

[19] Ex. 73.

[20] Ex. 203 at 2.

even monitored until 2007 when WPO did a "deep dive review" of the process.[21] The review findings showed a "[l]ack of clarity & controls to assure consistency throughout the process," and noted several control gaps, including "[a]ccountability to ensure RC comments [were] incorporated," and that violations were neither documented nor tracked.[22] The results of the 2Q07 review committee self-monitoring surveys showed that there was only 61% compliance with the review committee comments on final produced field aids and the review committee meetings scored well below average for effectiveness.[23]

There was also a lack of training initiatives in numerous areas, including the review committees where control gaps included insufficient and outdated guidelines and a decentralized review committee member training process that was not standardized to "ensure a consistent understanding of key FDA requirements."[24] The Independent Review Organization ("IRO") Promotional and Product Services Engagement report conducted by PricewaterhouseCoopers under the Corporate Integrity Agreement also highlighted the lack of training, stating there were "no policies and limited formal training in place providing guidance on how sales representatives should interact with the RMRS group."[25] The IRO recommended that "Pfizer develop formal policies and training around the level and nature of allowable interactions between sales representatives and both Medical Information and RMRS personnel."[26] Despite this recommendation, in a subsequent report,

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[21] Ex. 203.

[22] Ex. 203 at 2.

[23] Ex. 183 at PFE DERIV 01076244.

[24] Ex. 203 at 3.

[25] Ex. 561 at PFE DERIV 01154208.

[26] Ex. 561 at PFE DERIV 01154209.

the IRO addressed "Prior Year Recommendations Not Implemented by Pfizer" and again reiterated that "Pfizer review training provided to its sales organization regarding requests for off-label information and enhance or provide additional training as necessary."[27]

Another area found lacking was regarding reviews or updates to Pfizer's policies and procedures. For example, in October 2006, IA noted the existence of guidelines such as the Orange and White Guides, but found that "often no one monitors [them] to ensure they are being followed," and "SOPs [standard operating procedures] may not exist to support the guidelines."[28]

Similar issues regarding the effectiveness of IA's compliance activities were brought up in 2005 when KPMG called into question IA's assertion that its internal auditing was a detective control.[29] KPMG told Pfizer that its detective controls were not 100% operational and that a "lack of a robust auditing protocol over sales and marketing is [a] weakness."[30]

B.8. Disputed. Pfizer neither remediated nor disclosed the extent of Pfizer's violations of policy to the Government.[31] In February 2004, McKinnell and the Pfizer Board of Directors were notified that the DOJ was investigating the marketing and sales of Bextra.[32] Despite knowledge of the investigation, there was rampant evidence of Bextra off-label marketing that continued until it was

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[27] Ex. 562 at PFE DERIV 00065003, 5005.

[28] Ex. 268 at PFE DERIV 01064282.

[29] Ex. 148 at KPMG-PFIZ-DS 033460-61.

[30] Ex. 148 at KPMG-PFIZ-DS 033460. Plaintiffs also note that KPMG did not issue an audit opinion regarding the adequacy of Pfizer's healthcare compliance internal controls in 2006. Ex. 44 (Chapman Depo.) at 117:8-24.

[31] "Government" refers to the U.S. Department of Justice ("DOJ") and/or the OIG.

[32] Ex. 195 at PFE-JONES 00005227.

pulled from the market in April 2005.[33] The offending conduct continued through the criminal investigation of Neurontin, two Corporate Integrity Agreements, self-disclosures, internal issues, and knowledge of *qui tam* complaints.[34] When asked what was done to proactively determine whether the sales force was promoting Bextra correctly, McKinnell said he was not aware of the specific activities being done, nor was he aware whether his request to expand the off-label investigation was ever undertaken.[35]

One example of McKinnell's knowledge of the sales forces' widespread off-label detailing was through the Bextra call notes program which Pfizer sales representatives used to memorialize their detailing session with physicians. As a part of its investigation into Bextra, the DOJ reviewed 3.7 million call notes which were rife with examples of off-label detailing to doctors.[36] Even though the 2004 Corporate Integrity Agreement required Pfizer to actively monitor how its sales force promoted drugs and the call notes function was clearly an effective monitoring tool, the call notes were not monitored and the program was actually discontinued when IA decided to audit the area "[b]ecause the subjects of the planned audit are at issue in pending state and federal government

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[33] *See, e.g.*, Exs. 251, 256, 258 at DOJ000194, 196-198. (The DOJ cited numerous instances of off-label promotion in their August 17, 2006 Review of Key Events & Factors presentation including the that the promotion of Bextra for acute pain and peri-operative use was ongoing in November 2003; in September of 2004 there was a promotional talk promoting both Bextra and Neurontin off-label, recall reports showing that Pfizer sales representatives main message to doctors was to use Bextra for acute pain, that the N.E. protocols were still available on Pfizer's website and incorrect promotion of 20 mg samples to orthopedic surgeons; in early 2005 there was a lunch and learn presentation on off-label uses of Bextra and that Pfizer continued to promote Bextra contrary to known safety risks.).

[34] Ex. 258 at DOJ000208.

[35] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 90:7-15, 252:24-253:9.

[36] Ex. 104 at PFE-JONES 00007005; Ex. 313 at DOJ000190 (DOJ concluded that "References to off-label indications during calls occurred in at least the same order of magnitude as on-label indications.").

investigations."[37] Despite the cancellation of the text portion of the program, the audit was completed and received an unsatisfactory rating.[38] In its report, IA recommended "management develop strong capabilities to monitor, enforce, and report on compliance to policies and regulations that govern promotional activities."[39]

IA also highlighted the ongoing challenges Pfizer was facing in the area of healthcare compliance,[40] including observing that the "[p]ace of [r]emediation is slow" with remediation in numerous areas taking over a year, and that findings from previous audits were not being applied to similar programs.[41] The presentation noted that while the free text portion of the call notes program was discontinued, there was "limited action[]" taken to address the behaviors of the sales representatives, further showing that remediation was not a priority.[42]

In February 2004, McKinnell was also informed of an internal audit finding of inadequate controls with respect to speakers programs.[43] He testified that he did not know when the control weaknesses were remediated.[44] The controls were not remediated.[45] McKinnell was also explicitly

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37 Ex. 103 at KPMG-PFIZ-DS 007294.

38 Ex. 103 at KPMG-PFIZ-DS 007294.

39 Ex. 103 at KPMG-PFIZ-DS 007294.

40 Ex. 268 at PFE DERIV 01064282.

41 Ex. 268 at PFE DERIV 01064282.

42 Ex. 268 at PFE DERIV 01064282.

43 Ex. 191.

44 Ex. 59 (11/11/13 McKinnell Depo.) at 146:7-17.

45 Ex. 161 at PFE-JONES 00005994.

informed of unsubstantiated superiority claims with respect to Zyvox that were not remediated during his tenure.[46]

By April 2005, McKinnell was also aware of other *qui tam* complaints.[47] This included allegations related to Bextra in regions other than the North East.[48]

The DOJ presentation in August 2006 specifically notes that despite Pfizer's awareness of the off-label promotional tactics in September 2004 that offending materials remained on the North East's website. They also detail offending conduct across the nation from Pfizer's own evidence,[49] that is corroborated by other evidence.[50] It further explains the vast use of 20 mg samples of Bextra when the drug (at that dose) was only approved to treat primary dysmenorrhea ("PD") (menstrual cramps).[51]

C.9. Disputed. The testimony cited does not support the facts represented.[52] Plaintiffs do not dispute that McKinnell received a warning letter from the U.S. Food and Drug Administration

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[46] Ex. 181; Ex. 237 at 2.

[47] Ex. 243 at PFE DERIV 00003275; Ex. 60 (9/19/14 McKinnell Depo.) at 18:11-22, 24:15-23, 28:6-15.

[48] Ex. 60 (9/9/14 McKinnell Depo.) at 20:9-14, 25:14-25.

[49] Ex. 258 at DOJ000196.

[50] Off-label promotion of Bextra was rampant throughout the country. *See, e.g.*, Ex. 41 (Burch Depo.) at 294:19-295:18; Ex. 300 at BEX 000132900-05 (PRO West POA I 2004 Playbook, covering Texas and the Southwest regarding post-operative orders followed by three examples of post-surgery protocols featuring Bextra); Ex. 281 (11/7/02 e-mail regarding a story for a Pfizer newsletter of how a new protocol was obtained at UC San Francisco for use of Bextra after hand surgery).

[51] Ex. 539.

[52] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 108:21-110:1.

("FDA") on or about July 20, 2005.[53] The warning letter informed McKinnell that, *inter alia*, "Pfizer's advertisement misbranded Zyvox by making misleading and unsubstantiated implied superiority claims" that "Zyvox is superior to vancomycin."[54]

C.10. Disputed. There was nothing "routine" about the Zyvox letter from the FDA. McKinnell testified that it was unusual for the letter to be addressed to the CEO and that he had only received two such letters, one being Zyvox, "probably to emphasize the importance [of] how strongly [the FDA] felt about this."[55] Further, the VP of Regulatory Robert Clark did not receive the warning letter from McKinnell but learned of it from the FDA website.[56]

C.11. Disputed. Pfizer did not ensure that Zyvox sales force materials that could be misinterpreted in a similar manner were discontinued or revised. Nor is there any admissible evidence cited that the relevant promotional materials were revised to the FDA's satisfaction; the cited document itself ends with "[w]e trust [that] the above information has adequately responded to the comments noted."[57] McKinnell's representations are also contrary to the facts Pfizer agreed were "true and accurate" in the settlement agreement with the Government, including that "Pfizer did not provide adequate guidance to its sales force" regarding what statements were permissible.[58]

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[53] Ex. 181; Ex. 237 at 1-2.

[54] Ex. 181; Ex. 237 at 1-2.

[55] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 108:21-110:1.

[56] Ex. 123.

[57] Musoff Decl., Ex. C-M at PFE DERIV 00040341.

[58] Ex. 237 at 1-2.

The warning letter demanded that the Company immediately cease any and all claims that Zyvox was superior to vancomycin.[59] The FDA informed McKinnell that the Company could not make the superiority claim because Pfizer had not demonstrated substantial evidence or provided clinical experience upon which to base the superiority claim.[60]

In September 2005, Pfizer informed its sales leadership that the July 2005 Warning Letter would not change the Company's detailing message that Zyvox was superior to vancomycin for the treatment of MRSA pneumonia and complicated skin structure infections.[61] On September 30, 2005, Pfizer instructed its sales force that when detailing to "[a]lways go back to ZYVOX proven efficacy: our data have shown that ZYVOX is better than vancomycin."[62]

Pfizer's sales force continued to promote Zyvox as superior to vancomycin between July 2005 and February 2008.[63] Between July 2005 and February 2008, the Company's sales force made unsubstantiated promotional claims that Zyvox was superior to vancomycin on a fairly broad basis.[64] Pfizer approved the sales force's use of clinical reprints during detailing sessions that contained unsubstantiated claims that Zyvox was superior to, or better than, vancomycin.[65] Pfizer's sales force

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[59] Ex. 181.

[60] Ex. 181.

[61] Ex. 177 at PZ0153370, PZ0153381.

[62] Ex. 140 at Greensmith003892.

[63] Ex. 218, Ex. A, Attachment A at 1-2, Settlement Agreement, *United States v. Pharmacia & Upjohn Co., Inc.*, No. 1:09-cv-10258-DPW (D. Mass. Sept. 2, 2009), at 80-81 (Attachment A).

[64] Ex. 204 at PFE DERIV A 00003642; Ex. 122 at PFE DERIV 00040542; Ex. 47 (C. Dowd Depo.) at 31:25-32:8; Ex. 50 (Greensmith Depo.) at 96:2-21, 383:8-20; Ex. 177 at PZ0153348, 361-63, 369-70 (POA-2 Zyvox sales kick-off presentation).

[65] Ex. 121 at PFE DERIV 00067564.

"relied heavily" on these clinical reprints during detailing sessions with physicians.[66] Not until November 2008 did Pfizer remove from circulation the offensive promotional reprints.[67]

C.12. Disputed. The testimony cited does not support the facts asserted. McKinnell testified that he "referred [the Zyvox FDA letter] to our medical and regulatory people" and that he thought the situation was "resolved" because he "didn't hear any more from the FDA."[68] McKinnell's representations are contrary to the facts that Pfizer agreed were "true and accurate" in the settlement agreement with the Government, including that "Pfizer did not provide adequate guidance to its sales force" regarding what statements were permissible.[69]

The warning letter demanded that the Company immediately cease any and all claims that Zyvox was superior to vancomycin.[70] The FDA informed McKinnell that the Company could not make the superiority claim because Pfizer had not demonstrated substantial evidence or provided clinical experience upon which to base the claim of superiority.[71]

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[66] Ex. 121 at PFE DERIV 00067564.

[67] Ex. 178 at PFE DERIV 01044619-20.

[68] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 109:22-110:1, 110:2-5.

[69] Ex. 218, Ex. A, Attachment A at 1-2, Settlement Agreement, *United States v. Pharmacia & Upjohn Co., Inc.*, No. 1:09-cv-10258-DPW (D. Mass. Sept. 2, 2009), at 80-81 (Attachment A).

[70] Exs. 123, 181.

[71] Exs. 123, 181.

[72] Ex. 177 at PZ0153370, PZ0153381.

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Pfizer's sales force continued to promote Zyvox as superior to or better than vancomycin between July 2005 and February 2008.[74] Between July 2005 and February 2008, the Company's sales force made unsubstantiated promotional claims that Zyvox was superior to vancomycin on a fairly broad basis.[75] Pfizer approved the sales force's use of clinical reprints during detailing sessions that contained unsubstantiated claims that Zyvox was superior to, or better than, vancomycin.[76] Pfizer sales force "relied heavily" on these clinical reprints during detailing sessions with physicians.[77] Pfizer did not remove the offending promotional reprints from circulation until November 2008.[78]

D.13. Disputed. Plaintiffs dispute this fact to the extent that it is intended to exclude McKinnell's knowledge of the scope of the *qui tam* cases or other investigations relating to Bextra. In 2004, McKinnell and the other defendants knew that the *qui tam* cases related to the "***improper*** promotion of Bextra."[79] McKinnell understood prior to and during the Class Period that it related to off-label

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[73] Ex. 140 at Greensmith003892.

[74] Ex. 218, Ex. A, Attachment A at 1-2,, Settlement Agreement, *United States v. Pharmacia & Upjohn Co., Inc.*, No. 1:09-cv-10258-DPW (D. Mass. Sept. 2, 2009), at 80-81 (Attachment A).

[75] Ex. 204 at PFE DERIV A 00003642; Ex. 122 at PFE DERIV 00040542; Ex. 47 (C. Dowd Depo.) at 31:25-32:8; Ex. 50 (Greensmith Depo.) at 96:2-21, 383:8-20; Ex. 177 at PZ0153348, 361-63, 369-70 (POA-2 Zyvox sales kick-off presentation).

[76] Ex. 121 at PFE DERIV 00067564.

[77] Ex. 121 at PFE DERIV 00067564.

[78] Ex. 178 at PFE DERIV 01044619-20.

[79] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 225:3-226:20; Ex. 417 at PFE DERIV 01146207 (describing the Bextra *qui tam* as "alleging the Company promoted Bextra off label"); Ex.

promotion of Bextra.[80] The notice from the U.S. Attorney's Office for the District of Massachusetts was not the first time Pfizer was made aware of an action alleging off-label marketing of Bextra by its sales force. In February 2003, Pfizer was notified of an action alleging off-label promotion of Bextra for acute pain.[81]

D.14. Undisputed.

D.15. Disputed. McKinnell's cited testimony does not support that the attorneys were qualified or that the investigation was very thorough. Having no personal knowledge, McKinnell's testimony is inadmissible.[82] McKinnell did not know the scope of the investigation and was instructed not to answer as to the results of the investigation of Bextra off-label for acute pain.[83] The evidence produced by Pfizer showed that the scope of the DOJ's findings were widespread.[84] Moreover, the lawyers referenced by the cited testimony either were not qualified, did not perform the investigation or are lawyers defendants cannot rely on in this case for advice of counsel. Dennis Block ("Block") never worked as a criminal law prosecutor or criminal defense attorney, nor does he have any experience performing calculations under the United States Sentencing Guidelines and is unfamiliar with the elements of a misbranding offense, or the elements or application of, *respondeat superior*

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467 at PFE-JONES 00039914 ("whistleblower allegations relating to off label promotion of Bextra").

[80] *E.g.*, Ex. 418 at PFE DERIV A 00000218 (2/24/05 Board meeting minutes: "Kindler . . . reviewed ongoing government investigations relating to off-label usage . . . ."); Ex. 540 at PFE DERIV 00009215 (12/06 Board pre-read indicated that "the government presented its version of the factual issues surrounding the alleged off-label promotion of Bextra.").

[81] Ex. 726 at PFE DERIV 00006746-47.

[82] *See* Fed. R. Evid. 602.

[83] Ex. 59 (11/11/13 McKinnell Depo.) at 210:19-214:20, 250:2-15, 252:24-253:12.

[84] *See, e.g.*, Exs. 251, 256, 309.

for corporate criminal liability.[85] Douglas Lankler ("Lankler"), when he was an assistant U.S. Attorney, was not involved in misbranding claims or healthcare fraud but rather general crimes, narcotics and organized crime. Jeffrey B. Kindler ("Kindler") testified that he looked at other lawyers regarding the government investigation of Bextra.[86] Similarly, Allen Waxman ("Waxman") testified that he worked with inside and outside criminal defense government investigation teams to learn about the investigation.[87]

McKinnell also testified in that Lawrence Fox ("Fox") and Block were not "litigators" and they relied on others' judgment, including outside attorneys.[88]

Defendants have expressly denied relying on any counsel other than Block or Fox for their defense in this case[89] (consistent with that denial, defendants successfully shielded Investigations Counsel[90] 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' Reliance on Advice of Counsel and Good Faith Defenses ("Plaintiffs' Motion for Partial Summary Judgment"), which was filed November 14, 2014. Neither Block nor Fox assessed critical portions of Pfizer's legal proceedings disclosure and the Statement of Financial Accounting Standards No. 5 ("FAS 5")

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[85] Ex. 37 (Block Depo.) at 13:12-14:6, 14:13-15:10, 16:6-17:8, 232:20-233:12.

[86] Ex. 54 (10/10/14 Kindler Depo.) at 31:10-33:8; 40:23-42:13.

[87] Ex. 68 (10/16/14 Waxman Depo.) at 14:10-16:14.

[88] Musoff Decl., Ex. B-M (9/19/14 McKinnell Depo.) at 90:14-91:16.

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

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

reserve decisions: the strengths or weaknesses of the Government's case[91] or Pfizer's defenses,[92] whether a loss or conviction was probable or whether such loss was reasonably estimable.[93] Moreover, defendants withheld from Block and Fox critical evidence concerning the Bextra Investigation,[94] including call notes,[95] documents that corroborated a *qui tam* relator's claims,[96] Bextra-related documents that Pfizer employees had attempted to delete or alter,[97] sales force survey results[98] and employee interview memoranda.[99] Instead, all information and input regarding the Bextra Investigation came from Investigations Counsel.[100] For example:

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[91] 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.

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

[93] 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.

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

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

[96] 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.

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

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

[99] 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.

[100] 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.[101]

Block never personally and professionally assessed nor advised defendants that Pfizer had substantial defenses to the Bextra Investigation.[102]

Fox never independently determined or advised defendants that Pfizer had substantial defenses to the Bextra Investigation.[103]

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.[104]

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.[105]

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.[106]

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

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

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

[104] 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.

[105] 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.

[106] 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.[107]

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 U.S. Securities and Exchange Commission ("SEC") filings: Pfizer's awareness that its sales representatives had, in fact, promoted Bextra off-label; the internal Bextra-related documents that were exhibits to John Kopchinski's ("Kopchinski") Complaint; the results from Pfizer's Bextra-related sales force surveys; the internal Bextra-related documents that Pfizer's 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.[108]

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

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[107] 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.

[108] 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.

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.[109]

Neither Block nor Fox has ever worked as a criminal law prosecutor or a criminal defense attorney.[110]

Neither Block nor Fox was familiar with the elements of a misbranding offense.[111]

Neither Block nor Fox was familiar with elements or application of *respondeat superior* liability.[112]

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.[113]

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[109] 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.

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

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

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

[113] 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.[114]

Fox incorrectly understood the terms grand jury "target" and grand jury "subject" to be interchangeable.[115]

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.[116]

Pfizer and its Investigations Counsel always represented to Block that Pfizer's sales representatives had not promoted Bextra off-label.[117] In fact, from February 2002 through April 2005: Pfizer promoted Bextra for uses that were not within Bextra's FDA-approved label, including (a) for general acute pain, (b) for pre-operative and post-operative surgical pain and (c) as opiod-sparing in the context of surgery;[118] 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 PD;[119] 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;[120] Pfizer promoted Bextra with an

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

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

[116] 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.

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

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

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

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

intent to defraud or mislead;[121] 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;[122] 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.[123]

No one provided Block a copy of Kopchinski's Complaint or any of the internal Pfizer documents that were exhibits to it.[124] The same appears to be true as to Fox, as the record does not indicate that he received those documents either.[125]

No one ever provided Block or Fox the internal documents that Pfizer's sales representatives had attempted to delete or alter.[126]

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.[127]

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

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

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

[124] 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.

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

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

[127] 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.[128]

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.[129]

No one provided Block or Fox copies of any of the interview memoranda from the Bextra Investigation.[130]

Neither Block nor Fox received access to any of Pfizer's Investigations Counsel's written work product concerning the Bextra Investigation.[131]

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.[132]

D.16. Disputed. McKinnell's cited testimony does not support a sufficient basis for this represented fact. McKinnell did not know the scope of the investigation and was instructed not to answer as to the results of the investigation of Bextra off-label for acute pain.[133] The scope of the DOJ's findings based on the evidence produced by Pfizer were widespread.[134]

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

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

[130] 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.

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

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

[133] Ex. 59 (11/11/13 McKinnell Depo.) at 210:19-214:20, 250:2-15, 252:24-253:12.

[134] *See, e.g.*, Ex. 309 (DOJ000018-30); Ex. 251 at DOJ000003 (Bryn Mawr, PA); Ex. 251 at DOJ000006 (Prestonsburg, KY); Ex. 251 at DOJ000007 (Dale City, VA); Ex. 251 at DOJ000009

Moreover, the lawyers referenced by the cited testimony either were not qualified, did not perform the investigation or are lawyers defendants cannot rely on in this case for advice of counsel. Block never worked as a criminal law prosecutor or criminal defense attorney, does not have any experience performing calculations under the United States Sentencing Guidelines and is unfamiliar with the elements of a misbranding offense or the elements or application of *respondeat superior* for corporate criminal liability.[135] Lankler, when he was an assistant U.S. Attorney, was not involved in misbranding claims or healthcare fraud but rather general crimes, narcotics and organized crime. Kindler testified that he looked to other lawyers regarding the Government investigation of Bextra.[136] Similarly, Waxman testified that he worked with inside and outside criminal defense government investigation teams to learn about the investigation.[137] The lawyers at Covington had dealings with the DOJ regarding the investigation.[138] McKinnell never spoke to attorneys at Covington regarding the investigation and had no recollection of their role in providing services regarding the investigation of Pfizer.[139]

McKinnell also testified that Fox and Block were not "litigators" and they relied on others' judgment, including outside attorneys.[140] Having no personal knowledge, McKinnell's testimony is

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(Dallas, TX); Ex. 251 at DOJ000010 (Portland, TN); Ex. 258 at DOJ000208 ("[n]umerous internal complaints and red flags").

[135] Ex. 37 (Block Depo.) at 13:12-14:6, 14:13-15:10, 16:6-17:8, 232:20-233:12.

[136] Ex. 54 (10/10/14 Kindler Depo.) at 31:10-33:8; 40:23-42:13.

[137] Ex. 68 (10/16/14 Waxman Depo.) at 14:10-16:14.

[138] *See, e.g.*, Ex. 211 at PFE-JONES 00006993-4; Ex. 397.

[139] Ex. 59 (11/11/13 McKinnell Depo.) at 165:14-166:3; *cf.* Ex. 60 (9/19/14 McKinnell Depo.) at 32:14-23.

[140] Musoff Decl., Ex. B-M (9/19/14 McKinnell Depo.) at 90:14-91:16.

inadmissible hearsay. McKinnell cannot assert an advice of counsel defense, including these outside lawyers, for the reason more fully explained in Plaintiffs' Motion for Partial Summary Judgment and in **D.15.** above.

D.17. Disputed. The evidence cited does not support the facts asserted. McKinnell knew of allegations relating to the promotion of Bextra for acute pain in 2003.[141] McKinnell testified that he knew of the Bextra investigation and the consideration of criminal charges but that he left the investigation to defendant Kindler and Pfizer's deputy compliance officer at the time, Lankler.[142] He also could not recall anything about the investigation of Bextra with respect to the Florida *qui tam* complaint in that state.[143] The scope and evidence of the DOJ investigation involved widespread violations of healthcare laws.[144]

D.18. Undisputed.

D.19. Disputed. Plaintiffs dispute the term "sales representatives," it was, in fact, a District Manager who instructed his field force to delete documents and McKinnell testified as such.[145]

D.20. Disputed. The employees believed they were following Company directives and documents produced reflect Pfizer approved conduct.[146] As to Bextra, Regional Manager Mary Holloway's

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[141] Ex. 541 at PFE DERIV 00006746-47.

[142] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 266:22-268:20.

[143] Ex. 60 (9/19/14 McKinnell Depo.) at 20:9-14; Ex. 243 at PFE DERIV 00003275.

[144] *See, e.g.*, Ex. 309 (DOJ000018-30); Exs. 251, 256; *see also* **D.31** *infra* for further explanation.

[145] Ex. 542; Musoff Decl., Ex. B-M (9/19/14 McKinnell Depo.) at 25:14-25.

[146] *See* Ex. 533 (Sentencing Memo) at 3 ("Farina believed at all times that the sale and marketing of Bextra and his actions as District Manager at Pfizer were lawful and consistent with how Pfizer wanted him to promote the product."); Ex. 563 (PFE DERIV 00006719) at PFE DERIV 00006720-21 ("[t]he documents Mr. Bermudez altered were several [approved documents including] pre-operative surgery instruction sheets that Mr. Bermudez had prepared for doctors," which is an off-label use). Another deleted document was "a document that related to helping doctors with matters

sentencing memo reflects that "Holloway believed at all times that her actions in this regard as a Regional Sales Manager at Pfizer were lawful and indeed consistent with how Pfizer wanted her to promote and sell the product."[147] At her deposition in this case, when asked whether obtaining Bextra protocols and standing orders was a company-wide initiative, consistent with corporate strategy, as instructed by executive leadership to increase sales, Holloway pled the Fifth Amendment.[148]

The off-label promotion of Bextra was also not limited to the North-East Region but was in fact widespread. For example, the review committee approved May 2003 POA Playbook instructed the sales force to obtain standing orders and protocols for Bextra from specialists, including surgeons.[149] The DOJ, using Pfizer's own documents, detailed the geographically widespread off-label promotion of Bextra, the percentage of off-label sales of the drug (which Pfizer itself tracked), as well the Company wide use of 20 mg samples.[150]

D.21. Disputed. McKinnell has no basis for the belief the conduct was isolated in nature, was investigated and remediated. The cited conclusory testimony does not support the facts represented and is inadmissible pursuant to Fed. R. Evid. 602 and 802. McKinnell's testimony was in response

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such as surgical protocols and surgery instruction sheets." Ex. 563 at PFE DERIV 000066722; Ex. 304 at BKLYN 000000043-49 (POA1 2004 Playbook); Ex. 304 at BKLYN 000000050-61 (article entitled Predicting Total Knee Replacement Pain); Ex. 304 at BKLYN 000000062-69 (2/18/04 e-mail from Mr. Farina, attaching POA 1 2004 Playbook); Ex. 563 at PFE DERIV 000066725.

[147] Ex. 543 (Holloway Sentencing Memo).

[148] Ex. 544 (Holloway Depo.) at 15:20-16:2, 20:4-8, 40:4-8.

[149] Ex. 41 (Burch Depo.) at 288:20-295:18; Ex. 545.

[150] *See, e.g.*, Ex. 309; Ex. 251 at DOJ000003 (Bryn Mawr, PA); Ex. 251 at DOJ000006 (Prestonsburg, KY); Ex. 251 at DOJ000007 (Dale City, VA); Ex. 251 at DOJ000009 (Dallas, TX); Ex. 251 at DOJ000010 (Portland, TN); Ex. 258 at DOJ000208 ("[n]umerous internal complaints and red flags").

to questions regarding what KPMG was informed of regarding possible violations of law and his knowledge of Pfizer's employees destroying documents.[151] The conduct was neither isolated nor remediated as set forth in Plaintiffs' Responses to McKinnell's Undisputed Fact Nos. **D.15.** and **B.8.**, incorporated by reference herein.

D.22. Disputed. The evidence cited does not support the fact represented that he received regular updates. McKinnell testified as to his recollection of what KPMG was told based on inadmissible hearsay (Fed. R. Evid. 802), not what he knew or how often he was updated, *see also* Fed. R. Evid. 602. McKinnell was instructed not to answer as to the results of a general counsel's investigation into the extent of the promotion of Bextra for acute pain.[152] He also recalled nothing about the investigation into the Bextra allegations in the Florida matter.[153] Plaintiffs do not dispute that McKinnell was aware of off-label promotion of Bextra or the Government investigation into such conduct.[154]

D.23. Disputed. McKinnell's self-serving "understanding" of what was told to KPMG is not fact but inadmissible hearsay pursuant to Fed. R. Evid. 602 and 802.[155] Moreover, he could not recall what defenses of possible violations of law were conveyed to KPMG.[156] Pfizer did not provide KPMG all the information necessary for KPMG to render advice regarding the Company's contingency reserves and disclosures relating to the Government's investigations into the off-label

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[151] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 246:18-248:6; Musoff Decl., Ex. B-M (9/19/14 McKinnell Depo.) at 25:14-27:6.

[152] Ex. 59 (11/11/13 McKinnell Depo.) at 210:19-214:20.

[153] Ex. 60 (9/19/14 McKinnell Depo.) at 20:9-14.

[154] Ex. 60 (9/19/14 McKinnell Depo.) at 28:6-15; Exs. 218, 251, 256, 258.

[155] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 232:16-24.

[156] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 232:16-233:2.

promotion of Bextra in the Company's legal proceedings disclosure, including that: (i) Pfizer concluded in 2005 that a settlement would likely be required to end the DOJ Bextra investigation;[157] (ii) despite Pfizer's experience with the DOJ investigation related to the off-label promotion of Neurontin and calculating the loss associated with off-label marketing of Neurontin, Pfizer misled KPMG by stating that the loss was not reasonably estimable and that the off-label promotion of Bextra was not the same as Neurontin;[158] and (iii) Pfizer internally recognized the lack of controls over Pfizer's HCC function could have a "material effect" on the Company's financial results.[159]

Additionally, 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 surgery.[160] The DOJ also presented to Pfizer the tactics Pfizer used to market Bextra for these off-label indications to hospitals via protocols, standing orders and 20 mg samples to physicians who did

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[157] Declaration of Joseph G. Petrosinelli in Support of Pfizer's Motion for Summary Judgment ("Petrosinelli Decl."), Ex. P-5.

[158] Ex. 546 at PFE-JONES 00028140-42; Petrosinelli Decl., Ex. B-6 at PFE-JONES 00059190; Ex. 436 (Kindler Deriv. Depo.) at 125:22-126:8; Ex. 152; Ex. 7 (Supplemental Expert Report of D. Paul Regan) at 30-35.

[159] Ex. 38 (8/8/13 Bradley Depo.) at 190:20-191:1, 207:23-210:1; Exs. 125, 149.

[160] Ex. 256 at DOJ000237.

not treat on-label use.[161] The DOJ further told Pfizer how the Company paid physicians to attend consultant meetings, advisory boards, speaker events and used a publication strategy, all to promote Bextra off-label.[162] 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 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.[163] Instead, KPMG was repeatedly told that the DOJ was still outlining the theories of liability.[164] 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.[165] 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 IA 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.[166] KPMG never received the presentation reviewed by Pfizer's Worldwide Pharmaceutical Operations

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[161] Ex. 256 at DOJ000238.

[162] Ex. 256 at DOJ000239.

[163] Ex. 258 at DOJ000207-08.

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

[165] Ex. 258 at DOJ000205.

[166] Ex. 161.

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.[167] This presentation set forth the complete lack of controls over the review committee and, thus, Pfizer's HCC function.[168] These failures are particularly glaring given: (1) Pfizer considered review committee procedures to be one of the top ten areas of greatest risk;[169] (2) KPMG's concern that Pfizer's controls over sales and marketing practices were impaired;[170] 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.[171]

KPMG was also 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.[172] KPMG relied on representations of Pfizer management in the form of quarterly management representation letters signed by the Chief Financial Officer ("CFO") and Controller, quarterly in-house legal representation letters signed by defendants 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 Generally

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[167] Ex. 203.

[168] Ex. 203.

[169] Ex. 120.

[170] Exs. 149, 150.

[171] Ex. 323 at KPMG PFIZ-DS 0003257 (2Q07 Interim Completion Document).

[172] Exs. 138, 139.

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.[173] 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 and $32,410,000 for services rendered in 2005 and 2006, respectively.[174] Fees paid to KPMG by Pfizer for services rendered were $28,220,000 and $27,735,000, for 2007 and 2008, and 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.[175]

D.24. Disputed. The evidence cited does not support the fact represented. McKinnell was asked whether there were further investigations into the promotion of Bextra off-label after hearing of the

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

[174] Ex. 14.

[175] Exs. 17-23.

allegations in the *qui tam*. He testified that Pfizer conducted an investigation into the Company's "compliance with laws and regulations with respect to Bextra" that resulted in findings that were of concern.[176] He did not testify that off-label promotion was not pervasive.[177] Further, he could not testify as to the basis of the results of the investigation and recalled nothing about the investigation into the allegations in the Florida *qui tam* matter.[178] He also testified that it was "unclear" in early 2005 whether violations of Company policy implicated the Company as a whole.[179]

D.25. Disputed. Plaintiffs also dispute facts for reasons set forth in Plaintiffs' Response to McKinnell's Undisputed Fact No. **D.24.**, *supra*, and are incorporated herein.

D.26. Disputed. Plaintiffs also dispute facts for reasons set forth in Plaintiffs' Response to McKinnell's Undisputed Fact No. **D.24.**, *supra*, and are incorporated herein.

D.27. Disputed. The Audit Committee Memo from defendants Waxman and Lankler dated December 1, 2005 indicates that the whistleblower complaint filed in 2003 alleges that: "Pfizer personnel [despite non-approval for acute pain] nevertheless promoted Bextra for acute pain during the period late 2001 to 2003, by (1) affirmatively referring to Bextra's efficacy and acute pain outside of the approved indications with physicians; (2) developing hospital and surgical protocols with physicians and hospitals that called for the use of Bextra for non-arthritic surgical pain; and (3) disseminating non-WLF journal articles referring to Bextra's efficacy in various acute pain models."[180] It goes on to reflect that the U.S. Attorney's Office for the District of Massachusetts "is

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[176] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 255:18-256:5.

[177] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 256:11-17.

[178] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 165:14-166:3; Musoff Decl., Ex. B-M (9/19/14 McKinnell Depo.) at 32:14-23.

[179] Musoff Decl., Ex. B-M (9/19/14 McKinnell Depo.) at 47:8-48:3.

[180] Musoff Decl., Ex. D-M at PFE-JONES 00006635.

presently reviewing documents and has begun to subpoena members of the field sales force that detailed Bextra to testify before the Grand Jury." Further, that "[w]e expect our discussions to continue." Other documents discuss *qui tam* complaints and do not reflect substantial defenses.[181] The Audit Committee memo itself was authored by Waxman and Lankler; privilege has not been waived as to these individuals.

To the extent McKinnell is claiming as fact that there were substantial defenses or that he believed there were, McKinnell cannot assert this as fact because plaintiffs have been shielded from discovery on this issue. Defendants, in particular McKinnell, cannot assert an advice of counsel or reliance on auditors defense for the reasons set forth in Plaintiffs' Motion for Partial Summary Judgment. While defendants have repeatedly told the Court they are only relying on Block and Fox as reliance counsel,[182] defendant McKinnell did not even mention Fox as someone he relied on in his first day of testimony but mentioned a whole host of other lawyers.[183] Further, he could not recall whether "substantial defenses" were even discussed in connection with the Form 10-K he signed months after the December 1, 2005 Audit Committee memo, or how the destruction of documents would affect any substantial defenses.[184] In addition, plaintiffs dispute these facts for the reasons set forth in Plaintiffs' Response to McKinnell's Undisputed Fact No. **D.15.**, *supra*, which is incorporated by reference herein.

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[181] Ex. 332 at PFE DERIV A 00001410 (2/23/06 Audit Committee minutes where there was a "discussion of the possible ramifications" of the Bextra matter); Ex. 547 at PFE DERIV 00008198 (June 2005); *see, e.g.*, Ex. 548 (12/9/04 e-mail regarding legal advice regarding government investigations); Ex. 446 at PFE-JONES 00026390 (3/14/05 e-mail containing legal advice regarding government investigation); Ex. 446 at PFE-JONES 00026458 (6/22/04 document containing legal advice regarding government investigations).

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

[183] Musoff Decl., Ex. B-M (9/19/14 McKinnell Depo.) at 56:16-57:3.

[184] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 276:23-278:3.

D.28. Disputed. McKinnell testified in September 2014 that with respect to who was telling him that Pfizer had substantial defenses that it was, among others, "outside advisors, outside law firms, outside lawyers."[185] He also testified in September 2014 that Fox and Block were not "litigators" and they relied on others' judgment, including outside attorneys "who were making the judgment about substantial defenses."[186] A year earlier, in November 2013, he had a different recollection, the experts included: Lankler, Kindler and Waxman and "for all I knew, they may have used outside attorneys," but he did not know that as a fact.[187] He also did not know the scope of the investigation or the basis for any results.[188] Further, McKinnell testified he did not know what substantial defenses were conveyed to KPMG.[189] To the extent that McKinnell is claiming as fact or that he believed there were substantial defenses, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to McKinnell's Undisputed Fact No. **D.15.**, *supra*, which is incorporated by reference herein.

D.29. Disputed. The citations to Pfizer's 2005 Form 10-K are incomplete and require context. The language at page 18 is to Pfizer's general risk factors.[190] The language at page 32 of the Financial Report to the Form 10-K is preceded by the statement that "[w]e and certain of our subsidiaries are involved in various patent, product liability, consumer, commercial, securities, environmental and tax litigations and claims; government investigations; and other legal proceedings that arise from

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[185] Musoff Decl., Ex. B-M (9/19/14 McKinnell Depo.) at 48:4-16.

[186] Musoff Decl., Ex. B-M (9/19/14 McKinnell Depo.) at 90:14-91:16.

[187] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 282:25-283:20.

[188] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 277:19-278:3.

[189] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 277:19-278:3, 283:22-284:1.

[190] Petrosinelli Decl., Ex. B-1 at 18.

time to time in the ordinary course of business. We do not believe any of them will have a material adverse effect on our financial position."[191] The language referenced by McKinnell is not in Note 18, Section F of the Financial Report regarding Government Investigations and Requests for Information (33 pages after the language in the Financial Report), which provides in pertinent part: "In 2003 and 2004, we received requests for information and documents concerning the marketing and safety of Bextra and Celebrex from the Department of Justice and a group of state attorneys general."[192]

D.30. Undisputed except to the extent the statements should be viewed in context.

D.31. Disputed. The actual presentations (as opposed to Pfizer's characterization) by the Government include several slide decks and hundreds of supporting documents "concerning contentions about alleged off-label promotion" of Bextra.[193] For example, 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 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

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[191] Petrosinelli Decl., Ex. B-1 (Financial Report) at 31-32.

[192] Petrosinelli Decl., Ex. B-1 (Financial Report) at 67.

[193] Exs. 256, 258.

Strategy"; and (5) that "HQ knowledge" was demonstrated by the "Bextra Positioning for Acute Pain" and "Headquarters knowledge of promotion for unapproved uses."[194]

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, which included Food & Drug Act charges, conspiracy to defraud, kickback charges and mail and wire fraud; and (3) the "Aggravating Factors," including "Knowledge at the Top," "A Deliberate Scheme," "Pervasive Misconduct" and "The Conducted 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."[195]

The slide deck entitled "Summary of Bextra Call Note Evidence" presented call note excerpts by sales representatives broadly across the United States reflecting the promotion of Bextra for acute pain.[196]

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 documents "concerning certain contentions about the marketing of Bextra" for off-label uses.[197] The slide decks also indicate 76% of Pfizer's revenue was for non-approved indications and 52% for

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[194] Ex. 256 at DOJ000234-40.

[195] Ex. 258 at DOJ000191, 199, 205, 207-08.

[196] Ex. 251; *see also* Ex. 309.

[197] Ex. 211 at PFE-JONES 00007014-25; Ex. 316 (slide deck entitled "Overview of United States Bextra Presentation"); Ex. 250 (slide deck entitled "Preliminary Statement: Investigation Continuing"); Ex. 314 (slide deck entitled "Review of Key Events & Facts").

unapproved doses.[198] Slides further discuss criminal charges and aggravating factors;[199] including "Knowledge at the Top," "Deliberate Scheme" and "Pervasive Misconduct." Plaintiffs do not dispute that Pfizer met with the DOJ regarding its investigation into Bextra, including meetings that McKinnell attended in 2004 as well as reflected in the DOJ's presentations.[200]

D.32. Disputed for the same reasons as set forth in Plaintiffs' Response to McKinnell's Undisputed Fact No. **C.31**, *supra* and fully incorporated herein. Additionally, as to "Pfizer's responses," the language is too vague and can be construed to refer to responses to the myriad of evidence presented and/or which of the aggravating factors Pfizer was agreeing to and Pfizer's self-serving recollection in its interrogatory responses is "not fact."

D.33. Disputed. The language is incomplete. The 2006 Form 10-K also describes Government investigations involving Genotropin, physician payments, potentially improper payments in Italy and Germany involving, *inter alia*, "criminal" investigations. Preceding the description of each of these investigations is the following language:

> Like other pharmaceutical companies, we are subject to extensive regulation by national, state and local government agencies in the U.S. and in the other countries in which we operate. As a result, we have interactions with government agencies on an ongoing basis. Among the investigations and requests for information by government agencies are those discussed below. It is possible that criminal charges and fines and/or civil penalties could result from pending government investigations.

D.34. Disputed. The evidence cited does not support the represented fact. Defendant Levin merely testified that to the best of his knowledge settlement discussions did not come up while he was CFO. He further testified he relied on counsel regarding the investigations.[201] Further, investigation

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[198] Ex. 258 at DOJ000201-02.

[199] Ex. 258 at DOJ000205-06.

[200] *E.g.*, Exs. 211, 258.

[201] Petrosinelli Decl., Ex. F-2 at 103:2-13; Ex. 58 (9/23/14 Levin Depo.) at 30:13-31:16.

counsel, including Covington, participated in the discussions with the Government along with non-reliance counsel.[202] Additionally, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to McKinnell's Undisputed Fact No. **D.15.**, *supra*, which plaintiffs incorporate by reference herein.

D.35. Disputed. Defendant Levin's characterization of the tenor of the investigation is disputed for the same reasons as **D.34**. above, which plaintiffs incorporate by reference herein. Levin testified regarding discussions with Lankler regarding settlement negotiations.[203] He testified as to what he thought, not fact.[204] His testimony is inadmissible hearsay. Pfizer met with the DOJ on numerous occasions prior to this time.[205] Further, Pfizer was in discussions with the DOJ far earlier and knew that in September 2005, "based on the facts and circumstances to date that we are likely to be forced to reach some form of settlement of this matter."[206]

D.36. Disputed. In a letter dated August 12, 2004 from the New York Attorney General's office, McKinnell was informed of a Government investigation regarding the marketing and sales of Geodon, among other drugs.[207] Further, McKinnell puts forth no evidence of when the DOJ investigations began, only when Pfizer received subpoenas.[208] Pfizer's reportable events to the OIG

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[202] Ex. 211 at PFE-JONES 00006992-7025.

[203] Petrosinelli Decl., Ex. F-2 at 137:1-18.

[204] Petrosinelli Decl., Ex. F-2 at 137:1-18.

[205] Ex. 167 at PFE-JONES 00006988.

[206] Petrosinelli Decl., Ex. P-5 at PFE-JONES 00043523-24; *see also* Exs. 251, 256, 258 at DOJ000206-08 (aggravating factors); Ex. 104 at PFE-JONES 00006992 (detailing meetings with DOJ beginning on 7/15/04).

[207] Ex. 213 at PFE DERIV 01099504.

[208] Petrosinelli Decl., Exs. J-5, R-5.

reflect that off-label promotion of other drugs was certainly occurring.[209] Further, the FDA had already informed McKinnell in 2005 of unsubstantiated superiority claims with respect to Zyvox and Zyvox's operating plans reflected the directive to continue these messages.[210]

D.37. Undisputed.

D.38. Undisputed.

D.39. Disputed. The evidence does not support that this was the "first time" that the DOJ requested Pfizer to make a financial proposal.[211] Pfizer was in discussions with the DOJ far earlier and knew that in September 2005, "based on the facts and circumstances to date that we are likely to be forced to reach some form of settlement of this matter."[212] This "fact" is also disputed for the reasons set forth in Plaintiffs' Response to McKinnell's Undisputed Fact No. **D.34.**, *supra*, and incorporated by reference herein.

D.40. Disputed. The evidence does not support the fact represented but rather indicates that the DOJ had "previously communicated" a "financial range" to Pfizer prior to April 4, 2008 as necessary to recommend resolution of the matter.[213]

D.41. Disputed. The title of the press release also included the language that "Fourth – Quarter 2008 Reported Diluted EPS of $0.04 Compared with $0.40 in the Year-Ago Quarter, Reflecting a

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[209] *E.g.*, Exs. 110-112, 214.

[210] Ex. 123.

[211] Musoff Decl., Ex. K-4 at KPMG-PFIZ-DS 003513.

[212] Petrosinelli Decl., Ex. P-5 at PFE-JONES 00043523-24; *see also* Exs. 251, 256, 258 at DOJ000206-08 (aggravating factors); Ex. 104 at PFE-JONES 00006992 (detailing meetings with DOJ beginning on 7/15/04).

[213] Petrosinelli Decl., Ex. Y-6 at PFE DERIV 0006638.

$2.3 Billion Charge Resulting from an Agreement in Principle to Resolve Previously Disclosed Investigations."[214]

D.42. Disputed. The press release also included the following language:

> For fourth-quarter 2008, Pfizer posted reported net income of $266 million, a decline of 90% compared with the prior-year quarter, and reported diluted EPS of $0.04, a decrease of 90% compared with the prior-year quarter. Fourth-quarter 2008 results were impacted by a $2.3 billion pre-tax and after-tax charge resulting from an agreement in principle with the Office of Michael Sullivan, the United States Attorney for the District of Massachusetts, to resolve previously disclosed investigations regarding allegations of past off-label promotional practices concerning Bextra, ***as well as other open investigations***.

D.43. Disputed. The testimony cited does not support the fact represented that $1.6 billion of the $2.3 billion settlement related to Bextra. Lankler testified that the agreement in principle was $2.3 billion and a felony plea to off-label promotion.[215] It is undisputed, however, that the settlement agreement sets forth the amounts that Pfizer was to pay.[216]

E.44. Disputed. The evidence cited does not reflect that McKinnell believed the financial statements he signed during the Class Period to be accurate and truthful but consists of his self-serving testimony. He relied on counsel as to whether he had substantial defenses but did not know the basis for the defenses but was informed there was "bad behavior."[217] He further testified that KPMG did not have expertise with respect to substantial defenses.[218] As to Fox, he testified Fox's

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[214] Petrosinelli Decl., Ex. K-1 (Jan. 26, 2009 Form 8-K).

[215] Musoff Decl., Ex. A-E at 192:17-193:8.

[216] Ex. 7 (Supplemental Expert Report of D. Paul Regan) at Ex. 21; Ex. 218 at 3.

[217] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 280:24-283:17; Musoff Decl., Ex. B-M (9/19/14 McKinnell Depo.) at 47:8-55:17.

[218] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 283:22-284:1; Musoff Decl., Ex. B-M (9/19/14 McKinnell Depo.) at 55:18-56:15.

role was to coordinate the review of financial disclosures.[219] He could not recall ever having a discussion regarding substantial defenses with Fox or anyone else in connection with the certification meetings concerning Pfizer's SEC filings.[220]

The evidence referenced by McKinnell also, for example, does not support the accuracy of McKinnell's statements in Class Period filings that "Compliance with all relevant statutes and rules is both the legacy of our 150-year history and one of our most important advantages in global business" and that Pfizer was "abiding by all laws that apply to [Pfizer's] marketing activities."[221] He testified that he was aware of possible violations of the law.[222] McKinnell testified that he did not personally review anything relating to the investigation but rather purportedly relied on others.[223]

In addition, plaintiffs dispute this fact because Defendants have expressly denied relying on any counsel other than Block or Fox for their defense in this case[224] (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 to Partial Summary Judgment on Defendants' Reliance on Advice of Counsel and Good Faith Defenses, which was filed November 14, 2014. Neither Block nor Fox assessed critical portions of Pfizer's legal proceedings disclosure

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[219] Musoff Decl., Ex. B-M (9/19/14 McKinnell Depo.) at 57:4-16.

[220] Musoff Decl., Ex. B-M (9/19/14 McKinnell Depo.) at 58:9-59:11; 57:17-20.

[221] Plaintiffs' FMS at Nos. 2, 4.

[222] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 246:18-248:16.

[223] Musoff Decl., Ex. B-M (9/19/14 McKinnell Depo.) at 45:25-46:9, 71:20-72:16.

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

and the FAS 5 reserve decisions: the strengths or weaknesses of the Government's case[225] or Pfizer's defenses,[226] whether a loss or conviction was probable, or whether such loss was reasonably estimable.[227] Moreover, defendants withheld from Block and Fox critical evidence concerning the Bextra Investigation, including call notes,[228] documents that corroborated a *qui tam* relator's claims,[229] Bextra-related documents that Pfizer employees had attempted to delete or alter,[230] sales force survey results[231] and employee interview memoranda.[232] Instead, all information and input regarding the Bextra Investigation came from Investigations Counsel.[233] 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.[234]

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[225] 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.

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

[227] 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.

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

[229] 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.

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

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

[232] 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.

[233] 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.

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

Block never personally and professionally assessed nor advised defendants that Pfizer had substantial defenses to the Bextra Investigation.[235]

Fox never independently determined or advised defendants that Pfizer had substantial defenses to the Bextra Investigation.[236]

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.[237]

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.[238]

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.[239]

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

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

[237] 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.

[238] 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.

[239] 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.[240]

Defendants did not seek or receive advice from Block regarding the propriety of representing that Pfizer had "substantial defenses" to the Bextra Investigation while omitting reference to any, let alone all, of the following in their SEC filings: Pfizer's awareness that its sales representatives had, in fact, promoted Bextra off-label; the internal Bextra-related documents that were exhibits to Kopchinski's Complaint; the results from Pfizer's Bextra-related sales force surveys; the internal Bextra-related documents that Pfizer's District Manager instructed Pfizer's sales representatives to alter or delete; the Bextra-related call notes of the Pfizer sales representatives who were involved in the attempted alteration and destruction of internal Bextra-related documents; the admissions of the Pfizer sales representatives who were involved in the attempted alteration and destruction of internal Bextra-related documents; the admissions of other Pfizer employees interviewed by Pfizer's Investigations Counsel; or the Bextra-related call notes quoted, summarized and/or analyzed in the Government's presentations to Pfizer and its Investigations Counsel.[241]

Defendants did not seek or receive advice from Fox regarding the propriety of representing that Pfizer had "substantial defenses" to the Bextra Investigation while omitting reference to any, let alone all, of the following in their SEC filings: the internal Bextra-related documents that were exhibits to Kopchinski's Complaint; the results from Pfizer's Bextra-related sales force surveys; the

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[240] 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.

[241] 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.[242]

Neither Block nor Fox has ever worked as a criminal law prosecutor or a criminal defense attorney.[243]

Neither Block nor Fox was familiar with the elements of a misbranding offense.[244]

Neither Block nor Fox was familiar with elements or application of *respondeat superior* liability.[245]

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.[246]

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[242] 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.

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

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

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

[246] 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.[247]

Fox incorrectly understood the terms grand jury "target" and grand jury "subject" to be interchangeable.[248]

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.[249]

Pfizer and its Investigations Counsel always represented to Block that Pfizer's sales representatives had not promoted Bextra off-label.[250] In fact, from February 2002 through April 2005: Pfizer promoted Bextra for uses that were not within Bextra's FDA-approved label, including (a) for general acute pain, (b) for pre-operative and post-operative surgical pain and (c) as opiod-sparing in the context of surgery;[251] 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;[252] Pfizer introduced Bextra into interstate commerce for the treatment of acute pain, surgical pain, other unapproved uses and at unapproved dosages even though it lacked adequate directions for such uses and dosages;[253] Pfizer promoted Bextra with an intent to defraud or mislead;[254] certain members of

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

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

[249] 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.

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

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

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

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

Pfizer's sales force promoted Bextra with false and misleading claims, including that Bextra had no dose proportional increase in hypertension and edema;[255] 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.[256]

No one provided Block a copy of Kopchinski's Complaint or any of the internal Pfizer documents that were exhibits to it.[257] The same appears to be true as to Fox, as the record does not indicate that he received those documents either. No one ever provided Block or Fox the internal documents that Pfizer's sales representatives had attempted to delete or alter.[258]

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.[259]

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.[260]

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

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

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

[257] 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.

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

[259] 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.

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

No one provided Block or Fox copies of any call notes, or summaries or analyses of any call notes, including the call notes that the Government quoted, referenced, summarized and/or analyzed in its August and September 2006 presentations to Pfizer and its Investigations Counsel.[261]

No one provided Block or Fox copies of any of the interview memoranda from the Bextra Investigation.[262]

Neither Block nor Fox received access to any of Pfizer's Investigations Counsel's written work product concerning the Bextra Investigation.[263]

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.[264]

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.[265] The DOJ also presented to Pfizer the tactics Pfizer used to market Bextra for these off-label indications to hospitals via protocols, standing orders and 20 mg samples to physicians who did

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

[262] 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.

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

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

[265] Ex. 256 at DOJ000237.

not treat on-label use.[266] The DOJ further told Pfizer how the Company paid physicians to attend consultant meetings, advisory boards, speaker events and used a publication strategy all to promote Bextra off-label.[267] 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.[268] Instead, KPMG was repeatedly told that the DOJ was still outlining the theories of liability.[269] 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.[270] 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 IA who headed up the HCC audit function, which explained how problems with Pfizer's HCC function could have a material impact on Pfizer's financial results.[271] 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

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[266] Ex. 256 at DOJ000238.

[267] Ex. 256 at DOJ000239.

[268] Ex. 258 at DOJ000207-08.

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

[270] Ex. 258 at DOJ000205.

[271] Ex. 161.

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.[272] This presentation set forth the complete lack of controls over the review committee and, thus, Pfizer's HCC function.[273] These failures are particularly glaring given: (1) Pfizer considered review committee procedures to be one of the top ten areas of greatest risk;[274] (2) KPMG's concern that Pfizer's controls over sales and marketing practices were impaired;[275] 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.[276]

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.[277] Similarly, KPMG was never informed that Pfizer received a target letter from the DOJ on February 5, 2008.[278] KPMG was never informed that the DOJ wrote Covington on April 4, 2008 and confirmed key elements of the proposed Bextra Investigation resolution, mentioned the structure and financial range previously communicated by the DOJ, indicated a severe escalation of the Bextra

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[272] Ex. 203.

[273] Ex. 203.

[274] Ex. 120.

[275] Exs. 149, 150.

[276] Ex. 323 at KPMG PFIZ-DS 0003257 (2Q07 Interim Completion Document).

[277] Ex. 310.

[278] Ex. 131; Ex. 38 (8/8/13 Bradley Depo.) at 242:13-16.

Investigation in that the DOJ intended to pursue criminal charges against Pfizer and offered a settlement of approximately $5 billion.[279]

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.[280] 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.[281] 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."[282] Similarly, Lankler told KPMG that the off-label marketing of Geodon had not been linked back to senior management at corporate headquarters.[283]

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

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

[280] Ex. 159.

[281] Exs. 138, 139.

[282] Ex. 204 at PFE DERIV A 00003642.

[283] Ex. 204.

argued that the fine in the Bextra Investigation should be calculated as it was in "analogous" cases such as Neurontin, Schering, Serono and Genotropin.[284]

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."[285] Chapman, KPMG audit partner, testified he had not been informed by November 3, 2007 that the probable "pillar" of FAS 5 had been met.[286] 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.[287]

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.[288] 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.[289] After becoming the engagement partner in early 2008, Bradley did not know that Lankler and Wessel were working on methodologies to calculate potential losses.[290]

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

[285] Petrosinelli Decl., Ex. N-6 (10/17/07, e-mail summarizing the 10/9/07 meeting attended by Block, Lankler, Wessel, Kim Dadlani and Paul Brockie); Ex. 265 (3Q07 Interim Completion Document showing as of 11/3/07 KPMG had been told loss not probable).

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

[287] Ex. 38 (8/8/13 Bradley Depo.) at 239:9-20.

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

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

[290] Ex. 38 (8/8/13 Bradley Depo.) at 234:1-236:2.

Again, instead, Block repeatedly told KPMG through the FY 2007 audit that the Government had neither spelled out statutory remedies nor the types of damages it would seek. Block also continued to falsely assure KPMG that the loss was neither probable nor estimable, even though Posner's response to the DOJ set forth a methodology to calculate the loss.[291]

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.[292] KPMG was never informed that on March 28, 2008, Covington made a $250 million offer to the DOJ to settle the Bextra investigation, which the Government rejected.[293] KPMG was never informed in or around June 2008, that Covington offered $750 million to settle the DOJ Bextra Investigation.[294] 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.[295] In fact, KPMG workpapers from June and July 2008 show that Pfizer told KPMG that no offers to settle to date had been made.[296]

KPMG relied on representations of Pfizer management in the form of quarterly management representation letters signed by the CFO and Controller, quarterly in-house legal representation letters signed by defendants Waxman and Kindler, and annual legal representation letters from

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

[292] Ex. 104; Ex. 38 (8/8/13 Bradley Depo.) at 236:3-11.

[293] Petrosinelli Decl., Ex.Y-6; Ex. 38 (8/8/13 Bradley Depo.) at 247:22-248:5.

[294] Ex. 158; Ex. 38 (8/8/13 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.").

[295] Ex. 158.

[296] Ex. 159.

Pfizer's outside counsel. The quarterly management representation letters confirmed that management was responsible for the fair presentation of the financial statements in conformity with GAAP and confirmed certain material matters, including a representation that all relevant information relating to certain compliance matters subject to the investigation of alleged fraud or potential illegal acts conducted by the Government Investigations Section and the Office of Corporate Compliance were disclosed by Pfizer to the Audit Committee, to the investigating team and to KPMG.[297] 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 and $32,410,000 for services rendered in 2005 and 2006, respectively.[298] Fees paid to KPMG by Pfizer for services rendered were $28,220,000 and $27,735,000 for 2007 and 2008, respectively, and 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.[299]

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

[298] Ex. 14.

[299] Exs. 17-23.

Moreover, to the extent McKinnell seeks 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."[300] 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."[301] In addition, she never received warning letters from the FDA,[302] letters to the OIG from Investigations Counsel regarding reportable events pursuant to Pfizer's Corporate Integrity Agreement,[303] documents concerning methodologies to evaluate damages for the Government investigation,[304] the February 5, 2008 target letter from the Government,[305] the April 4, 2008 letter in which Investigations Counsel made a $250 million offer to the Government to settle its investigation,[306] or documents relating to the review committee process or reforms or initiatives concerning it.[307]

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

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

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

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

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

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

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

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

E.45. Disputed. The testimony does not support the facts asserted. Additionally, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to McKinnell's Undisputed Fact No. **E.44.**, *supra*, and incorporate them by reference herein.

E.46. Disputed. The testimony does not support the facts asserted. McKinnell testified that he relied on Kindler, Waxman, Lankler and Block for assurances that there were substantial defenses with respect to off-label promotion.[308] He further testified that he relied on others, including outside attorneys/auditors.[309] Also that Fox and Block were not litigators and they would have relied on other counsel.[310] McKinnell cannot rely on these individuals/entities for the reasons set forth in Plaintiffs' Response to McKinnell's Undisputed Fact No. **E.44.**, *supra*, and incorporate it by reference herein.

E.47. Disputed. Plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to McKinnell's Undisputed Fact No. **E.44.**, *supra*, and incorporate it by reference herein.

E.48. Disputed. The testimony cited does not support the facts asserted. He testified that he relied on a process that involved hundreds of people, a disclosure committee, KPMG and "outside advisors."[311] Additionally, McKinnell cannot rely on these individuals/entities for the reasons set forth in Plaintiffs' Response to McKinnell's Undisputed Fact No. **E.44.**, *supra*, and incorporate it by reference herein.

E.49. Disputed. The testimony cited does not support the facts asserted. He testified that he relied on a process that involved hundreds of people, a disclosure committee, KPMG and "outside

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[308] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 282:8-19.

[309] Musoff Decl., Ex. B-M (9/19/14 McKinnell Depo.) at 28:16-30:18.

[310] Musoff Decl., Ex. B-M (9/19/14 McKinnell Depo.) at 90:14-91:16.

[311] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 295:10-296:17.

advisors."[312] Additionally, McKinnell cannot rely on these individuals/entities for the reasons set forth in Plaintiffs' Response to McKinnell's Undisputed Fact No. **E.44.**, *supra*, and incorporate it by reference herein.

E.50. Disputed. The testimony cited does not support the facts asserted. He testified that he relied on a process that involved hundreds of people, a disclosure committee, KPMG and "outside advisors."[313] Additionally, McKinnell cannot rely on these individuals/entities for the reasons set forth in Plaintiffs' Responses to McKinnell's Undisputed Fact Nos. **B.6.**, **B.7.** and **E.44.**, *supra*, and incorporate them by reference herein.

E.51. Disputed. The testimony cited does not support the facts asserted. He testified that he relied on a process that involved hundreds of people, a disclosure committee, KPMG and "outside advisors."[314] Additionally, McKinnell cannot rely on these individuals/entities for the reasons set forth in Plaintiffs' Response to McKinnell's Undisputed Fact Nos. at **B.6.**, **B.7.** and **E.44.**, *supra*, and incorporate them by reference herein.

E.52. Disputed. The testimony cited does not support the purported fact that KPMG was fully informed of all relevant developments concerning Pfizer's internal controls. KPMG's audit partner testified that KPMG did not audit healthcare compliance controls.[315] In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to McKinnell's Undisputed Fact No. **D.23.**, *supra*, and incorporate it by reference herein.

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[312] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 295:10-296:17.

[313] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 295:10-296:17.

[314] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 295:10-296:17.

[315] Ex. 44 (Chapman Depo.) at 114:20-115:4; 295:14-296:17.

E.53. Disputed. McKinnell testified that the certification process involves "hundreds of people" that provide him with a clean draft based on their review and that he meets with 20 or more people and he insists on certifications by the heads of the functional areas, including defendant Levin.[316] He also testified KPMG did an independent audit of Pfizer's financial controls, but according to KPMG that did not include healthcare compliance controls. KPMG did not audit Pfizer's health care compliance in 2006.[317] In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to McKinnell's Undisputed Fact No. **E.44.**, *supra*, and incorporate it by reference herein.

E.54. Disputed. McKinnell testified that the certification process involves "hundreds of people" that provide him with a clean draft based on their review and that he meets with 20 or more people and he insists on certifications by the heads of the functional areas, including defendant Levin.[318] He also testified KPMG did an independent audit of Pfizer's financial controls, but according to KPMG that did not include healthcare compliance controls.[319] Additionally, McKinnell cannot rely on these individuals/entities for the reasons set forth in Plaintiffs' Response to McKinnell's Undisputed Fact No. **E.44.**, *supra*, and incorporate it by reference herein.

E.55. Disputed. The testimony cited does not support the facts asserted. For example, McKinnell testified that "KPMG was told that there were possible violations of law, that we had defenses" but that he did not recall those defenses.[320] When asked what he did to analyze whether or not potential

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[316] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 295:14-296:17.

[317] *Compare* Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 296:18-299:22 *with* Ex. 44 (Chapman Depo.) at 114:20-115:4, 117:8-24.

[318] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 295:14-296:17.

[319] *Compare* Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 296:18-299:22 *with* Ex. 44 (Chapman Depo.) at 114:20-115:4, 117:8-24.

[320] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 232:16-233:2.

liabilities were probable with respect to the Bextra matter, he testified that there were discussions by others and he relied on Lankler and Kindler with respect to estimates.[321] He further testified that he did not know if KPMG was privy to all the discussions with the Government regarding the off-label promotion of Bextra and that he did not know if KPMG had any expertise in estimating the potential penalties/fines for the off-label promotion of drugs.[322] In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to McKinnell's Undisputed Fact No. **E.44.**, *supra*, and incorporate it by reference herein.

E.56. Disputed. The testimony cited does not support the facts asserted. For example, McKinnell testified that "KPMG was told that there were possible violations of law, that we had defenses" but that he did not recall those defenses.[323] When asked what he did to analyze whether or not potential liabilities were probable with respect to the Bextra matter, he testified that there were discussions by others and he relied on Lankler and Kindler with respect to estimates.[324] He further testified that he did not know if KPMG was privy to all the discussions with the Government regarding the off-label promotion of Bextra and that he did not know if KPMG had any expertise in estimating the potential penalties/fines for the off-label promotion of drugs.[325] In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to McKinnell's Undisputed Fact No. **E.44.**, *supra*, and incorporate it by reference herein.

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[321] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 237:2-239:2.

[322] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 245:6-246:5.

[323] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 232:16-233:2.

[324] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 237:2-239:2.

[325] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 245:6-246:5.

E.57. Disputed. The testimony cited does not support the fact asserted. McKinnell testified that "KPMG was told that there were possible violations of law, that we had defenses" but that he did not recall those defenses.[326] When asked what he did to analyze whether or not potential liabilities were probable with respect to the Bextra matter, he testified that there were discussions by others and he relied on Lankler and Kindler with respect to estimates.[327] He further testified that he did not know if KPMG was privy to all the discussions with the Government regarding the off-label promotion of Bextra and that he did not know if KPMG had any expertise in estimating the potential penalties/fines for the off-label promotion of drugs.[328] In addition, plaintiffs dispute this fact for the reasons set forth in plaintiffs' response to McKinnell's Statement of Undisputed Facts at **E.44.**, *supra*, and incorporate it by reference herein.

E.58. Disputed. KPMG was not in the position to correctly evaluate Pfizer's reserving decisions for reasonableness and compliance with GAAP due to the fact that they did not have access to relevant information regarding Pfizer's legal matters and investigations at issue. Pfizer management was ultimately responsible for reserving decisions and McKinnell, along with the CFO, for certifying that the financial statements did not contain "any untrue statement of a material fact or omit to state a material fact necessary to make the statements made . . . not misleading" as well as assuring investors that the financial statements complied with GAAP.[329] In 2005, the KPMG lead partner noted that he received "significant push-back by Pfizer OGC [Office of the General Counsel]

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[326] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 232:16-233:2.

[327] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 237:2-239:2.

[328] Musoff Decl., Ex. A-M (11/11/13 McKinnell Depo.) at 245:6-246:5.

[329] *See, e.g.*, Petrosinelli Decl., Ex. B-1 at Ex. 31.1; Petrosinelli Decl., Ex. B-1 (2005 Financial Report) at 32-33.

claiming privilege . . . covering the investigations."[330] A year-end 2006 SOX process-related documents workpaper showing which documents KPMG used for control testing for each legal process, showed that in the area of domestic litigation, KPMG had "limited" access to the matter management database, no access to the monthly activity report and no access to the monthly financial controls reports.[331] They were also only allowed to access attorney certifications that all significant "A" matters have been included in the monthly activity report but were not allowed to review any attachments to the certifications.[332]

In addition, plaintiffs dispute this fact for the reasons set forth in Plaintiffs' Response to McKinnell's Undisputed Fact No. **D.23.**, *supra*, and incorporate it by reference herein.

F.59. Undisputed.

F.60. Undisputed that the Form 14A reflects this, but it is not evidence of the truth of the matter.

F.61. Undisputed that the Form 14A reflects this, but it is not evidence of the truth of the matter.

DATED: November 26, 2014

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[330] Ex. 549 at KPMG-PFIZ-DS 0000144; *see also* Ex. 550 at PFE-JONES 00006571-72 (4/13/05 e-mail from Chapman discussing sanctions for an audit partner in connection with the claim of privilege over potential illegal acts).

[331] Ex. 551 at KPMG-PFIZ-DS 034835.

[332] Ex. 551 at KPMG-PFIZ-DS 034835.

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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.

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Case Number: 1:10-cv-03864-AKH
Filer: Mary K. Jones
Stichting Philips Pensioenfonds
Document Number: 311

Docket Text:
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