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' STATEMENT OF MATERIAL FACTS REQUIRING DENIAL OF DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT

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GLOSSARY OF DEFINED TERMS

"2004 CIA": Corporate Integrity Agreement Between the OIG and the Department of Health and Human Services and Pfizer, dated May 11, 2004.

"AUSA": Assistant U.S. Attorney

"Bextra Investigation" or "Government Investigations": Used alternatively to reference the Government's investigation into alleged misbranding ("off-label promotion") of Bextra, Geodon, Lyrica, and Zyvox

"Block": Dennis Block, Pfizer's outside Disclosure Counsel

"Cangialosi": Loretta Cangialosi, Pfizer SVP and Controller (Principle Accounting Office)

"CIA": Corporate Integrity Agreement

"Class Period": January 19, 2006 through January 23, 2009

"CME": Continuing Medical Education

"Covington": Covington & Burling LLP

"Davis Polk": Davis Polk & Wardwell

"Donnelly": Hugh Donnelly, V.P. Internal Audit

"DOJ": Department of Justice

"DPN": Diabetic peripheral neuropathy

"ELT": Executive Leadership Team

"EPS": Earnings Per Share

"Epstein": Epstein Becker & Green, P.C.

"FAS 5": Statement of Financial Accounting Standards No. 5

"Farina": Thomas Farina, Pfizer District Manager

"FDA": U.S. Food and Drug Administration

"FMS": False & Misleading Statements Chart

"Fox": Lawrence Fox, Pfizer's in-house Disclosure Counsel

"GAAP": Generally Accepted Accounting Principles

"GAP": Generalized Anxiety Disorder

"Giampetruzzi": Gary Giampetruzzi, Pfizer's in-house Investigation Counsel

"Government Investigations" or "Bextra Investigation": Used alternatively to reference the Government's

GLOSSARY OF DEFINED TERMS

investigation into alleged misbranding ("off-label promotion") of Bextra, Geodon, Lyrica, and Zyvox

"Government": Refers collectively to the U.S. Department of Justice, the U.S. Attorney's Office, Health and Human Services Office of Inspector General, and/or any other federal governmental agency

"GSK": GlaxoSmithKline

"HCC": Healthcare compliance

"HHS": Department of Health and Human Services

"IA": Pfizer's Internal Audit Department.

"Investigation Counsel": Refers to all lawyers who investigated, provided input, or conveyed to others information concerning the Government Investigations, including outside counsel Covington & Burling LLP, Sidley Austin (Bextra), King & Spalding (Bextra), Ropes & Gray (Bextra and Zyvox), Davis Polk & Wardwell (Lyrica), and DLA Piper (Geodon). In terms of in-house Investigation Counsel, they included, among others, Douglas Lankler, Carlton Wessel, and Gary Giampetruzzi.

"KOLs": Key Opinion Leaders

"KPMG": KPMG LLP

"Lankler": Douglas Lankler, Chief Compliance and Risk Officer

"Mooney": Chuck Mooney, Director of Internal Audit

"NeP": Neuropathic pain

"OA": Osteoarthritis

"OIG": Health and Human Services Office of Inspector General

"PD": Primary dysmenorrhea

"Pfizer" or the "Company": Refers to Pfizer Inc. and its wholly owned subsidiaries, as well as any entities that later became its wholly owned subsidiaries

"PHN": Postherpetic neuralgia

"PLT": Pfizer Leadership Team

"POA": Plan of Action

"RA": Rheumatoid arthritis

"Sonnenschein": Sonnenschein Nath & Rosenthal

"SOX": Sarbanes-Oxley Act of 2002, 15 U.S.C. §7201, *et seq.*

GLOSSARY OF DEFINED TERMS

"USAO": U.S. Attorney's Office

"USPO": Pfizer's U.S. Pharmaceutical Operations

"USSG": U.S. Sentencing Guidelines

"Wessel": Carlton Wessel, Pfizer's in-house Investigation Counsel

"WPO": Pfizer Worldwide Pharmaceutical Operations

I. BACKGROUND[1]

1. On May 13, 2004, Pfizer announced the settlement of the government investigations regarding Neurontin, including payment of $430 million to settle civil and criminal charges for off-label promotion and a plea to two misdemeanor counts of misbranding, or off-label promotion, under the United States Sentencing Guidelines under the Federal Food, Drug and Cosmetics Act.[2] The calculation of the $240 million criminal fine was based on the gain attributable to the defendants' illegal conduct and multiplier based on certain criteria.[3] The illegal conduct alleged included marketing Neurontin for off-label uses and for doses at which the drug was not approved and involved (i) encouraging sales representatives to detail physicians about off-label uses, (ii) paying physicians through trips and dinners to attend consultant and advisory meetings in which they received off-label presentations, and (iii) sponsoring medical education events on off-label Neurontin uses where there was extensive input from the Company regarding the events.[4]

2. The settlement also included Pfizer entering into a Corporate Integrity Agreement (the "2004 CIA").[5] The settlement was in exchange for the OIG's agreement not to exclude Pfizer from participating in federally funded healthcare programs such as Medicare and Medicaid.[6]

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[1] For ease of reading, Plaintiffs' Statement of Material Facts uses headings and focuses on specific defendants in different sections. These headings and sections, however, are not meant to restrict the application of any facts to any defendant for any reason.

[2] Ex. 382 at PFE DERIV 00007338; Ex. 527 at BEX006359904; Ex. 231 at 9-10.

[3] Ex. 229 at 2.

[4] Ex. 229 at 1; Ex. 230 at 7-8 (detailing off-label promotion through medical liasons), 9-11 (Ad Boards, etc).

[5] Ex. 382 at PFE DERIV 00007338; Ex. 73 (Corporate Integrity Agreement Between the Office of the Inspector General of the Department of Health and Human Services and Pfizer).

[6] Ex. 415 at PFE DERIV 01039752.

3. The 2004 CIA had a five-year term through May 10, 2009.[7] In the CIA Pfizer represented that it "has in place strong review and disciplinary measures to ensure that its activities . . . are in compliance with all Federal health care program requirements."[8] The 2004 CIA required Pfizer to maintain a compliance program with a Compliance Officer "responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements and FDA requirements."[9] Further, the "Compliance Officer and the Deputy Compliance Officer [senior management] shall be responsible for monitoring the day-to-day compliance activities engaged in by Pfizer."[10]

4. The 2004 CIA required Pfizer to have policies that prohibited improper off-label promotion.[11] It also required that Pfizer make "adherence to[] the Blue Book [*i.e.* written code of conduct], or other relevant compliance policies and procedures, an element in evaluating the performance of all employees."[12] Additionally, Pfizer was required to train its employees regarding the proper methods for "disseminating information about off-label uses of Pfizer's products."[13]

5. Further, the 2004 CIA required that it notify the OIG of any determination by Pfizer of a Reportable Event, which is defined by the 2004 CIA as:

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7 Ex. 382 at PFE DERIV 00007338; Ex. 73 at 2.

8 Ex. 73 at 1.

9 Ex. 73 at 5.

10 Ex. 73 at 6.

11 Ex. 73 at 8-9.

12 Ex. 73 at 6.

13 Ex. 73 at 11-13.

> [A]nything that involves a matter, brought to the attention of senior management at Pfizer's New York headquarters, that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program, and/or applicable to any FDA requirements relating to the off-label promotion of drugs, for which penalties or exclusion may be authorized. [14]

6. The 2004 CIA also required Pfizer to "provide to [the] OIG a list and explanation of all actively promoted Pfizer products and, if available from third parties, information about the estimated relative usage (*e.g.*, the percentage) of those products for off-label purposes."[15] Further, it required Pfizer to obtain and review "Verbatims or similar records" "detailing interactions between sales representatives and [Health Care Professionals]" and identify off-label discussions or dissemination of off-label information.[16]

7. Pursuant to the 2004 CIA's annual reporting requirement, in 2005, 2006, 2007 and 2008, Pfizer described the nature of the Bextra Investigation as a "qui tam complaint alleging the company promoted Bextra off label."[17] According to Doug Lankler ("Lankler"), Pfizer's Chief Compliance and Risk Officer, this description was accurate and complete in all material respects because, in terms of completeness, Pfizer was writing to a very informed audience, *i.e.*, the OIG.[18]

II. DEFENDANTS' CLASS PERIOD STATEMENTS

8. Defendants Pfizer, Levin, Kindler, and McKinnell made the statement in FMS No. 1 on January 19, 2006.[19]

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14 Ex. 73 at 21.

15 Ex. 73 at 22.

16 Ex. 73 at 22-23.

17 Exs. 232-235.

18 Ex. 55 (Lankler Depo.) at 41:7-42:13.

19 "FMS" refers to Defendants' Class Period False & Misleading Statements Chart, attached hereto as Attachment 1.

9. Defendants Pfizer, McKinnell, Kindler, and Levin made the statement in FMS No. 2 on March 1, 2006.

10. Defendants McKinnell and Levin made the statement in FMS No. 3 on March 1, 2006.

11. Defendants Pfizer and McKinnell made the statement in FMS No. 4 on March 16, 2006.

12. Defendants Pfizer, McKinnell, Levin, and Kindler made the statement in FMS No. 5 on April 19, 2006.

13. Defendants McKinnell and Levin made the statement in FMS No. 6 on May 8, 2006.

14. Defendants Pfizer, McKinnell, Kindler, and Levin made the statement in FMS No. 7 on May 8, 2006.

15. Defendants Pfizer, Levin, Kindler and McKinnell made the statement in FMS No. 8 on July 20, 2006.

16. Defendants Kindler and Levin made the statement in FMS No. 9 on August 11, 2006.

17. Defendants Pfizer, Kindler, Levin, and Waxman made the statement in FMS No. 10 on August 11, 2006.

18. Defendants Pfizer, Kindler, Levin, Waxman, and Read made the statement in FMS No. 11 on October 19, 2006.

19. Defendants Kindler and Levin made the statement in FMS No. 12 on November 3, 2006.

20. Defendants Pfizer, Kindler, Levin, Waxman and Read made the statement in FMS No. 13 on November 3, 2006.

21. Defendants Pfizer, Read and Kindler made the statement in FMS No. 14 on January 22, 2007.

22. Defendants Pfizer, Kindler, Levin, Waxman, and Read made the statement in FMS No. 15 on January 22, 2007.

23. Defendants Pfizer, Kindler, Waxman, Levin, and Read made the statement in FMS No. 16 on March 1, 2007.

24. Defendants Kindler and Levin made the statement in FMS No. 17 on March 1, 2007.

25. Defendants Pfizer and Kindler made the statement in FMS No. 18 on March 15, 2007.

26. Defendants Pfizer, Kindler, Levin, Waxman, and Read made the statement in FMS No. 19 on April 2, 2007.

27. Defendants Pfizer, Kindler, Levin, Waxman, and Read made the statement in FMS No. 20 on April 20, 2007.

28. Defendants Kindler and Levin made the statement in FMS No. 21 on May 4, 2007.

29. Defendants Pfizer, Kindler, Levin, Waxman, and Read made the statement in FMS No. 22 on May 4, 2007.

30. Defendants Pfizer, Kindler, Levin, Waxman, and Read made the statement in FMS No. 23 on July 18, 2007.

31. Defendants Kindler and Levin made the statement in FMS No. 24 on August 6, 2007.

32. Defendants Pfizer, Kindler, Levin, Waxman, and Read made the statement in FMS No. 25 on August 6, 2007.

33. Defendants Pfizer, Kindler, D'Amelio, Waxman, and Read made the statement in FMS No. 26 on October 18, 2007.

34. Defendants Pfizer and Kindler made the statement in FMS No. 27 on October 18, 2007.

35. Defendants Kindler and D'Amelio made the statement in FMS No. 28 on November 5, 2007.

36. Defendants Pfizer, Kindler, D'Amelio, Waxman, and Read made the statement in FMS No. 29 on November 5, 2007.

37. Defendants Pfizer, Kindler, D'Amelio, Waxman, and Read made the statement in FMS No. 30 on January 22, 2008.

38. Defendants Pfizer, Kindler, D'Amelio, Waxman, and Read made the statement in FMS No. 31 on February 29, 2008.

39. Defendants Kindler and D'Amelio made the statement in FMS No. 32 on February 29, 2008.

40. Defendants Pfizer, Read, Kindler, and D'Amelio made the statement in FMS No. 33 on March 05, 2008.

41. Defendants Pfizer and Kindler made the statement in FMS No. 34 on March 14, 2008.

42. Defendants Pfizer, Kindler, D'Amelio, and Read made the statement in FMS No. 35 on April 17, 2008.

43. Defendants Kindler and D'Amelio made the statement in FMS No. 36 on May 2, 2008.

44. Defendants Pfizer, Kindler, D'Amelio, and Read made the statement in FMS No. 37 on May 2, 2008.

45. Defendants Pfizer, Kindler, D'Amelio, and Read made the statement in FMS No. 38 on July 23, 2008.

46. Defendants Kindler and D'Amelio made the statement in FMS No. 39 on August 8, 2008.

47. Defendants Pfizer, Kindler, D'Amelio, and Read made the statement in FMS No. 40 on August 8, 2008.

48. Defendants Pfizer and Read made the statement in FMS No. 41 on September 22, 2008.

49. Defendants Pfizer, Kindler, D'Amelio, and Read made the statement in FMS No. 42 on October 21, 2008.

50. Defendants Pfizer, Kindler and D'Amelio made the statement in FMS No. 43 on November 7, 2008.

51. Defendants Pfizer, Kindler, D'Amelio, and Read made the statement in FMS No. 44 on November 7, 2008.

III. WHY DEFENDANTS' CLASS PERIOD STATEMENTS ARE MISLEADING

A. Defendants Marketed the Company's Products in Violation of the Law

1. Bextra

52. In 2001, Pfizer submitted an application to the U.S. Food and Drug Administration ("FDA") for the drug Bextra seeking approval for the indications of osteoarthritis ("OA"), rheumatoid arthritis ("RA"), primary dysmenorrhea ("PD"), acute pain, pre-operative pain and opioid-sparing in the context of surgery, and for the dosages of 10-20 mg for OA/RA and 40 mg for PD.[20]

[20] Ex. 241 at BEX001360555.

53. In November 2001, the FDA denied Pfizer's application as to all but the following indications and dosages: 10 mg (once per day) for OA/RA and 20 mg (twice per day) for PD.[21] Pfizer began distributing Bextra to physicians, in February 2002.[22]

54. In support of its nonapproval, the FDA noted that the study submitted in support of the acute pain indication, including opioid-sparing and prevention of operative pain, "demonstrated an excess of serious adverse events including death" at 40 mg doses when added to injectable pre-operative painkillers, and that at doses higher than the 10 mg daily dose for OA and RA "findings of more hypertension and edema are frequently reproduced."[23]

55. Pfizer was never able to obtain FDA approval for an acute pain indication for Bextra before it took the drug off the market in April 2005 due to the FDA's concern with the increased risk of serious skin reactions and cardiovascular events.[24]

56. By June 2002, Pfizer's sales representatives were "successfully conveying Power message; Bextra perceived as equipotent to Vioxx."[25] When physicians were "interested in Bextra's role in acute pain[,] [r]eps use[d] the dysmenorrhea indication to address this topic."[26] By July 2002, many sales representatives were communicating to physicians that Bextra is for "'acute pain states,

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21 Ex. 241 at BEX001360555; Ex. 259 at BEX005818115.

22 Ex. 283 at BEX001800573.

23 Ex. 242 at BEX004849786.

24 Ex. 278 at BEX000757329-30.

25 Ex. 82 at BEX002805792.

26 Ex. 83 at BEX 000001024.

such as the pain associated with primary dysmenorrhea'" and "'10 mg. is for OA and RA and 20 mg. is for acute pain states.'"[27]

57. As of October 31, 2002, sales representatives were "telling doctors to use 10 for OA/RA and 20 for Pain."[28] By March 24, 2003, "[t]he majority of Pfizer SRs ["Sales Representatives"] use[d] a 'chronic/acute' or 'persistent/acute' distinction to describe how the physician can use Celebrex and Bextra."[29] Detailing "MESSAGES THAT [WE]RE WORKING" as of August 2003 included Bextra for "Acute pain" and for an "Acute, younger patient."[30]

58. The detailing message frequently (over 40%) used by the sales force that was "Aligned with Sales Strategy" as of September 30, 2003 was "Use Bextra instead of Vioxx."[31] By March 25, 2004, Bextra was "most commonly mentioned by reps in connection to the treatment of acute pain/inflammation."[32] Other "Top of Mind Bextra Main Message[s]" during "Bextra Details" included "'Bextra can be used pre- and post-operatively for pain,'" "'Celebrex for chronic pain, Bextra for acute pain,'" and "'safe and can dose 10mg or 20mg per day.'"[33]

59. Call notes entered by Pfizer's sales representatives from 2002 to 2005 indicate that they detailed Bextra to physicians for acute pain and use in surgical settings.[34]

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27 Ex. 83 at BEX 000001029.

28 Ex. 187 at Levy-L 10000118163.

29 Ex. 188 at Levy-L 10000371110, 128-29.

30 Ex. 279 at BEX001015138.

31 Ex. 282 at BEX001599945.

32 Ex. 189 at Levy-L 10000300183.

33 Ex. 189 at Levy-L 10000300174.

34 *E.g.*, Ex. 251 at DOJ00001-017 ("Summary of Bextra Call Note Evidence" of Pfizer sales representatives throughout the country detailing physicians for acute pain presented by the DOJ); Ex.

60. From 2001 to 2005, Pfizer hosted advisory board and consultant meetings as part of its marketing strategy to present Bextra use in the surgical setting and for the treatment of acute pain, dental pain and migraines.[35]

61. During advisory board and consultant meetings, Pfizer made recommendations to use Bextra at "[s]pecifically off label increasing dosages" and for acute pain indications for which the drug was not FDA approved.[36] Attendees of certain consultant meetings also learned about "Bextra effectiveness in acute pain," "Valdecoxib – high dose acute pain," "pre op use of Bextra" and Bextra "40 mg safer and works faster."[37]

62. From 2002 to 2005, Pfizer's sales representatives detailed physicians for non-FDA approved indications through Continuing Medical Education ("CME") events.[38]

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290 at BEX 000000015 ("Detailed . . . on using Bextra for acute situations" and "Cover[ed] pre- and post-op use of Bextra for surgery" during detailing); Ex. 291 at BEX 000000018-19 ("Talked about [Bextra] use for post and pre-op due to narcotic sparing effect," "Talked about pre-op [Bextra] and asked if he has tried it," "Talked to her again about pre and post op usage of [Bextra]" and "Reminded him of the 20 mg Bextra for acute pain"); Ex. 292 at BEX 000000025, 31 ("Gave her more reasons to use Bex pre and post op," "Asked him to use Bex pre and post op for narcotic reduction" and "Detailed on using Bextra pre and post op at Weston out patient surgical center"); Ex. 293 at BEX 000000034-35, 37, 39 ("Detailed Celebrex and Bextra[,] [f]ocused on acute pain" and "positioning Bextra for that acute pain[,] [w]here ever he would use Vioxx"); Ex. 294 at BEX 000000045 ("Reminded him of Bextra's strength and how using pre-emptive analgesia helps reduce pain and inflammation post op"); Ex. 295 at BEX 000000053-56 ("Discussed Celebrex and Bextra for acute pain," "Explained acute pain dosing with stock bottles," "Tried to convince her to use Bextra pre and post-op," "Suggested Bextra post-op" and "Remi[n]ded about using Bextra post-op").

[35] *E.g.*, Ex. 74 at Levy-L 10000279416, 422, 438, 442, 464, 485, 492-94; Ex. 532 at BEX005427312-14; Ex. 285 at BEX005091636-37; Ex. 297 at BEX 000107051-52, 54-55; Ex. 275; Ex. 276 at BEX000503561, 571-72; Ex. 284 at BEX004487564-66, 568-70; Ex. 274 at BEX000495832-33, 836, 842.

[36] *E.g.*, Ex. 285 at BEX005091664-65.

[37] Ex. 298 at BEX 000125875-76; Ex. 299 at BEX000126891.

[38] *E.g.*, Ex. 291 at BEX 000000021 (Call note stating "[t]alked to him about Bxtr and post and pre-op info. Left copy of pain CME."); Ex. 292 at BEX 000000031 (Call note stating "CME

63. From 2002 to 2005, Pfizer published abstracts and studies regarding the use of Bextra to treat acute, surgical, dental, ankle-sprain and low-back pain as part of its "Promotional Campaign."[39] Pfizer further approved the issuance of a March 25, 2002 press release which reported the results of a study showing "superior efficacy for Bextra vs Vioxx" in severe postsurgical dental pain.[40]

64. From 2002 to 2005, as part of its "selling approach," Pfizer's sales force obtained peri-operative hospital protocols, briefing sheets and standing orders prescribing Bextra for pain before and/or after surgery.[41]

65. From 2002 to 2005, Pfizer's sales representatives "submit[ted] to their own supervisors false, fake requests indicating that doctors had requested off-label information when, in fact, they had not."[42]

66. By August 2004, "Bextra 20mg represent[ed] 25% of [Pfizer's] Bextra starters. Market [was] only 2% dysmenorrhea. Over 50% of [Pfizer's] Bextra 20mg ha[d] been going to providers who don't typically treat primary dysmenorrhea."[43] Based on the call notes produced to it,

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conference in Naples . . . discussing where Celebrex and Bextra fit into his practice. Does he have standing orders pre and post op . . . .").

[39] *E.g.*, Ex. 286 at BEX005414624, 640-42 (specifically targeting Anesthesiologists and Orthopedic Surgeons); Ex. 227 at BEX003565880-82.

[40] Ex. 228 at BEX003567530-32.

[41] *E.g.*, Ex. 281; Ex. 302 at 2BEX000137182; Ex. 303. Pfizer sales representatives' call notes indicate that they showed physicians such standing orders during detailing. *See, e.g.*, Ex. 291 at BEX 000000019 ("[w]ent over pre and post op study as well as standing orders" and "[s]hared pre and post op standing orders w/ him").

[42] *E.g.*, Ex. 240 at 52:6-9.

[43] Ex. 288 at BEX006002253; *see also* Ex. 437 at PFE-JONES 00002308-10.

the DOJ found that 35% of 20 mg starters were distributed to surgeons, podiatrists, dentists and cardiovascular specialists.[44]

67. The Government's repeated threat to charge Pfizer with off-label promotion was a "powerful threat given the way the exclusion rules work" and that "people who are wise and reasonably conservative, don't, you know, expose all of the constituents, the stakeholders of a company the size of Pfizer to ruin [from exclusion] if it can be avoided."[45]

2. Geodon

68. After sending Pfizer a non-approval letter for Geodon (*ziprasidone*) as an antipsychotic drug in June 1998, the FDA approved Geodon for the treatment of schizophrenia on February 5, 2001, for injection in the treatment of acute agitation in schizophrenic patients on June 21, 2002, and as monotherapy in the treatment of acute manic or mixed episodes in Bipolar I Disorder on August 19, 2004.[46]

69. On September 3, 2002, the Department of Health and Human Services ("HHS") sent Pfizer a letter after identifying "misleading oral statements regarding Geodon at Pfizer's promotional booth at the annual meeting of the American Psychiatric Association (APA) . . . in May 2002" made by a Company representative who "volunteered that Geodon 'has antidepressant effects through SSRI [activity].'"[47] HHS informed Pfizer that such a claim was "misleading because Geodon is not

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[44] Ex. 315 at DOJ000230.

[45] Ex. 62 (O'Connor Depo.) at 124:14-125:8.

[46] Ex. 317 at FLAG0012159-60; Ex. 318; http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/20919ltr.pdf; available at http://www.accessdata.fda.gov/drugsatfda_docs/ appletter/2004/20825s009rev2.pdf.

[47] Ex. 319 at FLAG0035512, 514.

indicated for depression" and requested that Pfizer "[i]mmediately discontinue the use of these and any other promotional materials and activities with the same or similar issues."[48]

70. Up to and during the Class Period, Pfizer's sales force continued to discuss the impact of Geodon on depression to physicians during details and the promotional materials provided to the sales force continued to contain references to the effect of Geodon on depressive symptoms.[49]

71. Even though the FDA rejected Pfizer's application to promote Geodon to the pediatric population, Pfizer's sales force detailed Geodon to psychiatrists who specialized in child and adolescent patients.[50]

72. Pfizer's sales force engaged physicians to speak at Pfizer-sponsored events during which the physicians presented information on the use of Geodon in children and adolescents at doses exceeding 160 mg per day and for indications not approved by the FDA.[51]

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[48] Ex. 319 at FLAG0035514.

[49] *See, e.g.*, Ex. 271 (June 5, 2005 call note recorded by sales representative who asked the physician she was detailing to "[c]ontinue to try Geodon [especially] in [patients] with underlying depression"); Ex. 384 at PFE DERIV 00014784-85 (Pfizer's September 2007 CIA provided the content of details for Geodon which referenced "[e]fficacy in depression" and "[g]ood for depression"); Ex. 185 at PG 000305 (promotional piece available to sales force beginning in March 2006 states that "GEODON improved depressive symptoms"); Ex. 186 at PG 000329, 333 (promotional piece available to sales force beginning in September 2006 states that Geodon "Improve[s] depressive symptoms" and "IMPROVE[S] SYMPTOMS[:] Depression).

[50] *See* Ex. 318 at FLAG 00351430; Ex. 498 (April 5, 2001 call note recorded by sales representative who "[s]tated to [child psychiatrist] we are approved for kids" after child psychiatrist indicated "[h]e would like more info on Geodon use in Kids"); Ex. 504 (September 26, 2003 call note recorded by sales representative who obtained a "Commitment" from a child psychiatrist to use Geodon "first line for all her kids"); Ex. 270 (March 9, 2004 call note recorded by sales representative "[t]old [child psychiatrist] that [Geodon] would be a real benefit for children and adolescent patients with the epidemic of obesity in children"); Ex. 384 at PFE DERIV 00014784 (Pfizer's September 2007 CIA provided the content of details for Geodon which referenced "[d]iscussion by phone with a psychiatrist who has experience with Geodon with children").

[51] *E.g.*, Ex. 174 at FLAG0037336 (notes of "pearls from [Dr. Risch's] talk" in January 2003 include "[c]hildren will benefit from G[eodon]," "if partial response to G[eodon], go as high as 240

73. Call notes recorded by Pfizer's sales representatives from 2002 to 2005 indicate that after physicians listened to speakers, including Key Opinion Leaders ("KOLs"), present at Pfizer-sponsored events, they were "more comfortable" prescribing Geodon to children and adolescents at doses exceeding 160 mg per day and for indications not approved by the FDA.[52]

74. Call notes from 2002 to 2005 indicate that Pfizer's sales force detailed Geodon to physicians using dosing information, strategies and/or data from speakers, including KOLs, who spoke at Pfizer-sponsored events regarding the drug's use in children and adolescents at doses exceeding 160 mg per day and for indications not approved by the FDA.[53]

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to 300" and "G[eodon] at 160 is a 'big gun antidepressant'"); Ex. 80 at PG 267295, 300, 302 (slides from Dr. Alessi's October 2003 teleconference titled "Ziprasidone *Applications in Children and Adolescents*" presented use of Geodon in children with Tourette's Syndrome, PDD/Autism and Schizoaffective Disorder/Bipolar with Psychosis and dosing up to 540 mg/day); Ex. 79 at PFE-JONES 00006131 (email attaching slides of Dr. Deutschman who had "approximately 700 patients on Geodon and [wa]s able to show the diagnosis (psychosis, bipolar, anxiety, unipolar depression, etc.), dose of Geodon (up to 480 mg QD), and the age of the patients (which ranges from age 3-88)"); Ex. 509 at PG 267407-08 (slides from Dr. Mech's teleconference, "approved by HQ and Legal," discuss Geodon dosing for treatment-resistant depression, geriatric patients and young children and at higher than approved doses by the FDA); Ex. 173 at FLAG0037887, 894-96, 898 (slides from Dr. Ishii's presentation went over "Geodon's applications: Indication versus off label use," including use in children and adolescents as well as for psychosis, aggression and depression).

[52] *E.g.*, Ex. 143 ("[F]ollowed up with [child psychiatrist] regarding discussion with Dr. Kaye. [S]aid he feels more comfortable to prescribe Geodon . . . will try it for aggression in adolescents."); Ex. 505 (Child psychiatrist "really enjoyed speaking with Dr. Crane for the morning Breakfast. Said it made him feel a lot more comfortable with dosing higher with Geodon in kids . . . ."); Ex. 503 ("After Dr. Kaye's talk, [child psychiatrist] is more comfortable using high dose Geodon."); Ex. 501 ("[child psychiatrist] really liked [M]ech, tried GEo[don] on a few [patients]"); Ex. 507 ("Dr enjoyed Crane program . . . said he will try Geodon lower doses for panic patients on Dr Crane's recommendation.").

[53] *E.g.*, Ex. 500 (child psychiatrist "starting kids on 20 mg geodon . . . I detailed kaye's dosing"); Ex. 497 (Child psychiatrist "very interested in trying Geodon to augment her patients with ADHD/OCD/Agression . . . . [Sales representative to] F/U with Crane's talk and augmentation strategy."); Ex. 506 (sales representative "mentioned Deutschman data showing Geodon's safety and efficacy in children); Ex. 502 (sales representative to follow up with a child psychiatrist by "SHOW[ING] STAHL DATA ON DOSE"); Ex. 142 at FLAG0036532-34 (email circulating slides from Dr. Kaye to Pfizer's sales force for their "VERBAL discussions" with their physicians which

75. On July 19, 2000, the FDA informed Pfizer "that there's no evidence from these trials that ziprasidone has a superior antipsychotic efficacy to" haloperidol (Haldol), thioridazine, olanzapine, risperidone and quetiapine.[54] Pfizer's sales representatives, however, detailed Geodon as superior to Haldol.[55]

3. Zyvox

76. On July 25, 2005, the FDA issued a warning letter to Pfizer and McKinnell concerning certain Zyvox promotional materials.[56] The warning letter demanded that the Company immediately cease any and all claims that Zyvox was superior to vancomycin.[57] The FDA informed Pfizer 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.[58]

77. Pfizer never had substantial evidence between July 2005 and January 2009 to support a claim of Zyvox being superior to, or better than, vancomycin.[59]

78. Pfizer's sales force continued to promote Zyvox as superior to or better than vancomycin between July 2005 and February 2008.[60]

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include dosing recommendations for children and adolescents as well as non-FDA approved indications).

54 Ex. 317 at FLAG0012161-63.

55 *E.g.*, Ex. 499 (June 9, 2004 call note recorded by sales representative detailing a child psychiatrist who "[s]howed Brook study[,] Geodon is 2X as effective as Haldol"); Ex. 508 (August 16, 2004 call note recorded by sales representative who went "over the [B]rook study with [physician] that displayed the superiority over Haldol. A- He said he will use [Geodon] 1st.").

56 Ex. 123 at PZ0034666.

57 Ex. 123 at PZ0034670-71.

58 Ex. 123 at PZ0034668.

59 Ex. 5 (Jewell Report), ¶2.

79. 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.[61]

80. 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.[62] Pfizer's sales force "relied heavily" on these clinical reprints during detailing sessions with physicians.[63]

81. In September 2005, Pfizer instructed its sales force to stand by the Company's detailing message that Zyvox was superior to vancomycin for the treatment of MRSA pneumonia and complicated skin structure infections.[64]

82. 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."[65]

83. During the June 2007 POA II for Zyvox, the message that Zyvox was the "[o]nly Agent to show superior efficacy over vanco[mycin] for MRSA infections" was approved for usage by the sales force.[66]

84. On August 5, 2007, one of Pfizer's consultants told the Company to "[s]top suggesting the superiority of Zyvox over vancomycin."[67]

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60 Ex. 512 at Attachment A.

61 Ex. 204 at PFE DERIV A 00003642; Ex. 512 at Attachment A.

62 Ex. 121 at PFE DERIV 00067564.

63 Ex. 121 at PFE DERIV 00067564.

64 Ex. 140 at Greensmith 003892, 95.

65 Ex. 140 at Greensmith 003892.

66 Ex. 510 at PZ0147345.

85. In December 2007, the DOJ raised the 2005 FDA warning letter concerning Zyvox in communications with Pfizer.[68] Pfizer subsequently admitted to "the scope of the improper [Zyvox] comparative messaging by late January 2008."[69]

4. Lyrica

86. On August 31, 2004, the FDA denied Pfizer the Generalized Anxiety Disorder ("GAD") indication it sought for Lyrica (pregabalin). On December 30, 2004, the FDA approved the drug for use in the management of postherpetic neuralgia ("PHN") and of neuropathic pain (or "NeP") associated with diabetic peripheral neuropathy ("DPN"). On June 10, 2005, the FDA approved Lyrica for use as adjunctive therapy for adult patients with partial onset seizures.[70]

87. From 2005 through 2008, Pfizer's sales force positioned Lyrica as better than Neurontin when detailing physicians.[71]

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[67] Ex. 472 at PFE-JONES 00099408.

[68] Ex. 121 at PFE DERIV 00067562.

[69] Ex. 121 at PFE DERIV 00067571.

[70] Ex. 86; Ex. 308; Ex. 514; Ex. 307 at DFP15404.

[71] *E.g.*, Ex. 359 at LYR000049343-44, 349-57, 359-64, 366, 369-71, 374-76, 379-82; Ex. 449 at PFE-JONES 00027779, 783; Ex. 98 at LYRC-001220787 (slide attached to March 13, 2007 email notes that "comparative claims like 'Lyrica is safer or more powerful that Neurontin'" were "discovered in the field"); Ex. 260 at LYR000003710, 712 (February 1, 2006 report by HawkPartners titled "Lyrica Early User Research – Wave II" stated that Pfizer's sales representatives "emphasized the following points during details": "[i]mproved efficacy relative to other NeP treatments (including Neurontin)" and "[f]aster onset than Neurontin"); Ex. 362 at LYRC-000675327 (slide from May 2006 POA states that "What's Working in the Field" was "[c]ompare & win vs. Neurontin"); Ex. 91 at LYRC-001195868 (A sales representative had "tremendous success asking one simple question – How many patients do you have maxed out on neurontin that are not getting adequate pain relief? [On October 6, 2005 alone, she] had 12 new starts on Lyrica because of this question."); Ex. 374 at LYRC-003155191 (A sales representative was "getting verbal commitments" by detailing with "'[m]y purpose today is to give you a couple of reasons why Lyrica would be a better option for patients with . . . than Neurontin . . . .").

88. During the Class Period, Pfizer's sales force targeted for detailing physicians who prescribed Neurontin.[72]

89. From 2005 through 2008, Pfizer's sales force detailed Lyrica for the treatment of neuropathic pain.[73]

90. During the Class Period, Pfizer's sales force obtained pain protocols prescribing Lyrica.[74]

91. From 2005 to 2008, physicians spoke on behalf of Pfizer regarding how Lyrica was better than Neurontin as well as on off-label uses of Lyrica.[75]

92. From 2005 through 2008, Pfizer's sales force detailed Lyrica by discussing secondary endpoints such as sleep.[76]

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[72] *E.g.*, Ex. 356 at LYR000003739 (A May 31, 2006 report by HawkPartners on "Lyrica Early Users Research" stated that "'Neurontin Switchers' report having been detailed quite frequently, many at least 10-15 times (or more) since Lyrica's arrival in the market."); Ex. 362 at LYRC-000675378 (slide from May 2006 POA states that "What's Working in the Field" was "Target the Gabapentin/Neurontin Business").

[73] *E.g.*, Ex. 358 at LYR000047318 (An October 19, 2005 memorandum by HawkPartners regarding "Topline findings, Lyrica Post-Launch Research" stated that "[m]ost commonly, physicians report that reps talk about Lyrica as a 'new option' for NeP."); Ex. 356 at LYR000003740 (A May 31, 2006 report by HawkPartners on "Lyrica Early Users Research" stated that "[a]cross the board, almost all physicians – Neuros included – note that while epilepsy is mentioned, the clear focus of the details have been on neuropathic pain."); Ex. 98 at LYRC-001220786 (slide attached to March 13, 2007 notes that statements like "'[f]or your patients with neuropathic pain, choose Lyrica'" were seen in sales documents); Ex. 449 at PFE-JONES 00027779-81, 783; Ex. 359 at LYR000049344, 346, 348-67, 369-73, 375-78, 380-81, 384, 386.

[74] *E.g.*, Ex. 373; Ex. 354 at LYR000003069-70; Ex. 365.

[75] *E.g.*, Ex. 363 (A sales representative who attended the MHNI symposium reported that a physician speaker there "referred to Lyrica as a 'cleaner neurontin'" and expressed concern that the speaker discussed Lyrica for "acute pain, generalized anxiety disorder and social anxiety disorder. She even discussed dosing for these indications????"); Ex. 401 at PFE DERIV 00068605 (Pfizer informed the OIG that a speaker who was an anesthesiologist "had discussed the use of Lyrica as part of a peri-operative surgical protocol during a Pfizer-sponsored program.").

B. Defendants' Class Period Statements Regarding the Nature, Status, Scope and Financial Risks of the Government Investigation Were False and Misleading

93. In June 2003, Pfizer and the DOJ reached a tentative proposed settlement with regard to the DOJ's investigation into the unlawful off-label promotion of Neurontin.[77]

94. In November 2003, Pfizer stressed to the DOJ that the Neurontin off-label promotional problems were due to Warner-Lambert's conduct prior to Pfizer's acquisition of Warner-Lambert, but that Pfizer "emphasizes integrity and enforces compliance" with regard to the promotion of all of its products.[78]

95. In early 2004, Pfizer publicly disclosed that the DOJ was "conducting investigations relating to the marketing and sale of Genotropin and Bextra."[79]

96. Pfizer's own disclosure counsel, Larry Fox, acknowledged that the term "marketing" "includes many other things" beyond off-label promotion.[80]

97. In August/September 2006, Assistant U.S. Attorney ("AUSA") Sara Bloom made a presentation to Pfizer's representatives that reflected the Government's awareness of the following occurrences from September 2004:

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[76] *E.g.*, Ex. 362 at LYRC-000675378 (slide from May 2006 POA states that "What's Working in the Field" was "[l]everage the Secondary Outcomes (not indicated)"); Ex. 354 at LYR000003071-72 (Chris Cuzzola's narrative describes a luncheon with a physician during which a fellow sales representative "explained how to access Lyrica outside of indication" and "suggested . . . 'increase the bedtime dose to decrease pain at night so the patient sleeps better, while reducing daytime side effects like dizziness and sleepiness'"); Ex. 359 at LYR000049356, 364, 368, 379, 385.

[77] Ex. 249 at DOJ000194.

[78] Ex. 249 at DOJ000194.

[79] Ex. 217 at 9.

[80] Ex. 49 (Fox Depo.) at 140:11-17.

- Pfizer sponsored a promotional program during which both Bextra and Neurontin were promoted for off-label purposes;
- a Message Recall Report stated that Pfizer's main detailing message to doctors was to prescribe Bextra for acute pain; and
- a Starter Optimization Report demonstrated that Pfizer was continuing to instruct the sales force to increase the number of 20 mg Bextra samples left with orthopedic surgeons.[81]

98. As AUSA Bloom outlined, Pfizer continued to unlawfully promote Bextra for off-label purposes despite:

- the DOJ's ongoing criminal investigation into the unlawful promotion of Neurontin;
- past promotional practices that had forced the Company to enter into two CIAs;
- the DOJ's disclosure to Pfizer of a Bextra *qui tam* complaint alleging the unlawful promotion of Bextra; and
- the DOJ's disclosure of its ongoing investigation into alleged off-label promotion of Bextra.[82]

99. On September 14, 2007, Pfizer met with the DOJ again to discuss the Bextra Investigation.[83] Shortly after that meeting, on October 1, 2007, Pfizer's criminal defense counsel, Covington, informed the Government that the proper way to determine the fine for the off-label promotion of Bextra would be to use the methodology employed in the "analogous" Neurontin case, where the Government based its fine calculation on the actual gain that was directly attributable to the defendant's illegal conduct.[84]

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81 Ex. 258 at DOJ000196.

82 Ex. 258 at DOJ000208.

83 Declaration of Joseph G. Petrosinelli in Support of Pfizer's Motion for Summary Judgment ("Petrosinelli Decl."), Ex. K-4.

84 Petrosinelli Decl., Ex. B-6.

100. On April 25, 2005, a Pfizer employee emailed KPMG about Pfizer's controls over sales and marketing expenses. He wrote, "[t]his is probably better discussed live though as I'm not sure we would agree that potential issues indicate a control deficiency."[85] The next day KPMG responded, "[t]hey are control deficiencies!! [A]nd they cannot be fully remediated until the DOJ investigation is complete."[86]

101. In 2005, IA issued unsatisfactory audit ratings concerning controls over Health Care Compliance ("HCC"). Several areas received an unsatisfactory rating, including Independent Research Grants, Salesforce Travel & Entertainment and Salesforce Call Notes & E-mail.[87]

102. The Call Notes audit report made no reference to any analysis of Bextra call notes, but acknowledged "[b]ecause the subjects of the planned audit are at issue in pending . . . federal government investigations . . . in-house Pfizer counsel and attorneys for the law firm of Covington and Burling provided direction to [IA] regarding the conduct of the audit."[88]

103. In 2005, Pfizer's IA Group issued an unsatisfactory report on the Company's Sales Travel & Entertainment reporting as it related to Pfizer's sales force.[89] Also, KPMG informed Pfizer's Audit Committee that the Company had a significant deficiency in its internal controls over

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85 Ex. 149 at KPMG-PFIZ-DS 033647.

86 Ex. 149 at KPMG-PFIZ-DS 033647.

87 Ex. 114 at PFE DERIV 01064278; Ex. 324 at KPMG-PFIZ-DS 007259 (observing internal controls over Independent Research Grants approval, closure and reconciliation unsatisfactory); *id.* (observing "overall lack of documentation procedures over the process and [no effective process to] track that all speakers have been trained on the FDA approved uses of Pfizer products"); Ex. 103 at 007298-7300 (call notes did not sufficiently monitor whether sales force was complying with HCC law).

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

89 Ex. 266 at KPMG-PFIZ-DS 0006230, 233; Ex. 7 (Regan Supplemental Report) at 71.

financial reporting as they relate to its sales and marketing practices pursuant to ¶140 of PCAOB Standard No. 2.

104. With regard to Sales Travel & Entertainment, in June 2007, IA issued another unsatisfactory report on the basis that "[t]here has been no recognizable improvement in T&E policy compliance, which we believe is the result . . . of an audit methodology that does not effectively identify and communicate high risk findings."[90]

105. On July 20, 2005, the FDA issued a "Warning Letter" to Pfizer instructing the Company to cease and desist from making the unsubstantiated and unlawful claim that Zyvox was superior to vancomycin.[91] Despite the FDA's issuance of the Warning Letter, the Company continued to actively promote Zyvox using the superiority claim on a widespread basis until at least February 2008.[92] Pfizer approved the detailing materials used by the sales force that claimed Zyvox to be "better" and/or "superior" to vancomycin.[93]

106. In March 2006, IA, in assessing Pfizer's HCC risks for 2006, concluded that unlawful off-label promotion was "Almost Certain/Highly Likely" to occur and was expected to have a "High" "severity of impact."[94] IA defined high severity to mean: (a) greater than $1 billion impact on profitability; (b) sustained loss of market share; (c) significant diminution in reputation; or (d) sustained reduction in market capitalization.[95]

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90 Ex. 119 at PFE DERIV 00077688.

91 Ex. 123 at PZ0034668.

92 *See* Ex. 512 at Attachment A.

93 Ex. 182 at PFE-JONES 00006231.

94 Ex. 105 at PFE DERIV 01002348, 350.

95 Ex. 105 at PFE DERIV 01002341.

107. During 2006, IA issued unsatisfactory audit ratings regarding HCC controls USMI 30, Advisory Board/Consultant Payments, and the remediation of a prior unsatisfactory Promotional Funds audit.[96]

108. On October 24, 2006, Hugh Donnelly ("Donnelly"), Vice President of IA, indicated that Pfizer was concerned that it may have a significant deficiency or material weakness over HCC controls.[97] Donnelly added that Pfizer's independent auditor, KPMG LLP ("KPMG"), did not see how the number of unsatisfactory audit reports concerning HCC controls did not rise at least to the level of a significant deficiency.[98]

109. Chuck Mooney ("Mooney"), Director of Corporate Internal Audit, authored a Healthcare Compliance Overview that was shared with Pfizer's executives on October 25, 2006.[99] In the document shared with Pfizer's CFO and other Pfizer executives, Mooney indicated a number of key observations, including: (i) lack of clear accountability; (ii) guidelines exist (White Guide, Orange Guide), but often no one monitors to ensure they are followed; (iii) SOPs may not exist to support the guidelines; (iv) a reactive approach to controls; and (v) a slow pace of remediation.[100]

110. In November 2006, Mooney circulated a memo that stated "we have reviewed the results of 2006 US Pharmaceutical Operations (USPO) Healthcare Compliance (HCC) audits, the remediation status of 2005 HCC audit issues and the results of recent HCC investigations undertaken

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96 Ex. 114 at PFE DERIV 01064279.

97 Ex. 114 at PFE DERIV 01064273.

98 Ex. 114 at PFE DERIV 01064273.

99 Ex. 114 at PFE DERIV 01064274.

100 Ex. 114 at PFE DERIV 01064282.

by Legal Corporate Compliance."[101] Mooney went on to conclude that because of the various control weaknesses recently identified, Pfizer's U.S. pharmaceutical operations ("USPO") "does not have an effective healthcare law regulatory compliance function."[102] Mooney further observed regarding the control weaknesses identified as existing in 3Q06:

> Violations of laws and regulations resulting from the failure to properly monitor and ensure compliance with HCC risks could subject the Company to harm to its reputation, as well as potentially significant fines and additional oversight by the government, through additional Corporate Integrity Agreements, or loss of government business. In general, such violations normally would ***not*** have a material effect on the reliability of financial reporting, which is necessary for an ineffective regulatory compliance function to result in a significant deficiency under PCAOB Standard #2. However, in the current unique and unprecedented regulatory environment facing USPO [United States Pharmaceutical Operations], where there are active discussions with regulators to resolve past HCC issues (and the real possibility of fines and other restrictions to our business), the link to financial reporting as a result of ongoing failures to properly monitor controls in this area becomes more direct.[103]

IA's conclusion that an ineffective regulatory compliance function existed as of 3Q06 was based on "a pattern of control issues, particularly around the monitoring element of the control framework."[104]

111. On November 9, 2006, Donnelly sent an email to Lankler, attaching Mooney's November 2006 memo concerning the evaluation of HCC control risks as of 3Q06.[105] Donnelly informed Lankler that the memo was authored to support Pfizer's conclusion it had a "significant deficiency in U.S. Sales and Marketing regulatory compliance area" and noted the following "sensitive language":

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101 Ex. 115 at PFE DERIV 01001559.

102 Ex. 115 at PFE DERIV 01001560.

103 Ex. 115 at PFE DERIV 01001560 (emphasis in original).

104 Ex. 151 at KPMG-PFIZ-DS 045076.

105 Ex. 161 at PFE-JONES 00005988.

> ***We conclude that [USPO] does not have an effective healthcare law regulatory compliance function. . . . It is possible, then, that violations of laws and regulations resulting from this ineffective HCC compliance function could be seen as having a material effect on the reliability of financial reporting and as a significant deficiency for SOX purposes.***[106]

112. As of December 31, 2006, Pfizer had not remediated the significant deficiency in the U.S. Sales and Marketing regulatory compliance area identified to be in existence as of September 30, 2006.[107]

113. On February 23, 2007, IA issued another unsatisfactory audit report on HCC controls in place governing Worldwide Medical Publications and Authorships.[108] One of the key control deficiencies identified was a lack of sufficient procedures and processes in place during 2006 to ensure that Pfizer sales and marketing employees did not alter scientific content in Pfizer-sponsored publications.[109]

114. As of March 31, 2007, Pfizer concluded that the "ineffective regulatory compliance function within USPO" remained unremediated.[110]

115. The Review Committee is described in Pfizer's policies and procedures manuals as one of the most important processes in place to ensure that the sales force complies with HCC law and regulations.[111]

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106 Ex. 161 at PFE-JONES 00005988, 91 (emphasis in original).

107 Ex. 326 at KPMG-PFIZ-DS 0070311.

108 Ex. 75 at PFE DERIV 00075605.

109 Ex. 75 at PFE DERIV 00075613.

110 Ex. 117.

111 Ex. 100 at BEX 000002856 ("***Only*** RC-approved materials may be used to promote our products.") (emphasis in original).

116. Pfizer's Worldwide Pharmaceutical Operations Compliance Committee reviewed a presentation in October 2007 summarizing the findings of the "deep dive" initiated by defendant Read in March 2007 in response to the existence of the 3Q06 significant deficiency.[112] The presentation describes how, between at least September 2006 and September 2007, Pfizer's Review Committee process lacked controls to assure consistency, a single owner of the process, and lacked accountability.[113] The presentation also noted that the Review Committee process neither documented nor tracked HCC issues and that the "guidelines do not include discipline for violations of compliance issues."[114]

117. KPMG never issued an audit opinion concerning Pfizer's internal controls over HCC.[115]

IV. SCIENTER

A. Neurontin Resolution

118. On May 13, 2004, the USAO sent a letter to Warner-Lambert LLC ("Warner-Lambert") setting forth the plea agreement between Warner-Lambert and the USAO concerning allegations of off-label promotion of Neurontin.[116] The letter describes how the $430 million settlement amount was calculated using the U.S. Sentencing Guidelines ("USSG").[117]

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112 Ex. 203 at 2.

113 Ex. 203 at 2.

114 Ex. 203 at 3.

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

116 Ex. 229.

117 Ex. 229 at 1-2.

119. On October 13, 2005, the USAO sent a letter to Serano Laboratories, Inc.'s counsel, Nixon Peabody, LLP, concerning allegations of, *inter alia*, fraudulently delivering adulterated medical devices and paying illegal remuneration to healthcare providers with regard to the drug Serostim.[118] The letter describes how the $137 million settlement amount was calculated using the USSG.[119]

120. On January 15, 2007, the USAO filed its Sentencing Memorandum with the United States District Court for the District of Massachusetts in the case captioned *United States v. Schering Sales Corp.*, No. 06-10260-PBS (Jan. 15. 2007).[120] The Sentencing Memorandum reflects the global agreement between the USAO and Schering Sales Corp. concerning various alleged unlawful conduct, including the off-label promotion of pharmaceutical products.[121] The Sentencing Memorandum describes how the $435 million settlement was calculated using the USSG.[122]

121. On March 21, 2007, the USAO sent a letter to Pharmacia & Upjohn Co., Inc.'s ("Pharmacia") counsel, Covington, concerning allegations of inflated payments on a contract to

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[118] Ex. 517 (Letter from Michael J. Sullivan, U.S. Attorney, District of Massachusetts, to Henry J. DePippo and Melissa Tearney, Nixon Peabody, LLP (October 13, 2005)).

[119] Ex. 517 at 3-5 (Letter from Michael J. Sullivan, U.S. Attorney, District of Massachusetts, to Henry J. DePippo and Melissa Tearney, Nixon Peabody, LLP (October 13, 2005)).

[120] *See* Ex. 518 (Government's Sentencing Memorandum, the United States District Court for the District of Massachusetts in the case captioned *United States v. Schering Sales Corp.*, No. 06-10260-PBS (Jan. 15, 2007) (Dkt. No. 30)).

[121] Ex. 518 at 4 (Government's Sentencing Memorandum, the United States District Court for the District of Massachusetts in the case captioned *United States v. Schering Sales Corp.*, No. 06-10260-PBS (Jan. 15, 2007) (Dkt. No. 30)).

[122] Ex. 518 at 29-32 (Government's Sentencing Memorandum, the United States District Court for the District of Massachusetts in the case captioned *United States v. Schering Sales Corp.*, No. 06-10260-PBS (Jan. 15, 2007) (Dkt. No. 30)).

induce another party to recommend purchasing or ordering Genotropin.[123] The letter describes how the $37 million settlement amount was calculated using the USSG.[124]

B. Bextra Resolution

122. In early 2004, the Government informed Pfizer that it was investigating the *qui tam* complaint of one of the Company's former Florida sales representatives, John Kopchinski ("Kopchinski"), who alleged that Pfizer had encouraged its sales representatives to promote Bextra for off-label uses, including for surgical and general acute pain ("Kopchinski's Complaint").[125]

123. Soon after learning of Kopchinski's Complaint, in March 2004, Pfizer issued a Company-wide document hold for all Bextra-related documents.[126]

124. Led by Covington, Pfizer's Investigation Counsel commenced an internal Bextra Investigation that paralleled the Government's investigation.[127]

125. On July 15, 2004, Pfizer's outside counsel, Covington, presented "a pretty extensive slide deck" relating to the marketing and sale of Bextra to the DOJ and OIG.[128] The slide deck noted that a *qui tam* complaint had been filed alleging the promotion of "Bextra for 'Acute Pain'" through "Improper Comparison to Vioxx," "Improper Dissemination of Medical Literature," "Protocols and Standing Orders," "Use of Physician Consultants" and for "Pre- and Post-Operative Use" as well as

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123 Ex. 519 (Letter from Michael J. Sullivan, U.S. Attorney, District of Massachusetts, to Ethan M. Posner, Covington & Burling LLP (March 27, 2007)).

124 Ex. 519 at 2-3 (Letter from Michael J. Sullivan, U.S. Attorney, District of Massachusetts, to Ethan M. Posner, Covington & Burling LLP (March 27, 2007)).

125 Ex. 283 at BEX001800573.

126 Ex. 236 at BEX000398151; Ex. 244 at PFE-JONES 00103712-13.

127 Ex. 242 at BEX004849786.

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

the promotion of Bextra "20 Mg for Uses Other Than Primary Dysmenorrhea."[129] The slide deck also noted Pfizer's "Review of Headquarters Bextra Sales Marketing Practices" and its "Ongoing Review of Select Geographic Areas," which included a finding from a "Physician Recall Report March 2004" that "acute pain/inflammation now [wa]s the leading Bextra usage discussion" between sales representatives and physicians.[130]

126. In or around August 2004, one of Pfizer's District Managers, Thomas Farina ("Farina"), instructed his subordinate sales representatives to delete or alter certain internal documents related to Bextra.[131]

127. In late fall 2004, Pfizer and its Investigation Counsel learned that the internal documents that Farina had instructed his subordinates to delete or alter included surgical protocols and instruction sheets as well as a Plan of Action ("POA") guide that included the following goals: "[g]et Bextra added to hospital formularies . . . for use in the acute, peri-operative setting with the overall goal of getting the patient to remain on Bextra long term," and "[g]et Bextra added to pre-op briefing sheets in other surgical subspecialties – podiatry, general surgery, plastic surgery, ENT, etc."[132]

128. During the November 16-17, 2004 meeting between Investigation Counsel and the Government, Pfizer made a presentation entitled "Pfizer Inc. Review and Voluntary Disclosure

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129 Ex. 247 at PFE DERIV 00066670.

130 Ex. 247 at PFE DERIV 00066698, 706.

131 Ex. 244 at PFE-JONES 00103713; Ex. 511 at TF0000197-99.

132 Ex. 244 at PFE-JONES 00103717-18; Ex. 304 at BKLYN 000000063-64.

Relating to Bextra Allegations."[133] The presentation included the results of Bextra-related surveys of Pfizer's sales force, which stated that:

(a) Pfizer's District Managers "find specific reference to OA, RA and PD needlessly restrictive."[134]

(b) "Several respondents from both Pfizer and Pharmacia mention their discomfort in delivering the desired positioning. They note that it is Celebrex that has the acute pain data vs. narcotics that they can show to physicians, yet they are being asked to position Bextra for the acute patient."[135]

(c) The slide deck noted that after "Hundreds of Thousands of Documents Reviewed" and "Over 70 Interviews Conducted," Pfizer found that it was a "Senior Management Decision to Make Available Under WLF" a Bextra reprint on "Dental Pain (vs. Tylox)," and that surveys of the sales force and the physicians they detailed revealed "[m]any [sales representatives] communicat[ing] '10 mg. is for OA and RA and 20 mg. is for acute pain states,'" and that "[t]he most common positioning is . . . 'Bextra for acute pain,'" although "[s]everal . . . mention[ed] their discomfort in delivering the desired positioning [because] it is Celebrex that has the acute pain data vs. narcotics that they can show to physicians, yet they are being asked to position Bextra for the acute patient."[136]

129. On September 26, 2005, Pfizer's Legal Division reported that "it is our estimation based on the facts and circumstances to date that we are likely to be forced to reach some form of

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133 Ex. 397; Ex. 211 at PFE-JONES 00006993-94.

134 Ex. 397 at PFE DERIV 00066528.

135 Ex. 397 at PFE DERIV 00066599.

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

settlement of [the Bextra Investigation]."[137] At the time, Kindler knew that Pfizer had admitted to the Government that Pfizer employees had destroyed documents relevant to the Bextra Investigation.[138]

130. On September 27, 2005, Pfizer and its Investigation Counsel produced to the DOJ the Bextra-related internal documents that Pfizer's sales representatives had attempted to delete or alter along with a detailed letter setting forth descriptions of the documents "corroborating the employees' confessions," which included "Mr. Bermudez's admission that he altered pre-operative surgery instructions sheets by deleting references to Bextra" and District Manager Farina's admission "that he made similar modifications to pre-operative surgery instructions sheets on his own laptop and likewise altered his laptop time setting to backdate the modifications."[139]

131. On August 17, 2006, the Government presented to Pfizer several slide decks and hundreds of documents demonstrating Pfizer's widespread off-label promotion of Bextra:

(a) The slide deck titled "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

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137 Petrosinelli Decl., Ex. P-5 at PFE-JONES 00043523-24.

138 Ex. 244; Ex. 160 at PFE-JONES 00005332; Ex. 54 (10/10/14 Kindler Depo.) at 37:12-38:6, 39:10-19; Ex. 55 (Lankler Depo.) at 81:13-19.

139 Ex. 244 at PFE-JONES 00103714, 718, 720.

Influence doctors" at "Consultant Meetings/Advisory Boards," "Control of purportedly independent CME," and the "Publication Strategy"; and (5) that "HQ knowledge" was demonstrated by the "Bextra Positioning for Acute Pain" and "Headquarters knowledge of promotion for unapproved uses."[140]

(b) The slide deck titled "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" the DOJ was considering bringing against Pfizer, which included Food, Drug and Cosmetic 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 Conduct continued despite: [o]ngoing Neurontin criminal investigation[,] Two CIA's[,] Two self-disclosures on other issues[,] [n]umerous internal complaints and red flags [and] [d]isclosure of the Bextra *qui tam* complaint and ongoing Bextra investigation."[141]

(c) The slide deck titled "Summary of Bextra Call Note Evidence" presented call note excerpts by sales representatives all over the United States.[142] Consistent with the *qui tam* complaint allegations and exhibits, as well as the deleted and altered documents, these call notes reflected the repeated promotion of Bextra for usages and dosages that the FDA had explicitly rejected: for general acute and pre/post/peri-operative pain.[143] The Government presented statistics gathered from Pfizer's call notes that demonstrated that the Company's sales representatives referred

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140 Ex. 256 at DOJ000235-40.

141 Ex. 258 at DOJ000199, 205, 207-08.

142 Ex. 251.

143 Ex. 251; Ex. 309 (SUF, ¶¶62-63).

to off-label indications during sales calls with physicians at least as often as they referred to on-label indications.[144]

(d) The Government estimated that 76% of total Bextra revenue was from non-approved indications and calculated that 52% of total Bextra revenue was for 20 mg doses.[145]

(e) The Government presented an analysis of call-note data that indicated that Pfizer's sales representatives had given out 20 mg Bextra samples in over 1.3 million sales calls to physicians who would not typically prescribe medication for patients suffering from PD (*e.g.*, surgeons, cardiovascular specialists and dentists) as evidence that Pfizer had promoted 20 mg Bextra for unapproved indications.[146]

(f) The Government quoted call notes from different Pfizer sales representatives in different states across the country, which reflected the promotion of Bextra with the false claim that Bextra had no dose-related increases in hypertension and edema.[147] This false representation was a "Core Message" in Pfizer's Northeast Region.[148] Yet, any such representation directly contradicted the FDA's documented concerns and observations that Bextra users did experience dose-related increases in hypertension and edema.[149] Defendants' own criminal law expert admitted that he was unaware of ***any*** defenses, let alone "substantial defenses," for such conduct.[150]

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144 Ex. 313 at 90 (SUF, ¶69).

145 Ex. 258 at DOJ000201, 203.

146 Ex. 315 at DOJ000230 (SUF, ¶64).

147 Ex. 311 (SUF, ¶65).

148 Ex. 253.

149 Ex. 242 at BEX004849876.

150 Ex. 66 (Theodorou Depo.) at 64:23-65:11.

132. 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.[151]

133. The Government's August/September 2006 presentations also reflected the Government's awareness of the following:

- Pfizer sponsored a promotional program during which both Bextra and Neurontin were promoted for off-label purposes;
- a Message Recall Report stated that Pfizer's main detailing message to doctors was to prescribe Bextra for acute pain; and
- a Starter Optimization Report demonstrated that Pfizer was continuing to instruct the sales force to increase the number of 20 mg Bextra samples left with orthopedic surgeons.[152]

134. As the Government outlined, Pfizer continued to unlawfully promote Bextra for off-label purposes despite:

- the DOJ's ongoing criminal investigation into the unlawful promotion of Neurontin;
- past promotional practices that had forced the Company to enter into two CIAs;
- the DOJ's disclosure to Pfizer of a Bextra *qui tam* complaint alleging the unlawful promotion of Bextra; and
- the DOJ's disclosure of its ongoing investigation into alleged off-label promotion of Bextra.[153]

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

152 Ex. 258 at DOJ000196.

153 Ex. 258 at DOJ000208.

135. The Government's presentation, which defendants either received, or chose not to receive, included multiple slides of "aggravating factors." These aggravating factors included:

- The FDA said ***No***.
- The FDA's concern was ***Safety***.
- Safety ***Is*** the issue.
- Knowledge at the Top.
- A Deliberate Scheme.

136. Pfizer possessed all the call notes that were the focus of the Government's presentations, and defendants had access to all of Pfizer's call notes, as well as a list of all the call notes that the Government cited during its presentations.[154] Defendants received, or chose not to seek, all of the information conveyed during those August and September 2006 presentations.[155]

137. On September 14, 2007, Pfizer met with the DOJ again to discuss the Bextra investigation.[156] Shortly after that meeting, on October 1, 2007, Pfizer's criminal defense counsel, Covington, informed the Government that the proper way to determine the fine for the off-label promotion of Bextra would be to use the methodology employed in the "analogous" Neurontin case, where the Government based its fine calculation on the actual gain that was directly attributable to the defendant's illegal conduct.[157]

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[154] Ex. 211 at PFE-JONES 00006996-7012; Ex. 54 (10/10/14 Kindler Depo.) at 53:10-54:2, 77:20-24; Ex. 58 (9/23/14 Levin Depo.) at 18:6-24 (a Pfizer Executive would receive any information he requested).

[155] Ex. 211 at PFE-JONES 00006996-7012; Ex. 54 (10/10/14 Kindler Depo.) at 53:10-54:2, 77:20-24; Ex. 58 (9/23/14 Levin Depo.) at 18:6-24 (a Pfizer Executive would receive any information he requested).

[156] Petrosinelli Decl., Ex. K-4.

[157] Petrosinelli Decl., Ex. B-6 at PFE-JONES 00059190.

138. On February 5, 2008, Pfizer authorized its counsel to communicate to the Government a "prepared-to-recommend" settlement offer of $50-$70 million.[158]

139. Later in the day on February 5, 2008, the Government sent Pfizer a grand jury target letter that expressly informed Pfizer that it was the target of a grand jury investigation concerning "the introduction of misbranded and unapproved drugs, including specifically Bextra, into interstate commerce."[159]

140. On March 28, 2008, Pfizer authorized its counsel to communicate to the Government a "prepared-to-recommend" $250 million settlement offer.[160]

141. On April 4, 2008, the Government sent Pfizer a letter outlining its demands in the Bextra Investigation: felony plea, a criminal fine of $3.6 billion, a civil fine of $1.2 billion and remedial measures.[161]

142. In or around June 2008, Pfizer authorized its counsel to communicate to the Government a "prepared-to-recommend" offer of $750 million to settle the Government Investigation.[162]

143. The Government's repeated threat to charge Pfizer with off-label promotion was a "powerful threat given the way the exclusion rules work" and that "people who are wise and

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158 Ex. 104 at PFE-JONES 0007028; Ex. 55 (Lankler Depo.) at 124:12-22.

159 Ex. 131 (target letter).

160 Petrosinelli Decl., Ex. Y-6 at PFE DERIV 00066378; Ex. 55 (Lankler Depo.) at 124:12-22.

161 Petrosinelli Decl., Ex. Y-6.

162 Ex. 55 (Lankler Depo.) at 124:12-22; Ex. 437 at PFE-JONES 00002261.

reasonably conservative, don't, you know, expose all of the constituents, the stakeholders of a company the size of Pfizer to ruin [from exclusion] if it can be avoided."[163]

C. Committees/Boards/Certification Meetings

144. Members of the Corporate Compliance Committee regularly attended meetings during which specific allegations of Pfizer's violations of laws concerning illegal kickbacks, improper use of starters, improper influencing of doctors through speaker programs, improper CME programs and the off-label promotion of various products – including Bextra – were compiled, analyzed and tracked through the legal process.[164] Compliance Committee members were responsible for helping "[a]void potential harm to reputation [of] Pfizer and allies."[165]

145. The Individual Defendants were high-ranking executives at Pfizer, who were members of the Company's Executive Committee or Executive Leadership Team ("ELT") and were

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163 Ex. 62 (O'Connor Depo.) at 124:14-125:8.

164 *E.g.*, Ex. 417 at PFE DERIV 01146196 (Distribution included Kindler, Levin and Waxman), 198, 206 ("improperly utilized speaker program funds"), 207 ("Bextra off label"), 208 (New York Attorney General requested documents relating to "clinical study disclosure and off-label issues" of Geodon and five other drugs), 215 ("District Manager [DM] provided inappropriate direction to representatives related to the use of unapproved detailing materials"), 218 ("improper promotion" and "improper payments to physicians" involving Bextra), 226 (representative "improperly paid doctors in connection with dinner and speaker programs" and "detailed a product using unapproved detailing material"), 230 ("improperly distributed samples"), 233 (District Manager "mis-uses grants and speaker programs to improperly influence doctors"); Ex. 409 at PFE DERIV 00069303-04, 312, 315 (same); Ex. 410 at PFE DERIV 00069325-26, 329 (same), 344 ("inappropriate and improper events in violations of Healthcare Law with doctors"); Ex. 386 at PFE DERIV 00023695, 697, 718-20, 730, 740 (same); Ex. 407 at PFE DERIV 00069214-16, 225 (same), 222 ("inappropriate direction to representatives related to the use of unapproved detail materials"); Ex. 408 at PFE DERIV 00069233-34, 237, 253 (same); Ex. 530 at PFE DERIV 00024320, 322, 331-32, 341, 349, 368; Ex. 385 at PFE DERIV 00023983, 3985, 4007, 4010, 4016, 4018-19, 4025-26; Ex. 389 at PFE DERIV 00024460, 464, 488, 492, 494, 497, 499-500; Ex. 406 at PFE DERIV 00069064, 68, 92, 95-96, 98, 101, 103-04; Ex. 390 at PFE DERIV 00024511, 513, 518, 522, 546, 550, 552, 555, 558).

165 Ex. 386 at PFE DERIV 00023700.

specifically identified as such in the Company's SEC filings.[166] Kindler was a member of the Pfizer Executive Committee until becoming Pfizer's CEO on August 1, 2006.[167] The Executive Committee, chaired by McKinnell, was the "company's top decision-making team, responsible for vision, strategic direction and operations of the company."[168] The Executive Committee reviewed and approved "all major management, operating and financial decisions."[169] Waxman and Read were members of Pfizer's ELT, which was formed by Kindler to replace the Executive Committee as the Company's decision-making team. The ELT, "comprised of Pfizer's senior-most leadership," was the "single senior operating body responsible for running the company."[170] The ELT was charged with "making decisions relating to issues of enterprise-wide significance, such as the company's strategic and operating plans."[171] The ELT held quarterly meetings to discuss quarterly results and significant matters. The ELT was responsible for identifying potential disclosure items to be communicated to the CFO.[172] The ELT also was responsible for reviewing the third draft of SEC filings and making comments on that draft.[173] Once the ELT's comments were incorporated into the document, the final version of the SEC filing was generated.[174] Pfizer's ELT was also responsible

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166 Petrosinelli Decl, Exs. B-1, D-1, F-1.

167 Kindler signed each of the Company's 10-Qs and 10-Ks after he was named Pfizer's CEO.

168 Ex. 238 at Litwac-A 10000354339.

169 Ex. 238 at Litwac-A 10000354339.

170 Ex. 202 at KPMG-PFIZ-DS 037982.

171 Ex. 202 at KPMG-PFIZ-DS 037982.

172 Ex. 452 at PFE-JONES 00032754.

173 Ex. 126.

174 Ex. 126.

for approving settlements of legal cases in amounts greater than $100 million or involving unusual issues.[175]

146. As Executive Committee/ELT members, McKinnell, Kindler, D'Amelio, Waxman and Read attended meetings to discuss quarterly results and significant matters on a quarterly basis.[176] For example, the ELT meeting minutes from April 10, 2007 state that ELT members (at that time) Kindler, Waxman and Read were asked to return their comments on the April 20, 2007 earnings release (FMS No. 20) by the end of the day.[177] Similarly, a draft of the July 20, 2006 earnings press release (FMS No. 8), was provided to the Executive Committee for approval.[178] Minutes of the ELT meeting on September 26, 2006 provide another example of its responsibility for press releases. At that meeting, Kindler, Read and Waxman discussed a proposed communication strategy for Pfizer to follow over the next six months, including the upcoming October 19, 2006 earnings call (FMS No. 11 was the press release ultimately issued that day) and the January 2007 earnings press release (FMS No. 15).[179] As Pfizer's CFOs during the Class Period, D'Amelio and Levin held an "earnings review meeting at the end of the quarter to discuss significant matters."[180] And "[d]uring this meeting, a first draft of the earnings release" was reviewed.[181] Later, the CFO (Levin or D'Amelio) was required to engage in a conference call with the Company's General

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175 Ex. 202 at KPMG-PFIZ-DS 037981, 986.

176 Ex. 452 at PFE-JONES 00032754.

177 Ex 341.

178 Ex. 239 at PFE DERIV 01029370 ("Final Draft for EC Approval").

179 Ex. 202 at KPMG-PFIZ-DS 037989, 981.

180 Ex. 452 at PFE-JONES 00032754.

181 Ex. 452 at PFE-JONES 00032754.

Counsel (Kindler or Waxman), "to review the quarterly earnings release and attached schedules (income statement, balance sheet and segment data)."[182]

147. Prior to ascending to the CEO role, Kindler was a member of the Company's Disclosure Committee.[183] Waxman, who was promoted to General Counsel when Kindler became CEO, replaced Kindler as a member of the Disclosure Committee in August 2006.[184] D'Amelio and Levin were also members of the Disclosure Committee at Pfizer.[185] The Disclosure Committee met each quarter before the earnings release.[186] The Disclosure Committee was charged with reviewing each disclosure document, including SEC filings, and evaluating issues of materiality and disclosure.[187] The chair of the Disclosure Committee reported findings and conclusions directly to the CFO.[188] The Disclosure Committee was charged with assisting the CFO and CEO in fulfilling their responsibility for overseeing Pfizer's disclosures.[189] They also reviewed disclosure controls and procedures relating to the preparation of "press releases containing financial information, guidance, information about material acquisitions or dispositions or other information material to the Company's security holders."[190] More importantly, the Disclosure Committee's role was to

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182 Ex. 452 at PFE-JONES 00032755.

183 Petrosinelli Decl., Ex. V-6 at PFE-JONES 00036383, 451, 457, 510, 684.

184 Ex. 126 at KPMG-PFIZ-DS 053822.

185 *E.g.*, Petrosinelli Decl., Ex. V-6 at PFE-JONES 00036383, 451, 457, 510, 589, 684, 688, 782, 798.

186 Ex. 126 at KPMG-PFIZ-DS 053822; *see also* Ex. 124 at PFE-JONES 00036746.

187 Ex. 452.

188 Ex. 452 at PFE-JONES 00032756.

189 Ex. 126 at KPMG-PFIZ-DS 053822.

190 Ex. 126 at KPMG-PFIZ-DS 053822; *see also* Ex. 124 at PFE-JONES 00036746.

"oversee the filing process by reviewing each disclosure document and evaluating issues of materiality and disclosure."[191] In their roles as General Counsel, both Kindler and Waxman were responsible for the Legal Proceedings Disclosures and were charged with their ultimate approval.[192] As CEO and CFO at different times during the Class Period, defendants McKinnell, Levin, Kindler and D'Amelio had ultimate authority over any Pfizer press releases.[193]

148. McKinnell was the Chair or Member of Pfizer's Board of Directors from April 2001 through February 2007.[194] As a Board Member, McKinnell reviewed drafts of the 2006 Annual Proxy Statement and approved the final version.[195] McKinnell had ultimate authority over the statements contained in that document.[196]

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191 Ex 452.

192 Ex. 452 at PFE-JONES 00032755.

193 Ex. 464 at PFE-JONES 00037198 (defining Disclosure Committee's role in assisting "the CEO and CFO ('the Senior Officers') in fulfilling their responsibility for oversight of the disclosures made by the Company").

194 Dkt. No. 270, ¶¶3, 5.

195 Ex. 264 at PFE-JONES 00037385 (noting a draft of the proxy was sent to all information providers, which included elected officers and directors, and that "[t]he Board of Directors received the final version of the proxy statement for their review in the materials that were sent to them in connection with the February 23, 2006 Meeting, at which they will be asked to approve its filing with the SEC"); Ex. 381 at PFE DERIV 00000458-59 (February 23, 2006 Board of Directors Minutes note that approval of the proxy occurred, although defendants redacted the details of the discussion).

196 Ex. 264 at PFE-JONES 00037385 (noting a draft of the proxy was sent to all information providers, which included elected officers and directors, and that "[t]he Board of Directors received the final version of the proxy statement for their review in the materials that were sent to them in connection with the February 23, 2006 Meeting, at which they will be asked to approve its filing with the SEC"); Ex. 381 at PFE DERIV 00000458-59 (February 23, 2006 Board of Directors Minutes note that approval of the proxy occurred, although defendants redacted the details of the discussion).

149. Kindler was the CEO and Chairman of Pfizer's Board of Directors at the time that Pfizer's Annual 2007 Proxy Statement (FMS No. 18) and Annual 2008 Proxy Statement (FMS No. 34) were issued. Again, Kindler approved the Proxy Statements and had ultimate authority over the statements contained therein.[197]

150. Pfizer's CEO and CFO held Certification Meetings at quarter and year end at which they sat in a conference room with the CEO and CFO to review the final version of the SEC filings.[198] Kindler and Waxman regularly attended Certification Meetings in their capacity as General Counsel, and Read attended at least one Certification Meeting in his capacity as an ELT member.[199] At those Certification Meetings, Kindler, Read and Waxman approved the SEC filings again before the CEO and CFO signed their Sarbanes-Oxley certifications that were filed with the SEC.[200] Kindler and Waxman, as part of that process, signed certifications as to the accuracy and completeness of the information contained therein.[201] Without Kindler's, Read's and Waxman's

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[197] *See* Ex. 128 at KPMG-PFIZ-DS 057288 (February 22, 2007 Pfizer Inc. Board of Directors Minutes, noting Kindler was present as Chairman of the Board and that the Board received drafts of the 2007 Proxy Statement in advance of the meeting and approved it for filing with the SEC at the February 22, 2007 meeting); Ex. 375 at PFE DERIV 00000107 (February 28, 2008 Pfizer Inc. Board of Director Minutes, noting Kindler was present as Chairman of the Board and containing an entry "Approval of Proxy Material," although defendants redacted the substance of the discussions as nonresponsive).

[198] *See, e.g.*, Kindler attending the Certification Meetings as General Counsel (Ex. 456; Ex. 458); Waxman attending Certification Meetings as General Counsel (Galin Decl., Exs. G-2-W, H-2-W, I-2-W, J-2-W, K-2-W); and Read attending as an ELT member (Galin Decl., Ex. I-2-W).

[199] *See, e.g.*, Kindler attending the Certification Meetings as General Counsel (Ex. 456; Ex. 458); Waxman attending Certification Meetings as General Counsel (Galin Decl., Exs. G-2-W, H-2-W, I-2-W, J-2-W, K-2-W); and Read attending as an ELT member (Galin Decl., Ex. I-2-W).

[200] Although defendants produced only one of Read's certifications (Ex. 344), other documents reflect that certifications were obtained from critical corporate officers and other executives. Ex. 452 at PFE-JONES 00032756.

[201] *See, e.g.*, Galin Decl., Ex. C-2-W at PFE-JONES 00045992; Strassberg Decl., Ex. CC-D.

certifications, Pfizer's disclosure process did not permit the CEO and CFO to sign Pfizer's SEC filings.[202]

D. Kindler Knew or Recklessly Disregarded that His Class Period Statements Were False and Misleading When Made

1. Kindler's Roles and Responsibilities at Pfizer

151. Starting in January 2002, Kindler was Pfizer's General Counsel and Chief Compliance Officer.[203] Kindler also chaired Pfizer's Corporate Compliance Committee during this time. [204] In his role as Chair of the Compliance Committee, it was Kindler's responsibility to help "[a]void potential harm to reputation [to] Pfizer and allies."[205]

152. From August 1, 2006 through the end of the Class Period, Kindler was the CEO and Chairman of the Board of Pfizer, and during that time he signed and certified the accuracy of all the Company's SEC filings. [206]

153. From September 2006 through the end of the Class Period, Kindler was a member of Pfizer's ELT and regularly attended ELT meetings.[207] In his capacity as a member of the ELT, Kindler was responsible for developing Pfizer's communication strategy and the approval of settlements of legal cases in amounts greater than $100 million or involving unusual issues.[208] From

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202 Ex. 468 at PFE-JONES 000399921 (sub-certifications were penultimate step in disclosure process that culminated with signing of CEO and CFO).

203 Ex. 436 at PFE-JONES 00000732 (Kindler 9/21/10 Deposition in *In re Pfizer, Inc. Shareholder Derivative Litigation*).

204 Ex. 386 at PFE DERIV 00023697; Ex. 390 at PFE DERIV 0024513.

205 Ex. 386 at PFE DERIV 00023700.

206 Dkt. No. 275, ¶1; *e.g.*, Petrosinelli Decl., Exs. D-1, F-1.

207 *E.g.*, Ex. 342; Ex. 208.

208 Ex. 202 at KPMG-PFIZ-DS 037981, 986.

January 2006 to August 2006 Kindler was General Counsel, Chief Compliance Officer and Vice Chairman of the Board, and in those capacities participated in each of Pfizer's Disclosure Committee meetings to prepare Pfizer's SEC filings and press releases.[209] Throughout the Class Period, Kindler regularly participated in Audit Committee meetings during which the accuracy of the Company's financial statements was discussed prior to their filing with the SEC.[210]

2. Kindler Knew or Recklessly Disregarded that His Statements Concerning Pfizer's Compliance with Healthcare Laws Were False and Misleading

154. While serving as the Chair of the Corporate Compliance Committee, Kindler regularly attended meetings during which specific allegations of Pfizer's violations of laws concerning illegal kickbacks, improper use of starters, improper influencing of doctors through speaker programs, improper CME programs and the off-label promotion of various products – including Bextra – were compiled, analyzed and tracked through the legal process.[211]

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209 Dkt. No. 275, ¶3.

210 *E.g.*, Ex. 332 at PFE DERIV A 00001407; Ex. 333; Ex. 334 at PFE DERIV A 00001392; Ex. 154 at PFE DERIV A 00001379; Ex. 340 at PFE DERIV A 00001365.

211 *E.g.*, Ex. 417 at PFE DERIV 01146196 (distribution included Kindler, Levin and Waxman), 198, 206 ("improperly utilized speaker program funds"), 207 ("Bextra off label"), 208 (New York Attorney General requested documents relating to "clinical study disclosure and off-label issues" of Geodon and five other drugs), 215 ("District Manager [DM] provided inappropriate direction to representatives related to the use of unapproved detailing materials"), 218 ("improper promotion" and "improper payments to physicians" involving Bextra), 226 (representative "improperly paid doctors in connection with dinner and speaker programs" and "detailed a product using unapproved detailing material"), 230 ("improperly distributed samples"), 233 (District Manager "mis-uses grants and speaker programs to improperly influence doctors"); Ex. 409 at PFE DERIV 00069303-04, 312, 315 (same); Ex. 410 at PFE DERIV 00069325-26, 329 (same), 344 ("inappropriate and improper events in violations of Healthcare Law with doctors"); Ex. 386 at PFE DERIV 00023695, 697, 718-20, 730, 740 (same); Ex. 407 at PFE DERIV 00069214-16, 225 (same), 222 ("inappropriate direction to representatives related to the use of unapproved detail materials"); Ex. 408 at PFE DERIV 00069233-34, 237, 253 (same); Ex. 385 at PFE DERIV 00024320, 322, 331-32, 341, 349, 368); Ex. 387 at PFE DERIV 00023983, 3985, 4007, 4010, 4016, 4018-19, 4025-26; Ex. 389 at PFE

155. On July 15, 2004, Pfizer's outside counsel, Covington, presented "a pretty extensive slide deck" relating to the marketing and sale of Bextra to the DOJ and OIG.[212] The slide deck noted that a *qui tam* complaint had been filed alleging the promotion of "Bextra for 'Acute Pain'" through "Improper Comparison to Vioxx," "Improper Dissemination of Medical Literature," "Protocols and Standing Orders," "Use of Physician Consultants" and for "Pre- and Post-Operative Use" as well as the promotion of Bextra "20 Mg for Uses Other Than Primary Dysmenorrhea."[213] The slide deck also noted Pfizer's "Review of Headquarters Bextra Sales Marketing Practices" and its "Ongoing Review of Select Geographic Areas," which included a finding from a "Physician Recall Report March 2004" that "acute pain/inflammation now [wa]s the leading Bextra usage discussion" between sales representatives and physicians.[214]

156. On August 12, 2004, the New York Attorney General sent a subpoena to Kindler and McKinnell concerning the off-label promotion of six drugs, including Geodon.[215] Kindler tracked the New York Attorney General's investigation during Compliance Committee Meetings.[216]

157. At the November 22, 2004 Pfizer Leadership Meeting, Kindler discussed a prior week's meeting with the USAO and informed members of the Pfizer Leadership Team, including

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DERIV 00024460, 464, 488, 492, 494, 497, 499-500; Ex. 406 at PFE DERIV 00069064, 68, 92, 95-96, 98, 101, 103-04; Ex. 390 at PFE DERIV 00024511, 513, 518, 522, 546, 550, 552, 555, 558.

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

213 Ex. 247 at PFE DERIV 00066670.

214 Ex. 247 at PFE DERIV 00066698, 706.

215 Ex. 213.

216 *E.g.*, Ex. 411 at PFE DERIV 00069448.

McKinnell and Shedlarz, that the USAO had asked Pfizer to preserve all documents regarding the cardiovascular safety of Bextra and that Pfizer had committed to do so.[217]

158. During the November 16-17, 2004 meeting between Covington and the Government, the Company made a presentation entitled "Pfizer Inc. Review and Voluntary Disclosure Relating to Bextra Allegations."[218] The slide deck noted that after "Hundreds of Thousands of Documents Reviewed" and "Over 70 Interviews Conducted," Pfizer found that it was a "Senior Management Decision to Make Available Under WLF" a Bextra reprint on "Dental Pain (vs. Tylox)," and that surveys of the sales force and the physicians they detailed revealed "[m]any [sales representatives] communicat[ing] '10 mg. is for OA and RA and 20 mg. is for acute pain states,'" and that "[t]he most common positioning is . . . 'Bextra for acute pain,'" although "[s]everal . . . mention[ed] their discomfort in delivering the desired positioning [because] it is Celebrex that has the acute pain data vs. narcotics that they can show to physicians, yet they are being asked to position Bextra for the acute patient."[219] Kindler was aware of Pfizer's presentations to the Government and he had access to the presentation slides and backup materials prior to, and throughout, the Class Period.[220] On December 1, 2005, Kindler was informed that the Government had "broadened the scope of their review to include payments made to physicians, in connection with both Bextra and other products."[221] Kindler was also informed that the *qui tam* complaint filed in 2003 specifically alleged that Pfizer employees detailed Bextra by "affirmatively referring to Bextra's efficacy and acute pain

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217 Ex. 434 at PFE DERIV A 00007406-07.

218 Ex. 397.

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

220 Ex. 85; Ex. 58 (9/23/14 Levin Depo.) at 18:6-24 (as a Pfizer Executive, he would receive any information they requested).

221 Ex. 224 at PFE DERIV 00003427-30 at PFE DERIV 00003429.

outside of the approved indications with physicians," "developing hospital and surgical protocols with physicians and hospitals that called for the use of Bextra for non-arthritic surgical pain" and "disseminating non-WLF journal articles referring to Bextra's efficacy in various acute pain models."[222]

159. Kindler has admitted that with regard to the unlawful promotion of Bextra in 2004, he "was made aware that there was wrongdoing, that people in our field force, including managers in our field force, and people at junior levels of our marketing organization, had engaged in conduct that resulted in off-label promotion."[223]

160. On April 7, 2005, Kindler received a report from IA entitled "U.S. Field Force Travel & Entertainment New York Headquarters."[224] Gifts to physicians from Pfizer sales representatives were among the violations that the report noted "could result in a fine or penalty to Pfizer."[225] IA gave this audit for this area (Travel & Entertainment) the lowest possible audit rating, *i.e.*, unsatisfactory.[226] The Company was understandably disappointed with this audit result.[227] On December 1, 2005, Waxman informed Kindler, McKinnell, Levin and Read that the Government had "broadened the scope of their review to include payments made to physicians, in connection with both Bextra and other products."[228] On December 16, 2005, Kindler received a report from IA

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222 Ex. 441 at PFE-JONES 00006635.

223 Ex. 436 at PFE-JONES 00000894 (9/21/10 Kindler Deposition in *In re Pfizer, Inc., Shareholder Derivative Litigation*).

224 Ex. 101.

225 Ex. 101 at PFE DERIV 00075597.

226 Ex. 101 at PFE DERIV 00075592.

227 Ex. 102 at Jenner-A 10000251931.

228 Ex. 224 at PFE DERIV 00003427-30.

entitled "U.S. Sales Force – Call Notes and E-mails New York Headquarters."[229] The report analyzed sales representatives' call notes and noted that "[d]etailing to and providing samples to physicians who may not typically use the product for its indicated use(s) could lead to the perception [that] the purpose of the visit was to promote the product for use beyond its approved indications."[230] IA gave this audit of call notes the lowest possible audit rating, *i.e.* unsatisfactory.[231] The report also informed Kindler that "[b]ecause the subjects of the planned [Call Notes and E-mails] audit are at issue in pending state and federal government investigations and in private civil litigation, in-house Pfizer counsel and attorneys at the law firm of Covington and Burling provided direction to [IA] regarding the conduct of this audit."[232]

161. On April 27, 2005, Kindler was informed that new *qui tam* complaints had been filed against Pfizer that "suggest a pattern of potentially improper promotional conduct" and that the one filed in the Eastern District of Virginia related to the improper promotion of Bextra.[233]

162. On July 26, 2005, the FDA issued a warning letter to Pfizer demanding the Company cease and desist from making unsubstantiated promotional claims regarding Zyvox.[234] The next day, Kindler, while serving as the Chair of the Compliance Committee, received a copy of the warning letter.[235]

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229 Ex. 103.

230 Ex. 103 at KPMG-PFIZ-DS 007301.

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

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

233 Ex. 412 at PFE DERIV 00076058; Ex. 160 at PFE-JONES 00005331-32.

234 Ex. 123 at PZ0034666.

235 Ex. 123 at PZ0034665.

163. On May 22, 2006, Kindler received a report from IA entitled "Marketing Promotional Speaker Programs New York Headquarters."[236] Again, IA gave this audit the lowest possible audit rating, *i.e.*, unsatisfactory.[237] IA reported to Kindler numerous serious weaknesses concerning marketing promotional speaker programs, including, but not limited to, inconsistencies that increased "risk that processes and controls may not be properly understood, communicated, or executed, which could result in violations of laws and regulations governing healthcare compliance."[238]

164. On June 21, 2006, Kindler attended the Audit Committee meeting during which the control weaknesses in the Marketing Promotional Speaker Programs report was discussed.[239]

165. On August 17, 2006, the Government presented to Pfizer several slide decks and hundreds of supporting documents "concerning contentions about alleged off-label promotion" of Bextra.[240] The slide deck titled "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

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236 Ex. 107.

237 Ex. 107 at PFE DERIV 00075210.

238 Ex. 107 at PFE DERIV 00075213.

239 Ex. 521 at 00004110.

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

Influence doctors" at "Consultant Meetings/Advisory Boards," "Control of purportedly independent CME," and the "Publication Strategy"; and (5) that "HQ knowledge" was demonstrated by the "Bextra Positioning for Acute Pain" and "Headquarters knowledge of promotion for unapproved uses."[241] The slide deck titled "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" the DOJ was considering bringing against Pfizer, which included Food, Drug and Cosmetic 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 Conduct continued despite: [o]ngoing Neurontin criminal investigation[,] Two CIA's[,] Two self-disclosures on other issues[,] [n]umerous internal complaints and red flags [and] [d]isclosure of the Bextra *qui tam* complaint and ongoing Bextra investigation."[242] The slide deck titled "Summary of Bextra Call Note Evidence" presented call note excerpts by sales representatives all over the United States reflecting the promotion of Bextra for acute pain.[243] 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.[244]

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241 Ex. 256 at DOJ000235-40.

242 Ex. 258 at DOJ000199, 205, 207-08.

243 Ex. 251.

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

166. In December 2006, Lankler informed Kindler, Read, Levin and Waxman of the details of the Government's August and September 2006 presentations of evidence demonstrating Pfizer's "off-label promotion of Bextra and the Company's interactions with physicians in the form of advisory boards, mentorships, continuing medical education and publication strategies."[245] On December 6, 2006, Read informed the Audit Committee that he would take "aggressive actions . . . to improve the control and compliance environment in the US organization."[246] Not surprisingly, Kindler had tasked Read with cleaning up some of the very areas that the DOJ had identified as evidence of improper off-label promotion of Bextra: "speaker programs, advisory boards and consultant payments as well as field force travel and entertainment."[247] Read admitted this work was "necessary" because of problems "in areas such as speaker programs, advisory boards and consultant payments as well as field force travel and entertainment."[248]

167. By December 8, 2006, Kindler was informed that Pfizer Corporate Compliance was "investigating several matters involving the alleged off-label promotion of Lyrica."[249]

168. On February 23, 2007, Kindler received a report from IA entitled "Publications & Authorships New York Headquarters."[250] Again, IA gave this audit the lowest possible audit rating, *i.e.*, unsatisfactory.[251] On February 28, 2007, KPMG expressed its "concern and objection" that this

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245 Ex. 433 at PFE DERIV A 00004035; Ex. 445 at PFE-JONES 00026243; Ex. 446 at PFE-JONES 00026338, 357, 360, 458, 590, 691, 697, 700, 702, 735-37, 740-41, 781, 789, 797, 801.

246 Ex. 155 at KPMG-PFIZ-DS 017942.

247 Ex. 155 at KPMG-PFIZ-DS 017942.

248 Ex. 155 at KPMG-PFIZ-DS 017942.

249 Ex. 433 at PFE DERIV A 00004035.

250 Ex. 75.

251 Ex. 75 at PFE DERIV 00075605.

audit report was issued the day ***after*** the Audit Committee meeting and was not discussed during the February 21, 2007 Audit Committee meeting.[252] In response to KPMG's objection, Kindler "corrected" the head of IA for this incident.[253]

169. On March 16, 2007, Kindler knew that Read's task of cleaning up serious weaknesses in the Company's controls over compliance with healthcare laws was in reaction to the Audit Committee's expressed concerns.[254]

170. On June 12, 2007, Pfizer's criminal defense counsel, DLA Piper, delivered a memo to Corporate Compliance detailing DLA Piper's findings concerning the off-label promotion of Geodon.[255] DLA Piper concluded that the Company's sales force "engaged third-party physicians for Pfizer-sponsored speaker programs during which the speakers affirmatively presented information on the use of Geodon (1) for children and adolescents, and (2) at doses exceeding 160 mg per day (primarily in adults) – uses that are not FDA approved."[256] DLA Piper also confirmed that, from 2003 to 2006, Pfizer spent at least $1.4 million[257] on "speaker programs for key physicians who regularly presented information on non-FDA approved uses of Geodon . . . across the country."[258]

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252 Ex. 162 at KPMG-PFIZ-DS 016175.

253 Ex. 162 at KPMG-PFIZ-DS 016175.

254 Ex. 118 at PFE DERIV A 00003833.

255 Ex. 168.

256 Ex. 168 at PFE-DERIV 00003754.

257 Ex. 168 at PFE-DERIV 00003758.

258 Ex. 168 at PFE-DERIV 00003757.

171. During the June 27, 2007 Audit Committee meeting, Lankler, the head of Corporate Compliance, reported a sales representative's allegation "that his supervisors had promoted the use of speakers who would discuss prescribing Geodon off-label to children and adolescents and at improper dosages," and that an investigation would be conducted as well as a review as to "whether any improper detailing occurred."[259] Lankler also informed Kindler and the Audit Committee "that effective immediately, child psychiatrists were being eliminated from credit and quota."[260]

172. On July 12, 2007, Kindler received a subpoena *duces tecum* from the DOJ seeking documents regarding allegations of off-label promotion of Lyrica.[261]

173. On September 18, 2007, Kindler was informed that the Lyrica subpoena presented Pfizer with its "first opportunity to showcase our risk mitigation approaches to government officials."[262]

174. On December 12, 2007, the DOJ served a subpoena on Pfizer concerning Detrol, Geodon, Zoloft and Zyvox, which included a request for documents "evidencing or referring to sales or promotion or use of [Detrol, Geodon, Zoloft and Zyvox] for an indication outside its approved labeling."[263] Also in December 2007, the Government raised the July 2005 Zyvox warning letter with Pfizer, and as a result, the Company incorporated the allegations of unsubstantiated superiority claims ("comparative claim practices") into its on-going investigation into the off-label promotion of

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259 Ex. 431 at PFE DERIV 00003787.

260 Ex. 431 at PFE DERIV A 00003790.

261 Ex. 465.

262 Ex. 379 at PFE DERIV 00003740.

263 Ex. 451 at PFE-JONES 00032572, 578.

Zyvox.[264] Pfizer acknowledged "the scope of the improper comparative messaging problem in January 2008."[265]

175. On June 11, 2008, Read informed Kindler that "[w]hen I was appointed as WPO President in the 2nd half of 2006, the status of Healthcare Compliance in the US Pharmaceuticals organization was not where it needed to be . . . . [T]he Audit Committee questioned whether there were certain activities that we should continue to engage in given the potential impact on our reputation as a company and whether compliance was embedded in the fabric of our organization to the extent it needed to be given the environment in which we operate."[266] Read acknowledged that his work addressed the fact that the Company's investigative load of improper promotional activity had increased six-fold between 2003 and 2007.[267]

3. Kindler Knew or Recklessly Disregarded that Pfizer's Legal Proceedings and FAS 5 Disclosures Were False and Misleading

176. As General Counsel and Chief Compliance Officer, Kindler was personally involved in the $430 million settlement of the Neurontin case and the CIA.[268]

177. Kindler was familiar with the United States Sentencing Guidelines and understood that those Guidelines were used to calculate, among other things, fines for corporate defendants if they were found guilty or pled guilty to alleged illegal off-label promotion of pharmaceuticals.[269]

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264 Ex. 121 at PFE DERIV 00067562.

265 Ex. 121 at PFE DERIV 00067571.

266 Ex. 120 at PFE DERIV 01072458-59.

267 Ex. 120 at PFE DERIV 01072461.

268 Ex. 54 (10/10/14 Kindler Depo.) at 104:3-8.

269 Ex. 54 (10/10/14 Kindler Depo.) at 105:4-14.

178. No later than June 2004, Kindler was aware that one of the bases for determining the criminal fine for illegal off-label promotion was the gain that a corporate entity realized from a crime.[270]

179. As part of the $430 million settlement of the Neurontin case, the fine was calculated using a well-established formula for estimating actual gain from off-label promotion.[271] Ultimately, and predictably, the fine in the Bextra case was calculated using the same gain-based formula [272]

180. Kindler knew what Pfizer's Bextra revenues were from the time it was introduced to the market to the time it was withdrawn.[273] Kindler could have applied the Neurontin methodology to calculate a reasonable estimate of the Company's liability for the Government Investigation into the unlawful off-label promotion of Bextra.[274]

181. On September 26, 2005, while Kindler was Pfizer's General Counsel, Pfizer's Legal Division reported that "it is our estimation based on the facts and circumstances to date that we are likely to be forced to reach some form of settlement of [the Bextra Investigation]."[275] At the time, Kindler knew that Pfizer had admitted to the Government that Pfizer employees had destroyed documents relevant to the Bextra Investigation.[276]

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270 Ex. 54 (10/10/14 Kindler Depo.) at 105:18-106:3.

271 Ex. 229 at 2.

272 Ex. 513 at 44-50; Ex. 179 at 2.

273 *See, e.g.*, Dkt. No. 247-1 at 63.

274 Ex. 7 at Ex. E.

275 Petrosinelli Decl., Ex. P-5 at PFE-JONES 00043523-24.

276 Ex. 244; Ex. 160 at PFE-JONES 00005332; Ex. 54 (10/10/14 Kindler Depo.) at 37:12-38:6, 39:10-19; Ex. 55 (Lankler Depo.) at 81:13-19.

182. On August 11, 2006, Kindler certified Pfizer's 2Q06 Form 10-Q.[277] Kindler stated with regard to certain state attorneys general investigations: "We received a letter from the Office of the Attorney General of the State of New York in 2004 requesting documents and information concerning clinical trials of certain of our pharmaceutical products for indications other than those approved by the FDA and concerning possible promotion of those products for such indications. We also received a letter from the Office of the Attorney General of the State of Connecticut in 2004 requesting similar materials concerning Zoloft."[278]

183. With regard to the Government Investigation, Kindler stated in Pfizer's 2Q06 Form 10-Q: "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."[279]

184. On October 24, 2006, IA noted that it would brief Kindler (or "JBK") as to "next steps" regarding a number of issues, including concerns that Pfizer might have a material weakness in its internal controls designed to prevent, among other violations, the off-label promotion of its pharmaceutical products.[280]

185. No later than December 2006, Lankler told Kindler and others about Pfizer's August and September 2006 meetings with the Government. Pfizer possessed all the call notes that were the focus of the Government's presentation, and Kindler had the (accurate) belief that the Government

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277 *See* Ex. 12 at 72.

278 *See, e.g.*, Ex. 12 at 6 (incorporating by reference Statements made in 2005 Form 10-K (Dkt. No. 247-1 at 147)).

279 *See* Ex. 12 at 6 (incorporating by reference Statements made in 2005 Form 10-K (Dkt. No. 247-1 at 147)).

280 Ex. 114 at PFE DERIV 01064273.

had made a very detailed presentation based on actual quotes from Pfizer's call notes. Kindler was aware of and had access to the evidence of call notes and sales-representative verbatims – showing off-label promotion – that the Government presented to Pfizer during their meetings. [281]

186. The Government's presentation to Pfizer included multiple slides of "aggravating factors." These aggravating factors included:

- The FDA said ***No***.
- The FDA's concern was ***Safety***.
- Safety ***Is*** the issue.
- Knowledge at the Top.
- A Deliberate Scheme.
- Pervasive Misconduct.[282]

187. Kindler knew, or chose not to seek the information, that during those August and September 2006 presentations, the Government had evidence indicating that the illegal promotion of Bextra was pervasive, that it was a deliberate scheme directed by upper management at Pfizer, and that the Government had specifically identified the crimes Pfizer had committed.[283] Kindler also knew or chose not to know of the notes taken by the attendees at those presentations, which revealed that the Government realized that the off-label promotion of Bextra continued despite the Government's criminal investigation into Neurontin.[284] Further, Kindler knew, or chose not to seek

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[281] Ex. 220 at PFE DERIV 00004034-35; Ex. 54 (10/10/14 Kindler Depo.) at 53:10-54:2, 77:20-24; Ex. 211 at PFE-JONES 00006996-7012.

[282] Ex. 211 at PFE-JONES 00007013-14; Ex. 258 at DOJ000205, 207; Ex. 314 at DOJ000224, 226.

[283] Ex. 258 at DOJ000205, 207; Ex. 314 at DOJ000224, 226.

[284] Ex. 258 at DOJ000208; Ex. 314 at DOJ000227.

the information, that the Government estimated that 76% of total Bextra revenue was from non-approved indications and calculated that 52% of total Bextra revenue was for 20 mg doses.[285]

188. On November 3, 2006, in Pfizer's 3Q06 Form 10-Q, Kindler misrepresented to investors the scope of the requests for information and documents received from certain state attorneys general and the DOJ regarding Bextra.[286]

189. On October 9, 2007, Kindler's outside disclosure counsel, Dennis Block ("Block"), and in-house counsel Lankler and Carlton Wessel ("Wessel") met to discuss a potential 3Q07 reserve for the Government's Bextra Investigation.[287] At that meeting, it was decided that the probable criteria for FAS 5 had been met.[288] In addition, it was acknowledged that the Government had demanded Pfizer propose an amount of damages for the Bextra Investigation.[289] It was further acknowledged that the Company was reviewing methodologies to prepare damage estimates for the Bextra Investigation, and that the range of loss at that time was $0 to several hundred million dollars.[290]

190. After receipt of the Lyrica, Geodon and Zyvox subpoenas in 2007, Pfizer's inside disclosure counsel, Lawrence Fox ("Fox"), sent an e-mail to Block, Lankler, Schulman, Giampetruzzi and Wessel, in which Fox advised that "the main reason for not naming the drug[] in question in [SEC filings] is to avoid highlighting [it] for the plaintiffs' bar, and we would not want

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285 Ex. 258 at DOJ000201, 203.

286 Ex. 13.

287 Petrosinelli Decl., Ex. N-6.

288 Petrosinelli Decl., Ex. N-6.

289 Petrosinelli Decl., Ex. N-6.

290 Petrosinelli Decl., Ex. N-6.

IR [Investor Relations] or Media Relations to name [it] either."[291] None of the recipients of this e-mail responded with any sort of disagreement with Fox's advice.

191. On February 5, 2008, Kindler had knowledge that Pfizer was "the target of a federal grand jury investigation."[292]

192. On February 5, 2008, Pfizer authorized its counsel to communicate to the Government a "prepared-to-recommend" settlement offer of $50 to 70 million dollars.[293] On March 28, 2008, Pfizer authorized its counsel to communicate to the Government a "prepared to recommend" $250 million settlement offer.[294] In or around June 2008, Pfizer authorized its counsel to communicate to the Government a "prepared to recommend" offer of $750 million to settle the Government Investigation.[295]

E. D'Amelio Knew or Recklessly Disregarded that His Class Period Statements Were False and Misleading When Made

1. D'Amelio's Roles and Responsibilities at Pfizer

193. From September 2007 through the end of the Class Period, D'Amelio was Pfizer's CFO.[296]

194. From September 2007 through the end of the Class Period, D'Amelio was a member of Pfizer's ELT and regularly attended ELT meetings with Kindler, Read and Waxman.[297] In his

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291 Ex. 130 at PFE-JONES 00044599.

292 Ex. 53 (12/6/13 Kindler Depo.) at 240:9-241:7.

293 Ex. 104 at PFE-JONES 0007028; Ex. 55 (Lankler Depo.) at 124:12-22.

294 Petrosinelli Decl., Ex. Y-6 at PFE DERIV 00066378; Ex. 55 (Lankler Depo.) at 124:12-22.

295 Ex. 55 (Lankler Depo.) at 124:12-22; Ex. 437 at PFE-JONES 00002261.

296 Dkt. No. 265, ¶1.

297 *E.g.*, Ex. 342; Ex. 208.

capacity as a member of the ELT, D'Amelio was responsible for Pfizer's communication strategy and the approval of settlements of legal cases in amounts greater than $100 million or involving unusual issues.[298] From October 30, 2007 through the end of the Class Period, he attended every Disclosure Committee meeting prior to the issuance of Pfizer's SEC filings, including press releases, as well as presentations to analysts and the investment community, and he was responsible for reviewing the procedures for the preparation of such documents and presentations.[299] From November 2007 through the end of the Class Period, he also attended every quarterly meeting prior to the issuance of each of Pfizer's SEC filings in order to certify them pursuant to the Sarbanes-Oxley Act of 2002 .[300] During that time, he also regularly attended the Company's Audit Committee meetings and Board of Directors meetings.[301]

2. D'Amelio Knew or Recklessly Disregarded that His Statements Concerning Pfizer's Compliance with Healthcare Law Were False and Misleading

195. Upon becoming the CFO of Pfizer in September 2007, D'Amelio talked to others and attended meetings through which he familiarized himself with the details of the Government Investigations into the Company's off-label promotion of Bextra and other drugs.[302]

196. D'Amelio was informed, or would have been informed had he cared to ask, that on August 17, 2006, the Government presented to Pfizer several slide decks and hundreds of supporting

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298 Ex. 202 at KPMG-PFIZ-DS 037981, 986.

299 *E.g.*, Ex. 343; Ex. 462.

300 *E.g.*, Ex. 198; Ex. 199; Ex. 463.

301 *E.g.*, Ex. 419; Ex. 423.

302 Ex. 46 (D'Amelio Depo.) at 182:17-184:4.

documents "concerning contentions about alleged off-label promotion" of Bextra.[303] The slide deck titled "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 Strategy"; and (5) that "HQ knowledge" was demonstrated by the "Bextra Positioning for Acute Pain" and "Headquarters knowledge of promotion for unapproved uses."[304] The slide deck titled "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" the DOJ was considering bringing against Pfizer, which included Food, Drug and Cosmetic 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 "[t]he Conduct continued despite: Ongoing Neurontin criminal investigation[,] Two CIA's[,] Two self-disclosures on other issues[,] Numerous internal complaints and red flags [and] Disclosure of the Bextra *qui tam* complaint and ongoing Bextra investigation."[305] The slide deck titled "Summary of Bextra Call Note Evidence" presented call note excerpts by sales representatives all over the United

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

304 Ex. 256 at DOJ000235-40.

305 Ex. 258 at DOJ000199, 205, 207-08.

States reflecting the promotion of Bextra for acute pain. Further, D'Amelio was advised by Pfizer's inside and outside counsel that 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.[306]

197. On September 18, 2007, D'Amelio was informed that the Lyrica subpoena presented Pfizer with its "first opportunity to showcase our risk mitigation approaches to government officials."[307]

3. D'Amelio Knew or Recklessly Disregarded that Pfizer's Legal Proceedings and FAS 5 Disclosures Were False and Misleading

198. On October 9, 2007, D'Amelio's outside disclosure counsel, Block, inside counsel Lankler and Wessel, and D'Amelio's direct subordinate, Kim Dadlani,[308] attended a meeting to discuss a potential 3Q07 reserve for the Government's Bextra Investigation.[309] At that meeting, it was decided that the probable criteria for FAS 5 had been met.[310] In addition, it was acknowledged that the Government had demanded Pfizer propose an amount of damages for the Bextra Investigation.[311] It was further acknowledged that Pfizer was reviewing methodologies to prepare

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306 Ex. 211 at PFE-JONES 00007014-25; Ex. 250 (slide deck titled "Preliminary Statement: Investigation Continuing"); Ex. 316 at DOJ000243-50 (slide deck titled "Overview of United States Bextra Presentation"); Ex. 314 at DOJ000210-28 (slide deck titled "Review of Key Events & Facts").

307 Ex. 379 at PFE DERIV 0000373740.

308 Ex. 46 (D'Amelio Depo.) at 188:11-189:13.

309 Petrosinelli Decl., Ex. N-6.

310 Petrosinelli Decl., Ex. N-6.

311 Petrosinelli Decl., Ex. N-6.

damage estimates for the Bextra Investigation, and that the range of loss at that time was $0 to several hundred million dollars.[312] D'Amelio was immediately advised of these facts when he became CFO in September 2007.[313]

199. On October 20, 2007, D'Amelio sent Loretta Cangialosi ("Cangialosi") a handwritten note in which he admitted that the Bextra Investigation "has the potential to be a very big charge (as you know)."[314]

200. On February 5, 2008, Pfizer authorized its counsel to communicate to the Government a "prepared-to-recommend" settlement offer of $50 to 70 million dollars.[315] On March 28, 2008, Pfizer authorized its counsel to communicate to the Government a "prepared to recommend" $250 million settlement offer.[316] In or around June 2008, Pfizer authorized its counsel to communicate to the Government a "prepared to recommend" offer of $750 million to settle the Government Investigation.[317]

F. Waxman Knew or Recklessly Disregarded that His Class Period Statements Were False and Misleading When Made

201. Waxman graduated from Harvard Law School in 1987. After graduating from Harvard Law School, Waxman clerked for the Honorable Judge Thomas Penfield in the United States District Court for the District of Columbia. Starting in 1989, Waxman worked at Williams

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312 Petrosinelli Decl., Ex. N-6.

313 Ex. 46 (D'Amelio Depo.) at 182:17-184:4; Ex. 210.

314 Ex. 133 at PFE-JONES 00038491.

315 Ex. 104 at PFE-JONES 0007028-36; Ex. 55 (Lankler Depo.) at 124:12-22.

316 Petrosinelli Decl., Ex. Y-6 at PFE DERIV 00066378-79; Ex. 55 (Lankler Depo.) at 124:12-22.

317 Ex. 55 (Lankler Depo.) at 124:12-22; Ex. 437 at PFE-JONES 00002261.

Connolly for 14 years, where he met former Pfizer CEO Kindler. At Williams Connolly, Waxman worked on a variety of cases, including white collar criminal cases.[318]

1. Waxman's Roles and Responsibilities at Pfizer

202. Waxman was a senior assistant General Counsel at Pfizer from 2003 until August 2006, when he was promoted to General Counsel.[319]

203. From September 2006 through March 2008, he was a member of Pfizer's ELT and regularly attended ELT meetings with Kindler, D'Amelio and Read.[320] As a member of the ELT, Waxman was responsible for Pfizer's communication strategy and approving settlements of legal cases in amounts greater than $100 million or involving unusual issues.[321] From July 2006 through January 2008, he attended Disclosure Committee meetings prior to the issuance of Pfizer's SEC filings, including press releases, as well as presentations to analysts and the investment community, and he was responsible for reviewing the procedures for the preparation of such documents and presentations.[322] From February 2006 through February 2008, he also regularly attended Certification Meetings prior to the issuance of Pfizer's SEC filings.[323] Between September 2005 and February 2008, he also attended Audit Committee meetings and from December 18, 2006 to January 2008, he signed the Audit Committee minutes as the Secretary.[324]

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318 Ex. 68 (10/16/14 Waxman Depo.) at 9:3-10:11.

319 Dkt. No. 261 at 1.

320 *E.g.*, Ex. 342; Ex. 208.

321 Ex. 202 at KPMG-PFIZ-DS037981, 986.

322 *E.g.*, Ex. 343; Ex. 336.

323 *E.g.*, Ex. 526; Ex. 461.

324 *E.g.*, Ex. 427; Ex. 421; Ex. 424; Ex. 422.

204. From at least February 2004 up to March 2008, Waxman was a member of Pfizer's Corporate Compliance Committee.[325] As a member of the Compliance Committee, it was Waxman's responsibility to help "[a]void potential harm to reputation [to] Pfizer and allies."[326]

2. Waxman Knew or Recklessly Disregarded that His Statements Concerning Pfizer's Compliance with the Law Were False and Misleading

205. While a member of the Corporate Compliance Committee, Waxman regularly attended meetings during which specific allegations of Pfizer's violation of laws concerning illegal kickbacks, improper use of starters, improper influencing of doctors through speaker programs, improper CME programs and the off-label promotion of various products – including Bextra – were compiled, analyzed and tracked through the legal process.[327]

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325 Ex. 404; Ex. 393.

326 Ex. 386 at 699-705.

327 *E.g.*, Ex. 417 at PFE DERIV 01146196 (distribution included Kindler, Levin and Waxman), 198, 206 ("improperly utilized speaker program funds"), 207 ("Bextra off label"), 208 (New York Attorney General requested documents relating to "clinical study disclosure and off-label issues" of Geodon and five other drugs), 215 ("District Manager [DM] provided inappropriate direction to representatives related to the use of unapproved detailing materials"), 218 ("improper promotion" and "improper payments to physicians" involving Bextra), 226 (representative "improperly paid doctors in connection with dinner and speaker programs" and "detailed a product using unapproved detailing material"), 230 ("improperly distributed samples"), 233 (District Manager "mis-uses grants and speaker programs to improperly influence doctors"); Ex. 409 at PFE DERIV 0006930-35, 312, 315 (same); Ex. 410 at PFE DERIV 00069325-26, 329 (same), 344 ("inappropriate and improper events in violations of Healthcare Law with doctors"); Ex. 386 at PFE DERIV 00023695, 697, 718-20, 730, 740 (same); Ex. 407 at PFE DERIV 00069214-16, 225 (same), 222 ("inappropriate direction to representatives related to the use of unapproved detail materials"); Ex. 408 at PFE DERIV 00069233-34, 237, 253 (same); Ex. 530 at PFE DERIV 00024320, 322, 331-32, 341, 349, 368); Ex. 387 at PFE DERIV 00023983, 985, 4007, 4010, 4016, 4018-19, 4025-26; Ex. 389 at PFE DERIV 00024460, 464, 488, 492, 494, 497, 499-500; Ex. 406 at PFE DERIV 00069064, 68, 92, 95-96, 98, 101, 103-04; Ex. 390 at PFE DERIV 00024511, 513, 518, 522, 546, 550, 552, 555, 558.

206. On May 28, 2004, Waxman participated in a Corporate Compliance Committee meeting during which the Neurontin CIA and criminal consent decree were discussed.[328]

207. On July 15, 2004, Pfizer's outside counsel, Covington, presented "a pretty extensive slide deck" relating to the marketing and sale of Bextra to the DOJ and OIG.[329] The slide deck noted that a *qui tam* complaint had been filed alleging the promotion of "Bextra for 'Acute Pain'" through "Improper Comparison to Vioxx," "Improper Dissemination of Medical Literature," "Protocols and Standing Orders," "Use of Physician Consultants" and for "Pre- and Post-Operative Use" as well as the promotion of Bextra "20 Mg for Uses Other Than Primary Dysmenorrhea."[330] The slide deck also noted Pfizer's "Review of Headquarters Bextra Sales Marketing Practices" and its "Ongoing Review of Select Geographic Areas," which included a finding from a "Physician Recall Report March 2004" that "acute pain/inflammation now [wa]s the leading Bextra usage discussion" between sales representatives and physicians.[331]

208. On August 12, 2004, the New York Attorney General sent a subpoena to the Chairman of the Compliance Committee concerning the off-label promotion of six drugs, including Geodon.[332] Waxman tracked the New York Attorney General's investigation during Compliance Committee Meetings.[333]

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328 Ex. 403; Ex. 405.

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

330 Ex. 247 at PFE DERIV 00066670.

331 Ex. 247 at PFE DERIV 00066698, 706.

332 Ex. 213.

333 *E.g.*, Ex. 411 at PFE DERIV 000694448.

209. During the November 16-17, 2004, meeting between Covington and the Government, the Company made a presentation entitled "Pfizer Inc. Review and Voluntary Disclosure Relating to Bextra Allegations."[334] The slide deck noted that after "Hundreds of Thousands of Documents Reviewed" and "Over 70 Interviews Conducted," Pfizer found that it was a "Senior Management Decision to Make Available Under WLF" a Bextra reprint on "Dental Pain (vs. Tylox)," and that surveys of the sales force and the physicians they detailed revealed "many [sales representatives] communicat[ing] 10 mg. is for OA and RA and 20 mg. is for acute pain states," and that "[t]he most common positioning is . . . 'Bextra for acute pain,'" although "[s]everal . . . mention[ed] their discomfort in delivering the desired positioning [because] it is Celebrex that has the acute pain data vs. narcotics that they can show to physicians, yet they are being asked to position Bextra for the acute patient."[335] Waxman was aware of Pfizer's presentations to the Government and he had access to the presentation slides and backup materials prior to, and throughout, the Class Period.[336] On December 1, 2005, Waxman was informed that the Government had "broadened the scope of their review to include payments made to physicians, in connection with both Bextra and other products."[337] Waxman was also informed that the *qui tam* complaint filed in 2003 specifically alleged that Pfizer employees detailed Bextra by "affirmatively referring to Bextra's efficacy and acute pain outside of the approved indications with physicians," "developing hospital and surgical protocols with physicians and hospitals that called for the use of Bextra for non-arthritic surgical

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334 Ex. 397.

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

336 Ex. 441 at PFE-JONES 00006635-36.

337 Ex. 441 at PFE-JONES 00006635-36.

pain" and "disseminating non-WLF journal articles referring to Bextra's efficacy in various acute pain models."[338]

210. On April 4, 2005, Waxman, Kindler and Levin attended a Corporate Compliance Committee meeting during which Lankler stated that he would brief the Corporate Compliance Committee on the ongoing Bextra-related self-assessment.[339]

211. On October 17, 2006, Pfizer's Disclosure Committee met.[340] Cangialosi, Levin, Waxman, Fox and Lankler participated in the meeting.[341] During the meeting, it was reported that there was "a possible significant deficiency in connection with internal controls over certain U.S. pharmaceutical sales and marketing practices."[342]

212. On November 1, 2006, Pfizer conducted its 3Q06 Certification Meeting.[343] Kindler, Levin, Waxman, Shedlarz, Cangialosi, Donnelly, Lankler and Fox participated in the meeting.[344] During the meeting, Donnelly reported on the significant deficiency in internal controls over U.S. pharmaceuticals sales and marketing practices and answered questions from Kindler, Shedlarz and Levin regarding the matter.[345]

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338 Ex. 441 at PFE-JONES 00006635.

339 Ex. 388.

340 Ex. 126.

341 Ex. 126.

342 Ex. 126 at PFE-JONES 00036560.

343 Ex. 128 at PFE-JONES 00036578.

344 Ex. 128 at PFE-JONES 00036578.

345 Ex. 128 at PFE-JONES 00036579.

213. On August 17, 2006, the Government presented to Pfizer several slide decks and hundreds of supporting documents "concerning contentions about alleged off-label promotion" of Bextra.[346] The slide deck titled "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 Strategy"; and (5) that "HQ knowledge" was demonstrated by the "Bextra Positioning for Acute Pain" and "Headquarters knowledge of promotion for unapproved uses."[347] The slide deck titled "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" the DOJ was considering bringing against Pfizer, which included Food, Drug and Cosmetic 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 Conduct continued despite: Ongoing Neurontin criminal investigation[,] Two CIA's[,] Two self-disclosures on other issues[,] Numerous internal complaints and red flags [and] Disclosure of the Bextra *qui tam* complaint and ongoing Bextra

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

347 Ex. 256 at DOJ000235-40.

investigation."[348] The slide deck titled "Summary of Bextra Call Note Evidence" presented call note excerpts by sales representatives all over the United States reflecting the promotion of Bextra for acute pain.[349] 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.[350]

214. In December 2006, Lankler informed Waxman of the details of the Government's August and September 2006 presentations of its evidence demonstrating Pfizer's "off-label promotion of Bextra and the Company's interactions with physicians in the form of advisory boards, mentorships, CME and publication strategies."[351]

215. The Government's presentation, which Waxman either received, or chose not to receive, included multiple slides of "aggravating factors." These aggravating factors included:

- The FDA said ***No***.
- The FDA's concern was ***Safety***.
- Safety ***Is*** the issue.
- Knowledge at the Top.
- A Deliberate Scheme.

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348 Ex. 251 at DOJ000199, 205, 207-08.

349 Ex. 257 at DOJ000001-17.

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

351 Ex. 433 at PFE DERIV A 00004035.

- Pervasive Misconduct.[352]

216. Waxman knew, or chose not to seek the information, that during those August and September 2006 presentations, the Government had evidence indicating that the illegal promotion of Bextra was pervasive, that it was a deliberate scheme directed by upper management at Pfizer, and that the Government had specifically identified the crimes Pfizer had committed.[353] Waxman also knew, or chose not to know, of the notes taken by attendees at those presentations, which revealed that the Government realized that the off-label promotion of Bextra had continued despite the Government's criminal investigation into Neurontin.[354] Further, Waxman knew, or chose not to seek the information, that the Government estimated that 76% of total Bextra revenue was from non-approved indications and calculated that 52% of total Bextra revenue was for 20 mg doses.[355]

217. On or about December 18, 2006, Waxman received a "Compliance Update" memo, which reflected that Pfizer's U.S. operations suffered from "an ineffective regulatory compliance function."[356] The memo also stated that IA was disappointed in employees' "non-proactive approach in identifying control weaknesses within the business, *i.e.* before Internal Audit and Compliance" are involved.[357] On or about December 6, 2006, Waxman was told that it was

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352 Ex. 211 at PFE-JONES 00007013-14; Ex. 258 at DOJ000205, 207; Ex. 314 at DOJ000224, 226.

353 Ex. 258 at DOJ000206-207; Ex. 314 at DOJ000225-226.

354 Ex. 258 at DOJ000208; Ex. 314 at DOJ000227.

355 Ex. 258 at DOJ000201, 203.

356 Ex. 155 at KPMG-PFIZ-DS 017940.

357 Ex. 155 at KPMG-PFIZ-DS 017940.

necessary to take "aggressive actions . . . to improve the control and compliance environment in the US organization."[358]

218. By December 8, 2006, Waxman was informed that Pfizer Corporate Compliance was "investigating several matters involving the alleged off-label promotion of Lyrica."[359]

219. On March 16, 2007, Read sent the Audit Committee a memorandum regarding his task of cleaning up serious weaknesses in Pfizer's controls over healthcare compliance in reaction to the Audit Committee's expressed concerns.[360]

220. On June 12, 2007, Pfizer's criminal defense counsel, DLA Piper, delivered a memo to Corporate Compliance detailing DLA Piper's findings concerning the off-label promotion of Geodon.[361] DLA Piper concluded that the Company's sales force "engaged third-party physicians for Pfizer-sponsored speaker programs during which the speakers affirmatively presented information on the use of Geodon (1) for children and adolescents, and (2) at doses exceeding 160 mg per day (primarily in adults) – uses that are not FDA approved."[362] DLA Piper also confirmed that, from 2003 to 2006, Pfizer spent at least $1.4 million[363] on "speaker programs for key physicians who regularly presented information on non-FDA approved uses of Geodon . . . across the country."[364]

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358 Ex. 155 at KPMG-PFIZ-DS 017942.

359 Ex. 433 at PFE DERIV A 00004035.

360 Ex. 118 at PFE DERIV A 00003833.

361 Ex. 168.

362 Ex. 168 at PFE-DERIV 00003754.

363 Ex. 168 at PFE-DERIV 00003758.

364 Ex. 168 at PFE-DERIV 00003757.

221. During the June 27, 2007 Audit Committee meeting, Lankler, the head of Corporate Compliance, reported a sales representative's allegation "that his supervisors had promoted the use of speakers who would discuss prescribing Geodon off-label to children and adolescents and at improper dosages," and that an investigation would be conducted as well as a review as to "whether any improper detailing occurred."[365] Lankler also informed Waxman and the Audit Committee "that effective immediately, child psychiatrists were being eliminated from credit and quota."[366]

222. On July 12, 2007, Pfizer received a subpoena *duces tecum* from the DOJ seeking Lyrica off-label promotion documents.[367] After receiving the subpoena, on September 11, 2007, Pfizer's criminal defense counsel, Davis Polk & Wardwell ("Davis Polk"), made a presentation to the DOJ describing, *inter alia*, the "Anticipation of Off-Label Use" of Lyrica by Pfizer from "the outset" of its introduction to the market and the various instances of alleged improper promotion of Lyrica that had been reported to the OIG from November 30, 2006 through March 30, 2007.

3. Waxman Knew or Recklessly Disregarded that Pfizer's Legal Proceedings and FAS 5 Disclosures Were False and Misleading

223. Prior to the Class Period, Waxman knew that the Company had promoted Bextra for unlawful off-label purposes.[368]

224. Waxman became aware that Pfizer employees destroyed documents relevant to the Bextra Investigation by March 2005.[369] He and others at Pfizer were generally aware that investigations "like the Bextra investigation usually ended up in a settlement."[370]

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365 Ex. 431 at PFE DERIV A 00003787.

366 Ex. 431 at PFE DERIV A 00003790.

367 Ex. 465 at PFE-JONES 00038274-86.

368 Ex. 68 (10/16/14 Waxman Depo.) at 49:24-50:5.

369 Ex. 68 (10/16/14 Waxman Depo.) at 31:7-20.

225. By September 8, 2006, Waxman, Levin and the Company's Controller, Cangialosi received an internal report acknowledging the Government's presentations and the fact that the investigation was into the "off-label promotion of Bextra."[371]

226. On November 1, 2006, Waxman participated in the certification committee meeting with Kindler and Levin.[372] As a result of his participation in these meetings, Pfizer stated in its 3Q06 Form 10-Q that with regard to certain state attorneys general investigations: "We received a letter from the Office of the Attorney General of the State of New York in 2004 requesting documents and information concerning clinical trials of certain of our pharmaceutical products for indications other than those approved by the FDA and concerning possible promotion of those products for such indications. We also received a letter from the Office of the Attorney General of the State of Connecticut in 2004 requesting similar materials concerning Zoloft."[373]

227. As a result of Waxman's participation in the November 2006 Certification Meeting, Pfizer stated in its 3Q06 Form 10-Q that with regard to the Government Investigation: "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."[374]

228. No later than December 2006, Lankler told Waxman and others about Pfizer's August 2006 meeting with the Government. Pfizer possessed all the call notes that were the focus of the

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370 Ex. 67 (11/14/13 Waxman Depo.) at 229:24-230:12.

371 Ex. 219 at PFE-JONES 00046199.

372 Ex. 128.

373 *See, e.g.*, Ex. 215 at 6 (incorporating by reference statements made in 2005 Form 10-K (Dkt. No. 247-1 at 147)).

374 *See, e.g.*, Ex. 215 at 6 (incorporating by reference statements made in 2005 Form 10-K (Dkt. No. 247-1 at 147)).

Government's presentation. Waxman testified that while he did not recall the exact date of the Government's presentation of the call-notes evidence, he did recall that the Government reviewed the call-notes.[375]

229. The Government's August and September 2006 presentations to Pfizer included multiple slides of "aggravating factors." These aggravating factors included:

- The FDA said ***No***.
- The FDA's concern was ***Safety***.
- Safety ***Is*** the issue.
- Knowledge at the Top.
- A Deliberate Scheme.
- Pervasive Misconduct.[376]

230. As Pfizer's General Counsel, Waxman either knew of the information presented or should have known, the Government had evidence indicating that the illegal promotion of Bextra was pervasive, that it was a deliberate scheme directed by upper management at Pfizer, and that the Government had specifically identified the crimes Pfizer had committed.[377] Waxman also knew or chose not to know of the notes taken by the attendees at those presentations, which revealed that the Government realized the off-label promotion of Bextra had continued despite the Government's criminal investigation into Neurontin.[378] Further, Waxman knew, or chose not to seek the

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375 Ex. 220 at PFE-DERIV 00004034-35; Ex. 67 (11/14/13 Waxman Depo.) at 70:22-72:8; Ex. 211 at PFE-JONES 00006996-7012.

376 Ex. 211 at PFE-JONES 00007013-14; Ex. 258 at DOJ000205, 207; Ex. 314 at DOJ000224, 226.

377 Ex. 258 at DOJ000205, 207; Ex. 314 at DOJ000224, 226.

378 Ex. 258 at DOJ000208; Ex. 314 at DOJ000227.

information, that the Government estimated that 76% of total Bextra revenue was from non-approved indications and calculated that 52% of total Bextra revenue was for 20 mg doses.[379]

231. Although the Government sent Pfizer a formal target letter on February 5, 2008, Waxman had known "all along [Pfizer was] a focus of the grand jury investigation."[380]

232. On February 5, 2008, Pfizer authorized its counsel to communicate to the Government a "prepared-to-recommend" settlement offer of $50 to 70 million dollars.[381] On March 28, 2008, Pfizer authorized its counsel to communicate to the Government a "prepared to recommend" $250 million settlement offer.[382] In or around June 2008, Pfizer authorized its counsel to communicate to the Government a "prepared to recommend" offer of $750 million to settle the Government Investigation.[383]

233. From at least February 2004 through February 2008, Waxman signed every quarterly in-house legal representation letter provided to KPMG, in which he purported to describe the status of Government Investigations, such as the ones involving Bextra, Geodon and Lyrica.[384]

G. Levin Knew or Recklessly Disregarded that His Class Period Statements Were False and Misleading When Made

1. Levin's Roles and Responsibilities at Pfizer

234. Between March 2005 and September 10, 2007, Levin served as Pfizer's CFO.[385]

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379 Ex. 258 at DOJ000201, 203.

380 Ex. 67 (11/14/13 Waxman Depo.) at 211:8-212:10.

381 Ex. 104 at PFE-JONES 0007028; Ex. 55 (Lankler Depo.) at 124:12-22.

382 Petrosinelli Decl., Ex. Y-6 at PFE DERIV 00066378-79; Ex. 55 (Lankler Depo.) at 124:12-22.

383 Ex. 55 (Lankler Depo.) at 124:12-22; Ex. 437 at PFE-JONES 00002261.

384 *E.g.*, Ex. 328 at 27-29; Ex. 466 at 36; Ex. 350 at KPMG-PFIZ-DS 0004486-90.

235. From July 2005 through December 2006, Levin was a member of Pfizer's Compliance Committee.[386] In his role as a member of the Compliance Committee, it was Levin's responsibility to help "avoid potential harm to the reputation [to] Pfizer and allies."[387]

236. Between February 19, 2004 and September 10, 2007, Levin was a member of the Disclosure Committee and regularly attended its meetings.[388] During the same time period, Levin attended the CEO/CFO Certification Meetings for the purpose of attesting to the accuracy of the Company's SEC filings.[389] Levin attended Audit Committee meetings between April 27, 2005 and November 1, 2007.[390] During the December 17, 2001 Audit Committee meeting he was apprised of the investigation by the U.S. Attorney's office in Boston regarding Neurontin.[391]

2. Levin Knew or Recklessly Disregarded that His Statements Concerning Pfizer's Compliance with Healthcare Law Were False and Misleading

237. While serving as a member of the Compliance Committee, Levin regularly attended meetings during which specific allegations of Pfizer's violation of laws concerning illegal kickbacks, improper use of starters, improper influencing of doctors through speaker programs, improper CME

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385 Dkt. No. 259, ¶7.

386 *See, e.g.*, Ex. 404; Ex. 471.

387 Ex. 386 at PFE DERIV 00023699-700.

388 *See, e.g.*, Ex. 414; Ex. 462.

389 Ex. 456; Ex. 197.

390 Exs. 534-538.

391 Ex. 537.

programs and the off-label promotion of various products – including Bextra – were compiled, analyzed and tracked through the legal process.[392]

238. On May 28, 2004, Levin participated in a Corporate Compliance meeting during which the Neurontin CIA and consent decree were discussed.[393]

239. On July 15, 2004, Pfizer's outside counsel, Covington, presented "a pretty extensive slide deck" relating to the marketing and sale of Bextra to the DOJ and OIG.[394] The slide deck noted that a *qui tam* complaint had been filed alleging the promotion of "Bextra for 'Acute Pain'" through "Improper Comparison to Vioxx," "Improper Dissemination of Medical Literature," "Protocols and Standing Orders," "Use of Physician Consultants" and for "Pre- and Post-Operative Use" as well as the promotion of Bextra "20 Mg for Uses Other Than Primary Dysmenorrhea."[395] The slide deck also noted Pfizer's "Review of Headquarters Bextra Sales Marketing Practices" and its "Ongoing Review of Select Geographic Areas," which included a finding from a "Physician Recall Report

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[392] *E.g.*, Ex. 417 at PFE DERIV 01146196 (Distribution included Kindler, Levin and Waxman), 198, 206 ("improperly utilized speaker program funds"), 207 ("Bextra off label"), 215 ("District Manager [DM] provided inappropriate direction to representatives related to the use of unapproved detailing materials"), 218 ("improper promotion" and "improper payments to physicians" involving Bextra and other drugs), 226 (representative "improperly paid doctors in connection with dinner and speaker programs" and "detailed a product using unapproved detailing material"), 230 ("improperly distributed samples"). Ex. 409 at PFE DERIV 00069302-35, 312, 315 (same); Ex. 410 at PFE DERIV 00069325-26, 329 (same); Ex. 407 at PFE DERIV 00069214-16, 225 (same), 222 ("inappropriate direction to representatives related to the use of unapproved detail materials"); Ex. 408 at PFE DERIV 00069233-34, 237, 253 (same); Ex. 387 at PFE DERIV 00023983, 985, 4007, 4010, 4016, 4018-19, 4025-26; Ex. 389 at PFE DERIV 00024460, 464, 488, 492, 494, 497, 499-500; Ex. 406 at PFE DERIV 00069064, 68, 92, 95-96, 98, 101, 103-04; Ex. 390 at PFE DERIV 00024511, 513, 518, 522, 546, 550, 552, 555, 558.

[393] Ex. 403; Ex. 405.

[394] Ex. 437 at PFE-JONES 00002299-300; Ex. 211 at PFE-JONES 00006992-93.

[395] Ex. 247 at PFE DERIV 00066670.

March 2004" that "acute pain/inflammation now [wa]s the leading Bextra usage discussion" between sales representatives and physicians.[396]

240. On August 12, 2004, the New York Attorney General sent a subpoena to Pfizer concerning the off-label promotion of six drugs, including Geodon.[397] As a Corporate Compliance member, Levin tracked the allegations of off-label promotion of Geodon and tracked the New York Attorney General's investigation during Compliance Committee meetings.[398]

241. Cangialosi, Levin and Lankler received Mooney's November 2006 memo concerning internal controls over HCC, which concluded that "It is possible, then, that violations of laws and regulations . . . could be seen as having a material effect on the reliability of financial reporting and as a significant deficiency for SOX purposes."[399]

242. During the November 16-17, 2004 meeting between Covington and the Government, the Company made a presentation entitled "Pfizer Inc. Review and Voluntary Disclosure Relating to Bextra Allegations."[400] The slide deck noted that after "Hundreds of Thousands of Documents Reviewed" and "Over 70 Interviews Conducted," Pfizer found that it was a "Senior Management Decision to Make Available Under WLF" a Bextra reprint on "Dental Pain (vs. Tylox)," and that surveys of the sales force and the physicians they detailed revealed "[m]any [sales representatives] communicat[ing] '10 mg. is for OA and RA and 20 mg. is for acute pain states,'" and that "[t]he most common positioning is . . . 'Bextra for acute pain,'" although "[s]everal . . . mention[ed] their

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396 Ex. 247 at PFE DERIV 00066698, 706.

397 Ex. 213.

398 *E.g.*, Ex. 441 at PFE DERIV 00069448.

399 Ex. 161 at PFE-JONES 00005991; Ex. 61 (5/31/13 Mooney Depo.) at 200:7-201:1.

400 Ex. 397.

discomfort in delivering the desired positioning [because] it is Celebrex that has the acute pain data vs. narcotics that they can show to physicians, yet they are being asked to position Bextra for the acute patient."[401] On December 1, 2005, Levin was informed of details of the Government's investigation into the off-label promotion of both Bextra and other products."[402] Levin was also informed that the *qui tam* complaint filed in 2003 specifically alleged that Pfizer employees detailed Bextra by "affirmatively referring to Bextra's efficacy and acute pain outside of the approved indications with physicians," "developing hospital and surgical protocols with physicians and hospitals that called for the use of Bextra for non-arthritic surgical pain" and "disseminating non-WLF journal articles referring to Bextra's efficacy in various acute pain models."[403]

243. When he became CFO, Levin knew that Pfizer was subject to the DOJ investigation into Bextra off-label promotion.[404]

244. On April 27, 2005, Levin was informed that new *qui tam* complaints had been filed against Pfizer that "suggest a pattern of potentially improper promotional conduct" and that the one filed in the Eastern District of Virginia related to the improper promotion of Bextra.[405]

245. On October 17, 2006, Pfizer's Disclosure Committee met.[406] Cangialosi, Levin, Waxman, Fox and Lankler participated in the meeting.[407] During the meeting, it was reported that

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401 Ex. 397 at PFE DERIV 00066 490, 512, 529, 599.

402 Ex. 224 PFE DERIV 00003429-30.

403 Ex. 441 at PFE-JONES 00006635.

404 Ex. 58 (9/23/14 Levin Depo.) at 10:21-11:7.

405 Ex. 412 at PFE DERIV 00076058; Ex. 160 at PFE-JONES 00005330-32.

406 Ex. 126.

407 Ex. 126.

there was "a possible significant deficiency in connection with internal controls over certain U.S. pharmaceutical sales and marketing practices."[408]

246. On October 31, 2006, the Disclosure Committee met again.[409] Cangialosi, Donnelly, Levin, Fox and Lankler participated in the meeting.[410] During the meeting, it was reported by Donnelly that:

> [A] significant deficiency in connection with internal controls over certain U.S. pharmaceutical sales and marketing practices [existed] and he answered various questions from members of the Committee. Mr. Donnelly indicated that he would bring this matter to the attention of the Audit Committee . . . in connection with the upcoming conference call with the Committee to review the [third quarter] 10-Q.[411]

247. On November 1, 2006, Pfizer conducted its 3Q06 Certification Meeting.[412] Kindler, Levin, Waxman, Shedlarz, Cangialosi, Donnelly, Lankler and Fox participated in the meeting.[413] During the meeting, Donnelly reported on the significant deficiency in internal controls over U.S. pharmaceuticals sales and marketing practices and answered questions from Kindler, Shedlarz and Levin regarding the matter.[414]

248. On April 7, 2005, Levin received a report from IA entitled "US Field Force Travel & Entertainment New York Headquarters."[415] Gifts to physicians from Pfizer sales representatives

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408 Ex. 126 at PFE-JONES 00036561.

409 Ex. 127.

410 Ex. 127.

411 Ex. 127 at KPMG-PFIZ-DS 0002898.

412 Ex. 128.

413 Ex. 128.

414 Ex. 128 at PFE-JONES 00036579.

415 Ex. 101.

were among the violations that the report noted "could result in a fine or penalty to Pfizer."[416] IA gave this audit for this area (Travel & Entertainment) the lowest possible audit rating, *i.e.*, unsatisfactory.[417] The Company was understandably disappointed with this audit result.[418] On December 1, 2005, Waxman informed Kindler, McKinnell, Levin and Read that the Government has "broadened the scope of their review to include payments made to physicians, in connection with both Bextra and other products."[419] On December 16, 2005, Levin received a report from IA entitled "U.S. Sales Force – Call Notes and E-mails New York Headquarters" which analyzed sales representatives' call notes and noted that "[d]etailing to and providing samples to physicians who may not typically use the product for its indicated use(s) could lead to the perception that the purpose of the visit was to promote the product for use beyond its approved indications."[420] IA gave this audit of call notes the lowest possible audit rating, *i.e.* unsatisfactory.[421] The report also stated that "[b]ecause the subjects of the planned [Call Notes and e-mails] audit are at issue in pending state and federal government investigations and in private civil litigation, in-house Pfizer counsel and attorneys at the law firm Covington and Burling provided directions to [IA] regarding the conduct of this audit."[422]

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416 Ex. 101 at PFE DERIV 00075597.

417 Ex. 101 at PFE DERIV 00075592.

418 Ex. 102 at Jenner-A 10000251931.

419 Ex. 224 at PFE DERIV 00003427-30.

420 Ex. 103 at KPMG-PFIZ-DS 007301.

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

422 Ex. 103 at KPMG-PDIZ-DS 007294.

249. On May 22, 2006, Levin received a report from IA entitled "Marketing Promotional Speaker Programs New York Headquarters."[423] Again, IA gave this audit the lowest possible audit rating, *i.e.*, unsatisfactory.[424] The audit report cited to numerous serious weaknesses concerning marketing promotional speaker programs, including, but not limited to, inconsistencies that increased "risk that processes and controls may not be properly understood, communicated, or executed, which could result in violations of laws and regulations governing healthcare compliance."[425]

250. On June 21, 2006, Levin attended the Audit Committee meeting during which the control weaknesses in the Marketing Promotional Speaker Programs report was discussed.[426]

251. On August 17, 2006, the Government presented to Pfizer several slide decks and hundreds of supporting documents "concerning contentions about alleged off-label promotion" of Bextra.[427] The slide deck titled "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

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423 Ex. 107.

424 Ex. 107 at PFE DERIV 00075210.

425 Ex. 107 at PFE DERIV 00075213.

426 Ex. 425 at PFE DERIV A 00001396, 98.

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

Influence doctors" at "Consultant Meetings/Advisory Boards," "Control of purportedly independent CME," and the "Publication Strategy"; and (5) that "HQ Knowledge" was demonstrated by the "Bextra Positioning for Acute Pain" and "Headquarters knowledge of promotion for unapproved uses."[428] The slide deck titled "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" the DOJ was considering bringing against Pfizer, which included Food, Drug and Cosmetic 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 Conduct continued despite: Ongoing Neurontin criminal investigation[,] Two CIA's[,] Two self-disclosures on other issues[,] Numerous internal complaints and red flags [and] Disclosure of the Bextra *qui tam* complaint and ongoing Bextra investigation."[429] The slide deck titled "Summary of Bextra Call Note Evidence" presented call note excerpts by sales representatives all over the United States reflecting the promotion of Bextra for acute pain.[430] 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.[431]

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428 Ex. 256 at DOJ 000235-40.

429 Ex. 258 at DOJ000199, 205, 207-08.

430 Ex. 251 at DOJ000001-17.

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

252. In December 2006, Lankler informed Levin, Kindler, Read and Waxman of the details of the Government's August and September 2006 presentations of evidence demonstrating Pfizer's "off-label promotion of Bextra and the Company's interactions with physicians in the form of advisory boards, mentorships, CME and publication strategies."[432] By December 6, 2006, Levin knew that Pfizer had tasked Read to take "aggressive actions . . . to improve the control and compliance environment in the US organization."[433] Further, Levin knew that Pfizer had also tasked Read with cleaning up the very areas that the DOJ had identified as evidence of improper off-label promotion of Bextra: "speaker programs, advisory boards and consultant payments as well as field force travel and entertainment."[434]

253. Pfizer's detailed internal summary of the Government's August 2006 presentation, which Levin either received (or chose not to receive), included multiple slides of "aggravating factors" which included:

- The FDA said ***No***.
- The FDA's concern was ***Safety***.
- Safety ***Is*** the issue.
- Knowledge at the Top.
- A Deliberate Scheme.
- Pervasive Misconduct.[435]

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[432] Ex. 433 at PFE DERIV A 00004035.

[433] Ex. 155 at KPMG-PFIZ-DS 017942.

[434] Ex. 155 at KPMG-PFIZ-DS 017942 (Read admitted this work was "necessary" because of problems "in areas such as speaker programs, advisory boards and consultant payments as well as field force travel and entertainment").

[435] Ex. 211 at PFE-JONES 00007013-14; Ex. 258 at DOJ000205, 207; Ex. 314 at DOJ000224, 226.

254. Levin knew (or chose not to seek) the information, that during those August and September 2006 presentations, the Government had evidence indicating that the illegal promotion of Bextra was pervasive, that it was a deliberate scheme known by upper management at Pfizer, and that the Government had specifically identified the crimes Pfizer had committed.[436] Levin also knew (or chose not to know) of the notes taken by attendees at those presentations, which revealed that the Government realized the off-label promotion of Bextra had continued despite the Government's criminal investigation into Neurontin.[437] Further, Levin knew, or chose not to seek the information, that the Government estimated that 76% of total Bextra revenue was from non-approved indications and calculated that 52% of total Bextra revenue was for 20 mg doses.[438]

255. By December 8, 2006, defendants Levin, Kindler, Read and Waxman were informed that Pfizer Corporate Compliance was "investigating several matters involving the alleged off-label promotion of Lyrica."[439]

256. On February 23, 2007, Levin received a report from IA entitled "Publications & Authorships New York Headquarters."[440] Again, IA gave this audit the lowest possible audit rating, *i.e.*, unsatisfactory.[441] On February 28, 2007, KPMG expressed its frustration that this audit report was not discussed during the February 21, 2007 Audit Committee meeting.[442] In response to

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436 Ex. 258 at DOJ000205, 207; Ex. 314 at DOJ000224, 226.

437 Ex. 258 at DOJ000208; Ex. 314 at DOJ000227.

438 Ex. 258 at DOJ000201, 203.

439 Ex. 433 at PFE DERIV A 00004035.

440 Ex. 75.

441 Ex. 75 at PFE DERIV 00075605.

442 Ex. 162 at KPMG-PFIZ-DS 016175.

KPMG's frustration, Levin witnessed Kindler "correct[ing]" the head of IA for his oversight regarding the unsatisfactory audit report.[443]

257. On March 16, 2007, Levin knew that Read's task of cleaning up serious weaknesses in the Company's controls over healthcare compliance was in reaction to the Audit Committee's expressed concerns.[444]

258. On June 12, 2007, Pfizer's criminal defense counsel, DLA Piper, delivered a memo to Corporate Compliance detailing DLA Piper's findings concerning the off-label promotion of Geodon.[445] DLA Piper concluded that the Company's sales force "engaged third-party physicians for Pfizer-sponsored speaker programs during which the speakers affirmatively presented information on the use of Geodon (1) for children and adolescents, and (2) at doses exceeding 160 mg per day (primarily in adults) – uses that are not FDA approved."[446] DLA Piper also confirmed that, from 2003 to 2006, Pfizer spent at least $1.4 million[447] on "speaker programs for key physicians who regularly presented information on non-FDA approved uses of Geodon . . . across the country."[448]

259. During the June 27, 2007 Audit Committee meeting, Lankler reported a sales representative's allegation "that his supervisors had promoted the use of speakers who would discuss prescribing Geodon off-label to children and adolescents and at improper dosages," and that an

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443 Ex. 162 at KPMG-PFIZ-DS 016175.

444 Ex. 118 at PFE DERIV A 00003833.

445 Ex. 168.

446 Ex. 168 at PFE-DERIV 00003754.

447 Ex. 168 at PFE-DERIV 00003758.

448 Ex. 168 at PFE-DERIV 00003757.

investigation would be conducted as well as a review as to "whether any improper detailing occurred."[449] Lankler also informed Kindler and the Audit Committee "that effective immediately, child psychiatrists were being eliminated from credit and quota."[450]

3. Levin Knew or Recklessly Disregarded that Pfizer's Legal Proceedings and FAS 5 Disclosures Were False and Misleading When Made

260. At the time Levin started as CFO, he was aware of the guilty plea and $430 million in fines and penalties in the Neurontin case.[451]

261. Prior to the Class Period, Levin knew that the Company had promoted Bextra for unlawful off-label purposes.[452]

262. On September 26, 2005, while Levin was CFO, Pfizer's Legal Division reported that "it is our estimation based on the facts and circumstances to date that we are likely to be forced to reach some form of settlement of [the Bextra Investigation]."[453] At the time, Levin knew that Pfizer had admitted to the Government that Pfizer employees had destroyed documents relevant to the Bextra Investigation.[454]

263. Pfizer's 2Q06 Form 10-Q, certified by Levin and dated August 11, 2006, described certain state attorneys general investigations as follows: "We received a letter from the Office of the Attorney General of the State of New York in 2004 requesting documents and information

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449 Ex. 431 at PFE DERIV A 00003787.

450 Ex. 431 at PFE DERIV A 00003790.

451 Ex. 58 (9/23/14 Levin Depo.) at 8:19-9:10.

452 Ex. 58 (9/23/14 Levin Depo.) at 24:5-11.

453 Petrosinelli Decl., Ex. P-5.

454 Ex. 244; Ex. 160 at PFE-JONES 00005332.

concerning clinical trials of certain of our pharmaceutical products for indications other than those approved by the FDA and concerning possible promotion of those products for such indications. We also received a letter from the Office of the Attorney General of the State of Connecticut in 2004 requesting similar materials concerning Zoloft."[455]

264. Pfizer's 2Q06 Form 10-Q signed by Levin, described the Bextra Investigation as follows: "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."[456]

265. On October 24, 2006, IA brought to the attention of Levin the fact that there was a significant deficiency in HCC controls. The head of IA, Donnelly, stated that he met with Levin and discussed the HCC issues with him. According to the email, KPMG was also certain of the significant deficiency.[457]

266. No later than December 2006, Lankler informed Levin and others about Pfizer's August 2006 meeting with the Government. Pfizer possessed all the call notes that were the focus of the Government's presentation. According to Levin, Lankler kept him apprised of what the government was thinking about the facts of the Bextra Investigation.[458]

267. The Government's presentation to Pfizer included multiple slides of "aggravating factors." These aggravating factors included:

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455 *See* Ex. 12 at 6 (incorporating by reference Statements made in 2005 Form 10-K (Dkt. No. 247-1 at 147).

456 *See* Ex. 12 at 6 (incorporating by reference Statements made in 2005 Form 10-K (Dkt. No. 247-1 at 147).

457 Ex. 114 at PFE DERIV 01064273.

458 Ex. 57 (12/10/13 Levin Depo.) at 101:11-25.

- The FDA said ***No***.
- The FDA's concern was ***Safety***.
- Safety ***Is*** the issue.
- Knowledge at the Top.
- A Deliberate Scheme.
- Pervasive Misconduct.[459]

268. On November 3, 2006, Levin in Pfizer's 3Q06 Form 10-Q misrepresented to investors the scope of the subpoenas received from certain attorneys general and the DOJ.[460]

H. Read Knew or Recklessly Disregarded that His Class Period Statements Were False and Misleading When Made

1. Read's Roles and Responsibilities at Pfizer

269. Prior to the Class Period and through August 15, 2006, Read was Area President for European, Canadian, Latin America and Africa Operations.[461] On August 15, 2006, Kindler promoted Read to President Worldwide Pharmaceutical Operations ("WPO").[462] As President of WPO, Read was responsible for operations and sales and marketing of Pfizer's pharmaceutical products.[463] Read served as WPO President from August 15, 2006 through the end of the Class Period.[464]

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459 Ex. 211 at PFE-JONES 00007013-14; Ex. 258 at DOJ000205, 207; Ex. 314 at DOJ000224, 226.

460 Ex. 215 at 6 (incorporating by reference Statements in 2005 Form-K (Dkt. No. 247-1 at 147).

461 Ex. 226 at Crosbi-H 10000212515; Ex. 63 (Read Depo.) at 40:4-18; Dkt. No. 262, ¶9.

462 Ex. 225 at WESTLOCK_JONES_046488.

463 *See* Ex. 63 (Read Depo.) at 40:19-24.

464 *See* Dkt. No. 262, ¶¶10, 12.

270. From August 15, 2006 through the end of the Class Period, Read was a member of Pfizer's ELT.[465] The ELT's time and decision-making responsibilities focused on, among other things, operating plans and "[m]atters with material enterprise-wide significance – *e.g.*, risk and reputation matters."[466] As a member of the ELT, Read was responsible for reviewing and approving the Company's communications to investors in SEC filings and press releases (Read to take the lead on assessing "statements to the investment community").[467] As a member of the ELT, Read was responsible for approving settlements greater than $100 million or cases involving unusual significance.[468]

271. Independent of his role on the ELT, Read was further responsible for reviewing and commenting on the entirety of the Company's SEC filings before their filing with the SEC and dissemination to the investment community.[469]

272. Between December 12, 2005 and December 15, 2008, Read regularly attended and presented during Audit Committee meetings.[470]

2. Read Knew or Recklessly Disregarded that His Statements Concerning Pfizer's Compliance with Healthcare Law Were False and Misleading When Made

273. On July 15, 2004, Pfizer's outside counsel, Covington, presented "a pretty extensive slide deck" relating to the marketing and sale of Bextra to the DOJ and OIG.[471] The slide deck noted

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465 Ex. 225 at WESTLOCK_JONES_046487; Ex. 202 at KPMG-PFIZ-DS 037981.

466 Ex. 202 at KPMG-PFIZ-DS 037983.

467 Ex. 202 at KPMG-PFIZ-DS 037997.

468 Ex. 202 at KPMG-PFIZ-DS 037981, 986.

469 *E.g.*, Ex. 200 at PFE-JONES 00036631-32; Ex. 201 at PFE-JONES 00036865-66, 869.

470 *E.g.*, Ex. 426 at PFE-DERIV A 00001414-15; Ex. 420 at PFE DERIV A 00001296; *see* Ex. 57 (12/10/13 Levin Depo.) at 288:9-289:12.

that a *qui tam* complaint had been filed alleging the promotion of "Bextra for 'Acute Pain'" through "Improper Comparison to Vioxx," "Improper Dissemination of Medical Literature," "Protocols and Standing Orders," "Use of Physician Consultants" and for "Pre- and Post-Operative Use" as well as the promotion of Bextra "20 Mg for Uses Other Than Primary Dysmenorrhea."[472] The slide deck also noted Pfizer's "Review of Headquarters Bextra Sales Marketing Practices" and its "Ongoing Review of Select Geographic Areas," which included a finding from a "Physician Recall Report March 2004" that "acute pain/inflammation now [wa]s the leading Bextra usage discussion" between sales representatives and physicians.[473]

274. During the November 16-17, 2004, meeting between Covington and the Government, the Company made a presentation entitled "Pfizer Inc. Review and Voluntary Disclosure Relating to Bextra Allegations."[474] The slide deck noted that after "Hundreds of Thousands of Documents Reviewed" and "Over 70 Interviews Conducted," Pfizer found that it was a "Senior Management Decision to Make Available Under WLF" a Bextra reprint on "Dental Pain (vs. Tylox)," and that surveys of the sales force and the physicians they detailed revealed "[m]any [sales representatives] communicat[ing] '10 mg. is for OA and RA and 20 mg. is for acute pain states,'" and that "[t]he most common positioning is . . . 'Bextra for acute pain,'" although "[s]everal . . . mention[ed] their discomfort in delivering the desired positioning [because] it is Celebrex that has the acute pain data

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471 Ex. 437 (9/20/10 O'Connor Deriv. Depo.) at 73:4-21; Ex. 211 at PFE-JONES 00006992-93.

472 Ex. 247 at PFE DERIV 00066670.

473 Ex. 247 at PFE DERIV 00066698, 706.

474 Ex. 397 at PFE DERIV 00066488.

vs. narcotics that they can show to physicians, yet they are being asked to position Bextra for the acute patient."[475]

275. In a December 1, 2005 memo to the Audit Committee, Waxman and Lankler made Read aware of the status of the Bextra Investigation, including several presentations Pfizer made to the Government.[476] The memo from Lankler and Waxman also informed Read that the *qui tam* complaint filed in 2003 specifically alleged that Pfizer employees detailed Bextra by "affirmatively referring to Bextra's efficacy and acute pain outside of the approved indications with physicians," "developing hospital and surgical protocols with physicians and hospitals that called for the use of Bextra for non-arthritic surgical pain" and "disseminating non-WLF journal articles referring to Bextra's efficacy in various acute pain models."[477]

276. On December 18, 2006, Read attended the Audit Committee meeting and reported how he was going to address significant weaknesses in the Company's healthcare compliance.[478]

277. The healthcare compliance issues Read was responsible for addressing are demonstrable by IA audit reports issued in 2005.[479]

278. During a December 2006 Audit Committee meeting, Read informed members that "there have been a number of unsatisfactory internal audits and reviews in areas such as speaker programs, advisory boards and consultant payments as well as field force travel and entertainment

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

476 Ex. 441 at PFE-JONES 00006635.

477 Ex. 441 at PFE-JONES 00006635.

478 *See* Ex. 155 at KPMG-PFIZ-DS 017939, 42.

479 *See* ¶160, *supra*.

that have contributed" to a significant deficiency rating.[480] Read informed the Audit Committee that "I will work . . . to ensure that aggressive actions are taken to improve the control and compliance environment in the US organization."[481]

279. By December 8, 2006, Read was informed that Pfizer Corporate Compliance was "investigating several matters involving the alleged off-label promotion of Lyrica."[482]

280. On February 23, 2007, IA issued an unsatisfactory rating in an internal audit report of Publications and Authorships.[483]

281. In March 2007, Read again reported what he was doing to address weaknesses in the Company's ability to ensure it complied with healthcare law and to "address the concerns of the Audit committee."[484]

282. On February 23, 2007, IA issued an unsatisfactory rating in an internal audit report of U.S. Field Force Travel & Entertainment Expenses (noting an increased risk of non-compliance with health care laws and regulations).[485]

283. On June 27, 2007, Read reported to the Audit Committee and updated his analysis of the key risks associated with healthcare compliance issues posed by the Company's promotional activities.[486] Read reported to the Audit Committee that the factors weighing most heavily in his

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480 Ex. 155 at KPMG-PFIZ-DS 017942.

481 Ex. 155 at KPMG-PFIZ-DS 017942.

482 Ex. 433 at PFE DERIV A 00004035.

483 Ex. 75 at PFE DERIV 00075605.

484 Ex. 118 at PFE DERIV A 00003833.

485 Ex. 119 at PFE DERIV 00077685, 690.

486 Ex. 380 at PFE DERIV 00003792.

analysis were "those risks deemed most potentially damaging to the company based on the sheer magnitude of the financial penalties involved, potential criminal prosecution and/or damage that they can cause to the company's image."[487] With regard to Pfizer's image, Read noted that the reputational impact associated with Pfizer's promotional conduct "is arguably among the greatest exposures facing the company."[488]

284. In October 2007, Read reported additional significant deficiencies in the key control designed to ensure that all the Company's promotional activities complied with U.S. healthcare law.[489] As noted in the WPO report, "[v]iolations . . . are not documented and tracked" and Company guidelines "do not include discipline for violations of compliance issues."[490]

3. Read Knew or Recklessly Disregarded that His Statements Concerning Pfizer's Drug Revenues, Legal Proceedings and FAS 5 Disclosures Were False and Misleading When Made

285. Prior to and after becoming a member of the ELT on August 15, 2006, Pfizer in-house attorneys, including Lankler, informed Read of the status of various governmental investigations, including the New York Attorney General's investigation into Pfizer's unlawful off-label promotion of Geodon, as well as the DOJ investigation into the off-label promotion of Bextra.[491]

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487 Ex. 380 at PFE DERIV 00003791-99 at 92.

488 Ex. 380 at PFE DERIV 00003791-99.

489 Ex. 203 at 3.

490 Ex. 203 at 3; *see also* Ex. 157 at PFE DERIV A 00003938, 943 (Appendix A).

491 *See, e.g.*, Ex. 433 at PFE DERIV A 00004034-35, December 8, 2006 Compliance Pre-Read Memo from Lankler to Read (discussing August 2006 meeting with DOJ regarding Bextra allegations); *see also* Ex. 447 (compilation of privilege log entries concerning government investigations) at PFE-JONES 00026830, 6834-35, 6871, 6927, 6987-88, 7003, 7006, 7030, 7521, 7527; Ex. 442 at PFE-JONES 00025994, 6023 (same); Ex. 443 at PFE-JONES 00026115 (same); Ex. 448 at PFE-JONES 0027635, 640, 644 (same); Ex. 444 at PFE-JONES 00026137 (same);

286. On October 20, 2006, IA reported that "[t]he Corporate Compliance Group has been looking into several compliance issues involving the alleged inappropriate promotion of Lyrica. Two of these matters have involved Regional Managers."[492]

287. On November 3, 2006, Pfizer's 3Q06 Form 10-Q stated with regard to state attorneys general investigations: "We received a letter from the Office of the Attorney General of the State of New York in 2004 requesting documents and information concerning clinical trials of certain of our pharmaceutical products for indications other than those approved by the FDA and concerning possible promotion of those products for such indications. We also received a letter from the Office of the Attorney General of the State of Connecticut in 2004 requesting similar materials concerning Zoloft."[493]

288. On November 3, 2006, Pfizer's 3Q06 Form 10-Q stated with regard to the Government Investigation: "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."[494]

289. Prior to December 6, 2006, Read was fully aware of the weaknesses associated with problematic promotional activities including, but not limited to, travel and entertainment, speaker

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Ex. 445 at PFE-JONES 00026243 (same); Ex. 446 at PFE-JONES 00026338, 357, 360, 458, 691, 697, 700, 702, 735, 736, 737, 740, 741, 781, 789, 801 (same).

492 Ex. 113 at 5.

493 Ex. 13.

494 *See, e.g.*, Ex. 215 at 6 (incorporating by reference statements made in 2005 Form 10-K (Dkt. No. 247-1 at 147)).

programs, advisory boards and consultant payments, and publications and authorships, all of which were used to promote Pfizer's products.[495]

290. On December 8, 2006, Read was specifically informed that Pfizer's Corporate Compliance group was investigating the off-label promotion of Lyrica.[496]

291. In December 2006, Lankler informed Read of the details of the Government's August and September 2006 presentations of evidence demonstrating Pfizer's "off-label promotion of Bextra and the Company's interactions with physicians in the form of advisory boards, mentorships, CME and publication strategies."[497]

292. On August 17, 2006, the Government presented to Pfizer several slide decks and hundreds of supporting documents "concerning contentions about alleged off-label promotion" of Bextra.[498] The slide deck titled "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 Strategy"; and (5) that "HQ Knowledge" was demonstrated by the

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495 Ex. 155 at KPMG-PFIZ-DS 017946-47.

496 Ex. 433 at PFE DERIV A 00004035.

497 Ex. 433 at PFE DERIV A 00004035.

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

"Bextra Positioning for Acute Pain" and "Headquarters knowledge of promotion for unapproved uses."[499] The slide deck titled "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" the DOJ was considering bringing against Pfizer, which included Food, Drug and Cosmetic 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 "[t]he Conduct continued despite: Ongoing Neurontin criminal investigation[,] Two CIA's[,] Two self-disclosures on other issues[,] Numerous internal complaints and red flags [and] Disclosure of the Bextra *qui tam* complaint and ongoing Bextra investigation."[500] The slide deck titled "Summary of Bextra Call Note Evidence" presented call note excerpts by sales representatives all over the United States reflecting the promotion of Bextra for acute pain.[501] 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.[502]

293. The Government's presentation, which Read either received, or chose not to receive, included multiple slides of "aggravating factors." These aggravating factors included:

- The FDA said ***No***.

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499 Ex. 256 at DOJ000235-40.

500 Ex. 258 at DOJ000199, 205, 207-08.

501 Ex. 251.

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

- The FDA's concern was ***Safety***.
- Safety ***Is*** the issue.
- Knowledge at the Top.
- A Deliberate Scheme.
- Pervasive Misconduct.[503]

294. Read knew, or chose not to seek the information, that during those August and September 2006 presentations, the Government had evidence indicating that the illegal promotion of Bextra was pervasive, that it was a deliberate scheme directed by upper management at Pfizer, and that the Government had specifically identified the crimes Pfizer had committed.[504] Read also knew or chose not to know of the notes taken by attendees at those presentations, which revealed that the Government realized the off-label promotion of Bextra had continued despite the Government's criminal investigation into Neurontin.[505] Further, Read knew, or chose not to seek the information, that the Government estimated that 76% of total Bextra revenue was from non-approved indications and calculated that 52% of total Bextra revenue was for 20 mg doses.[506]

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503 Ex. 211 at PFE-JONES 00007013-14; Ex. 258 at DOJ000205, 207; Ex. 314 at DOJ000224, 226.

504 Ex. 258 at DOJ000205, 207; Ex. 314 at DOJ000224, 226.

505 Ex. 258 at DOJ000208; Ex. 314 at DOJ000227.

506 Ex. 258 at DOJ000201, 203.

I. McKinnell Knew or Recklessly Disregarded that His Class Period Statements Were False and Misleading When Made

1. McKinnell's Roles and Responsibilities at Pfizer

295. Between April 2001 and July 2006, McKinnell served as Pfizer's CEO and Chairman of the Board of Directors.[507] McKinnell continued to serve on Pfizer's Board until February 2007.[508] McKinnell served as the Company's CFO before becoming CEO.[509]

296. Before stepping down as Pfizer's CEO, McKinnell served as the head of Pfizer's Leadership Team.[510]

297. McKinnell attended Audit Committee meetings between May 24, 2001 and June 21, 2006, during which the accuracy of the Company's financial statements were discussed prior to their filing with the SEC.[511] McKinnell attended the February 24, 2006 and May 3, 2006 CEO and CFO Certification Meetings.[512]

2. McKinnell Knew or Recklessly Disregarded that His Statements Concerning Pfizer's Compliance with the Law Were False and Misleading When Made

298. Pfizer had been informed of the Government's Investigation into the off-label promotion by, at the latest, February 2004.[513] On July 15, 2004, Pfizer's outside counsel, Covington,

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507 Dkt. No. 270, ¶¶2-4.

508 Dkt. No. 270, ¶¶2-4.

509 Ex. 59 (11/11/13 McKinnell Depo.) at 10:16-22.

510 Ex. 59 (11/11/13 McKinnell Depo.) at 47:25-48:17.

511 *See* Ex. 429; Ex. 425.

512 *See* Ex. 456 PFE-JONES 00036401-02; Ex. 458.

513 Ex. 59 (11/11/13 McKinnell Depo.) at 224:10-227:4 (learned February 2004 of the *qui tam* complaint); Ex. 195 at PFE-JONES 0005227 (Feb. 26, 2004).

presented "a pretty extensive slide deck" relating to the marketing and sale of Bextra to the DOJ and OIG.[514] The slide deck noted that a *qui tam* complaint had been filed alleging the promotion of "Bextra for 'Acute Pain'" through "Improper Comparison to Vioxx," "Improper Dissemination of Medical Literature," "Protocols and Standing Orders," "Use of Physician Consultants" and for "Pre- and Post-Operative Use" as well as the promotion of Bextra "20 Mg for Uses Other Than Primary Dysmenorrhea."[515] The slide deck also noted Pfizer's "Review of Headquarters Bextra Sales Marketing Practices" and its "Ongoing Review of Select Geographic Areas," which included a finding from a "Physician Recall Report March 2004" that "acute pain/inflammation now [wa]s the leading Bextra usage discussion" between sales representatives and physicians.[516]

299. On August 12, 2004, the New York Attorney General sent a subpoena to Kindler and McKinnell concerning the off-label promotion of six drugs, including Geodon.[517]

300. At the November 22, 2004 Pfizer Leadership Meeting, Kindler discussed a prior week's meeting with the USAO and informed members of the Pfizer Leadership Team, including McKinnell and Shedlarz, that the USAO had asked Pfizer to preserve all documents regarding the cardiovascular safety of Bextra and that Pfizer had committed to do so.[518]

301. During the November 16-17, 2004 meeting between Covington and the Government, the Company made a presentation entitled "Pfizer Inc. Review and Voluntary Disclosure Relating to

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

515 Ex. 247 at PFE DERIV 00066670.

516 Ex. 247 at PFE DERIV 00066698, 706.

517 Ex. 213.

518 Ex. 434 at PFE DERIV A 00007406-07.

Bextra Allegations."[519] The slide deck noted that after "Hundreds of Thousands of Documents Reviewed" and "Over 70 Interviews Conducted," Pfizer found that it was a "Senior Management Decision to Make Available Under WLF" a Bextra reprint on "Dental Pain (vs. Tylox)," and that surveys of the sales force and the physicians they detailed revealed "[m]any [sales representatives] communicat[ing] '10 mg. is for OA and RA and 20 mg. is for acute pain states,'" and that "[t]he most common positioning is . . . 'Bextra for acute pain,'" although "[s]everal . . . mention[ed] their discomfort in delivering the desired positioning [because] it is Celebrex that has the acute pain data vs. narcotics that they can show to physicians, yet they are being asked to position Bextra for the acute patient."[520] McKinnell was aware of Pfizer's presentations to the Government and he had access to the presentation slides and backup materials prior to, and throughout, the Class Period.[521]

302. On December 1, 2005, McKinnell was informed that the Government had "broadened the scope of their review to include payments made to physicians, in connection with both Bextra and other products."[522] McKinnell was also informed that the *qui tam* complaint filed in 2003 specifically alleged that Pfizer employees detailed Bextra by "affirmatively referring to Bextra's efficacy and acute pain outside of the approved indications with physicians," "developing hospital and surgical protocols with physicians and hospitals that called for the use of Bextra for non-arthritic surgical pain" and "disseminating non-WLF journal articles referring to Bextra's efficacy in various acute pain models."[523]

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519 Ex. 397.

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

521 Ex. 441 at PFE-JONES 00006634-35.

522 Ex. 441 at PFE-JONES 00006634-35.

523 Ex. 441 at PFE-JONES 00006634-35.

303. On April 27, 2005, McKinnell was informed that new *qui tam* complaints had been filed against Pfizer that "suggest a pattern of potentially improper promotional conduct" and that the one filed in the Eastern District of Virginia related to the improper promotion of Bextra.[524]

304. McKinnell was aware in 2005 that Pfizer employees had violated healthcare law in promoting Bextra for unapproved uses.[525]

305. McKinnell admitted that he knew in May 2005 that Pfizer employees (three sales representatives and one district manager) had attempted to destroy documents relevant to the DOJ's investigation into Pfizer's illegal off-label promotion of Bextra.[526]

306. On July 20, 2005, the FDA sent McKinnell a letter demanding the Company cease and desist from unlawful promotion of Zyvox (*i.e.*, that it was purportedly superior to vancomycin) because the Company had no scientific proof to back up the advertising claim.[527]

307. On April 7, 2005, McKinnell received a report from IA entitled "US Field Force Travel & Entertainment New York Headquarters."[528] Gifts to physicians from Pfizer sales representatives were among the violations that the report noted "could result in a fine or penalty to Pfizer."[529] IA gave this audit for this area (Travel & Entertainment) the lowest possible audit rating, *i.e.*, unsatisfactory.[530] The Company's disappointment with this audit result reached to the highest

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524 Ex. 412 at PFE DERIV 00076056-96 at 058; Ex. 160 at PFE-JONES 00005331-32.

525 Ex. 59 (11/11/13 McKinnell Depo.) at 255:18-257:1; Ex. 60 (9/19/14 McKinnell Depo.) at 27:24-28:5.

526 Ex. 412 at PFE DERIV 00076059; Ex. 60 (9/9/14 McKinnell Depo.) at 27:24-28:15.

527 Ex. 123 at PZ0034666, 669, 670 and 672.

528 Ex. 101.

529 Ex. 101 at PFE DERIV 00075597.

530 Ex. 101 at PFE DERIV 00075592.

levels of the organization, including defendant McKinnell, who was "understandably angry and embarrassed by these findings . . . as indeed we ALL should be."[531] On December 1, 2005, Waxman informed Kindler, McKinnell, Levin and Read that the Government had "broadened the scope of their review to include payments made to physicians in connection with both Bextra and other products."[532] On December 16, 2005, McKinnell received a report from IA entitled "U.S. Sales Force – Call Notes and E-mails New York Headquarters."[533] The report analyzed sales representatives' call notes and noted that, "[d]etailing to and providing samples to physicians who may not typically use the product for its indicated use(s) could lead to the perception the purpose of the visit was to promote the product for use beyond its approved indications."[534] IA gave this audit of call notes the lowest possible audit rating, *i.e.* unsatisfactory.[535] The report informed its recipients, including McKinnell, that "[b]ecause the subjects of the planned [Call Notes and E-mails] audit are at issue in pending state and federal government investigations and in private civil litigation, in-house Pfizer counsel and attorneys at the law firm Covington and Burling provided direction to [IA] regarding the conduct of this audit."[536]

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531 Ex. 102 at Jenner-A 10000251931.

532 Ex. 224 at PFE DERIV 00003429.

533 Ex. 103.

534 Ex. 103 at KPMG-PFIZ-DS 007301.

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

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

308. No later than May 2005, McKinnell knew that a whistleblower complaint had been filed that included allegations of Bextra being promoted for off-label use (for acute pain, improper hospital and surgical protocols, and non-arthritic surgical pain).[537]

309. On May 22, 2006, McKinnell received an IA report with an unsatisfactory rating for Marketing Promotional Speaker Programs (noting "[f]ailure to adequately train speakers . . . increases the risk of off-label content at speaker programs" and "not all contracts included FDA requirements to speak on-label").[538]

310. On June 21, 2006, McKinnell attended the Audit Committee meeting during which the Marketing Promotional Speaker Programs was further discussed.[539]

3. McKinnell Knew or Recklessly Disregarded that His Statements Concerning Pfizer's Legal Proceedings and FAS 5 Disclosures Were False and Misleading

311. As CEO of Pfizer, McKinnell had knowledge of the civil and criminal settlement with the DOJ for the off-label promotion of Neurontin.[540]

312. On September 26, 2005, Pfizer's Legal Division reported that "it is our estimation based on the facts and circumstances to date that we are likely to be forced to reach some form of settlement of [the Bextra Investigation]."[541] At the time, McKinnell knew that Pfizer had admitted to

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537 *See* Ex.60 (9/19/14 McKinnell Depo.) at 27:24-28:15, Dkt. No. 273-4 (Exhibit D-M at PFE-JONES 0006635).

538 Ex. 107 at PFE DERIV 00075214 and 75211.

539 Ex. 333 at PFE DERIV A 00001398.

540 Ex. 59 (11/11/13 McKinnell Depo.) at 83:20-84:8.

541 Petrosinelli Decl., Ex. P-5 at PFE-JONES 00043523-24.

the Government that Pfizer employees had destroyed documents relevant to the Bextra Investigation.[542]

313. On January 16, 2004, McKinnell and Kindler presented to the Board of Directors the proposed resolution of the Neurontin case, including payments of over $400 million.[543]

314. As part of the $430 million settlement of the Neurontin case, the fine was calculated using a well-established formula for estimating actual gain from off-label promotion.[544]

315. McKinnell regularly received financial reports that included information such as Bextra sales revenue.[545] McKinnell knew that Pfizer had data showing the uses for which its drugs were sold.[546]

316. Prior to the Class Period, McKinnell knew that the Company had promoted Bextra for unlawful off-label purposes.[547]

J. Defendants Knew or Recklessly Disregarded the Unlawful Marketing of Pfizer's Products

1. Bextra

317. From 2002 to 2008, multiple complaints were filed against Pfizer alleging the off-label promotion of Bextra.[548]

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542 Ex. 244; Ex. 160 at PFE-JONES 00005332.

543 Ex. 376 at PFE DERIV 00000372-74.

544 Ex. 513 at 44-50; Ex. 179 at 2.

545 Ex. 59 (11/11/13 McKinnell Depo.) at 138:2-140:20; Ex. 531.

546 Ex. 59 (11/11/13 McKinnell Depo.) at 293:15-22; *see also* Ex. 41 (Burch Depo.) at 125:18-126:3.

547 Ex. 59 (11/11/13 McKinnell Depo.) at 256:7-9.

548 *E.g.*, Ex. 84 (Representative Action Complaint filed in Los Angeles Superior Court on December 28, 2002); Ex. 440 (*Kopchinski Qui Tam* Complaint filed under seal in 2003, filed with

318. "In February 2004, the Department of Justice alerted the [C]ompany that it and the HHS, OIG are investigating allegations that the company promoted Bextra for generalized acute pain in possible violation of federal criminal law."[549]

319. On July 15, 2004, Pfizer's outside counsel, Covington, presented "a pretty extensive slide deck" relating to the marketing and sale of Bextra to the DOJ and OIG.[550] The slide deck noted that a *qui tam* complaint had been filed alleging the promotion of "Bextra for 'Acute Pain'" through "Improper Comparison to Vioxx," "Improper Dissemination of Medical Literature," "Protocols and Standing Orders," "Use of Physician Consultants" and for "Pre- and Post-Operative Use" as well as the promotion of Bextra "20 Mg for Uses Other Than Primary Dysmenorrhea."[551] The slide deck also noted Pfizer's "Review of Headquarters Bextra Sales and Marketing Practices" and its "Ongoing Review of Select Geographic Areas," which included a finding from a "Physician Recall Report March 2004" that "acute pain/inflammation now [wa]s the leading Bextra usage discussion" between sales representatives and physicians.[552]

320. By August 2004, Pfizer had changed its Bextra "'sampling activity to best fit current indications'" and was not "'sampl[ing] Bextra 20mg to surgeons anymore,'" because with the "'Department of Justice investigation [still] ongoing . . . Bextra 20 mg starters is one area to focus

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the USAO on October 24, 2005 and received by Pfizer on April 10, 2008); Ex. 160 at PFE-JONES 00005331-32 (April 27, 2005 Audit Committee meeting minutes note "a complaint filed in the Eastern District of Virginia regarding alleged improper promotion of Bextra"); Ex. 495 (*Spencer Qui Tam* Complaint filed under seal in 2005); Ex. 496 PFE-JONES 00104814-906 (*DeMott Qui Tam* Complaint filed under seal in 2005).

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

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

551 Ex. 247 at PFE DERIV 00066670.

552 Ex. 247at PFE DERIV 00066698, 706.

on. Starters can't be introduced to the market with the intent to promote off label. It would not be difficult for the government to make a case regarding this . . . . Currently Bextra 20 mg represents 25% of our Bextra starters. Market is only 2% primary dysmenorrhea. Over 50% of our Bextra 20mg has been going to providers who don't typically treat primary dysmenorrhea.'"[553]

321. In December 2004, Pfizer received a subpoena from the USAO for the District of Massachusetts requesting documents concerning, *inter alia*, clinical studies, sales, promotion and marketing of Bextra.[554]

322. From December 2004 to September 2005, Covington conducted interviews of Pfizer employees who confirmed the deletion of electronic documents related to the promotion of Bextra for non-FDA approved indications.[555]

2. Geodon

323. On September 25, 2006, Pfizer's outside counsel, Epstein Becker & Green, P.C. ("Epstein"), informed the OIG of an Ohio sales representative's allegations that his "district manager encouraged him to detail doctors about the unapproved use of Geodon in children and told him that doses higher than those approved for Geodon were safe and more efficacious than approved doses," and that "he and other sales representatives used specific doctors as promotional speakers because they had clinical experience with off-label uses and the sales representatives knew the doctors would speak off-label."[556] Epstein further informed the OIG that Pfizer and its outside counsel's investigation corroborated the Ohio sales representative's allegations "and showed that certain

553 Ex. 288 at BEX006002253-54.

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

555 Ex. 473; Ex. 246; Ex. 245; Ex. 474; Ex. 475 at PFE-JONES 00103607-14; Ex. 476 at PFE-JONES 00103615-18; Ex. 493 at PFE-JONES 00104197-201.

556 Ex. 214 at PFE DERIV 00068510.

Geodon sales representatives were aware that doctors hired for Pfizer-sponsored speaker programs were discussing Geodon off-label uses in children/adolescents or at high doses."[557]

324. Epstein followed-up with the OIG on the allegations of the Ohio sales representative on February 28, 2007, reiterating that "Pfizer sales representatives were using Pfizer-sponsored speaker programs to promote the use of Geodon in children and adolescents (not FDA approved labeling) and at higher than FDA approved doses," and revealing that Pfizer and its outside counsel's investigation "has been expanded beyond the Ohio and Michigan Sales districts."[558]

325. On October 3, 2006, Epstein informed the OIG that a Wisconsin sales representative "detail[ed] Geodon using an unapproved detailing piece with a physician" that "potentially contains off-label information . . . to the extent the information regarding binding affinities is used to make comparative or efficacy claims versus other products or focuses on antidepressant like effects."[559] On February 9, 2007, Epstein further informed the OIG that "Pfizer's investigation revealed that the unapproved piece could potentially be utilized to promote off-label uses of Geodon."[560]

326. On March 16, 2007, Epstein informed the OIG that a Connecticut sales representative "orally promoted Geodon for use in children and adolescents, for refractory depression and for add-on therapy (not FDA approved indications), as well as for treatment of acute bipolar mania before Geodon was approved as a treatment for this condition, and at higher than FDA approved doses," and "sent via email to one physician, allegedly at the physician's request, articles that were not approved for distribution," which "contained unsubstantiated comparative efficacy and tolerability

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557 Ex. 214 at PFE DERIV 00068510.

558 Ex. 398.

559 Ex. 111 at PFE DERIV 00068543.

560 Ex. 111 at PFE DERIV 00068547.

information about Geodon and other atypical antipsychotic drugs."[561] Pfizer's outside counsel, Sonnenschein Nath & Rosenthal ("Sonnenschein"), further informed the OIG on August 6, 2007 that the Connecticut sales representative has alleged "that other current and former employees had improperly promoted Geodon."[562]

327. Minutes from the June 27 and 28, 2007 meetings of Pfizer's Board of Directors, attended by defendants Kindler, Read, Waxman and Levin, reference "Mr. Lankler's presentation of major compliance issues including investigations of off-label promotion of Geodon."[563]

328. The Audit Committee's "Compliance Matters/Government Investigations Tracking Chart" lists the "Boston US Attorney Subpoena re Detrol, Geodon, Zyvox and Zoloft" as being first reported and the investigation commenced in October 2007.[564]

329. On January 25, 2008, Pfizer's outside counsel, Covington, provided to KPMG information regarding "items involving amounts exceeding $5 million individually or items involving lesser amounts that exceed $15 million in the aggregate," which included the DOJ's requests for information and documents "relating to the marketing and promotion of" Geodon and Zyvox and "to the marketing and safety of" Lyrica.[565]

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561 Ex. 400 at PFE DERIV 00068600.

562 Ex. 400 at PFE DERIV 00068603.

563 Ex. 377 at PFE DERIV 0000507, 511.

564 Ex. 430 at PFE DERIV A 00003577.

565 Ex. 343 at KPMG-PFIZ-DS 0004288, 291.

330. From 2007 to 2008, multiple complaints were filed against Pfizer alleging the off-label promotion of Geodon.[566]

331. On June 4, 2002, Senior Vice President Dee Mahoney emailed the sales force a study entitled *Weight Gain Associated with Olanzapine and Risperdone in Adolescent Patients: A Comparative Prospective Study* and stated that as "discussed at our POA2 Meeting, many of Geodon's biggest supporters are Child and Adol. Psys. This business is 'low hanging fruit.'"[567] DLA Piper concluded in its June 12, 2007 memorandum to Pfizer Corporate Compliance that "coming from a VP of sales who bore responsibility for ensuring the Roerig sales force complied with FDA and Pfizer rules and policies governing promotional conduct . . . this e-mail could easily be interpreted as direction to the Geodon sales force to detail child and adolescent psychiatrists."[568]

332. At Pfizer's National Sales Meeting in November 2002, the Company's national head of Geodon marketing, Efren Olivares, informed the sales managers in attendance (which included district managers, regional managers, regional medical research specialists and vice presidents from Pfizer corporate sales) that the Company's goal was to grow the Geodon market by promoting its use beyond the only FDA-approved use (at the time) for the treatment of schizophrenia, including unapproved uses such as borderline personality disorder, refractory mood disorders (depression, obsessive compulsive disorder, post-traumatic stress disorder), dementia in the elderly, bipolar mania, bipolar maintenance, and pediatric/adolescent conduct disorders.[569]

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566 *See, e.g.*, Ex. 321 (Kruszewski *qui tam* complaint filed under seal in 2007, First Amended Complaint filed under seal in 2009); Ex. 320 (Westlock *qui tam* complaint filed under seal in 2008), (Westlock *qui tam* Second Amended Complaint filed under seal in 2009); Ex. 172.

567 Ex. 145 at PG 267416.

568 Ex. 168 at PFE DERIV 00003761.

569 Ex. 172 at 47; Ex. 69 (Westlock Depo) at 27:10-30:12.

333. Pfizer's sales force was provided with Geodon dosing information for children as well as for indications that were not FDA-approved, including anxiety, autism, bipolar II, body dysmorphic disorder, borderline personality disorder, impulsivity, obsessive-compulsive disorder, post-traumatic stress disorder and refractory depression, to utilize during details.[570]

334. The strategy laid out in Pfizer's operating plans for Geodon from 2004 to 2007 included expanding use beyond the FDA-approved indication, schizophrenia, to other disorders through detailing by sales representatives and utilizing physician speakers, including KOLs.[571]

335. Sales representative Mark Westlock's notes from a June 21, 2007 meeting describe the concern he expressed regarding detailing Geodon to a physician who only has geriatric patients and another physician who has mostly children or adolescent patients as well as his district manager's response, which was that "'***Pfizer is hoping that Physicians will see the utility of Geodon in other uses***'" and that "in the past, physicians learned about products and used them in states that benefitted people."[572]

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[570] *E.g.*, Ex. 175 at WESTLOCK_JONES_014977; Ex. 142 at FLAG0036526, 532-34; Ex. 140 at PG 266745-47.

[571] *E.g.*, Ex. 77 at PG 009617-18, PG 009648, PG 009655 (2004 operating plan slides note "Coordinated Weekly Calling Will Continue to Increase Sales!," "Driving Adoption Through Advocates and Experienced Prescribers" and "Efficacy-Based Positioning Focuses on Symptom Control Across Multiple Disorders," including depression and anxiety); Ex. 221 at PG 009718, PG 009746-7 (2005 operating plan slides note "Roerig Has Potential to Increase Details," "Work With Cross-Functional Team to Leverage National and Regional KOLs to Drive Key Geodon Messages"); Ex. 78 at PG 009898, PG 009932, PG 009948 (2006 operating plan slides note "Competitive Detail Share of Voice Critical to Driving Growth," "KOLs Support Geodon's Strategies Through Multiple Initiatives," "Expand Use Across Mood Disorders," and "Atypicals Widely Used Outside of Core Indications"); Ex. 184 at PG 010019-21 (2007 operating plan slides note "develop local strategies to address developing KOL and prescriber advocates," "Improv[e] Targeting and Increas[e] Frequency for [Detailing] Geodon on Key Targets; Driv[e] Increas[ing] Share" and "Establish use in mood disorders").

[572] Ex. 176.

336. Pfizer continued to train its sales force in 2008 to convey the message during details that Geodon improves "depressive symptoms" and "symptoms of depression."[573]

3. Lyrica

337. By October 20, 2006, Pfizer IA's memorandum titled "Evaluation of Internal Controls over US Healthcare Compliance Risks – Third Quarter 2006" noted that "[t]he Corporate Compliance Group has been looking into several compliance issues involving the alleged inappropriate promotion of Lyrica. Two of these matters have involved Regional Managers . . . ."[574]

338. On November 30, 2006, Pfizer informed the OIG through its outside counsel, Epstein, of an allegation that a district manager had "improperly direct[ed] his sales team to make comparative efficacy claims about Lyrica."[575] Pfizer also informed the FDA that a Company-approved detail piece may have been used by "some members of its sales force . . . to make inappropriate superiority claims with respect to efficacy."[576]

339. On December 4, 2006, Pfizer informed the OIG through Epstein that a regional manager and a district manager had "improperly direct[ed] the use of a homemade promotional piece to make inappropriate comparative claims."[577]

340. On August 3, 2007, Pfizer informed KPMG that the DOJ was "looking into allegations made in the following areas: (A) promotion of Lyrica for broad neuropathic pain beyond

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573 *E.g.*, Ex. 396 at PFE DERIV 00044615, 617, 621-22, 624-25, 632-33, 635-36, 645-46, 657-58, 660; Ex. 371at LYRC-003373693, 695; Ex. 372 at LYRC-003404384-86, 392, 398.

574 Ex. 113 at PFE DERIV 01000999, 1003.

575 Ex. 112 at PFE DERIV 0068016.

576 Ex. 112 at PFE DERIV 0068019-21.

577 Ex. 399 at PFE DERIV 00068555.

Lyrica's approved pain indications; (B) promotion to psychiatrists; and (C) broad comparative statements about Lyrica and Neurontin that were made in the course of detailing."[578]

341. After reviewing Pfizer's proposed master visual aid ("MVA") for Lyrica, the FDA warned Pfizer on March 9, 2005, that the promotional claim "Neuropathic Pain Scalded From Within" was "misleading because it broadens Lyrica's indication by implying that it is FDA approved to treat all types of neuropathic pain, when such is not the case."[579] The FDA further warned Pfizer against making unsubstantiated and misleading claims about Lyrica's "sustained" efficacy, "simple" or "easy" dosing and impact on secondary endpoints such as sleep.[580]

342. Lyrica operating plans for 2005 to 2008 contained strategies for increasing Lyrica's market share in neuropathic pain (or NeP) and comparing Lyrica to Neurontin.[581]

343. Pfizer provided training and training materials to its sales force which made comparisons between Lyrica and Neurontin and described Lyrica as treatment for neuropathic pain.[582]

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578 Ex. 347 at KPMG-PFIZ-DS 0003311.

579 Ex. 84 at PFE-JONES 00027765.

580 Ex. 84 at PFE-JONES 00027766.

581 *E.g.*, Ex. 222 at PFE-JONES 00003628, 649 (slide deck titled "2005 LYRICA Operating Plan" presented "Strategies to Differentiate and Improve Treatment Outcome Critical to NeP Success," which included "Differentiate Lyrica as a 'Treatment Advance' in NeP" and "Shape Understanding of NeP via Scientific Discussion and Advocacy Development," and a "Neurontin Transition Strategy" for "Field Force Messaging," which positioned "Lyrica as [a] 'Treatment Advance'" to Neurontin); Ex. 353 at LYR000002876 (August 4, 2006 slide deck titled "US Operating Plan" noted that "NeP Clinical Program Leads to Expansion beyond DPN/PHN" and listed "Capture gabapentin NRxs/TRxs" among the "Key Objectives" and "Elevate Rxer treatment expectations by extending ***beyond label comparison*** to highlight 'real world' patient experience with efficacy and ease of use").

582 *E.g.*, Ex. 88 at LYR000001370, 379 (Pfizer's "Neuropathic Pain Implementation Guide" for its sales force included "Detail points" such as "Encourage physicians to listen for the specific language of neuropathic pain in their patient consultations," and "LYRICA has a different

344. At POAs from 2005 to 2008, Pfizer's sales force was given instruction on how to detail physicians who were prescribing Neurontin.[583]

345. The memorandum titled "Evolution of Pfizer's Corporate Compliance Program – January 2002 to Present" notes that not until November 2008 was "a previously approved detail piece comparing Lyrica's and gabapentin's oral bioavailability (absorption rate) and Lyrica's linear

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pharmacokinetic profile from Neurontin, which may make LYRICA easier to dose"); Ex. 89 at LYRC-002669762, 771 (August 10, 2005 script for "DPN/PHN Visual Aid Walk-through Workshop" states that the MVA's "headline – 'Piercing, shooting, scalded from within' – describes the kind of severe symptoms that patients with neuropathic pain experience. When physicians hear pain described that way, it helps them identify the pain as having a neuropathic . . . origin," that "Lyrica is a new agent, designed to treat neuropathic pain" and that "[t]he predictability of its pharmacokinetic profile supports the efficacy of Lyrica, and underscores its advantage over Neurontin and other drugs used in neuropathic pain") (*see* Ex. 352 for Lyrica MVA that was provided to the sales force for detailing); Ex. 70 at LYRC-001304484-88 (E-mail attaching "a 'compare and win' training piece for Lyrica"); Ex. 368 ("PHR [Pfizer Healthcare Representative] Field Coaching Guide" dated June 28, 2007, instructs representative to "ask the physicians to use his products in the specific patient types (*i.e.* . . . upgrade from Neurontin . . .)").

583 *E.g.*, Ex. 369 at LYRC-003084598 (the "30-60-90 Day Plan" discussed at POA 1 2006 instructed the sales force to "Leverage the efficacy data . . . to accelerate the conversion of Neurontin treated patients to Lyrica (Halo Effect)," "Target EEK recipients for BRC [Business Reply Card] follow-up: these are your former/current Neurontin prescribers"); Ex. 361 at LYRC-000658790, 792 (Notes from mid-POA 2006 relayed instruction to the sales force on addressing objections from physicians satisfied with Neurontin, such as stating that "Lyrica is best choice," "Lyrica is drug that . . . you wanted out of Neurontin" and "Lyrica is better than Neurontin," and on using the "pain chart [in the Unbranded Pain Poster] to get moderate to severe pain"); Ex. 81 at PFE-JONES 00003709, 727 (POA 2 2006 slides note "Targeting Is Effective But Opportunity Exists to Increase Productivity" with Neurontin prescribers and list "Continue successful differentiation from Neurontin" in the "POA 2 Priorities"); Ex. 362 at LYRC-000675327, 368 (POA 2 2006 slides presented "appropriate closes" for sales representatives to obtain "Gabapentin switches" and notes from the meeting relayed detailing closes that included "Based on a 53% response rate, will you upgrade your Neurontin patients?"); Ex. 258 at LYRC-000286538, 550 (POA 1 2007 slides direct the sales force to "Increase call frequency to 3x/mos to high gabapentin RXers" and to "leverag[e] the Lyrica/Neurontin profiler to elevate DPN/PHN treatment expectations and differentiate vs. Neurontin. . . . Use this tool with high gabap/low Lyrica prescribers to: Sell the strong efficacy benefits of Lyrica first using the master visual aid before comparing and winning vs. gabap."); Ex. 97 at LYRC-000731019, 027; Ex. 367 at LYRC-002031331; Ex. 371 at LYRC-003373698-99.

pharmacokinetics (absorption rate as dose is increased) . . . pulled from the field, and sales force instructed to no longer make any pharmacokinetic comparisons."[584]

346. At POAs during the Class Period, Pfizer's sales force was given instruction on how to detail physicians when discussing secondary endpoints.[585]

347. Sales representatives were encouraged to obtain pain protocols prescribing Lyrica during the Class Period.[586]

348. Beginning in October 2006, Pfizer provided its sales force with a new "tool to bridge from Celebrex to Lyrica," internally referred to as the "Unbranded ID Pain Kit," to "Help MDs Identify NeP" as opposed to musculoskeletal pain.[587] However, "because of the unbranded nature of this kit, [Pfizer] can't suggest tying this message to Lyrica for regulatory purposes."[588]

349. Beginning in 2005, "Lyrica KOL-related Strategies" included non-FDA approved indications such as "NeP," "GAD," "Ped[iatric] Epilepsy" and "Monotherapy" for epilepsy with

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584 Ex. 272 at KPMG-PFIZ-DS 0005695, 710.

585 *E.g.*, Ex.362 at LYRC-000675327 (Notes from POA 2 2006 relay suggested closes that included "With the improved quality of sleep and mood, will Rx Lyrica over amatryptaline? (Mentioned that secondary end-points are off label)" and "You're patients are depressed because they are in pain. Will you make them pain-free and happy . . . by Rxing Lyrica?").

586 *E.g.*, Ex. 369 at LYRC-003084598 (the "30-60-90 Day Plan" discussed at POA 1 2005 instructed the sales force to "Obtain Neuropathic Pain protocols & Clinical pathways" prescribing Lyrica and "Leverage existing Pain Protocols to drive Lyrica NRx growth with high decile targets"); Ex. 354 at LYR0000066, 076 (A sales representative was told in July 2006 "that the only way for us to win is with Lyrica protocols" because "our quota is so large in the north that this is the only way we can win."); Ex. 360 (E-mail attaching an article on "a multi-model pain protocol" and noting "Did I mention Celebrex and Lyrica are used in this scenario? Not a bad way to provide value and get a little margin in return eh?").

587 Ex. 95 at LYRC-000286553; Ex. 94.

588 Ex. 74 [LYRC-001191252]; Ex. 93 at LYRC-001191219.

tactics that included "Publications," "Advisory Boards" and "Speaker Programs."[589] Speakers hired by Pfizer were to be trained on the "Selling points between Lyrica and Neurontin" as well as the use of Lyrica "in sleep disorders" and "restless leg" syndrome.[590]

350. By March 2006, Pfizer modified an "Implied Superiority Claim" and deleted a "Misleading Claim" from a Lyrica direct-to-consumer print advertisement after the Division of Drug Marketing, Advertising and Communications indicated that the claim "'you may have tried some other common pain medicines and not found relief' was misleading [and implied superiority] because it suggested Lyrica will be effective where other drugs will not be effective," and that the claim "'As Different as Your Pain' [was misleading] because it implied we are unlike any other medications but Lyrica belongs to the anticonvulsant class of drugs and is structurally similar to other members of that class."[591]

351. Even though regional manager Mary Holloway expressed concern that Pfizer was "incentivising a representative to detail an off-label indication in order to make quota" by having quota/credit for "a physician who is primarily a headache specialist [and] show[s] up on our high writers list" in August 2006, such quota/credit was not changed.[592]

352. In March 2006, whistleblower Casey Schildhauer notified Andrew Powell, Director of Human Resources at Pfizer, and Suzanne Brackley, Senior Corporate Counsel at Pfizer, that a

589 Ex. 90 at LYRC-002564176.

590 Ex. 370 at LYRC-003348709, 711.

591 Ex. 92 at LYRC-001192974.

592 Ex. 96 at LYRC-001855087.

sales representative had been asked "to promote Lyrica off label to a psychiatrist."[593] Not until February 2007 were psychiatrists blocked from getting Lyrica details and samples.[594]

353. From 2005 to 2007, multiple complaints were filed against Pfizer alleging the off-label promotion of Lyrica.[595]

V. LOSS CAUSATION

354. Prior to the trading day, on January 23, 2009, *The Wall Street Journal* reported that Pfizer and Wyeth had been in discussions for months regarding a merger, the value of which would be "well over $60 billion."[596] In response to the news of the Pfizer and Wyeth transaction on January 23, 2006, the price of both companies' common stock increased.[597]

355. Prior to the trading day, on January 26, 2009, Pfizer announced financial results for 4Q08 and FY2008.[598] Earnings per share ("EPS") for 4Q08 declined by 90% to $0.04 per share compared to the 4Q07 quarter.[599] This decline was due to the $2.3 billion charge Pfizer accrued in

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593 Ex. 355 at LYR000003467.

594 Ex. 357 at LYR000040849-50.

595 *E.g.*, Ex. 496 at PFE-JONES 00104814-906 (*DeMott Qui Tam* Complaint filed under seal in 2005); Ex. 454 at PFE-JONES 00034734-54 (*Liter Qui Tam* Complaint filed under seal in 2006); Ex. 322 at FLAG0049690-781 (*Farber* and *Schildhauer Qui Tam* Complaint filed under seal in 2007).

596 Ex. 520, Matthew Karnitschnig & Jonathan D. Rockoff, *Pfizer in Talks to Buy Wyeth*, Wall S. J., Jan. 23, 2009, at A1.

597 Ex. 4 (Feinstein Report), ¶105.

598 Ex. 34, *Pfizer Reports Fourth-Quarter and Full-Year 2008 Results and 2009 Financial Guidance*, Business Wire, Jan. 26, 2009.

599 Ex. 34, *Pfizer Reports Fourth-Quarter and Full-Year 2008 Results and 2009 Financial Guidance*, Business Wire, Jan. 26, 2009.

connection with the settlement of the DOJ's investigation into the off-label marketing of Bextra, and other investigations.[600]

356. Prior to the trading day, on January 26, 209, Pfizer announced that it had cut its quarterly dividend from $0.32 to $0.16.[601]

357. The Company's 4Q08 and FY2008 earnings press release also included Pfizer's 2009 financial guidance.[602] For FY2009, the Company expected revenue of between $44 and $46 billion, and for adjusted EPS to be between $1.85 and $1.95 per share.[603] Defendants attributed the decline in 2009 revenue, versus FY 2008, to the effects of the strengthening U.S. dollar. Defendants attributed the $0.50 decline in EPS, versus FY2008, to the following factors:

> Looking to 2009, we expect . . . on the bottom line, adjusted diluted EPS in the range of $1.85 to $1.95. . . .
>
> Now I would expect to provide a bridge from '08 actuals to 2009 guidance. We expect '09 adjusted diluted EPS to be negatively impacted by approximately $0.21 due to the expected $3 billion year-over-year revenue decline related to foreign exchange, $0.21 relating to increasing the effective tax rate to 30% reflecting financial strategies in connection with the proposed acquisition of Wyeth, $0.04 due to increased pension expenses and $0.04 resulting from a decrease in interest income. All of these factors translate into a negative impact of roughly $0.50 on 2009 adjusted diluted EPS versus 2008.[604]

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600 Ex. 34, *Pfizer Reports Fourth-Quarter and Full-Year 2008 Results and 2009 Financial Guidance*, Business Wire, Jan. 26, 2009.

601 Ex. 34, *Pfizer to Acquire Wyeth, Creating the World's Premier Biopharmaceutical Company*, Business Wire, Jan. 26, 2009.

602 Ex. 34, *Pfizer Reports Fourth-Quarter and Full-Year 2008 Results and 2009 Financial Guidance*, Business Wire, Jan. 26, 2009.

603 Ex. 34, *Pfizer Reports Fourth-Quarter and Full-Year 2008 Results and 2009 Financial Guidance*, Business Wire, Jan. 26, 2009.

604 Ex. 521, *PFE-Pfizer to Acquire Wyeth, Creating the World's Premier Biopharmaceutical Company*, Thompson StreetEvents, Jan. 26, 2009, at 7.

358. In response to the news announced on January 26, 2009, the price of Pfizer's common stock decreased by 10.89%.[605]

359. Plaintiffs' loss causation and damages expert performed an event study to: (a) test the efficiency of the market for Pfizer's common stock during the relevant time period; (b) investigate the responsiveness of Pfizer's common stock price to information about the Company and the government's investigation into alleged unlawful off-label promotion of pharmaceutical products, including the January 26, 2009 disclosures; and (c) identify the abnormal return of Pfizer's common stock price in response to information about the Company and the government's investigation into Pfizer's unlawful promotional practices.[606] Defendants' expert, Dr. Kenneth Lehn, did not identify any flaw in the methodology or computations used by Dr. Feinstein with regard to Dr. Feinstein's event study.[607]

360. By the close of the market on January 26, 2009, in response to the disclosure in the press releases issued prior to the start of trading on that day, Pfizer's stock price dropped $1.80 per share from $17.45 to $15.65. Plaintiffs' loss causation and damages expert has opined that the abnormal, or residual, return on January 26, 2009, was -11.53% or -$1.90.[608] The negative abnormal return was statistically significant.[609] Defendants' expert, Dr. Lehn, has no material dispute with this conclusion.[610]

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605 Ex. 4 (Feinstein Report), ¶147.

606 Ex. 4 (Feinstein Report), ¶¶128-149.

607 Ex. 262 (Lehn Report), ¶20.

608 Ex. 4 (Feinstein Report), ¶147.

609 Ex. 4 (Feinstein Report), ¶¶147-149.

610 Ex. 262 (Lehn Report), ¶20.

361. Plaintiffs' loss causation and damages expert has opined that of the $1.90 per share residual decline in Pfizer's common stock on January 26, 2009, $1.26 of the residual decline is related to plaintiffs' allegations of fraud.[611]

362. Plaintiffs' loss causation and damages expert found that the per-share impact of defendants disclosing the alleged fraud to be: (a) with regard to the $2.3 billion charge, $0.34;[612] and (b) with regard to the reputational impact on Pfizer and its management as a consequence of the $2.3 billion fine, $0.92.[613]

363. The negative abnormal return on January 26, 2009 cannot be explained by general economic conditions, stock-market-wide factors or macro-economic factors.[614]

364. The negative abnormal return on January 26, 2009 cannot be explained by industry-specific factors.[615]

365. The negative abnormal return on January 26, 2009 was due to disclosures regarding the $2.3 billion settlement with the government concerning alleged unlawful off-label marketing, the cut to Pfizer's dividend, Pfizer's estimate of how the strengthening of the U.S. dollar would impact 2009 sales and earnings and the Company's estimate of how an increased marginal tax rate would impact 2009 earnings.[616]

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611 Ex. 4 (Feinstein Report), ¶256.

612 Ex. 4 (Feinstein Report), ¶¶233-235.

613 Ex. 4 (Feinstein Report), ¶¶252-255.

614 Ex. 4 (Feinstein Report), ¶147.

615 Ex. 4 (Feinstein Report), ¶147.

616 Ex. 4 (Feinstein Report), ¶¶165, 205, 224, 235, 255.

366. Plaintiffs' loss causation and damages expert, in arriving at the $1.26 per-share damage figure, accounted for confounding, non-fraud related disclosures made by Pfizer on January 26, 2009.[617] The non-fraud related factors that were disclosed by Pfizer on January 26, 2009 include: (a) strengthening of the U.S. dollar; (b) increased pension expense; (c) the acquisition of Wyeth; (d) a dividend cut; (e) S&P and Moody's placing Pfizer on a credit watch; (f) lower interest income; (g) increased tax rate; and (h) Wyeth earnings and outlook.[618]

367. Plaintiffs' loss causation and damages expert found the per-share impact of the non-fraud factors to be: (a) strengthening of the U.S. dollar, $0.06;[619] (b) increased pension expense, $0.00;[620] (c) the acquisition of Wyeth, $0.00;[621] (d) dividend cut, $0.22;[622] (e) credit watch, $0.00;[623] (f) lower interest income, $0.00;[624] (g) increased tax rate, $0.34;[625] and (h) Wyeth earnings and outlook, $0.00.[626]

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617 Ex. 4 (Feinstein Report), ¶¶150-238.

618 Ex. 4 (Feinstein Report), ¶152.

619 Ex. 4 (Feinstein Report), ¶165.

620 Ex. 4 (Feinstein Report), ¶174.

621 Ex. 4 (Feinstein Report), ¶181.

622 Ex. 4 (Feinstein Report), ¶205.

623 Ex. 4 (Feinstein Report), ¶211.

624 Ex. 4 (Feinstein Report), ¶216.

625 Ex. 4 (Feinstein Report), ¶224.

626 Ex. 4 (Feinstein Report), ¶228.

368. In a presentation at the HCCA 2005 Annual Compliance Institute, Lankler recognized that reputation was a cost of business when being prosecuted "for [f]ailure to [c]omply with [r]elevant [l]aws and [s]tatutes."[627]

369. Pfizer's documents also recognize reputational harm as a result of healthcare law violations. In a June 20, 2007 letter to the Audit Committee, Read deemed off-label promotion as one of the risks that was "potentially damaging to the company based on the sheer magnitude of the financial penalties involved, potential criminal prosecution and/or damage that [it] can cause to the company's image." Read also told the Audit Committee that reputational impact was "arguably among the greatest exposures facing the company."[628]

370. Pfizer's March 1, 2006 IA presentation also reflects the potential reputational harm in being caught off-label promoting. The document rates off-label promotion as a risk that was "almost certain/highly likely" and to have a "high impact" on the Company in the event it occurred. "High impact" was described as greater than $1 billion on profitability, sustained loss of market share, significant diminution to reputation and sustained reduction in market cap.[629]

371. In November 2006, Mooney drafted a memo entitled, Evaluation of Internal Controls over US Healthcare Compliance Risks – Third Quarter 2006. The memo recognized that "[v]iolations of laws and regulations resulting from the failure to properly monitor and ensure compliance with [Healthcare Compliance] risks could subject the Company to harm to its reputation,

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627 Ex. 438 at PFE-JONES 00005597-98.

628 Ex. 380 at PFE DERIV 00003792.

629 Ex. 105 at PFE DERIV 01002341-51.

as well as potentially significant fines and additional oversight by the government, through additional Corporate Integrity Agreements, or loss of government business."[630]

372. According to BlackRock managing director Daniel Hanson, his group at BlackRock had a longstanding 27,000,000 share position in Pfizer up until at least January 26, 2009. Mr. Hanson was deposed in this case on May 16, 2012. Mr. Hanson stated that the information he considered in connection with his work was "[g]eneral news, securities filings, brokerage research, conference call transcripts."[631]

373. Mr. Hanson refuted the suggestion that the announcement of the $2.3 billion settlement was not a big deal. Mr. Hanson stated that he was surprised by the magnitude of the $2.3 billion fine.[632]

374. A number of January 26, 2009 news articles provided additional color on the settlement, with journalists describing the payment as "brutal" and "enormous."[633]

375. Defendants' expert has not estimated the damages caused by the announcement of the $2.3 billion settlement and related charge to Pfizer's 4Q08 earnings.[634]

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630 Ex. 156 at PFE DERIV 01062960.

631 Ex. 305; Ex. 51 (Hanson Depo.) at 86:18-23.

632 Ex. 51 (Hanson Depo.) at 145:5-10, 161:1-15.

633 *Pfizer to Pay $2.3 Billion Drug Probe*, Bloomberg, Jan. 26, 2009; Declaration of Trig R. Smith in Support of Plaintiffs' Memorandum in Opposition to Defendants' Motion to Exclude Plaintiffs' Expert Dr. Steven Feinstein ("Smith Decl."), filed concurrently herewith, Ex. 4, Aaron Smith, *Pfizer to Buy Wyeth for $68 billion*, CNN Money, Jan. 26, 2009; Smith Decl., Ex. 6, Linda A. Johnson, *Pfizer to buy Wyeth for $68 billion, cut jobs*, Record Searchlight, Jan. 26, 2009; Smith Decl., Ex. 7, Sarah Rubenstein, *Pfizer Takes $2.3 Billion Charge Linked to Bextra Probe*, WSJ Health Blog, Jan. 26, 2009; Smith Decl., Ex. 8, *Pfizer 4Q Profits Plunges on Legal Charges*, Associated Press, Jan. 26, 2009.

634 Ex. 56 (Lehn Depo.) at 88:19-89:8.

376. Plaintiffs' loss causation and damages expert disaggregated for the dividend cut announced on January 26, 2009, which he determined accounted for $0.22 of the residual stock decline. Plaintiffs' loss causation and damages expert relied on finance literature, analyst reports, news articles, trading data, and Pfizer documents to support his analysis of the dividend cut.[635]

377. During his deposition, Mr. Hanson discussed BlackRock's views on the dividend cut. Mr. Hanson stated that the dividend "wasn't an important part of [his] investment thesis." And as to the dividend cut in relation to the Wyeth acquisition, Mr. Hanson recalled that he "viewed that favorably as an investment input." Mr. Hanson elaborated on his investment philosophy in relation to dividends, "I can be relatively indifferent as to whether they pay me that dividend in cash – cash dividend or if they return the cash through the form of buybacks or prudent cap allocation."[636]

378. Defendants were also aware that the dividend cut was expected and would have minimal impact on Pfizer's stock price. In October 2007, D'Amelio was already tempering the market's expectations concerning Pfizer's dividend. When discussing with Kindler the issue of addressing the dividend with the market, D'Amelio stated, "On the dividend, I could go with the we will announce in Dec and also say the rate of increase will moderate . . . ." Another D'Amelio e-mail in October 2007 explains that the dividend increase had gradually been reduced since 2006, going from "32% in 06 to 21% in 07" to 15% or 14% in 08.[637]

379. In a June 3, 2008 *Wall Street Journal* article, sophisticated investor Croft Leomister noted, "seems like it's going to be difficult" for Pfizer to maintain its dividend payout. D'Amelio stated that "subsequent to the June 3 Wall Street Journal article entitled *Dividend May Test Pfizer*

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635 Ex. 4 (Feinstein Report), ¶¶182-205.

636 Ex. 51 (Hanson Depo.) at 50:5-21, 51:13-52:10, 138:15-139:13.

637 Ex. 205 at PFE DERIV 01099816; Ex. 766 at PFE DERIV 01133313.

and recent sell-side analysts' reports about the perceived lack of cash domiciled in the U.S., to fund Pfizer's dividend obligations, there is a lack of confidence among investors in both Pfizer's willingness and ability to fund the dividend going forward."[638]

380. Defendants' expert has not estimated the impact the January 26, 2009 announcement of the dividend cut had on Pfizer's stock.[639]

381. Plaintiffs' loss causation and damages expert also conducted an analysis of the impact the January 26, 2009 Wyeth merger announcement had on Pfizer's stock price. Plaintiffs' loss causation and damages expert relied on analyst reports and news articles in conducting his analysis and determined that the January 26, 2009 Wyeth merger announcement did not have a negative impact on the price of Pfizer stock.[640]

382. Mr. Hanson also provided testimony concerning the Wyeth merger. Mr. Hanson stated, "I do recall having a favorable view ahead of the Wyeth – the pending acquisition of Wyeth. I had a favorable view that that was – and so, in my mind, I would call that short-term." Mr. Hanson also testified that he had given consideration to a deal with Wyeth prior to the January 26, 2009 announcement, "I believe, yes, there was some wide spread belief that Pfizer would be – continue to be inquisitive as it had been in the past."[641]

383. Defendants' expert has not estimated the price impact the January 26, 2009 Wyeth merger announcement had on Pfizer's stock.[642]

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638 Ex. 528, Avery Johnson and Joann S. Lubin, *Dividend May Test Pfizer*, Wall St. J., June 3, 2008; Ex. 207 at PFE DERIV 01144517.

639 Ex. 56 (Lehn Depo.) at 92:14-22.

640 Ex. 4 (Feinstein Report), ¶¶173-181.

641 Ex. 51 (Hanson Depo.) at 80:4-20, 137:21-138:4.

642 Ex. 56 (Lehn Depo.) at 89:9-19.

384. Plaintiffs' loss causation and damages expert evaluated the effect Pfizer's 2009 earnings guidance announced on January 26, 2009 had on Pfizer's stock price. Plaintiffs' loss causation and damages expert specifically analyzed the four factors Pfizer stated contributed to the lower than expected guidance: strengthening of the U.S. dollar, increased pension expense, lower interest income and increased tax rate. Plaintiffs' loss causation and damages expert determined that the 2009 earnings guidance announcement caused $0.40 of Pfizer's stock price decline on January 26, 2009.[643]

385. Defendants' expert has not estimated the price impact the 2009 earnings guidance announcement had on Pfizer's stock.[644]

Plaintiffs' expert Edward Buthusiem testified regarding disclosures at GSK when it was being investigated for alleged off-label promotion.[645] GSK revealed what Pfizer concealed: that it was being investigated for off-label promotion.[646] Disclosing that investigation concerned off-label promotion critical because that inherently revealed risk of exclusion, which is "so material that nobody is going to really test that theory and take it to court and fight it."[647] GSK took a reserve nearly ***three years*** before announcing a resolution.[648]

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643 Ex. 4 (Feinstein Report), ¶¶154-172, 212-224.

644 Ex. 56 (Lehn Depo.) at 92:14-18.

645 *Compare* FMS Nos. 2, 16, 31 *with* Ex. 269 at 2.

646 Ex. 269 at 7.

647 *See* Ex. 42 (Buthusiem Depo.) at 232:20-23; *see also* Ex. 42 (Buthusiem Depo.) at 232:25-242:10.

648 *See* GlaxoSmithKline 1/29/09 Form 6-K at 1-2 (available at: http://hsprod.investis.com/shared/v2/irwizard/sec_item_new.jsp?epic=gskqc1&ipage=6093936&DSEQ=1&SEQ=1&SQDESC=SECTION_PAGE); GlaxoSmithKline 11/3/2011 Form 6-K at 1-2 (available at: http://hsprod.investis.com/shared/v2/irwizard/sec_item_new.jsp?epic=gskqc1&ipage=7884450&DSEQ=1&SEQ=1&SQDESC=SECTION_PAGE).

Knowing off-label promotion triggers mandatory exclusion from federal health benefits programs and "people who are wise and reasonably conservative, don't, you know, expose all of the constituents, the stakeholders of a company the size of Pfizer to ruin [from exclusion] if it can be avoided."[649]

VI. DEFENDANTS' RELIANCE DEFENSES FAIL

A. Defendants Have Not Established a Reliance on Counsel Defense

386. Defendants' counsel informed this Court on July 8, 2013 that "[t]he only outside counsel that provided legal advice to Pfizer regarding the Waived Subjects was Dennis Block of Cadwalader Wickersham & Taft."[650]

387. Defendants' counsel informed this Court on July 19, 2013 that "Your Honor there's one in-house lawyer, Larry Fox."[651]

388. Pfizer stated in its Memorandum of Law in Support of Its Motion for Summary Judgment that "Pfizer relied on unequivocal advice from outside disclosure counsel (Dennis Block), inside disclosure counsel (Lawrence Fox), and outside auditors (KPMG) that its disclosures and reserving judgments were proper," and that "Pfizer and its executives relied on two experienced securities disclosure lawyers – Dennis Block of Cadwalader, Wickersham & Taft, and Lawrence Fox of Pfizer's internal legal department – to advise on which matters to disclose and how to describe them."[652]

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649 Ex. 62 (O'Connor Depo.) at 124:14-125:8.

650 Dkt. No. 172 at 25.

651 July 19, 2013 Hearing Transcript at 12:1-2.

652 Dkt. No. 246 at 1, 5.

389. Defendants' memoranda filed in support of summary judgment contained at least 99 references to counsel other than Block and Fox: Covington, Lankler, Carlton Wessel and Covington's "white paper."[653]

390. Pfizer's SEC filings during the Class Period (January 19, 2006 to January 23, 2009) represented that "[a]lthough we believe we have substantial defenses in these matters, we could in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations in any particular period."[654]

391. In 2001, Pfizer submitted an application to the FDA for the drug Bextra seeking approval for the indications of OA, RA, PD, acute pain, pre-operative pain and opioid-sparing in the context of surgery, and for the dosages of 10-20 mg for OA/RA and 40 mg for PD.[655]

392. In November 2001, the FDA denied Pfizer's application as to all but the following indications and dosages: 10 mg (once per day) for OA/RA and 20 mg (twice per day) for PD.[656] Pfizer began distributing Bextra in February 2002.[657]

393. In support of its nonapproval, the FDA noted that the study submitted in support of the acute pain indication, including opioid-sparing and prevention of operative pain, "demonstrated an excess of serious adverse events including death" at 40 mg doses when added to injectable pre-

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653 *E.g.*, Dkt. No. 246 at 14, 16-17, 19, 21-25, 27, 53; Dkt. No. 253 at 18-21; Dkt. No. 258 at 167-168, 170, 172, 174, 176, 185-88, 192, 194; Dkt. No. 263 at 247, 250, 268, 272; Dkt. No. 269 at 213; Dkt. No. 274 at 83, 86, 89, 91-95, 100, 102.

654 Petrosinelli Decl., Ex. B-1 at 18; Petrosinelli Decl., Ex. C-1 at 239; Ex. 12 at 59; Ex. 215 at 62; Petrosinelli Decl., Ex. D-1 at 17, 34, 67; Petrosinelli Decl., Ex. E-1 at 523; Ex. 216 at 55; Ex. 16 at 59; Petrosinelli Decl., Ex. F-1 at 17, 35, 69; Petrosinelli Decl., Ex. G-1 at 35; Petrosinelli Decl., Ex. H-1 at 87-88; Petrosinelli Decl., Ex. I-1 at 142.

655 Ex. 241 at BEX001360555.

656 Ex. 241 at BEX00136055; Ex. 259 at BEX005818115.

657 Ex. 283 at BEX001800573.

operative painkillers, and that at doses higher than the 10 mg daily dose for OA and RA "the findings of more hypertension and edema are frequently reproduced."[658]

394. In or around February 2004, the DOJ informed Pfizer that it was investigating a *qui tam* complaint filed by one if its former Florida sales representatives, John Kopchinski, which alleged the off-label promotion of Bextra ("Kopchinski's Complaint").[659]

395. Led by Covington, Pfizer's "Investigation Counsel" (*i.e.*, lawyers other than Block and Fox) were involved in Pfizer's internal investigation that paralleled the Government's investigation concerning Pfizer's misbranding (*i.e.*, off-label promotion) of Bextra.[660]

396. Block was not involved in Pfizer's Bextra Investigation.[661]

397. Fox was not involved in Pfizer's Bextra Investigation.[662]

398. 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.[663]

399. Block never personally and professionally assessed nor advised defendants that Pfizer had substantial defenses to the Bextra Investigation.[664]

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658 Ex. 242 at BEX004849786.

659 Ex. 529 at KPMG-PFIZ-DS 0000385-86 (February 2004); Ex. 437 at PFE-JONES 00002295 (identifying Kopchinski as relator).

660 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 32:10-20.

661 Ex. 37 (Block Depo.) at 54:4-7, 56:2-11, 73:21-74:16, 76:5-23.

662 Ex. 49 (Fox Depo.) at 10:9-12, 11:14-20, 53:23-55:3, 60:3-22, 61:3-11.

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

664 Ex. 37 (Block Depo.) at 104:6-23.

400. Fox never independently determined or advised defendants that Pfizer had substantial defenses to the Bextra Investigation.[665]

401. Neither Block nor Fox made an independent assessment or advised defendants as to the strengths and weaknesses of Pfizer's defenses or of the Government's case.[666]

402. Neither Block nor Fox made an independent 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.[667]

403. Block and Fox deferred to, and relied upon, Pfizer's Investigation Counsel to assess the Bextra Investigation including the strengths and weaknesses of Pfizer's defenses and of the Government's case, the probability of a criminal conviction in or losses from the Bextra Investigation, and whether the loss from the Bextra Investigation was reasonably estimable.[668]

404. 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 Financial Accounting Standards ("FAS 5") determination.[669]

405. Defendants' own expert, John Coates, testified that determining whether a loss was probable or reasonably estimable under FAS 5 required accounting, not legal, advice and that the

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

666 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.

667 Ex. 37 (Block Depo.) at 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 44:24-45:7, 76:15-19, 80:5-21, 90:21-91:8.

668 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.

669 Ex. 37 (Block Depo.) at 33:7-25, 36:15-24, 39:10-41:5; Ex. 49 (Fox Depo.) at 44:24-45:7, 80:5-21, 90:21-91:8.

advice of lawyers would only be sought if the loss related to litigation, in which case advice would be sought typically from litigators who were involved in or were knowledgeable about the litigation.[670]

406. In connection with its 2007 audit, KPMG referenced Investigation Counsel's "white paper" as support for Pfizer's FAS 5 determination with regard to the Bextra Investigation.[671]

407. Block testified that "Pfizer had – close to the American Bar Association – has lawyers assisting it in connection with the criminal matters."[672]

408. Brien O'Connor informed the presiding judge in *United States v. Pharmacia & Upjohn Co., Inc.*, the Honorable Douglas P. Woodlock, that the calculation of Pfizer's gain from its off-label promotion, $664 million, was made with the "assist[ance of] a very good expert firm called The Analysis Group, and we had a lot of good heads on it, not just Ropes & Gray, not just Pfizer and Pharmacia, but also others as well. So it was very much arm's length negotiated and I think everyone was doing the best they could."[673]

409. 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:

(a) Pfizer's awareness that its sales representatives had, in fact, promoted Bextra off-label;

(b) the information set forth in ¶¶422-427 *infra*;

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670 Ex. 45 (Coates Depo.) at 152:8-154:21.

671 Dkt. No. 246 at 10.

672 Ex. 37 (Block Depo.) at 46:23-47:1.

673 Ex. 240 at 7:19-20, 12:11-17; Ex. 218 at 2.

(c) the internal Bextra-related documents that were exhibits to Kopchinski's Complaint;

(d) the results from Pfizer's Bextra-related sales force surveys;

(e) the internal Bextra-related documents that Pfizer's district manager instructed Pfizer's sales representatives to alter or delete;

(f) the Bextra-related call notes of the Pfizer sales representatives who were involved in the attempted alteration and destruction of internal Bextra-related documents;

(g) the admissions of the Pfizer sales representatives who were involved in the attempted alteration and destruction of internal Bextra-related documents;

(h) the admissions of other Pfizer employees interviewed by Pfizer's Investigation Counsel; or

(i) the Bextra-related call notes quoted, summarized and/or analyzed in the Government's presentations to Pfizer and its Investigation Counsel.[674]

410. 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:

(a) the information set forth in ¶¶422-427 *infra*;

(b) the internal Bextra-related documents that were exhibits to Kopchinski's Complaint;

(c) the results from Pfizer's Bextra-related sales force surveys;

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[674] Ex. 37 (Block Depo.) at 49:16-50:20, 54:8-22, 56:2-11, 56:21-58:9, 59:14-60:1, 63:25-64:4, 69:6-15, 73:21-74:16, 76:5-23, 104:15-23, 105:3-13, 128:14-21; 144:21-145:4, 230:21-231:6, 232:3-12, 233:17-23; 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.

(d) the internal Bextra-related documents that Pfizer's district manager instructed Pfizer's sales representatives to alter or delete;

(e) the Bextra-related call notes of the Pfizer sales representatives who were involved in the attempted alteration and destruction of internal Bextra-related documents;

(f) the admissions of the Pfizer sales representatives who were involved in the attempted alteration and destruction of internal Bextra-related documents;

(g) the admissions of other Pfizer employees interviewed by Pfizer's Investigation Counsel; or

(h) the Bextra-related call notes quoted, summarized and/or analyzed in the Government's presentations to Pfizer and its Investigation Counsel.[675]

411. Neither Block nor Fox has ever worked as a criminal law prosecutor or a criminal defense attorney; nor did either have any experience performing calculations under the United States Sentencing Guidelines.[676]

412. Neither Block nor Fox was familiar with the elements of a misbranding offense.[677]

413. Neither Block nor Fox was familiar with elements or application of *respondeat superior* for corporate criminal liability.[678]

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[675] Ex. 49 (Fox Depo.) at 13:2-8, 49:9-50:16, 53:23-54:14, 60:3-22, 61:3-11, 66:3-6, 74:22-80:1, 90:12-20, 97:11-18, 211:16-212:1; 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.

[676] Ex. 37 (Block Depo.) at 13:12-14:6, 14:13-15:10, 16:6-8; Ex. 49 (Fox Depo.) at 18:24-19:2, 35:21-36:12.

[677] Ex. 37 (Block Depo.) at 16:6-17:8; Ex. 49 (Fox Depo.) at 37:10-38:17.

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

414. 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.[679]

415. Fox 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.[680]

416. Pfizer's Investigation Counsel was aware that the possibility of automatic debarment from federal health benefits programs was "enormous leverage that the government has over a big entity that is so heavily regulated and makes a lot of its money from government programs."[681]

417. Fox understood the terms grand jury "target" and grand jury "subject" to be interchangeable.[682]

418. Defendants' own expert, Nicholas Theodorou ("Theodorou"), testified that whether a defense in any case is "substantial" depends "on the facts and circumstances and a number of factors," including the evidence of guilt.[683]

419. By the year 2006, defendants Kindler, Levin, Waxman and McKinnell were aware that certain Pfizer sales representatives had promoted Bextra for off-label indications.[684]

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679 42 U.S.C. §1320a-7.

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

681 Ex. 62 (O'Connor Depo.) at 118:12-19.

682 Ex. 49 (Fox Depo.) at 106:3-107:1.

683 Ex. 66 (Theodorou Depo.) at 5:16-7:9.

684 Ex. 247 at PFE DERIV 00066706; Ex. 397 at PFE DERIV 00066490, 512, 529, 599; Ex. 244 at PFE-JONES 00103713-15, 718-20; Ex. 436 at PFE-JONES 00000893-94; Ex. 57 (12/10/13 Levin Depo.) at 114:6-13; Ex. 58 (9/23/14 Levin Depo.) at 23:20-24:11, 107:18-21; Ex. 68 (10/16/14 Waxman Depo.) at 41:12-19, 52:3-19, 68:12-20; Ex. 60 (9/19/14 McKinnell Depo.) at 27:16-28:5.

420. 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.[685]

421. Pfizer and its Investigation Counsel always represented to Block that Pfizer's sales representatives had ***not*** promoted Bextra off-label.[686]

422. From February 2002 through April 2005, Pfizer promoted Bextra for uses that were not within Bextra's FDA-approved label, including (a) for general acute pain, (b) for pre-operative and post-operative surgical pain and (c) as opioid-sparing in the context of surgery.[687]

423. 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.[688]

424. 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.[689]

425. Pfizer promoted Bextra with an intent to defraud or mislead.[690]

426. 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.[691]

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685 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.

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

687 Ex. 240 at 51:10-17.

688 Ex. 240 at 51:17-18.

689 Ex. 240 at 51:19-21.

690 Ex. 240 at 51:22-23.

691 Ex. 240 at 52:1-4.

427. 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.[692]

428. No one shared with Block any of the information set forth in ¶¶422-427 *supra*.[693]

429. Kopchinski's Complaint alleged that Pfizer, *inter alia*, had encouraged its sales force to promote Bextra at dosages and for uses outside of its FDA-approved label, including for general acute and perioperative surgical pain.[694]

430. Kopchinski's Complaint attached as exhibits, *inter alia*, internal Pfizer documents, including an email from a Pfizer District Manager to dozens of Pfizer employees which attached a surgery protocol prescribing Bextra for pre-operative use and congratulated and rewarded the Pfizer sales representative who obtained the protocol in accordance with the Company's POA (directive to sales representatives).[695]

431. The exhibits to Kopchinski's Complaint were either internal Pfizer documents (mostly emails) or publicly available, so defendants had access to them from the time the Government informed them of Kopchinski's Complaint in 2004.[696]

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692 Ex. 240 at 52:5-9.

693 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. At 57:4-22 of Block's testimony, he refers to a "female supervisor." The "female supervisor" to whom Block was referring to in his testimony on September 16, 2013 was Regional Manager Mary Holloway, who was not charged and did not plead guilty until after the Class Period had ended. *See* Ex. 56.

694 Ex. 440.

695 Ex. 254.

696 Ex. 440 at PFE-JONES 00006353, 356-57, 359-88.

432. By April 2008, defendants had received Kopchinski's Complaint itself, including its specific descriptions of the exhibits.[697]

433. No one provided Block with a copy of Kopchinski's Complaint or any of the internal Pfizer documents that were exhibits to it.[698] The same appears to be true as to Fox, as the record does not indicate that he received a copy of Kopchinski's Complaint or any of the internal Pfizer documents that were exhibits to it either.[699]

434. Soon after learning of Kopchinski's Complaint, Pfizer issued a Company-wide document hold for all "documentary evidence, records, files or documents, whether paper, electronic or otherwise, that relate to Bextra" in March 2004.[700]

435. In or around August 2004, one of Pfizer's District Managers, Thomas Farina ("Farina"), instructed his subordinate sales representatives to delete or alter certain internal documents related to Bextra.[701]

436. Pfizer and its Investigation Counsel learned that the internal documents that Farina had instructed his subordinates to delete or alter included surgical protocols and instruction sheets as well as a POA guide that included the following goals: "[g]et Bextra added to hospital formularies . . . for use in the acute, peri-operative setting with the overall goal of getting the patient

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697 Ex. 494.

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

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

700 Ex. 236 at BEX000398151; Ex. 244 at PFE-JONES 00103712-13.

701 Ex. 244 at PFE-JONES 00103713; Ex. 511 at TF0000197-99.

to remain on Bextra long term" and "[g]et Bextra added to pre-op briefing sheets in other surgical subspecialties – podiatry, general surgery, plastic surgery, ENT, etc."[702]

437. Pfizer and its Investigation Counsel produced to the DOJ the Bextra-related internal documents that Pfizer's sales representatives had attempted to delete or alter along with a detailed letter setting forth descriptions of the documents "corroborating the employees' confessions," which included "Mr. Bermudez's admission that he altered pre-operative surgery instructions sheets by deleting references to Bextra" and District Manager Farina's admission "that he made similar modifications to pre-operative surgery instructions sheets on his own laptop and likewise altered his laptop time setting to backdate the modifications."[703]

438. No one ever provided Block or Fox the internal documents that Pfizer's sales representatives had attempted to delete or alter.[704]

439. Pfizer's Investigation Counsel interviewed its employees who were involved in the attempted deletion and alteration of Bextra-related documents.[705]

440. Pfizer provided the Government with redacted versions of its Investigation Counsel's interview memoranda of the Pfizer employees involved in the attempted deletion and alteration of Bextra-related documents.[706]

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[702] Ex. 304 at BKLYN 000000063-64; Ex. 244 at PFE-JONES 00103717-18.

[703] Ex. 244 at PFE-JONES 00103714, 718, 720.

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

[705] Ex. 244 at PFE-JONES 00103713, 720; Ex. 473; Ex. 246; Ex. 245; Ex. 474; Ex. 475; Ex. 476; Ex. 493.

[706] Ex. 244 at PFE-JONES 00103720.

441. 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.[707]

442. Pfizer and its Investigation Counsel reviewed Bextra-related surveys of its sales force, which stated that:

(a) Pfizer's District Managers "find specific reference to OA, RA and PD needlessly restrictive";[708] and

(b) "Several respondents from both Pfizer and Pharmacia mention their discomfort in delivering the desired positioning. They note that it is Celebrex that has the acute pain data vs. narcotics that they can show to physicians, yet they are being asked to position Bextra for the acute patient."[709]

443. 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.[710]

444. Pfizer and its Investigation Counsel provided to the Government millions of contemporaneous "call notes" entered by Pfizer's sales representatives summarizing their Bextra-related sales calls with physicians.[711]

445. In an August 17, 2006 presentation to Pfizer and its Investigation Counsel (*i.e.*, attorneys ***other than*** Block and Fox), the Assistant U.S. Attorney running the Government's Bextra

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

708 Ex. 397 at PFE DERIV 00066528.

709 Ex. 397 at PFE DERIV 00066599.

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

711 Exs. 477, 488.

Investigation quoted multiple contemporaneous "call notes" by Pfizer's sales representatives promoting Bextra for the non-FDA approved indication of general acute pain.[712]

446. In an August 17, 2006 and/or September 19, 2006 presentation to Pfizer and its Investigation Counsel, the Assistant U.S. Attorney running the Government's Bextra Investigation quoted multiple contemporaneous "call notes" by Pfizer's sales representatives promoting Bextra for the non-FDA approved indication of pre/post/peri operative pain.[713]

447. In an August 17, 2006 and/or September 19, 2006 presentation to Pfizer and its Investigation Counsel, the Assistant U.S. Attorney running the Government's Bextra Investigation showed, based on the number of contemporaneous "call notes" by Pfizer's sales representatives which referenced samples, that Pfizer's sales representatives had given out 20 mg Bextra samples in over 1.3 million sales calls to physicians who would not typically prescribe medication for patients suffering from PD (*e.g.*, Surgeons, Cardiovascular and Dentists) as evidence that Pfizer's sales representatives had promoted the 20 mg dosage of Bextra for unapproved indications.[714]

448. In an August 17, 2006 and/or September 19, 2006 presentation to Pfizer and its Investigation Counsel, the Assistant U.S. Attorney running the Government's Bextra Investigation quoted multiple contemporaneous "call notes" by Pfizer's sales representatives promoting Bextra with the false claim that Bextra had no dose-related increases in hypertension and edema.[715]

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712 Ex. 251 at DOJ000003-17.

713 Ex. 309.

714 Ex. 315 at DOJ000230.

715 Ex. 311.

449. The sales force who promoted Bextra was divided into eight geographic regional teams across the country: Northeast, MidAtlantic, Southeast, Great Lakes, Midwest, Gulf Coast, Rocky Mountain and Western.[716]

450. The Northeast Product Action Guide listed as a core message for the promotion of Bextra that "there is no dose proportional response with hypertension and edema."[717]

451. Defendants' expert Theodorou testified that the facts to which Pfizer had no defense included the "fraudulent activities" related to making "false and misleading claims" that with Bextra, there was "no dose-proportional increase in hypertension and edema" and to submitting "false and fake" medical requests.[718]

452. In an August 17, 2006 and/or September 19, 2006 presentation to Pfizer and its Investigation Counsel, the Assistant U.S. Attorney running the Government's Bextra Investigation provided statistics gathered from the contemporaneous "call notes" by Pfizer's sales representatives from which the Government concluded that references to off-label indications during sales calls with physicians had occurred "in at least the same order of magnitude as on-label indications."[719]

453. 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 Investigation Counsel.[720]

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716 *E.g.*, Ex. 170 at Dowd-C 10000042331; Ex. 171 at BEX006488816, 820.

717 Ex. 253 at TF0000347.

718 Ex. 66 (Theodorou Depo.) at 60:9-61:2, 62:23-65:11.

719 Ex. 313 at DOJ000190.

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

454. Pfizer's Investigation Counsel interviewed hundreds of additional Pfizer employees in connection with the Bextra Investigation and generated interview memoranda for most or all of these interviews.[721]

455. No one provided Block or Fox copies of any of the interview memoranda from the Bextra Investigation.[722]

456. Neither Block nor Fox received access to any of Pfizer's Investigation Counsel's written work product concerning the Bextra Investigation.[723]

457. 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.[724]

B. Defendants Have Not Established a Reliance on Auditors Defense

458. KPMG relied on representations of Pfizer management in the form of quarterly management representation letters signed by the CFO and Controller ("Management Representation Letters").[725] The Management Representation Letters confirmed that management was "responsible for the fair presentation in the consolidated financial statements of financial position, results of operations, and cash flows in conformity" with GAAP and confirmed certain representations, including that "all relevant information relating to the facts and circumstances . . . which are the subject of the investigation of alleged fraud or potential illegal acts conducted by the Government

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721 Ex. 153 at KPMG-PFIZ-DS 053290.

722 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.

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

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

725 *E.g.*, Ex. 134 at KPMG-PFIZ-DS 017129; Ex. 135 at KPMG-PFIZ-DS 0003059; Ex. 136 at KPMG-PFIZ-DS 0003104; Ex. 137 at KPMG-PFIZ-DS 025622.

Investigations Section and the Office of Corporate Compliance has been disclosed by us to the Audit Committee, to the investigating team, and to [KPMG]."[726]

459. KPMG relied on representations of Pfizer management in the form of quarterly in-house legal representation letters signed by defendants Waxman and Kindler.[727] The quarterly in-house legal representation letters were to provide KPMG with "an update of significant litigation pending against Pfizer," which assessed "their materiality" and opined whether they "could have a material adverse impact on the Company's financial statements."[728]

460. KPMG relied on representations of Pfizer management through its outside counsel in annual legal representation letters from Pfizer's outside counsel.[729] Each year, Pfizer directed its outside counsel to furnish KPMG information in connection with its year-end audit of the Company regarding matters outside counsel had been engaged by Pfizer "to give substantive attention to, or represent the Company in connection with, material loss contingencies," or "items involving amounts exceeding $5 million individually or items involving lesser amounts that exceed $15 million in the aggregate."[730]

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[726] *E.g.*, Ex. 134 at KPMG-PFIZ-DS 017116, 125; Ex. 135 at KPMG-PFIZ-DS 0003048, 55; Ex. 136 at KPMG-PFIZ-DS 0003093, 100; Ex. 137 at KPMG-PFIZ-DS 025607, 610.

[727] *E.g.*, Petrosinelli Decl., K-4 at KPMG-PFIZ-DS 0003522; Petrosinelli Decl., L-4 at KPMG-PFIZ-DS 0006149; Petrosinelli Decl., O-4 at KPMG-PFIZ-DS 018449A.

[728] *E.g.*, Petrosinelli Decl., K-4 at KPMG-PFIZ-DS 0003513; Petrosinelli Decl., L-4 at KPMG-PFIZ-DS 0006133-4; Petrosinelli Decl., O-4 at KPMG-PFIZ-DS 018424A.

[729] *E.g.*, Petrosinelli Decl., S-4 at KPMG-PFIZ-DS 0000406; Petrosinelli Decl., N-4 at KPMG-PFIZ-DS 017652A; Petrosinelli Decl., D-4 at KPMG-PFIZ-DS 000600A; Petrosinelli Decl., Y-4 at KPMG-PFIZ-DS 056016.

[730] *E.g.*, Petrosinelli Decl., S-4 at KPMG-PFIZ-DS 0000406; Petrosinelli Decl., N-4 at KPMG-PFIZ-DS 017647A; Petrosinelli Decl., D-4 at KPMG-PFIZ-DS 000596A; Petrosinelli Decl., Y-4 at KPMG-PFIZ-DS 056016.

461. Pfizer paid KPMG $30,285,000, $32,410,000, $28,220,000, and $27,735,000 for professional services rendered in 2005, 2006, 2007 and 2008, respectively.[731] Pfizer paid KPMG $37,353,000, $38,993,000, $38,999,000, $50,267,000, and $32,014,200 for professional services rendered in 2009, 2010, 2011, 2012, and 2013, respectively, after the Class Period.[732]

462. At the beginning of the Class Period, defendants told KPMG a loss related to the Bextra Investigation was not estimable when, in fact, based on the May 2004 settlement with the DOJ regarding the off-label marketing of Neurontin and the negotiations of that settlement, defendants had the tools to calculate an estimated loss.[733] Defendants also told KPMG a loss related to the Bextra Investigation was not probable even though they knew on September 26, 2005 that Pfizer will "likely be forced to reach some form of settlement of this [Bextra Investigation] matter."[734]

463. Pfizer's in-house counsel, Lankler, further assured KPMG in February 2006 that "the potential Bextra off-label promotion is not as clear [as in the case of Neurontin] because the promotion was related to different type of pain (Acute vs. Chronic)" and that "the allegation of off-label promotion related to Bextra does not appear to be to the same extent as the off-label promotion in the case of Neurontin."[735] However, Pfizer's internal investigation by outside counsel had confirmed by July 2004 that the *qui tam* complaint alleged the promotion of Bextra "20 Mg for Uses Other Than Primary Dysmenorrhea" and the promotion of "Bextra for 'Acute Pain'" through

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731 Exs. 14, 17-18.

732 Exs. 19-23.

733 Ex. 255 at 44-52 ("Calculation of the Appropriate Fine under the Guidelines" in the Neurontin Action); Ex. 7at 30-35.

734 Petrosinelli Decl., P-5 at PFE-JONES 00043524.

735 Ex. 152 at KPMG-PFIZ-DS 007248.

"Improper Comparison to Vioxx," "Improper Dissemination of Medical Literature," "Protocols and Standing Orders," "Use of Physician Consultants" and for "Pre- and Post-Operative Use,"[736] and by November 2004 that it was a "Senior Management Decision to Make Available Under WLF" a Bextra reprint on "Dental Pain (vs. Tylox)," and that surveys of the sales force and the physicians they detailed revealed "[m]any [sales representatives] communicat[ing] '10 mg. is for OA and RA and 20 mg. is for acute pain states,'" and that "[t]he most common positioning is . . . 'Bextra for acute pain,'" although "[s]everal . . . mention[ed] their discomfort in delivering the desired positioning [because] it is Celebrex that has the acute pain data vs. narcotics that they can show to physicians, yet they are being asked to position Bextra for the acute patient."[737]

464. Defendants further did not provide KPMG specific facts they learned from August and September 2006 meetings with the DOJ regarding the Bextra Investigation.[738] Those specific facts included that "HQ Knowledge" was demonstrated through the sales force's "Bextra Positioning for Acute Pain" and "Headquarters knowledge of promotion for unapproved uses," and that the "Unapproved, False and/or Misleading Claims Made For Bextra" included "Acute Pain generally," "Pre and Post Op Pain, Opioid Sparing," "Doses above 10 mg (Outside PD)" and "No Dose Proportional Response in Hypertension and Edema."[739] Those specific facts also included (1) that Bextra had "$2.4 billion in Revenues," but the "Majority of Sales [were] for Unapproved Uses"; (2) the "Potential Criminal Charges" the DOJ was considering bringing against Pfizer, which included Food, Drug and Cosmetic Act charges, conspiracy to defraud, kickback charges and mail and wire

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736 Ex. 247 at PFE DERIV 00066670.

737 Ex. 397 at PFE DERIV 00066512, 529, 599.

738 *Compare* Petrosinelli Decl., O-4 *with* Exs. 256, 258, 314.

739 Ex. 256 at DOJ000237, 240; Ex. 250 at DOJ000254, 256.

fraud; and (3) the "Aggravating Factors," including "Knowledge at the Top," "A Deliberate Scheme," "Pervasive Misconduct" and "The Conduct continued despite: [o]ngoing Neurontin criminal investigation, [t]wo CIA's, [t]wo self-disclosures on other issues, [n]umerous internal complaints and red flags [and] [d]isclosure of the Bextra *qui tam* complaint and ongoing Bextra investigation."[740]

465. In response to information defendants provided to KPMG regarding Pfizer's "controls over sales and marketing practices" in April 2005, KPMG stated "Clearly there are control weaknesses which are evident by the number of compliance matters," requested a "proposed timeline for remediation and control enhancements" and confirmed that "[t]hey are control deficiencies!! and they cannot by fully remediated until the DOJ investigation is complete."[741] In 2Q07, defendants informed KPMG that the "ineffective regulatory compliance function within US Pharmaceuticals [which] resulted in a significant deficiency in the sales and marketing compliance area" in 2006 had been remediated.[742]

466. However, there is no evidence defendants provided KPMG a November 2006 memo by Mooney, a director of IA who headed up the HCC audit function, which explained how problems with Pfizer's HCC function could "have a material effect on the reliability of financial reporting" and thus on Pfizer's financial results.[743] Nor did Pfizer provide KPMG an October 2007 presentation entitled "'RC [Review Committee] Reform' Why, What, When, How & Who," which summarized the results from a "WPO Compliance 'Deep Dive' Review" that confirmed the review

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740 Ex. 258 at DOJ000199, 205, 207-08; Ex. 314 at DOJ000222-27.

741 Exs. 149 at KPMG-PFIZ-DS 033647-49.

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

743 Ex. 161 at PFE-JONES 00005991.

committee process still had a "Lack of clarity & controls to assure consistency throughout the process" and "Several control gaps" at that point in time.[744] Read had initiated this "detailed 'deep dive' assessment[] of controls" in March 2007 "to address the concerns of the Audit committee and to enhance controls, focus and ownership for Healthcare Compliance" by "address[ing] existing weakness" in the Company's ability to ensure it complied with healthcare law, because "[w]hen [he] was appointed as WPO President in the 2nd half of 2006, the status of Healthcare Compliance in the US Pharmaceuticals organization was not where it needed to be" and "Review Committee Procedures" were one of "the top 10 risk areas/programs."[745]

467. In addition, defendants never informed KPMG that Pfizer's outside Investigation Counsel, Covington, received a letter from the DOJ on June 19, 2007 confirming that Pfizer and Pharmacia Corp. "wish[ed] to pursue joint civil and criminal discussions and negotiations with respect to the investigations currently pending . . . concerning Bextra and other Pfizer drugs."[746]

468. Defendants also did not tell KPMG that during the Company's September 14, 2007 meeting with the DOJ, the DOJ proposed use of an "'intended loss' by Pfizer to determine an approximate fine in connection with the Government's Bextra investigation of the promotion of Bextra."[747] Nor did defendants disclose to KPMG that on October 9, 2007, Pfizer's disclosure counsel and in-house Investigation Counsel and Finance Team confirmed "that the 'probable'

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744 Ex. 38 (8/8/13 Bradley Depo.) at 190:20-191:1, 207:23-210:1; Ex. 125 at PFE DERIV 00072341-42; Ex. 203 at 2-3.

745 Ex. 118 at PFE DERIV A 00003833-34, 836; Ex. 120 at PFE DERIV 01072458, 460.

746 Ex. 310.

747 *Compare* Petrosinelli Decl., K-4 at KPMG-PFIZ-DS 0003513, *to* Petrosinelli Decl., B-6 at PFE-JONES 00059186.

criteria of FAS 5 ha[d] been met"[748] or that Lankler and Wessel had begun "reviewing methodologies" in order "to propose a range of potential loss" since the DOJ "suggested the Company propose an amount as damages."[749]

469. Instead, KPMG was told at an October 2007 "all-hands meeting," during which John Chapman "had a face-to-face with Dennis [Block] and everyone, all [Pfizer's] in-house counsel," and stated that "a loss, if any, is not estimable at this time [because the DOJ] is still outlining its theories [of liability and damages] and has not made any demand; nor has it spelled out the statutory remedies or the types of damages/penalties that it may seek."[750] As a result of defendants' representations, KPMG stated in its 3Q07 "Interim Completion Document" that "[t]he off-label promotion of Bextra continues to be a topic of dialogue between Pfizer and the US Attorney's office. To date, no major settlement has been reached, and no probable or estimable range for a settlement has been determined."[751]

470. In 2008, the Bextra Investigation escalated, at the DOJ sent Pfizer a target letter on February 5, 2008, but KPMG was never informed of the target letter.[752] Defendants also withheld from KPMG an April 4, 2008 letter the DOJ sent to the Company's outside counsel "confirm[ing] the key elements of the proposed resolution" for the Bextra Investigation, including a criminal plea,

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748 Ex. 44 (Chapman Depo.) at 122:19-123:16; Ex. 38 (8/8/13 Bradley Depo.) at 234:1-235:5; Petrosinelli Decl., N-6 (October 17, 2007 email summarizing an October 9, 2007 meeting attended by Block, Lankler, Wessel, Dadlani and Brockie "to discuss the potential of a Q3 reserve applicable to Bextra DOJ allegations");

749 Ex. 38 (8/8/13 Bradley Depo.) at 234:1-236:2; Ex. 44 (Chapman Depo.) at 127:15-129:7; Petrosinelli Decl., N-6.

750 Ex. 44 (Chapman Depo.) at 185:3-190:5; Petrosinelli Decl., P-5 at PFE-JONES 00043524; Petrosinelli Decl., C-6 at PFE-JONES 00060497.

751 Ex. 265 at KPMG-PFIZ-DS 018702.

752 Ex. 38 (8/8/13 Bradley Depo.) at 242:13-243:4; Ex. 131.

criminal fine of $3.6 billion, criminal forfeiture of $180 million and civil resolution of $1.2 billion pursuant to False Claims Act and civil disgorgement.[753]

471. Nor did defendants inform KPMG that Pfizer's counsel made a $50-$70 million "prepared-to-recommend" settlement offer which the Government rejected in February 2008,[754] a $250 million "prepared-to-recommend" settlement offer on April 4, 2008 which the Government rejected,[755] or a $750 million "prepared-to-recommend" settlement offer in or around June 2008 which the Government rejected.[756] Defendants also never told KPMG of the September 11, 2008 letter its counsel sent to senior DOJ officials regarding the rejection of Pfizer's $750 million "prepared-to-recommend" settlement offer.[757] Accordingly, KPMG workpapers from June and July 2008 state that KPMG "confirmed that no settlement offers have been made or authorized by management."[758]

472. KPMG's June and July 2008 workpapers also state that with regard to the Zyvox and Geodon Government Investigations, knowledge had "not been linked back to senior management at Corporate Headquarters" as to the practice of promoting Zyvox with unsubstantiated superiority

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753 Petrosinelli Decl., Y-6 at PFE DERIV 00066378-9; Ex. 258 at DOJ000205; Ex. 314 at DOJ000224.

754 Ex. 38 (8/8/13 Bradley Depo.) at 236:3-11; Ex. 104 at PFE-JONES 00007028; Ex. 55 (Lankler Depo.) at 124:12-22.

755 Ex. 38 (8/8/13 Bradley Depo.) at 247:22-248:5; Petrosinelli Decl., Y-8 at PFE DERIV 00066378; Ex. 55 (Lankler Depo.) at 124:12-22.

756 Ex. 38 (8/8/13 Bradley Depo.) at 268:4-18 ("I was not aware of a specific dollar amount that had been proposed by or prepared to recommend by Pfizer counsel."), 276:16-21 (same), 278:3-8 (same); Ex. 55 (Lankler Depo.) at 124:12-22; Ex. 437 (O'Connor Deriv Depo.) at 34:3-18.

757 Ex. 158 at KS_00001-2; Ex. 39 (8/9/13 Bradley Depo.) at 268:4-18.

758 Ex. 159 at KPMG-PFIZ-DS 0005508.

claims and Geodon for off-label use in adolescents.[759] KPMG was thus never informed by defendants that immediately after Pfizer received the July 2005 Warning Letter from the FDA, the Company's senior management at corporate headquarters continued to approve operating plans and direct its sales force to use the core marketing messages and strategies contained therein to promote Zyvox as superior to vancomycin.[760]

DATED: November 26, 2014

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759 Ex. 159 at KPMG-PFIZ-DS 0005508.

760 *E.g.*, Ex. 50 (Greensmith Depo.) at 36:8-38:6; Ex. 177 at PZ0153348, 361, 369-70, 372-73; Ex. 36 (Abelardo Depo.) at 187:3-20; Ex. 40 (Brown Depo.) at 162:10-18.

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Lead Counsel for Plaintiffs

ATTACHMENT 1

DEFENDANTS' CLASS PERIOD FALSE & MISLEADING STATEMENTS

<table>
<tr><th>No.</th><th>Date/ Type</th><th>Source</th><th>Statement</th><th>Defendants</th></tr>
<tr><td>1.</td><td>1/19/06 Press Release</td><td>Ex. 26</td><td>The performance of the central nervous system portfolio was fueled by the launch of Lyrica. Since its September launch, more than 500,000 prescriptions have been written for Lyrica in the U.S. as of December 23, 2005. Lyrica had already gained more than a 7-percent new-prescription share of the U.S. anti-epileptic market as of December 23, continuing its performance as one of Pfizer's most successful pharmaceutical launches. . . . In the U.S., Geodon is the second-fastest-growing atypical anti-psychotic oral medication in new-prescription volume as of November year-to-date. Its balance of powerful efficacy and a favorable metabolic profile positions it for further growth.

* * *

Defendants caused Pfizer to issue false and misleading financial results, including Pfizer's net income and diluted earnings per share ("EPS") as follows:

<table><tr><th>Fiscal Period</th><th>Other Income/ (Other Deductions) – Net (in millions)</th><th>Net Income (in millions)</th><th>Diluted EPS</th><th>Filed with the SEC</th></tr><tr><td>4Q 2005</td><td>$323</td><td>$2,732</td><td>$0.37</td><td>1/19/06</td></tr><tr><td>2005</td><td>($347)</td><td>$8,085</td><td>$1.09</td><td>1/19/06</td></tr></table></td><td>Pfizer
Alan Levin
Jeff Kindler
Henry McKinnell</td></tr>
<tr><td>2.</td><td>3/1/06 2005 Form 10-K</td><td>Petrosinelli Decl., Ex. B-1</td><td>In a time when the news media is full of stories of business leaders and companies whose actions have engendered public suspicion and mistrust, Pfizer truly stands apart. Pfizer is proud of our record of compliance. 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.

* * *

[T]hese policies and practices are the foundation of our drive to become the</td><td>Pfizer
Henry McKinnell
Jeff Kindler
Alan Levin</td></tr>
</table>

<table>
<tr><th>No.</th><th>Date/ Type</th><th>Source</th><th>Statement</th><th>Defendants</th></tr>
<tr><td></td><td></td><td></td><td>
world’s most valued company

* * *

At Pfizer, we are committed to fair competition. This means, among other things, abiding by all laws that apply to our marketing activities. Under these laws it is illegal to use unfair methods of competition or unfair or deceptive acts or practices in commerce. This prohibition includes, but is not limited to:

■ false or misleading advertising, or any other form of misrepresentation made in connection with sales;

* * *

Regulatory Requirements

On a global basis, Pfizer also follows all applicable laws governing the manufacturing and distribution of drugs or biological products. In particular, Pfizer observes all requirements of the U.S. Food and Drug Administration (FDA). . . .

Pfizer’s Policies on Business Conduct (Blue Book) incorporated by reference

* * *

Defendants caused Pfizer to issue false and misleading financial results, including Pfizer’s net income and diluted earnings per share (“EPS”) as follows:

<table>
<tr><th>Fiscal Period</th><th>Other Income/ (Other Deductions) – Net (in millions)</th><th>Net Income (in millions)</th><th>Diluted EPS</th><th>Filed with the SEC</th></tr>
<tr><td>Full Year 2005</td><td>($347)</td><td>$8,085</td><td>$1.09</td><td>3/1/06</td></tr>
</table>
</td><td></td></tr>
</table>

No.	Date/ Type	Source	Statement	Defendants
			Financial Results * * * **Financial Review** * * * **Legal Proceedings and Contingencies** We 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 time to time in the ordinary course of our business. We do not believe any of them will have a material adverse effect on our financial position. We record accruals for such contingencies to the extent that we conclude their occurrence is probable and the related damages are estimable. If a range of liability is probable and estimable and some amount within the range appears to be a better estimate than any other amount within the range, we accrue that amount. If a range of liability is probable and estimable and no amount within the range appears to be a better estimate than any other amount within the range, we accrue the minimum of such probable range. * * * Consequently, we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for these contingencies. . . . Our assessments are based on estimates and assumptions that have been deemed reasonable by management. . . . Although we believe we have substantial defenses in these matters, we could in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations in any particular period. * * *	

No.	Date/ Type	Source	Statement	Defendants
			ITEM 3. LEGAL PROCEEDINGS Certain legal proceedings in which we are involved are discussed in Note 18 to our consolidated financial statements, *Legal Proceedings and Contingencies*, in our 2005 Financial Report, which is incorporated by reference. * * * 18. Legal Proceedings and Contingencies We 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 time to time in the ordinary course of our business. We do not believe any of them will have a material adverse effect on our financial position. We record accruals for such contingencies to the extent that we conclude their occurrence is probable and the related damages are estimable. If a range of liability is probable and estimable and some amount within the range appears to be a better estimate than any other amount within the range, we accrue that amount. If a range of liability is probable and estimable and no amount within the range appears to be a better estimate than any other amount within the range, we accrue the minimum of such probable range. . . . Consequently, we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for these contingencies. . . . Our assessments are based on estimates and assumptions that have been deemed reasonable by management. . . . Although we believe we have substantial defenses in these matters, we could in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations in any particular period. * * * F. Government Investigations and Requests for Information 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. The principal pending investigations and requests for information by government agencies are as follows:	

No.	Date/ Type	Source	Statement	Defendants
			* * * 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. In 2005, we received a similar request from the staff of the Securities and Exchange Commission.	
3.	3/1/06 2005 Form 10-K	Petrosinelli Decl., Ex. B-1	"in all material respects the financial condition [and] results of [Pfizer's] operations": I, [defendant], certify that: 1. I have reviewed this report on [Form 10-Q/Form 10-K] of Pfizer Inc.; 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report; 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report; **Executive Certifications**	Henry McKinnell Alan Levin
4.	3/16/06 Annual 2006 Proxy Statement	Ex. 10	In a time when the news media is full of stories of business leaders and companies whose actions have engendered public suspicion and mistrust, Pfizer truly stands apart. Pfizer is proud of our record of compliance. 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. * * * [T]hese policies and practices are the foundation of our drive to become the world's most valued company **Pfizer's Policies on Business Conduct (Blue Book) incorporated by reference**	Pfizer Henry McKinnell

<table>
<tr><th>No.</th><th>Date/ Type</th><th>Source</th><th>Statement</th><th>Defendants</th></tr>
<tr><td></td><td></td><td></td><td>* * *

At Pfizer, we are committed to fair competition. This means, among other things, abiding by all laws that apply to our marketing activities. Under these laws it is illegal to use unfair methods of competition or unfair or deceptive acts or practices in commerce. This prohibition includes, but is not limited to:

■ false or misleading advertising, or any other form of misrepresentation made in connection with sales;

* * *

Regulatory Requirements

On a global basis, Pfizer also follows all applicable laws governing the manufacturing and distribution of drugs or biological products. In particular, Pfizer observes all requirements of the U.S. Food and Drug Administration (FDA). . . .</td><td></td></tr>
<tr><td>5.</td><td>4/19/06 Press Release</td><td>Ex. 27</td><td><table><tr><th>Fiscal Period</th><th>Other Income/ (Other Deductions) – Net (in millions)</th><th>Net Income (in millions)</th><th>Diluted EPS</th><th>Filed with the SEC</th></tr><tr><td>1Q 2006</td><td>$272</td><td>$4,111</td><td>$0.56</td><td>4/19/06</td></tr></table>
Defendants caused Pfizer to issue false and misleading financial results, including Pfizer’s net income and diluted earnings per share (“EPS”) as follows:</td><td>Pfizer
Henry McKinnell
Alan Levin
Jeff Kindler</td></tr>
<tr><td>6.</td><td>5/8/06 1Q06 Form 10-Q</td><td>Petrosinelli Decl., Ex. C-1</td><td>“in all material respects the financial condition [and] results of [Pfizer’s] operations”:
I, [defendant], certify that:

1. I have reviewed this report on [Form 10-Q/Form 10-K] of Pfizer Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;</td><td>Henry McKinnell
Alan Levin</td></tr>
</table>

<table>
<tr><th>No.</th><th>Date/ Type</th><th>Source</th><th>Statement</th><th>Defendants</th></tr>
<tr><td></td><td></td><td></td><td>3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

Executive Certifications</td><td></td></tr>
<tr><td>7.</td><td>5/8/06
1Q06 Form 10-Q</td><td>Petrosinelli Decl., Ex. C-1</td><td>Defendants caused Pfizer to issue false and misleading financial results, including Pfizer’s net income and diluted earnings per share (“EPS”) as follows:

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<tr><th>Fiscal Period</th><th>Other Income/ (Other Deductions) – Net</th><th>Net Income</th><th>Diluted EPS</th><th>Filed with the SEC</th></tr>
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</table>

Financial Results

* * *

<u>Legal Proceedings and Contingencies</u>

We 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 time to time in the ordinary course of our business. We do not believe any of them will have a material adverse effect on our financial position.

We record accruals for such contingencies to the extent that we conclude their occurrence is probable and the related damages are estimable. If a range of liability is probable and estimable and some amount within the range appears to be a better estimate than any other amount within the range, we accrue that amount. If a range of liability is probable and estimable and no amount within the range appears to be a better estimate than any other amount within the range, we accrue the minimum of such probable range. . . . Consequently, we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for these contingencies. . . . Our assessments are based on estimates and assumptions that have been deemed reasonable by</td><td>Pfizer
Henry McKinnell
Jeff Kindler
Alan Levin</td></tr>
</table>

No.	Date/ Type	Source	Statement	Defendants
			management. . . . Although we believe we have substantial defenses in these matters, we could in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations in any particular period. * * * Item 1. Legal Proceedings Certain legal proceedings in which we are involved are discussed in Note 18 to the consolidated financial statements included in our 2005 Financial Report and in Part I, Item 3, of our Annual Report on Form 10-K for the year ended December 31, 2005. The following discussion is limited to certain recent developments concerning our legal proceedings and should be read in conjunction with those earlier Reports. Unless otherwise indicated, all proceedings discussed in those earlier Reports remain outstanding. Reference also is made to the Legal Proceedings and Contingencies section in Part I, Item 2, of this Form 10-Q.	
8.	7/20/06 Press Release	Ex. 28	"Our second-quarter 2006 performance is quite encouraging. . . . Celebrex, Geodon, and six other major in-line products, each delivered double-digit revenue growth in the quarter. Particularly impressive was the robust performance of two of our new products, Lyrica and Sutent, evidencing their rapid acceptance by physicians and patients." * * * Worldwide sales of Geodon increased 14 percent in the quarter to $165 million, driven by the better understanding by clinicians of its efficacy, increased benefits from optimal dosing, and favorable metabolic profile. We continue to expect full-year Geodon revenues of about $800 million. For example, Lyrica worldwide sales reached $271 million in the second quarter of 2006, reflecting strong market acceptance by physicians and patients since its initial launch nearly two years ago. In the U.S., Lyrica had $172 million in revenues for the second quarter of 2006. * * *	Pfizer Alan Levin Jeff Kindler Henry McKinnell

<table>
<tr><th>No.</th><th>Date/ Type</th><th>Source</th><th>Statement</th><th>Defendants</th></tr>
<tr><td></td><td></td><td></td><td>In the U.S., Lyrica performance has been robust, with new prescriptions continuing to grow steadily through the second quarter of 2006 to reach a 9.8-percent share of the total anti-epileptic drug market in June 2006 (IMS).

* * *

Defendants caused Pfizer to issue false and misleading financial results, including Pfizer's net income and diluted earnings per share ("EPS") as follows:

<table><tr><th>Fiscal Period</th><th>Other Income/ (Other Deductions) – Net (in millions)</th><th>Net Income (in millions)</th><th>Diluted EPS</th><th>Filed with the SEC</th></tr><tr><td>2Q 2006</td><td>$359</td><td>$2,415</td><td>$0.33</td><td>7/20/06</td></tr></table></td><td></td></tr>
<tr><td>9.</td><td>8/11/06 2Q06 Form 10-Q</td><td>Ex. 12</td><td>"in all material respects the financial condition [and] results of [Pfizer's] operations":
I, [defendant], certify that:
1. I have reviewed this report on [Form 10-Q/Form 10-K] of Pfizer Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
Executive Certifications</td><td>Jeff Kindler
Alan Levin</td></tr>
<tr><td>10.</td><td>8/11/06 2Q06 Form 10-Q</td><td>Ex. 12</td><td>Defendants caused Pfizer to issue false and misleading financial results, including Pfizer's net income and diluted earnings per share ("EPS") as follows.</td><td>Pfizer
Jeff Kindler
Alan Levin
Allen Waxman</td></tr>
</table>

<table>
<tr><th>No.</th><th>Date/ Type</th><th>Source</th><th>Statement</th><th>Defendants</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><th>Fiscal Period</th><th>Other Income/ (Other Deductions) – Net</th><th>Net Income</th><th>Diluted EPS</th><th>Filed with the SEC</th></tr>
<tr><td>2Q 2006</td><td>$359</td><td>$2,415</td><td>$0.33</td><td>8/11/06</td></tr>
</table>
Financial Results
* * *
<u>Legal Proceedings and Contingencies</u>
We 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 time to time in the ordinary course of our business. We do not believe any of them will have a material adverse effect on our financial position.
We record accruals for such contingencies to the extent that we conclude their occurrence is probable and the related damages are estimable. If a range of liability is probable and estimable and some amount within the range appears to be a better estimate than any other amount within the range, we accrue that amount. If a range of liability is probable and estimable and no amount within the range appears to be a better estimate than any other amount within the range, we accrue the minimum of such probable range. . . . Consequently, we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for these contingencies. . . . Our assessments are based on estimates and assumptions that have been deemed reasonable by management. . . . Although we believe we have substantial defenses in these matters, we could in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations in any particular period.
* * *
<u>Item 1. Legal Proceedings</u>
Certain legal proceedings in which we are involved are discussed in Note 18 to the consolidated financial statements included in our 2005 Financial Report; Part
</td><td></td></tr>
</table>

<table>
<tr><th>No.</th><th>Date/ Type</th><th>Source</th><th>Statement</th><th>Defendants</th></tr>
<tr><td></td><td></td><td></td><td>I, Item 3, of our Annual Report on Form 10-K for the year ended December 31, 2005; and Part II, Item 1, of our Quarterly Report on Form 10-Q for the quarter ended April 2, 2006. The following discussion is limited to certain recent developments concerning our legal proceedings and should be read in conjunction with those earlier Reports. Unless otherwise indicated, all proceedings discussed in those earlier Reports remain outstanding. Reference also is made to the Legal Proceedings and Contingencies section in Part I, Item 2, of this Form 10-Q.</td><td></td></tr>
<tr><td>11.</td><td>10/19/06 Press Release</td><td>Ex. 29</td><td>Defendants caused Pfizer to issue false and misleading financial results, including Pfizer’s net income and diluted earnings per share (“EPS”) as follows:
<table>
<tr><th>Fiscal Period</th><th>Other Income/ (Other Deductions) – Net (in millions)</th><th>Net Income (in millions)</th><th>Diluted EPS</th><th>Filed with the SEC</th></tr>
<tr><td>3Q 2006</td><td>$343</td><td>$3,362</td><td>$0.46</td><td>10/19/06</td></tr>
</table></td><td>Pfizer
Jeff Kindler
Alan Levin
Allen Waxman
Ian Read</td></tr>
<tr><td>12.</td><td>11/3/06 3Q06 Form 10-Q</td><td>Ex. 13</td><td>“in all material respects the financial condition [and] results of [Pfizer’s] operations”:
I, [defendant], certify that:
1. I have reviewed this report on [Form 10-Q/Form 10-K] of Pfizer Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
Executive Certifications</td><td>Jeff Kindler
Alan Levin</td></tr>
<tr><td>13.</td><td>11/3/06 3Q06 Form</td><td>Ex. 13</td><td>Defendants caused Pfizer to issue false and misleading financial results, including Pfizer’s net income and diluted earnings per share (“EPS”) as follows:</td><td>Pfizer
Jeff Kindler</td></tr>
</table>

<table>
<tr><th>No.</th><th>Date/ Type</th><th>Source</th><th>Statement</th><th>Defendants</th></tr>
<tr><td></td><td>10-Q</td><td></td><td>
<table>
<tr><th>Fiscal Period</th><th>Other Income/ (Other Deductions) – Net (in millions)</th><th>Net Income (in millions)</th><th>Diluted EPS</th><th>Filed with the SEC</th></tr>
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Financial Results
* * *
<u>Legal Proceedings and Contingencies</u>
We 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 time to time in the ordinary course of our business. We do not believe any of them will have a material adverse effect on our financial position.
We record accruals for such contingencies to the extent that we conclude their occurrence is probable and the related damages are estimable. If a range of liability is probable and estimable and some amount within the range appears to be a better estimate than any other amount within the range, we accrue that amount. If a range of liability is probable and estimable and no amount within the range appears to be a better estimate than any other amount within the range, we accrue the minimum of such probable range. . . . Consequently, we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for these contingencies. . . . Our assessments are based on estimates and assumptions that have been deemed reasonable by management. . . . Although we believe we have substantial defenses in these matters, we could in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations in any particular period.
* * *
<u>Item 1. Legal Proceedings</u>
Certain legal proceedings in which we are involved are discussed in Note 18 to the consolidated financial statements included in our 2005 Financial Report; Part</td><td>Alan Levin
Allen Waxman
Ian Read</td></tr>
</table>

No.	Date/ Type	Source	Statement	Defendants
			I, Item 3, of our Annual Report on Form 10-K for the year ended December 31, 2005; and Part II, Item 1, of our Quarterly Reports on Form 10-Q for the quarters ended April 2 and July 2, 2006. The following discussion is limited to certain recent developments concerning our legal proceedings and should be read in conjunction with those earlier Reports. Unless otherwise indicated, all proceedings discussed in those earlier Reports remain outstanding. Reference also is made to the Legal Proceedings and Contingencies section in Part I, Item 2, of this Form 10-Q.	
14.	1/22/07 Analyst Meeting	Carlinsky Decl., Ex. C-R	[Defendant Read:] Lyrica's launch has gone extremely well, and with excellent feedback from both patients and physicians, we have an exciting new marketing initiative aimed at improving the appropriate diagnosis of patients, and we are optimistic about the potential new indication for fibromyalgia. Another drug, Geodon, is a quiet but impressive success story. It is now the fastest-growing atypical agent in the US, and I will give you an update on what is driving this. * * * Let's now look at Geodon, a growing success story. Geodon's 2006 sales of over $600 million and a growth of 31% is a clear sign that the atypical antipsychotic market is changing. * * * Better understanding of Geodon's dosing, as well as its superior metabolic profile, has made Geodon the fastest-growing atypical medicine in the US market.	Pfizer Ian Read Jeff Kindler
15.	1/22/07 Press Release	Ex. 30	Defendants caused Pfizer to issue false and misleading financial results, including Pfizer's net income and diluted earnings per share ("EPS") as follows:	Pfizer Jeff Kindler Alan Levin Allen Waxman Ian Read

<table>
<tr><th>No.</th><th>Date/ Type</th><th>Source</th><th>Statement</th><th>Defendants</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><th>Fiscal Period</th><th>Other Income/ (Other Deductions) – Net (in millions)</th><th>Net Income (in millions)</th><th>Diluted EPS</th><th>Filed with the SEC</th></tr>
<tr><td>4Q 2006</td><td>($54)</td><td>$9,449</td><td>$1.32</td><td>1/22/07</td></tr>
<tr><td>2006</td><td>$904</td><td>$19,337</td><td>$2.66</td><td>1/22/07</td></tr>
</table>
</td><td></td></tr>
<tr><td>16.</td><td>3/1/07
2006 Form 10-K</td><td>Petrosinelli Decl., Ex. D-1</td><td>At Pfizer, we are committed to fair competition. This means, among other things, abiding by all laws that apply to our marketing activities. Under these laws it is illegal to use unfair methods of competition or unfair or deceptive acts or practices in commerce. This prohibition includes, but is not limited to:
■ false or misleading advertising, or any other form of misrepresentation made in connection with sales;
* * *
Regulatory Requirements
On a global basis, Pfizer also follows all applicable laws governing the manufacturing and distribution of drugs or biological products. In particular, Pfizer observes all requirements of the U.S. Food and Drug Administration (FDA). . . .
Pfizer’s Policies on Business Conduct (Blue Book) incorporated by reference
* * *
Defendants caused Pfizer to issue false and misleading financial results, including Pfizer’s net income and diluted earnings per share (“EPS”) as follows:</td><td>Pfizer
Jeff Kindler
Allen Waxman
Alan Levin
Ian Read</td></tr>
</table>

<table>
<tr><th>No.</th><th>Date/ Type</th><th>Source</th><th>Statement</th><th>Defendants</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><th>Fiscal Period</th><th>Other Income/ (Other Deductions) - Net (in millions)</th><th>Net Income (in millions)</th><th>Diluted EPS</th><th>Filed with the SEC</th></tr>
<tr><td>Full Year 2006</td><td>$904</td><td>$19,337</td><td>$2.66</td><td>3/1/07</td></tr>
</table>
Financial Results
* * *
Financial Review
* * *
Legal Proceedings and Contingencies
We 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 time to time in the ordinary course of our business. We do not believe any of them will have a material adverse effect on our financial position.
We record accruals for such contingencies to the extent that we conclude their occurrence is probable and the related damages are estimable. If a range of liability is probable and estimable and some amount within the range appears to be a better estimate than any other amount within the range, we accrue that amount. If a range of liability is probable and estimable and no amount within the range appears to be a better estimate than any other amount within the range, we accrue the minimum of such probable range. . . . Consequently, we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for these contingencies. . . . Our assessments are based on estimates and assumptions that have been deemed reasonable by management. . . . Although we believe we have substantial defenses in these matters, we could in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations in any particular period.
</td><td></td></tr>
</table>

No.	Date/ Type	Source	Statement	Defendants
			* * * ITEM 3. LEGAL PROCEEDINGS Certain legal proceedings in which we are involved are discussed in Note 19 to our consolidated financial statements, *Legal Proceedings and Contingencies*, in our 2006 Financial Report, which is incorporated by reference. * * * <u>19. Legal Proceedings and Contingencies</u> We 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 time to time in the ordinary course of our business. We do not believe any of them will have a material adverse effect on our financial position. We record accruals for such contingencies to the extent that we conclude their occurrence is probable and the related damages are estimable. If a range of liability is probable and estimable and some amount within the range appears to be a better estimate than any other amount within the range, we accrue that amount. If a range of liability is probable and estimable and no amount within the range appears to be a better estimate than any other amount within the range, we accrue the minimum of such probable range. . . . Consequently, we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for these contingencies. . . . Our assessments are based on estimates and assumptions that have been deemed reasonable by management. . . . Although we believe we have substantial defenses in these matters, we could in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations in any particular period. * * * <u>F. Government Investigations and Requests for Information</u> Like other pharmaceutical companies, we are subject to extensive regulation by	

No.	Date/ Type	Source	Statement	Defendants
			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. Since 2003, we have 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. We have been considering various ways to resolve these matters.	
17.	3/1/07 2006 Form 10-K	Petrosinelli Decl., Ex. D-1	"in all material respects the financial condition [and] results of [Pfizer's] operations": I, [defendant], certify that: 1. I have reviewed this report on [Form 10-Q/Form 10-K] of Pfizer Inc.; 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report; 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report; **Executive Certifications**	Jeff Kindler Alan Levin
18.	3/15/07 Annual 2007 Proxy Statement	Ex. 14	At Pfizer, we are committed to fair competition. This means, among other things, abiding by all laws that apply to our marketing activities. Under these laws it is illegal to use unfair methods of competition or unfair or deceptive acts or practices in commerce. This prohibition includes, but is not limited to: ■ false or misleading advertising, or any other form of misrepresentation made in connection with sales; * * * **Regulatory Requirements**	Pfizer Jeff Kindler

<table>
<tr><th>No.</th><th>Date/ Type</th><th>Source</th><th>Statement</th><th>Defendants</th></tr>
<tr><td></td><td></td><td></td><td>On a global basis, Pfizer also follows all applicable laws governing the manufacturing and distribution of drugs or biological products. In particular, Pfizer observes all requirements of the U.S. Food and Drug Administration (FDA). . . .

Pfizer's Policies on Business Conduct (Blue Book) incorporated by reference</td><td></td></tr>
<tr><td>19.</td><td>4/2/07 Press Release</td><td>Galin Decl., Ex. Q-W</td><td>HEADLINE: Pharmacia Subsidiaries Reach $34.7 Million Settlement with DOJ; Resolve Allegations of Improper Activities Prior to Acquisition by Pfizer;
* * *
"As the Department of Justice has acknowledged, Pfizer voluntarily and fully self-disclosed the off-label promotion of Genotropin by a Pharmacia subsidiary before Pharmacia was acquired by Pfizer," said Allen Waxman, senior vice president and general counsel. "Pfizer's marketing and promotion practices are not involved in the settlement. The company has internal controls to guard against these types of practices."</td><td>Pfizer
Jeff Kindler
Alan Levin
Allen Waxman
Ian Read</td></tr>
<tr><td>20.</td><td>4/20/07 Press Release</td><td>Ex. 31</td><td>Defendants caused Pfizer to issue false and misleading financial results, including Pfizer's net income and diluted earnings per share ("EPS") as follows:
<table>
<tr><th>Fiscal Period</th><th>Other Income/ (Other Deductions) – Net (in millions)</th><th>Net Income (in millions)</th><th>Diluted EPS</th><th>Filed with the SEC</th></tr>
<tr><td>1Q 2007</td><td>$402</td><td>$3,392</td><td>$0.48</td><td>4/20/07</td></tr>
</table></td><td>Pfizer
Jeff Kindler
Alan Levin
Allen Waxman
Ian Read</td></tr>
<tr><td>21.</td><td>5/4/07 1Q07 Form 10-Q</td><td>Petrosinelli Decl., Ex. E-1</td><td>"in all material respects the financial condition [and] results of [Pfizer's] operations":
I, [defendant], certify that:
1. I have reviewed this report on [Form 10-Q/Form 10-K] of Pfizer Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements</td><td>Jeff Kindler
Alan Levin</td></tr>
</table>

<table>
<tr><th>No.</th><th>Date/ Type</th><th>Source</th><th>Statement</th><th>Defendants</th></tr>
<tr><td></td><td></td><td></td><td>made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

Executive Certifications</td><td></td></tr>
<tr><td>22.</td><td>5/4/07
1Q07 Form 10-Q</td><td>Petrosinelli Decl., Ex. E-1</td><td>Defendants caused Pfizer to issue false and misleading financial results, including Pfizer’s net income and diluted earnings per share (“EPS”) as follows:

<table>
<tr><th>Fiscal Period</th><th>Other Income/ (Other Deductions) - Net (in millions)</th><th>Net Income (in millions)</th><th>Diluted EPS</th><th>Filed with the SEC</th></tr>
<tr><td>1Q 2007</td><td>$402</td><td>$3,392</td><td>$0.48</td><td>5/4/07</td></tr>
</table>

Financial Results

* * *

<u>Legal Proceedings and Contingencies</u>

We and certain of our subsidiaries are involved in various patent, product liability, consumer, commercial, securities and environmental litigations and claims; government investigations; and other legal proceedings that arise from time to time in the ordinary course of our business. We do not believe any of them will have a material adverse effect on our financial position.

We record accruals for such contingencies to the extent that we conclude their occurrence is probable and the related damages are estimable. If a range of liability is probable and estimable and some amount within the range appears to be a better estimate than any other amount within the range, we accrue that amount. If a range of liability is probable and estimable and no amount within the range appears to be a better estimate than any other amount within the range, we accrue the minimum of such probable range. . . . Consequently, we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for these contingencies. . . . Our assessments</td><td>Pfizer
Jeff Kindler
Alan Levin
Allen Waxman
Ian Read</td></tr>
</table>

<table>
<tr><th>No.</th><th>Date/ Type</th><th>Source</th><th>Statement</th><th>Defendants</th></tr>
<tr><td></td><td></td><td></td><td>are based on estimates and assumptions that have been deemed reasonable by management. . . . Although we believe we have substantial defenses in these matters, we could in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations in any particular period.

* * *

<u>Item 1. Legal Proceedings</u>

Certain legal proceedings in which we are involved are discussed in Note 19 to the consolidated financial statements included in our 2006 Financial Report and in Part I, Item 3, of our Annual Report on Form 10-K for the year ended December 31, 2006. The following discussion is limited to certain recent developments concerning our legal proceedings and should be read in conjunction with those earlier Reports. Unless otherwise indicated, all proceedings discussed in those earlier Reports remain outstanding. Reference also is made to the Legal Proceedings and Contingencies section in Part I, Item 2, of this Form 10-Q.</td><td></td></tr>
<tr><td>23.</td><td>7/18/07 Press Release</td><td>Ex. 32</td><td>Defendants caused Pfizer to issue false and misleading financial results, including Pfizer’s net income and diluted earnings per share (“EPS”) as follows:
<table>
<tr><th>Fiscal Period</th><th>Other Income/ (Other Deductions) – Net (in millions)</th><th>Net Income (in millions)</th><th>Diluted EPS</th><th>Filed with the SEC</th></tr>
<tr><td>2Q 2007</td><td>$487</td><td>$1,267</td><td>$0.18</td><td>7/18/07</td></tr>
</table></td><td>Pfizer
Jeff Kindler
Alan Levin
Allen Waxman
Ian Read</td></tr>
<tr><td>24.</td><td>8/6/07 2Q07 Form 10-Q</td><td>Ex. 15</td><td>“in all material respects the financial condition [and] results of [Pfizer’s] operations”:
I, [defendant], certify that:

1. I have reviewed this report on [Form 10-Q/Form 10-K] of Pfizer Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;</td><td>Jeff Kindler
Alan Levin</td></tr>
</table>

<table>
<tr><th>No.</th><th>Date/ Type</th><th>Source</th><th>Statement</th><th>Defendants</th></tr>
<tr><td></td><td></td><td></td><td>3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

Executive Certifications</td><td></td></tr>
<tr><td>25.</td><td>8/6/07
2Q07 Form 10-Q</td><td>Ex. 15</td><td>Defendants caused Pfizer to issue false and misleading financial results, including Pfizer’s net income and diluted earnings per share (“EPS”) as follows:
<table>
<tr><th>Fiscal Period</th><th>Other Income/ (Other Deductions) - Net (in millions)</th><th>Net Income (in millions)</th><th>Diluted EPS</th><th>Filed with the SEC</th></tr>
<tr><td>2Q 2007</td><td>$487</td><td>$1,267</td><td>$0.18</td><td>8/6/07</td></tr>
</table>
Financial Results

* * *

<u>Legal Proceedings and Contingencies</u>

We and certain of our subsidiaries are involved in various patent, product liability, consumer, commercial, securities and environmental litigations and claims; government investigations; and other legal proceedings that arise from time to time in the ordinary course of our business. We do not believe any of them will have a material adverse effect on our financial position.

We record accruals for such contingencies to the extent that we conclude their occurrence is probable and the related damages are estimable. If a range of liability is probable and estimable and some amount within the range appears to be a better estimate than any other amount within the range, we accrue that amount. If a range of liability is probable and estimable and no amount within the range appears to be a better estimate than any other amount within the range, we accrue the minimum of such probable range. . . . Consequently, we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for these contingencies. . . . Our assessments are based on estimates and assumptions that have been deemed reasonable by management. . . . Although we believe we have substantial defenses in these</td><td>Pfizer
Jeff Kindler
Alan Levin
Allen Waxman
Ian Read</td></tr>
</table>

<table>
<tr><th>No.</th><th>Date/ Type</th><th>Source</th><th>Statement</th><th>Defendants</th></tr>
<tr><td></td><td></td><td></td><td>matters, we could in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations in any particular period.

* * *

<u>Item 1. Legal Proceedings</u>

Certain legal proceedings in which we are involved are discussed in Note 19 to the consolidated financial statements included in our 2006 Financial Report; Part I, Item 3, of our Annual Report on Form 10-K for the year ended December 31, 2006; and Part II, Item 1, of our Quarterly Report on Form 10-Q for the quarter ended April 1, 2007. The following discussion is limited to certain recent developments concerning our legal proceedings and should be read in conjunction with those earlier Reports. Unless otherwise indicated, all proceedings discussed in those earlier Reports remain outstanding. Reference also is made to the Legal Proceedings and Contingencies section in Part I, Item 2, of this Form 10-Q.</td><td></td></tr>
<tr><td>26.</td><td>10/18/07 Press Release</td><td>Strassberg Decl., Ex. H-D</td><td>Lyrica revenues grew 37% to $465 million in the third quarter of 2007 compared to the same period last year. Lyrica’s growth continues to be fueled by strong efficacy as well as high patient and physician satisfaction in the marketplace.

Defendants caused Pfizer to issue false and misleading financial results, including Pfizer’s net income and diluted earnings per share (“EPS”) as follows:

<table>
<tr><th>Fiscal Period</th><th>Other Income/ (Other Deductions) – Net (in millions)</th><th>Net Income (in millions)</th><th>Diluted EPS</th><th>Filed with the SEC</th></tr>
<tr><td>3Q 2007</td><td>$260</td><td>$761</td><td>$0.11</td><td>10/18/07</td></tr>
</table></td><td>Pfizer
Jeff Kindler
Frank D’Amelio
Allen Waxman
Ian Read</td></tr>
<tr><td>27.</td><td>10/18/07 3Q07 Earnings Conference</td><td>Strassberg Decl., Ex. N-D</td><td>[Defendant Kindler:] Geodon is growing at a rate of two times the market for atypical antipsychotics.</td><td>Pfizer
Jeff Kindler</td></tr>
</table>

<table>
<tr><th>No.</th><th>Date/ Type</th><th>Source</th><th>Statement</th><th>Defendants</th></tr>
<tr><td></td><td>Call</td><td></td><td>* * *

[Defendant D’Amelio:] As you can see, all the key in-line products posted positive results in the third quarter compared to the same period last year. I would also like to emphasize the strong growth being delivered by our key new products. . . . Revenues of Lyrica, our medicine for the management of neuropathic pain and most recently fibromyalgia, increased 37% to $465 million.</td><td></td></tr>
<tr><td>28.</td><td>11/5/07 3Q07 Form 10-Q</td><td>Ex. 16</td><td>“in all material respects the financial condition [and] results of [Pfizer’s] operations”:
I, [defendant], certify that:
1. I have reviewed this report on [Form 10-Q/Form 10-K] of Pfizer Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
Executive Certifications</td><td>Jeff Kindler
Frank D’Amelio</td></tr>
<tr><td>29.</td><td>11/5/07 3Q07 Form 10-Q</td><td>Ex. 16</td><td>Defendants caused Pfizer to issue false and misleading financial results, including Pfizer’s net income and diluted earnings per share (“EPS”) as follows:
<table>
<tr><th>Fiscal Period</th><th>Other Income/ (Other Deductions) - Net (in millions)</th><th>Net Income (in millions)</th><th>Diluted EPS</th><th>Filed with the SEC</th></tr>
<tr><td>3Q 2007</td><td>$260</td><td>$761</td><td>$0.11</td><td>11/5/07</td></tr>
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Financial Results

* * *</td><td>Pfizer
Jeff Kindler
Frank D’Amelio
Allen Waxman
Ian Read</td></tr>
</table>

No.	Date/ Type	Source	Statement	Defendants
			Legal Proceedings and Contingencies We and certain of our subsidiaries are involved in various patent, product liability, consumer, commercial, securities and environmental litigations and claims; government investigations; and other legal proceedings that arise from time to time in the ordinary course of our business. We do not believe any of them will have a material adverse effect on our financial position. We record accruals for such contingencies to the extent that we conclude their occurrence is probable and the related damages are estimable. If a range of liability is probable and estimable and some amount within the range appears to be a better estimate than any other amount within the range, we accrue that amount. If a range of liability is probable and estimable and no amount within the range appears to be a better estimate than any other amount within the range, we accrue the minimum of such probable range. . . . Consequently, we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for these contingencies. . . . Our assessments are based on estimates and assumptions that have been deemed reasonable by management. . . . Although we believe we have substantial defenses in these matters, we could in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations in any particular period. * * * Item 1. Legal Proceedings Certain legal proceedings in which we are involved are discussed in Note 19 to the consolidated financial statements included in our 2006 Financial Report; Part I, Item 3, of our Annual Report on Form 10-K for the year ended December 31, 2006; and Part II, Item 1, of our Quarterly Reports on Form 10-Q for the quarters ended April 1, 2007 and July 1, 2007. The following discussion is limited to certain recent developments concerning our legal proceedings and should be read in conjunction with those earlier Reports. Unless otherwise indicated, all proceedings discussed in those earlier Reports remain outstanding. Reference also is made to the Legal Proceedings and Contingencies section in Part I, Item 2, of this Form 10-Q.	

<table>
<tr><th>No.</th><th>Date/ Type</th><th>Source</th><th>Statement</th><th>Defendants</th></tr>
<tr><td></td><td></td><td></td><td>* * *

Celebrex and Bextra Matters

* * *

As previously reported, since 2003 we have received requests for information and documents in connection with potential claims concerning the marketing and safety of Bextra and Celebrex from a group of state attorneys general. We believe that we have strong defenses to any potential claims that may be asserted by members of the attorney general group, and we continue to explore various ways to resolve any such potential claims.</td><td></td></tr>
<tr><td>30.</td><td>1/22/08 Press Release</td><td>Strassberg Decl., Ex. I-D</td><td>Defendants caused Pfizer to issue false and misleading financial results, including Pfizer's net income and diluted earnings per share ("EPS") as follows:
<table>
<tr><th>Fiscal Period</th><th>Other Income/ (Other Deductions) – Net (in millions)</th><th>Net Income (in millions)</th><th>Diluted EPS</th><th>Filed with the SEC</th></tr>
<tr><td>4Q 2007</td><td>$610</td><td>$2,878</td><td>$0.42</td><td>1/23/08</td></tr>
<tr><td>2007</td><td>$1,759</td><td>$8,298</td><td>$1.20</td><td>1/23/08</td></tr>
</table></td><td>Pfizer
Jeff Kindler
Frank D'Amelio
Allen Waxman
Ian Read</td></tr>
<tr><td>31.</td><td>2/29/08 2007 Form 10-K</td><td>Petrosinelli Decl., Ex. F-1</td><td>At Pfizer, we are committed to fair competition. This means, among other things, abiding by all laws that apply to our marketing activities. Under these laws it is illegal to use unfair methods of competition or unfair or deceptive acts or practices in commerce. This prohibition includes, but is not limited to:

■ false or misleading advertising, or any other form of misrepresentation made in connection with sales;

* * *</td><td>Pfizer
Jeff Kindler
Frank D'Amelio
Allen Waxman
Ian Read</td></tr>
</table>

<table>
<tr><th>No.</th><th>Date/ Type</th><th>Source</th><th>Statement</th><th>Defendants</th></tr>
<tr><td></td><td></td><td></td><td>
Regulatory Requirements

On a global basis, Pfizer also follows all applicable laws governing the manufacturing and distribution of drugs or biological products. In particular, Pfizer observes all requirements of the U.S. Food and Drug Administration (FDA). . . .

Pfizer's Policies on Business Conduct (Blue Book) incorporated by reference

* * *

Defendants caused Pfizer to issue false and misleading financial results, including Pfizer's net income and diluted earnings per share ("EPS") as follows:

<table>
<tr><th>Fiscal Period</th><th>Other Income/ (Other Deductions) - Net (in millions)</th><th>Net Income (in millions)</th><th>Diluted EPS</th><th>Filed with the SEC</th></tr>
<tr><td>Full Year 2007</td><td>$1,759</td><td>$8,144</td><td>$1.18</td><td>2/29/08</td></tr>
</table>

Financial Results

* * *

Financial Review
</td><td></td></tr>
</table>

No.	Date/ Type	Source	Statement	Defendants
			* * * **Legal Proceedings and Contingencies** We 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 time to time in the ordinary course of our business. We do not believe any of them will have a material adverse effect on our financial position. * * * We record accruals for all other contingencies to the extent that we conclude their occurrence is probable and the related damages are estimable, and we record anticipated recoveries under existing insurance contracts when assured of recovery. If a range of liability is probable and estimable and some amount within the range appears to be a better estimate than any other amount within the range, we accrue that amount. If a range of liability is probable and estimable and no amount within the range appears to be a better estimate than any other amount within the range, we accrue the minimum of such probable range. . . . Consequently, we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for these contingencies. . . . Our assessments are based on estimates and assumptions that have been deemed reasonable by management. . . . Although we believe we have substantial defenses in these matters, we could in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations in any particular period. * * * ITEM 3. LEGAL PROCEEDINGS Certain legal proceedings in which we are involved are discussed in Note 20 to our consolidated financial statements, *Legal Proceedings and Contingencies*, in our 2007 Financial Report, which is incorporated by reference.	

No.	Date/ Type	Source	Statement	Defendants
			* * * 20. Legal Proceedings and Contingencies We 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 time to time in the ordinary course of our business. We do not believe any of them will have a material adverse effect on our financial position. * * * We record accruals for all other contingencies to the extent that we conclude their occurrence is probable and the related damages are estimable, and we record anticipated recoveries under existing insurance contracts when assured of recovery. If a range of liability is probable and estimable and some amount within the range appears to be a better estimate than any other amount within the range, we accrue that amount. If a range of liability is probable and estimable and no amount within the range appears to be a better estimate than any other amount within the range, we accrue the minimum of such probable range. . . .Consequently, we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for these contingencies. . . . Our assessments are based on estimates and assumptions that have been deemed reasonable by management. . . . Although we believe we have substantial defenses in these matters, we could in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations in any particular period. * * * D. Government Investigations and Requests for Information 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	

No.	Date/ Type	Source	Statement	Defendants
			criminal charges and fines and/or civil penalties could result from pending government investigations, including but not limited to those discussed below. The Department of Justice continues to actively investigate the marketing and safety of our COX-2 medicines, particularly Bextra. The investigation has included requests for information and documents. We also have received requests for information and documents in connection with threatened claims concerning the marketing and safety of Bextra and Celebrex from a group of state attorneys general. We have been considering various ways to resolve these matters.	
32.	2/29/08 2007 Form 10-K	Petrosinelli Decl., Ex. F-1	"in all material respects the financial condition [and] results of [Pfizer's] operations": I, [defendant], certify that: 1. I have reviewed this report on [Form 10-Q/Form 10-K] of Pfizer Inc.; 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report; 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report; **Executive Certifications**	Jeff Kindler Frank D'Amelio
33.	3/05/08 Analyst Meeting	Carlinsky Decl., Ex. D-R	[Defendant Read:] Lyrica has demonstrated rapid and sustained uptake. 2007 U.S. sales were up 46% with international sales growing 78% to $781 million. On this slide, you can see how the product positively responded to the launch of the fibromyalgia indication in the third quarter of last year in the U.S.	Pfizer Ian Read Jeff Kindler Frank D'Amelio
34.	3/14/08 Annual 2008 Proxy Statement	Ex. 17	At Pfizer, we are committed to fair competition. This means, among other things, abiding by all laws that apply to our marketing activities. Under these laws it is illegal to use unfair methods of competition or unfair or deceptive acts or practices in commerce. This prohibition includes, but is not limited to: ■ false or misleading advertising, or any other form of misrepresentation made in connection with sales;	Pfizer Jeff Kindler

<table>
<tr><th>No.</th><th>Date/ Type</th><th>Source</th><th>Statement</th><th>Defendants</th></tr>
<tr><td></td><td></td><td></td><td>* * *

Regulatory Requirements

On a global basis, Pfizer also follows all applicable laws governing the manufacturing and distribution of drugs or biological products. In particular, Pfizer observes all requirements of the U.S. Food and Drug Administration (FDA). . . .

Pfizer's Policies on Business Conduct (Blue Book) incorporated by reference</td><td></td></tr>
<tr><td>35.</td><td>4/17/08 Press Release</td><td>Strassberg Decl., Ex. K-D</td><td>Defendants caused Pfizer to issue false and misleading financial results, including Pfizer's net income and diluted earnings per share ("EPS") as follows:
<table>
<tr><th>Fiscal Period</th><th>Other Income/ (Other Deductions) – Net (in millions)</th><th>Net Income (in millions)</th><th>Diluted EPS</th><th>Filed with the SEC</th></tr>
<tr><td>1Q 2008</td><td>$333</td><td>$2,784</td><td>$0.41</td><td>4/17/08</td></tr>
</table></td><td>Pfizer
Jeff Kindler
Frank D'Amelio
Ian Read</td></tr>
<tr><td>36.</td><td>5/2/08 1Q08 Form 10-Q</td><td>Petrosinelli Decl., Ex. G-1</td><td>"in all material respects the financial condition [and] results of [Pfizer's] operations":
I, [defendant], certify that:

1. I have reviewed this report on [Form 10-Q/Form 10-K] of Pfizer Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

Executive Certifications</td><td>Jeff Kindler
Frank D'Amelio</td></tr>
<tr><td>37.</td><td>5/2/08 1Q08 Form</td><td>Petrosinelli Decl., Ex. G-1</td><td>Defendants caused Pfizer to issue false and misleading financial results, including Pfizer's net income and diluted earnings per share ("EPS") as follows:</td><td>Pfizer
Jeff Kindler</td></tr>
</table>

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<tr><th>No.</th><th>Date/ Type</th><th>Source</th><th>Statement</th><th>Defendants</th></tr>
<tr><td></td><td>10-Q</td><td></td><td>
<table>
<tr><th>Fiscal Period</th><th>Other Income/ (Other Deductions) - Net (in millions)</th><th>Net Income (in millions)</th><th>Diluted EPS</th><th>Filed with the SEC</th></tr>
<tr><td>1Q 2008</td><td>$333</td><td>$2,784</td><td>$0.41</td><td>5/2/08</td></tr>
</table>
Financial Results

* * *

<u>Legal Proceedings and Contingencies</u>

We 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 time to time in the ordinary course of our business. We do not believe any of them will have a material adverse effect on our financial position.

* * *

We record accruals for all other contingencies to the extent that we conclude their occurrence is probable and the related damages are estimable, and we record anticipated recoveries under existing insurance contracts when assured of recovery. If a range of liability is probable and estimable and some amount within the range appears to be a better estimate than any other amount within the range, we accrue that amount. If a range of liability is probable and estimable and no amount within the range appears to be a better estimate than any other amount within the range, we accrue the minimum of such probable range. . . . Consequently, we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for these contingencies. . . . Our assessments are based on estimates and assumptions that have been deemed reasonable by management. . . . Although we believe we have substantial defenses in these matters, we could in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations in any particular period.
</td><td>Frank D’Amelio
Ian Read</td></tr>
</table>

<table>
<tr><th>No.</th><th>Date/ Type</th><th>Source</th><th>Statement</th><th>Defendants</th></tr>
<tr><td></td><td></td><td></td><td>* * *

<u>Item 1. Legal Proceedings</u>

Certain legal proceedings in which we are involved are discussed in Note 20 to the consolidated financial statements included in our 2007 Financial Report, which is incorporated by reference in Part I, Item 3, of our Annual Report on Form 10-K for the year ended December 31, 2007. The following discussion is limited to certain recent developments concerning our legal proceedings and should be read in conjunction with our 2007 Financial Report. Unless otherwise indicated, all proceedings discussed in our 2007 Financial Report remain outstanding. Reference also is made to the Legal Proceedings and Contingencies section in Part I, Item 2, of this Form 10-Q.</td><td></td></tr>
<tr><td>38.</td><td>7/23/08 Press Release</td><td>Ex. 33</td><td>Lyrica revenues in the second-quarter 2008 were $614 million, an increase of 52% compared with the prior-year quarter, driven by strong efficacy and high patient and physician satisfaction in managing nerve pain associated with diabetes and nerve pain after shingles, the June 2007 U.S. approval for the management of fibromyalgia, a branded and unbranded advertising strategy focused on increasing both Lyrica and fibromyalgia awareness as well as the favorable impact of foreign exchange. In the U.S., Lyrica revenues rose to $335 million, an increase of 55% compared to the prior-year quarter, while international revenues grew to $279 million, an increase of 48%.

Defendants caused Pfizer to issue false and misleading financial results, including Pfizer’s net income and diluted earnings per share (“EPS”) as follows:

<table><tr><th>Fiscal Period</th><th>Other Income/ (Other Deductions) – Net (in millions)</th><th>Net Income (in millions)</th><th>Diluted EPS</th><th>Filed with the SEC</th></tr><tr><td>2Q 2008</td><td>$167</td><td>$2,776</td><td>$0.41</td><td>7/23/08</td></tr></table></td><td>Pfizer
Jeff Kindler
Frank D’Amelio
Ian Read</td></tr>
<tr><td>39.</td><td>8/8/08 2Q08 Form 10-Q</td><td>Petrosinelli Decl., Ex. H-1</td><td>“in all material respects the financial condition [and] results of [Pfizer’s] operations”:
I, [defendant], certify that:

1. I have reviewed this report on [Form 10-Q/Form 10-K] of Pfizer Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a</td><td>Jeff Kindler
Frank D’Amelio</td></tr>
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<tr><td></td><td></td><td></td><td>material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

Executive Certifications</td><td></td></tr>
<tr><td>40.</td><td>8/8/08
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Financial Results

<u>Legal Proceedings and Contingencies</u>

We 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 time to time in the ordinary course of our business. We do not believe any of them will have a material adverse effect on our financial position.

* * *

We record accruals for all other contingencies to the extent that we conclude their occurrence is probable and the related damages are estimable, and we record anticipated recoveries under existing insurance contracts when assured of recovery. If a range of liability is probable and estimable and some amount within the range appears to be a better estimate than any other amount within the range, we accrue that amount. If a range of liability is probable and estimable and no amount within the range appears to be a better estimate than any other amount</td><td>Pfizer
Jeff Kindler
Frank D’Amelio
Ian Read</td></tr>
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No.	Date/ Type	Source	Statement	Defendants
			within the range, we accrue the minimum of such probable range. . . . Consequently, we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for these contingencies. . . . Our assessments are based on estimates and assumptions that have been deemed reasonable by management. . . . Although we believe we have substantial defenses in these matters, we could in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations in any particular period. * * * <u>Item 1. Legal Proceedings</u> Certain legal proceedings in which we are involved are discussed in Note 20 to the consolidated financial statements included in our 2007 Financial Report, which is incorporated by reference in Part I, Item 3, of our Annual Report on Form 10-K for the year ended December 31, 2007; and Part II, Item 1, of our Quarterly Report on Form 10-Q for the quarter ended March 30, 2008. The following discussion is limited to certain recent developments concerning our legal proceedings and should be read in conjunction with those earlier Reports. Unless otherwise indicated, all proceedings discussed in those earlier Reports remain outstanding. Reference also is made to the Legal Proceedings and Contingencies section in Part I, Item 2, of this Form 10-Q.	
41.	9/22/08 UBS Global Life Sciences Conference	Carlinsky Decl., Ex. E-R	[Defendant Read:] Lyrica is demonstrating strong performance in the United States and around the world, primarily driven by the rapid uptake of fibromyalgia indication in the US and by global growth in neuropathic pain conditions. There continues to be the leading branded agent for diabetic peripheral neuropathy and post-hepatic neuralgia. We're differentiating it based on its rapid onset of action, persistence of efficacy and lack of titration, as well as clinical development for new indications such as post-stroke pain, cancer pain, restless leg syndrome and postoperative pain.	Pfizer Ian Read
42.	10/21/08 Press Release	Strassberg Decl., Ex. L-D	"We remain on-track to meet our 2008 objectives, despite the turbulent global economy," said Chairman and Chief Executive Officer Jeff Kindler. "We continued to deliver steady results this quarter, with many of our most important medicines performing well around the world, including Lyrica, Celebrex, Viagra,	Pfizer Jeff Kindler Frank D'Amelio Ian Read

<table>
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<tr><td></td><td></td><td></td><td>Sutent, Zyvox and Geodon, as well as Lipitor in a highly competitive market.”

* * *

Lyrica revenues in third-quarter 2008 were $675 million, an increase of 45% compared with the prior-year quarter, driven by high patient and physician satisfaction globally demonstrated by strong physician prescribing patterns, as well as growth in the U.S. fibromyalgia market, where we continue to expand our leadership position. In the U.S., Lyrica revenues rose to $379 million, an increase of 40% compared with the prior-year quarter, while international revenues grew to $296 million, an increase of 51% primarily from operation growth.

* * *

Defendants caused Pfizer to issue false and misleading financial results, including Pfizer’s net income and diluted earnings per share (“EPS”) as follows:

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<tr><td>43.</td><td>11/7/08
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I, [defendant], certify that:
1. I have reviewed this report on [Form 10-Q/Form 10-K] of Pfizer Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
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Financial Results
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<u>Legal Proceedings and Contingencies</u>
We 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 time to time in the ordinary course of our business. We do not believe any of them will have a material adverse effect on our financial position.</td><td>Pfizer
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No.	Date/ Type	Source	Statement	Defendants
			* * * We record accruals for all other contingencies to the extent that we conclude their occurrence is probable and the related damages are estimable, and we record anticipated recoveries under existing insurance contracts when assured of recovery. If a range of liability is probable and estimable and some amount within the range appears to be a better estimate than any other amount within the range, we accrue that amount. If a range of liability is probable and estimable and no amount within the range appears to be a better estimate than any other amount within the range, we accrue the minimum of such probable range. . . . Consequently, we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for these contingencies. . . . Our assessments are based on estimates and assumptions that have been deemed reasonable by management. . . . Although we believe we have substantial defenses in these matters, we could in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations in any particular period. * * * <u>Item 1. Legal Proceedings</u> Certain legal proceedings in which we are involved are discussed in Note 20 to the consolidated financial statements included in our 2007 Financial Report, which is incorporated by reference in Part I, Item 3, of our Annual Report on Form 10-K for the year ended December 31, 2007; and Part II, Item 1, of our Quarterly Reports on Form 10-Q for the quarters ended March 30, 2008 and June 29, 2008. The following discussion is limited to certain recent developments concerning our legal proceedings and should be read in conjunction with those earlier Reports. Unless otherwise indicated, all proceedings discussed in those earlier Reports remain outstanding. Reference also is made to the Legal Proceedings and Contingencies section in Part I, Item 2, of this Form 10-Q.	

CERTIFICATE OF SERVICE

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

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

s/ HENRY ROSEN
HENRY ROSEN

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

E-mail: henryr@rgrdlaw.com

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

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  michael.bailey@skadden.com
- **Sidney Bashago**
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- **Sheila L. Birnbaum**
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- **George Anthony Borden**
  gborden@wc.com
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- **Michael Barry Carlinsky**
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- **Lauren Kristina Collogan**
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- **Keir Nicholas Dougall**
  kdougall@dougallpc.com
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- **Alexander C Drylewski**
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- **Steven M.. Farina**
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- **Jay B. Kasner**
  jkasner@skadden.com
- **Joe Kendall**
  administrator@kendalllawgroup.com,jkendall@kendalllawgroup.com,hlindley@kendalllawgroup.com

- **Brant Duncan Kuehn**
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- **Leigh R. Lasky**
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  dmigliori@motleyrice.com
- **Eugene Mikolajczyk**
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- **Seema Mittal**
  smittal@wc.com
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- **Juliana Newcomb Murray**
  juliana.murray@davispolk.com,ecf.ct.papers@davispolk.com
- **Scott D. Musoff**
  smusoff@skadden.com,david.carney@skadden.com
- **Danielle Suzanne Myers**
  dmyers@rgrdlaw.com
- **William H. Narwold**
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- **Ivy T. Ngo**
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- **Willow E. Radcliffe**
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- **Darren J. Robbins**
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- **Daniel Prugh Roeser**
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- **Henry Rosen**
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- **David Avi Rosenfeld**
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- **James P. Rouhandeh**
  james.rouhandeh@dpw.com,ecf.ct.papers@davispolk.com
- **Samuel Howard Rudman**
  srudman@rgrdlaw.com,e_file_ny@rgrdlaw.com,mblasy@rgrdlaw.com,e_file_sd@rgrdlaw.com
- **Stuart Michael Sarnoff**
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- **William E. Schurmann**
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- **Trig Randall Smith**
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- **Jennifer Lynn Spaziano**
  jen.spaziano@skadden.com
- **Richard Mark Strassberg**
  rstrassberg@goodwinprocter.com,nymanagingclerk@goodwinprocter.com
- **Mitchell M.Z. Twersky**
  mtwersky@aftlaw.com
- **John K. Villa**
  jvilla@wc.com

Manual Notice List

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

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

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

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

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

Regan Karstrand

From: NYSD_ECF_Pool@nysd.uscourts.gov
Sent: Wednesday, November 26, 2014 10:51 PM
To: CourtMail@nysd.uscourts.gov
Subject: Activity in Case 1:10-cv-03864-AKH Jones et al v. Pfizer, Inc. et al Response in Opposition to Motion

This is an automatic e-mail message generated by the CM/ECF system. Please DO NOT RESPOND to this e-mail because the mail box is unattended.
*****NOTE TO PUBLIC ACCESS USERS*** Judicial Conference of the United States policy permits attorneys of record and parties in a case (including pro se litigants) to receive one free electronic copy of all documents filed electronically, if receipt is required by law or directed by the filer. PACER access fees apply to all other users. To avoid later charges, download a copy of each document during this first viewing. However, if the referenced document is a transcript, the free copy and 30 page limit do not apply.**

U.S. District Court

Southern District of New York

Notice of Electronic Filing

The following transaction was entered by Rosen, Henry on 11/26/2014 at 10:51 PM EST and filed on 11/26/2014

Case Name: Jones et al v. Pfizer, Inc. et al
Case Number: 1:10-cv-03864-AKH
Filer: Mary K. Jones
Stichting Philips Pensioenfonds
Document Number: 303

Docket Text:
RESPONSE in Opposition to Motion re: [256] MOTION for Summary Judgment ., [244] MOTION for Summary Judgment ., [255] MOTION for Summary Judgment ., [260] MOTION for Summary Judgment ., [271] MOTION for Summary Judgment ., [268] MOTION for Summary Judgment ., [252] MOTION for Summary Judgment . *Plaintiffs' Statement of Material Facts Requiring Denial of Defendants' Motions for Summary Judgment*. Document filed by Mary K. Jones(on behalf of all others similarly situated), Stichting Philips Pensioenfonds. (Rosen, Henry)

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

Alexander C Drylewski alexander.drylewski@skadden.com

Amanda M. MacDonald amacdonald@wc.com

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