

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MARY K. JONES, Individually and on Behalf of All Others Similarly Situated,	:	Civil Action No. 1:10-cv-03864-AKH
	:	
Plaintiff	:	<u>CLASS ACTION</u>
	:	
vs.	:	STATEMENT OF UNDISPUTED FACTS IN
	:	SUPPORT OF PLAINTIFFS' MOTION FOR
PFIZER INC., et al.,	:	PARTIAL SUMMARY JUDGMENT ON
	:	DEFENDANTS' RELIANCE ON ADVICE
Defendants.	:	OF COUNSEL AND GOOD FAITH
	:	DEFENSES

I. DEFENDANTS EXPRESSLY LIMIT THEIR RELIANCE ON ADVICE OF COUNSEL DEFENSE TO DENNIS BLOCK AND LAWRENCE FOX

1. 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."¹

2. Defendants' counsel informed this Court on July 19, 2013 that "Your Honor there's one in-house lawyer, Larry Fox."²

3. Pfizer³ stated in its Memorandum in 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."⁴

4. Defendants' memoranda filed in support of summary judgment contained at least 99 references to counsel other than Dennis Block ("Block") and Lawrence Fox ("Fox"): Covington &

¹ Dkt. No. 172 at 25.

² July 19, 2013 Hearing Transcript at 12:1-2.

³ "Pfizer" or the "Company" refers to Pfizer Inc. and its current and former wholly owned subsidiaries.

⁴ Dkt. No. 246 at 1, 5.

Burling LLP (“Covington”), Douglas Lankler (“Lankler”), Carlton Wessel and Covington’s “white paper.”⁵

II. DEFENDANTS FALSELY REPRESENTED “SUBSTANTIAL DEFENSES” AND RELATEDLY FAILED TO TAKE A RESERVE

5. Pfizer’s Securities and Exchange Commission (“SEC”) filings during the period January 19, 2006 to January 23, 2009 (the “Class Period”) represented, “[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.”⁶

III. THE FDA APPROVED BEXTRA FOR LIMITED USAGES AND DOSAGES

6. 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.⁷

⁵ *E.g.*, Dkt. No. 246 at 14, 16-17, 19, 21-25, 27, 53; Dkt. No. 253 at 122, 125; 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.

⁶ Ex. 1 at 22, 100, 166; Ex. 2 at 49; Ex. 3 at 59; Ex. 4 at 62; Ex. 5 at 21, 96, 165-66; Ex. 6 at 46; Ex. 7 at 55; Ex. 8 at 59; Ex. 9 at 19, 100, 171; Ex. 10 at 44; Ex. 11 at 51; Ex. 12 at 56. All “Ex. ___” references herein are exhibits attached to the Declaration of Jason A. Forge in Support of Plaintiffs’ Motion for Partial Summary Judgment on Defendants’ Reliance on Advice of Counsel and Good Faith, submitted herewith, unless otherwise noted.

⁷ Ex. 13 at BEX001360555.

7. 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.⁸ Pfizer began distributing Bextra to physicians in February 2002.⁹

8. 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 higher than the 10 mg daily dose for OA and RA, "the findings of more hypertension and edema are frequently reproduced."¹⁰

IV. NEITHER BLOCK NOR FOX WERE INVOLVED IN THE BEXTRA INVESTIGATION

9. In or around February 2004, the U.S. Department of Justice ("DOJ") informed Pfizer that it was investigating a *qui tam* complaint filed by one of its former Florida sales representatives, John Kopchinski, which alleged the off-label promotion of Bextra ("Kopchinski's Complaint").¹¹

10. 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's¹² investigation concerning Pfizer's misbranding (*i.e.*, off-label promotion) of Bextra (the "Bextra Investigation").¹³

⁸ Ex. 13 at BEX001360555; Ex. 14 at BEX005818115.

⁹ Ex. 15 at BEX001800573.

¹⁰ Ex. 16 at BEX004849786.

¹¹ Ex. 59 at KPMG-PFIZ-DS 0553290 (February 2004); Ex. 17 at PFE-JONES 00002295 (identifying Kopchinski as relator).

¹² "Government" refers collectively to the DOJ and the Health and Human Services Office of Inspector General.

¹³ Ex. 18 at 231:9-16; Ex. 19 at 20:19-21:4; Ex. 21 at 32:18-20.

11. Block was not involved in Pfizer's Bextra Investigation.¹⁴

12. Fox was not involved in Pfizer's Bextra Investigation.¹⁵

V. NEITHER BLOCK NOR FOX RENDERED LEGAL ADVICE TO DEFENDANTS CONCERNING THE BEXTRA INVESTIGATION

13. 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.¹⁶

14. Block never personally and professionally assessed nor advised defendants that Pfizer had substantial defenses to the Bextra Investigation.¹⁷

15. Fox never independently determined or advised defendants that Pfizer had substantial defenses to the Bextra Investigation.¹⁸

16. 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.¹⁹

17. 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.²⁰

¹⁴ Ex. 22 at 54:4-7, 56:2-11, 73:21-74:16, 76:5-23.

¹⁵ Ex. 23 at 10:9-12, 11:14-20, 53:23-55:3, 60:3-22, 61:3-11.

¹⁶ Ex. 24 at 92:23-97:21.

¹⁷ Ex. 22 at 104:6-23.

¹⁸ Ex. 23 at 86:13-19, 90:12-20.

¹⁹ Ex. 22 at 104:15-23, 34:1-22; Ex. 23 at 32:11-18, 60:17-22, 90:12-20, 224:22-225:6.

²⁰ Ex. 22 at 34:1-22, 35:4-11, 36:15-24, 39:3-41:12, 71:13-25, 142:18-143:2; Ex. 23 at 44:24-45:7, 76:15-19, 80:5-21, 90:21-91:8.

18. 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 or of the Government's case, the probability of a criminal conviction in or losses from the Bextra Investigation, or whether the loss from the Bextra Investigation was reasonably estimable.²¹

19. 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.²²

20. 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 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.²³

VI. DEFENDANTS DID NOT RELY ON BLOCK AND FOX FOR ADVICE REGARDING THE BEXTRA INVESTIGATION

21. In connection with its 2007 audit, KPMG LLP referenced Investigation Counsel's "white paper" as support for Pfizer's FAS-5 determination with regard to the Bextra Investigation.²⁴

22. Block testified that "Pfizer had – close to the American Bar Association – has lawyers assisting it in connection with the critical matters."²⁵

²¹ Ex. 22 at 36:15-24, 104:15-23, 168:18-169:15; Ex. 23 at 44:24-45:7, 47:2-7, 60:17-22, 61:25-62:7, 87:11-88:14, 222:21-225:6; Ex. 21 at 20:15-21.

²² Ex. 22 at 33:7-25, 36:15-24, 39:10-41:5; Ex. 23 at 43:17-45:7, 80:5-21, 90:21-91:8.

²³ Ex. 25 at 152:8-154:21.

²⁴ Dkt. No. 246 at 10.

²⁵ Ex. 22 at 46:23-47:1.

23. 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."²⁶

24. 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 §§37-42 *infra*;
- (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;

²⁶ Ex. 26 at 7:19-20, 12:11-17; Ex. 27 at 2.

(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.²⁷

25. 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 ¶¶37-42 *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;

(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

²⁷ Ex. 22 at 49:16-50, 50:5-20, 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. 24 at 108:2-10; Ex. 28 at 39:25-40:24, 43:11-44:1, 99:19-100:4, 113:10-114:10, 115:6-116:2; Ex. 19 at 31:10-32:8; Ex. 21 at 16:2-14, 20:15-21, 38:13-23.

(h) the Bextra-related call notes quoted, summarized and/or analyzed in the Government's presentations to Pfizer and its Investigation Counsel.²⁸

VII. NEITHER BLOCK NOR FOX PRETENDED TO BE QUALIFIED TO OFFER ADVICE REGARDING THE BEXTRA INVESTIGATION

26. 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.²⁹

27. Neither Block nor Fox was familiar with the elements of a misbranding doctrine of offense.³⁰

28. Neither Block nor Fox was familiar with elements or application of *respondereat superior* for corporate criminal liability.³¹

29. 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.³²

30. 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.³³

²⁸ Ex. 23 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. 24 at 107:22-108:1; Ex. 28 at 39:25-40:24, 43:11-44:1, 99:19-100:4, 113:10-114:10, 115:6-116:2; Ex. 19 at 31:10-32:8; Ex. 21 at 16:2-14, 20:15-21.

²⁹ Ex. 22 at 13:12-14:6, 14:13-15:10, 16:6-8; Ex. 23 at 18:24-19:2, 35:21-36:12.

³⁰ Ex. 22 at 16:6-17:8; Ex. 23 at 37:10-38:17.

³¹ Ex. 22 at 232:20-233:12; Ex. 23 at 36:13-37:9.

³² 42 U.S.C. §1320a-7.

³³ Ex. 23 at 130:7-15, 218:21-219:5.

31. 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."³⁴

32. Fox understood the terms grand jury "target" and grand jury "subject" to be interchangeable.³⁵

VIII. DEFENDANTS DID NOT SHARE WITH BLOCK OR FOX THE MOST SIGNIFICANT FACTS AND EVIDENCE IN THE BEXTRA INVESTIGATION

33. 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.³⁶

34. By the year 2006, defendants Jeffrey Kindler, Alan Levin and Allen Waxman were informed that certain Pfizer sales representatives may have, in fact, promoted Bextra for general acute and surgical pain, both of which were off-label indications.³⁷

35. 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.³⁸

³⁴ Ex. 29 at 118:12-19.

³⁵ Ex. 23 at 106:3-23.

³⁶ Ex. 30 at 5:16-7:9.

³⁷ Ex. 31 at PFE DERIV 00066706; Ex. 32 at PFE DERIV 00066490, 512, 529, 599; Ex. 33 at PFE-JONES 00103713-15, 718-20; Ex. 34 at PFE-JONES 00000893-94; Ex. 18 at 114:6-13; Ex. 28 at 23:20-24:11, 107:18-21; Ex. 21 at 41:12-18, 52:3-19, 68:12-20.

³⁸ Ex. 22 at 49:16-50:20, 56:21-58:9, 63:25-64:4; Ex. 28 at 24:12-16.

36. Pfizer and its Investigation Counsel always represented to Block that Pfizer's sales representatives had *not* promoted Bextra off-label.³⁹

37. 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.⁴⁰

38. 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.⁴¹

39. Pfizer introduced Bextra into interstate commerce for the treatment of acute pain, surgical pain, other unapproved uses and at unapproved dosages even though it lacked adequate directions for such uses and dosages.⁴²

40. Pfizer promoted Bextra with an intent to defraud or mislead.⁴³

41. 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.⁴⁴

42. 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

³⁹ Ex. 22 at 50:5-20, 232:3-12.

⁴⁰ Ex. 26 at 51:10-17.

⁴¹ *Id.* at 51:17-18.

⁴² *Id.* at 51:19-21.

⁴³ *Id.* at 51:22-23.

⁴⁴ *Id.* at 52:1-4.

had not, and medical information letters regarding such off-label uses and/or dosages were sent to those physicians.⁴⁵

43. No one shared with Block any of the information set forth in ¶¶37-42 *supra*.⁴⁶

44. 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.⁴⁷

45. 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.⁴⁸

46. 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 Plan of Action (“POA”) (directive to sales representatives).⁴⁹

47. 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 2004.⁵⁰

⁴⁵ *Id.* at 52:5-9.

⁴⁶ Ex. 22 at 49:16-50:20, 56:21-58:9, 63:25-64:4; Ex. 28 at 24:12-16.

⁴⁷ Ex. 60.

⁴⁸ Ex. 36.

⁴⁹ Ex. 37.

⁵⁰ Ex. 36 at PFE-JONES 00006353, 356-57, 359-88.

48. By April 2008, defendants had received Kopchinski's Complaint itself, including its specific descriptions of the exhibits.⁵¹

49. No one provided Block a copy of Kopchinski's Complaint or any of the internal Pfizer documents that were exhibits to it.⁵²

50. No one provided Fox a copy of Kopchinski's Complaint or any of the internal Pfizer documents that were exhibits to it.⁵³

51. 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 2004.⁵⁴

52. 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.⁵⁵

53. 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 to remain on

⁵¹ Ex. 38.

⁵² Ex. 19 at 34:19-24; Ex. 39 at 60:7-10; Ex. 22 at 128:14-21.

⁵³ Ex. 19 at 35:18-36:10.

⁵⁴ Ex. 40 at BEX000398151; Ex. 33 at PFE-JONES 00103712-13.

⁵⁵ Ex. 33 at PFE-JONES 00103713; Ex. 41 at TF0000197-99.

Bextra long term” and “[g]et Bextra added to pre-op briefing sheets in other surgical subspecialties – podiatry, general surgery, plastic surgery, ENT, etc.”⁵⁶

54. 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.”⁵⁷

55. No one ever provided Block or Fox the internal documents that Pfizer’s sales representatives had attempted to delete or alter.⁵⁸

56. Pfizer’s Investigation Counsel interviewed its employees who were involved in the attempted deletion and alteration of Bextra-related documents.⁵⁹

57. 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.⁶⁰

⁵⁶ Ex. 33 at PFE-JONES 00103717-18; Ex. 42 at BKLYN 000000063-64.

⁵⁷ Ex. 33 at PFE-JONES 00103714, 718, 720.

⁵⁸ Ex. 22 at 59:14-60:1, 230:21-231:8, 233:17-23; Ex. 23 at 49:9-23.

⁵⁹ Ex. 33 at PFE-JONES 00103713, 720; Exs. 43-49.

⁶⁰ Ex. 33 at PFE-JONES 00103720.

58. 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.⁶¹

59. 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";⁶² 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."⁶³

60. 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.⁶⁴

61. 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.⁶⁵

62. 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

⁶¹ Ex. 22 at 54:8-22, 56:2-11, 105:3-13, 230:25-231:6; Ex. 23 at 13:2-8, 49:9-50:16, 66:3-6.

⁶² Ex. 32 at PFE DERIV 00066528.

⁶³ *Id.* at PFE DERIV 00066599.

⁶⁴ Ex. 22 at 54:8-22, 56:2-11; Ex. 23 at 97:11-18, 211:16-212:1.

⁶⁵ Exs. 50-51.

Investigation quoted multiple contemporaneous “call notes” by Pfizer’s sales representatives promoting Bextra for the non-FDA approved indication of general acute pain.⁶⁶

63. 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.⁶⁷

64. 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 primary dysmenorrhea (*e.g.*, Surgeons, Cardiovascular and Dentists) as evidence that Pfizer’s sales representatives had promoted the 20 mg dosage of Bextra for unapproved indications.⁶⁸

65. 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.⁶⁹

⁶⁶ Ex. 52.

⁶⁷ Ex. 53.

⁶⁸ Ex. 54 at DOJ000230.

⁶⁹ Ex. 55.

66. 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.⁷⁰

67. 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.”⁷¹

68. 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.⁷²

69. 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.”⁷³

70. No one provided Block or Fox copies of any call notes, or summaries or analyses of any call notes, including the call notes that the Government quoted, referenced, summarized and/or analyzed in its August and September 2006 presentations to Pfizer and its Investigation Counsel.⁷⁴

⁷⁰ *E.g.*, Ex. 56 at Dowd-C 10000042331; Ex. 57 at BEX006488816, 820.

⁷¹ Ex. 27 at 26.

⁷² Ex. 30 at 62:23-63:11.

⁷³ Ex. 58 at DOJ000190.

⁷⁴ Ex. 22 at 76:5-23, 144:21-145:4; Ex. 23 at 60:3-22, 61:3-11.

71. 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.⁷⁵

72. No one provided Block or Fox copies of any of the interview memoranda from the Bextra Investigation.⁷⁶

73. Neither Block nor Fox received access to any of Pfizer's Investigation Counsel's written work product concerning the Bextra Investigation.⁷⁷

74. 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.⁷⁸

DATED: November 14, 2014

Respectfully submitted,

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

s/ JASON A. FORGE
JASON A. FORGE

⁷⁵ Ex. 59 at KPMG-PFIZ-DS 053290.

⁷⁶ Ex. 22 at 54:8-22, 56:2-11, 105:3-13; Ex. 23 at 13:2-8, 53:23-54:14, 211:16-212:1.

⁷⁷ Ex. 24 at 101:1-11; Ex. 22 at 54:8-22; Ex. 23 at 97:11-18.

⁷⁸ Ex. 22 at 69:6-15, 73:21-74:16; Ex. 23 at 74:22-80:1.

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

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

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

Lead Counsel for Plaintiffs

CERTIFICATE OF SERVICE

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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 14, 2014.

s/ JASON A. FORGE

JASON A. FORGE

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: JForge@rgrdlaw.com

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

Electronic Mail Notice List

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

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

- **Paul T. Hourihan**
phourihan@wc.com
- **James M. Hughes**
jhughes@motleyrice.com,kweil@pacernotice.com,erichards@motleyrice.com,kweil@motleyrice.com
- **Jay B. Kasner**
jkasner@skadden.com
- **Joe Kendall**
administrator@kendalllawgroup.com,jkendall@kendalllawgroup.com,hindley@kendalllawgroup.com
- **Brant Duncan Kuehn**
brantkuehn@quinnemanuel.com
- **Leigh R. Lasky**
lasky@laskyrifkind.com
- **Hamilton Philip Lindley**
hlindley@deanslyons.com,mgoens@deanslyons.com
- **Ryan A. Llorens**
ryanl@rgrdlaw.com,nbear@rgrdlaw.com,kirstenb@rgrdlaw.com
- **Amanda M. MacDonald**
amacdonald@wc.com
- **Lori McGill**
lorialvinomcgill@quinnemanuel.com
- **Matthew Melamed**
mmelamed@rgrdlaw.com
- **Donald Alan Migliori**
dmigliori@motleyrice.com
- **Eugene Mikolajczyk**
genem@rgrdlaw.com
- **Seema Mittal**
smittal@wc.com
- **Cynthia Margaret Monaco**
cmonaco@cynthiamonacolaw.com,cmmonaco@gmail.com
- **Juliana Newcomb Murray**
juliana.murray@davispolk.com,ecf.ct.papers@davispolk.com
- **Scott D. Musoff**
smusoff@skadden.com,david.carney@skadden.com
- **Danielle Suzanne Myers**
dmyers@rgrdlaw.com
- **William H. Narwold**
bnarwold@motleyrice.com,vlphine@motleyrice.com,ajanelle@motleyrice.com

- **Ivy T. Ngo**
ingo@rgrdlaw.com,e_file_sd@rgrdlaw.com
- **Joseph G. Petrosinelli**
jpetrosinelli@wc.com
- **Willow E. Radcliffe**
willowr@rgrdlaw.com,ptiffith@rgrdlaw.com
- **Joseph F. Rice**
jrice@motleyrice.com
- **Darren J. Robbins**
e_file_sd@rgrdlaw.com
- **Daniel Prugh Roeser**
droeser@goodwinprocter.com
- **Henry Rosen**
henryr@rgrdlaw.com,dianah@rgrdlaw.com
- **David Avi Rosenfeld**
drosenfeld@rgrdlaw.com,e_file_ny@rgrdlaw.com,e_file_sd@rgrdlaw.com
- **James P. Rouhandeh**
james.rouhandeh@dpw.com,ecf.ct.papers@davispolk.com
- **Samuel Howard Rudman**
srudman@rgrdlaw.com,e_file_ny@rgrdlaw.com,mblasy@rgrdlaw.com,e_file_sd@rgrdlaw.com
- **Stuart Michael Sarnoff**
ssarnoff@omm.com
- **William E. Schurmann**
wschurmann@wc.com
- **Trig Randall Smith**
trigs@rgrdlaw.com,e_file_sd@rgrdlaw.com,nhorstman@rgrdlaw.com
- **Jennifer Lynn Spaziano**
jen.spaziano@skadden.com
- **Richard Mark Strassberg**
rstrassberg@goodwinprocter.com,nymanagingclerk@goodwinprocter.com
- **Mitchell M.Z. Twersky**
mtwersky@aftlaw.com
- **John K. Villa**
jvilla@wc.com

Manual Notice List

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

Daniel **E. Hill**

Kendall Law Group, LLP
3232 McKinney Avenue
Suite 700
Dallas, TX 75204

Catherine **J. Kowalewski**

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

Jamie **J. McKey**

Kendall Law Group, LLP
3232 McKinney Avenue
Suite 700
Dallas, TX 75204

David **C. Walton**

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

Regan Karstrand

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Filer: Mary K. Jones
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Document Number: [289](#)

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

Alexander C Drylewski alexander.drylewski@skadden.com

Amanda M. MacDonald amacdonald@wc.com

Brant Duncan Kuehn brantkuehn@quinnemanuel.com

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

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

Daniel Prugh Roeser droeser@goodwinprocter.com

Danielle Suzanne Myers dmyers@rgrdlaw.com

Darren J. Robbins e_file_sd@rgrdlaw.com

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

Donald Alan Migliori dmigliori@motleyrice.com

Eugene Mikolajczyk genem@rgrdlaw.com

Gary John Hacker ghacker@skadden.com

George Anthony Borden gborden@wc.com

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

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

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

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

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

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

James R. Harper coljamesrharper@me.com

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

Jay B. Kasner jkasner@skadden.com

Jennifer Lynn Spaziano jen.spaziano@skadden.com

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

John K. Villa jvilla@wc.com

Joseph F. Rice jrice@motleyrice.com

Joseph G. Petrosinelli jpetrosinelli@wc.com

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

Keir Nicholas Dougall kdougall@dougallpc.com

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

Lauren Kristina Collogan lcollogan@wc.com

Leigh R. Lasky lasky@laskyrifkind.com

Lori McGill lorialvinomcgill@quinnemanuel.com

Matthew Melamed mmelamed@rgrdlaw.com

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

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

Michael Scott Bailey michael.bailey@skadden.com

Mitchell M.Z. Twersky mtwersky@aftlaw.com

Paul T. Hourihan phourihan@wc.com

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

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

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

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

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

Seema Mittal smittal@wc.com

Sheila L. Birnbaum sheilabirnbaum@quinnemanuel.com

Sidney Bashago sidney.bashago@dpw.com

Steven M. Farina sfarina@wc.com

Stuart Michael Sarnoff ssarnoff@omm.com

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

William E. Schurmann wschurmann@wc.com

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

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

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

Catherine J. Kowalewski

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

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

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

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

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