

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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MARY K. JONES, Individually and on Behalf :
of All Others Similarly Situated, : 10-cv-03864-AKH
 :
Plaintiff, : **ECF Case**
 :
v. : **Electronically Filed**
 :
PFIZER INC., et al., :
 :
Defendants. :
----- X

**LOCAL RULE 56.1 STATEMENT OF UNDISPUTED FACTS IN
SUPPORT OF HENRY A. MCKINNELLS MOTION FOR SUMMARY JUDGMENT**

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Pursuant to Rule 56 of the Federal Rules of Civil Procedure and Rule 56.1 of the Local Rules of the United States District Court for the Southern and Eastern Districts of New York, defendant Henry A. McKinnell, in connection with his Motion for Summary Judgment, sets forth the following statement of material facts as to which no genuine issue exists:¹

A. McKinnell's Relationship with Pfizer

1. McKinnell joined Pfizer in 1971 and worked at Pfizer in a number of capacities for the next thirty years. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 10:3-10.)

2. In January 2001, McKinnell was appointed as Pfizer's Chief Executive Officer. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 10:23-12:16.)

3. In April 2001, McKinnell became the Chairman of Pfizer's Board of Directors. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 10:23-12:16.)

4. McKinnell voluntarily resigned from his position as Chief Executive Officer in July 2006. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 11:8-13:12.)

5. To ensure an orderly transition of responsibilities, McKinnell continued to serve on Pfizer's Board of Directors and as a Pfizer employee until the end of February 2007. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 11:8-13:12.)

B. McKinnell's Understanding of Pfizer's Controls

6. During McKinnell's tenure as Chief Executive Officer, Pfizer implemented and maintained various controls to ensure that the Company's sales force complied with legal standards and Pfizer's policies. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 22:10-23, 26:25-

¹ McKinnell incorporates by reference the Rule 56.1 statement submitted by Pfizer Inc. ("Pfizer" or the "Company") in connection with its Motion for Summary Judgment ("Pfizer Rule 56.1 Statement") insofar as it is relevant to the claims asserted against him. All references to "Ex." refer to exhibits to the Declarations of Joseph G. Petrosinelli and Scott D. Musoff, dated October 30, 2014, as noted.

27:23, 28:10-31:6, 41:13-44:12, 56:8-57:3, 84:23-88:13; 91:8-92:23, 222:25-223:22, 312:23-323:21.)

7. These controls included, but were not limited to: (1) product review committees comprised of regulatory, medical and marketing personnel that reviewed marketing materials; (2) ongoing training in laws, regulations and best practices; (3) ongoing review of and updates to Pfizer's policies and procedures; (4) compliance review of sales force practices; (5) internal audit activities; and (6) a ten-fold increase in spending on compliance. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 22:10-23, 26:25-27:23, 28:10-31:6, 41:13-44:12, 56:8-57:3, 84:23-88:13; 91:8-92:23, 222:25-223:22, 312:23-323:21.)

8. During McKinnell's tenure as Chief Executive Officer, Pfizer investigated reports of violations of Company policies and procedures and, where necessary, remediated issues and reported them to the government. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 86:17-87:6, 222:25-223:22.)

C. McKinnell's Response to the July 2005 FDA Letter

9. On or about July 20, 2005, McKinnell received a letter from the United States Food and Drug Administration ("FDA") advising Pfizer that the FDA had rejected one of Pfizer's advertisements for Zyvox because it made comparative claims that the FDA determined to be unsupported. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 108:13-114:1.)

10. In accordance with his routine practice, McKinnell forwarded the letter to Pfizer's medical and regulatory groups. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 109:22-111:13.)

11. Although Pfizer disagreed with the FDA's view on the advertisement, it nonetheless revised the relevant promotional material to the FDA's satisfaction and ensured that

any other Zyvox sales force materials that could be misinterpreted in a similar manner were discontinued or revised. (Musoff Ex. C-M, PFE DERIV 00040339.)

12. McKinnell believed the FDA's concerns, as reflected in the July 2005 letter, had been resolved. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 109:22-111:13.)

D. McKinnell's Knowledge of the Government Investigations

13. In or around February 2004, McKinnell learned that the Department of Justice ("DOJ") was investigating a *qui tam* lawsuit involving Pfizer's marketing and sale of Bextra. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 224:10-227:4.)

14. An investigation by in-house and outside counsel was initiated to investigate the matters alleged in the lawsuit. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 224:10-227:4.)

15. McKinnell believed that experienced and qualified attorneys were involved in this "very thorough investigation." (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 226:21-228:18, 251:25-253:6, 258:7-259:12, 282:8-24; Musoff Ex. B-M, 09/19/14 McKinnell Tr. at 94:11-96:9.)

16. These individuals included, but were not limited to: (1) Jeffrey Kindler, Pfizer's former General Counsel; (2) Allan Waxman, who assumed the position of General Counsel from Mr. Kindler; (3) Douglas Lankler, Pfizer's Chief Compliance Officer; and (4) other government investigations attorneys outside and within Pfizer. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 226:21-228:18, 251:25-253:6, 258:7-259:12, 282:8-24; Musoff Ex. B-M, 09/19/14 McKinnell Tr. at 94:11-96:9.)

17. Throughout 2004 and 2005, McKinnell received periodic updates on the status of the investigation and Pfizer's response. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 266:22-268:20.)

18. Among other things, McKinnell learned that Pfizer produced documents and gave presentations to the DOJ, that the DOJ had issued a formal subpoena for Bextra-related

documents, that the DOJ was reviewing documents and that the DOJ had begun to subpoena members of the field sales force to testify before a grand jury. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 266:22-268:20.)

19. McKinnell also learned sometime in mid-2005 that Pfizer's investigation had uncovered a small number of Pfizer sales representatives in a district in Brooklyn attempting to delete Bextra-related documents from their computers, in violation of a litigation hold. (Musoff Ex. B-M, 09/19/14 McKinnell Tr. at 25:14-25.)

20. McKinnell understood that these employees had violated Company policies and possibly the law by using promotional material involving off-label indications that had not been approved by Pfizer. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 247:10-248:21.)

21. McKinnell believed that the conduct was isolated in nature, was investigated and remediated (including through the termination of the responsible employees) and had been "reported [to the government] as good companies do." (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 247:10-248:21; Musoff Ex. B-M, 09/19/14 McKinnell Tr. at 26:13-27:2.)

22. McKinnell also received updates on the status of Pfizer's internal investigation. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 232:19-24, 255:18-256:17.)

23. McKinnell understood that the internal investigation uncovered "possible violations of law [but] that we had good defenses, that we had done what good companies do, which is we investigated, we remediated and reported our findings to the Government." (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 232:19-24, 255:18-256:17.)

24. McKinnell was not aware of any pervasive off-label marketing practices or of practices being driven by Pfizer senior management. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 255:18-256:17; Musoff Ex. B-M, 09/19/14 McKinnell Tr. at 46:10-48:3.)

25. According to McKinnell:

We heard of allegations from the qui tam action which the Department of Justice joined. Any violation of law is of concern to me as the CEO. We then launched a very thorough investigation of our compliance with laws and regulations with respect to Bextra. . . . My concern was how widespread [the conduct] was . . . and the answer I got was it did not involve senior Pfizer executives, [but] it did involve a group of sales representatives and that we needed to remediate those problems by removing a number of those sales representatives and reporting the results of our investigation to Government.

(Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 255:18-256:17.)

26. McKinnell further stated:

We certainly were aware of allegations [of off-label promotion of Bextra in early 2005]. We certainly were aware of a small group of employees who were violating company policy with respect to promotion and destruction of documents. Whether that implicated, quote, the company, I think was unclear.

(Musoff Ex. B-M, 09/19/14 McKinnell Tr. at 46:10-48:3.)

27. In a memorandum to the Audit Committee of the Pfizer Board of Directors, with copies sent to McKinnell among others, Allen Waxman and Douglas Lankler noted that “[i]n early November [2005], we met with the government to discuss the substantial defenses that we believe the Company has with respect to issues raised in the [qui tam] complaint.”

(Musoff Ex. D-M, PFE-JONES 00006634-36.)

28. During discussions within Pfizer, McKinnell was informed that Pfizer had substantial defenses to the issues raised in the Bextra qui tam complaint. (See Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 282:25-283:17; Musoff Ex. B-M, 09/19/14 McKinnell Tr. at 48:4-16, 90:14-91:16.)

29. Pfizer’s 2005 Form 10-K, filed on March 1, 2006, stated:

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. Litigation is inherently unpredictable, and **excessive verdicts do occur**. 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...**

* * * *

Many claims involve highly complex issues relating to causation, label warnings, scientific evidence, actual damages and other matters. Often these issues are subject to substantial uncertainties and, therefore, the probability of loss and an estimation of damages are difficult to ascertain. Consequently, we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for these contingencies. These assessments can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions Our assessments are based on estimates and assumptions that have been deemed reasonable by management. **Litigation is inherently unpredictable, and excessive verdicts do occur**. 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**.

(Petrosinelli Ex. B-1, Pfizer's March 1, 2006 Form 10-K at 18, 32 (emphasis added).)

30. Note 18 to Pfizer's 2005 consolidated financial statement, attached to the 2005 Form 10-K, stated:

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:

....

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.

(Petrosinelli Ex. B-1, Pfizer's March 1, 2006 Form 10-K, 2005 Financial Report at 67.)

31. In August and September 2006, the DOJ met with Pfizer's lawyers and presented its view of the documents it had received concerning the promotion of Bextra. (Petrosinelli Ex. X-2, PFE JONES 00025621 at 25626-55.)

32. At the conclusion of the meetings, the DOJ stated that it "wants to hear Pfizer's responses, but [it] cannot delay timing and wants a further substantive discussion in thirty days" and that "by the beginning of next year, [it] anticipates making a recommendation on how the investigation should proceed." (Petrosinelli Ex. X-2, PFE JONES 00025621 at 25655.)

33. Pfizer's 2006 Form 10-K, filed on March 1, 2007, stated:

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.** Since 2005, we have received requests for information and documents from the Department of Justice concerning certain physician payments budgeted to our prescription pharmaceutical products.

(Petrosinelli Ex. D-1, Pfizer's March 1, 2007 Form 10-K, 2006 Financial Report at 73 (emphasis added).)

34. At the time McKinnell left Pfizer in February 2007, Pfizer was not engaged in settlement discussions with the DOJ. (Petrosinelli Ex. F-2, 12/10/13 Levin Tr. at 103:2-13.)

35. The tenor of the investigation at that time "was much more around review of documents, summary of the government's interpretation of the facts, [and] perhaps some theories of liability." (Petrosinelli Ex. F-2, 12/10/13 Levin Tr. at 137:1-23.)

36. At the time McKinnell left Pfizer in February 2007, the DOJ investigation did not include sales and marketing practices with respect to Lyrica, Geodon or Zyvox. (Petrosinelli Ex. J-5, PFE-JONES 00033813; Petrosinelli Ex. R-5, PFE-JONES 00044700.)

37. Lyrica was the subject of a DOJ subpoena served in July 2007. (Petrosinelli Ex. J-5, PFE-JONES 00033813.)

38. Geodon and Zyvox were the subject of a DOJ subpoena served in December 2007. (Petrosinelli Ex. R-5, PFE-JONES 00044700.)

39. On September 14, 2007, the DOJ suggested to Pfizer for the first time that Pfizer make a financial proposal to the government for a resolution of the Bextra matter. (*See* Petrosinelli Ex. K-4 , KPMG-PFIZ-DS 0003496 at 0003513.)

40. On April 4, 2008, the DOJ made its first proposal for settlement of its Bextra investigation. (Petrosinelli Ex. Y-6 , PFE DERIV 00066378-80.)

41. On January 26, 2009, Pfizer issued a press release reporting Pfizer's 2008 fourth quarter and year-end results and 2009 financial guidance. (Petrosinelli Ex. K-1, January 26, 2009 Pfizer 8-K.)

42. In the January 26, 2009 press release, Pfizer disclosed that it had entered into an agreement in principle to pay a total of \$2.3 billion to resolve "previously disclosed investigations regarding allegations of past off-label promotional practices concerning Bextra, as well as other open investigations." (Petrosinelli Ex. K-1, January 26, 2009 Pfizer 8-K.)

43. \$1.6 billion of the \$2.3 billion settlement related to Bextra while the remainder related to the government's investigations into Pfizer's promotion and marketing of Geodon, Lyrica and Zyvox. (Petrosinelli Ex. E-2, Lankler Tr. 192:17-193:8.)

E. McKinnell's Reliance on Robust Processes and Informed Counsel and Auditors

44. McKinnell believed the financial statements he signed during the Class Period to be accurate and truthful. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 258:7-18, 280:24-283:17; Musoff Ex. B-M, 09/19/14 McKinnell Tr. at 47:8-49:9, 51:11-65:5, 88:19-91:16.)

45. McKinnell's belief in the accuracy and truthfulness of the financial statements he signed during the Class Period was based on (i) his personal knowledge of the Bextra investigation, (ii) Pfizer's robust and comprehensive process for drafting and approving disclosures regarding government investigations, (iii) input from dozens of lawyers and accountants and (iv) his reliance on the advice of Lawrence Fox and Dennis Block, Pfizer's in-house and outside disclosure counsel, with respect to the "adequacy of disclosure." (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 258:7-18, 280:24-283:17; Musoff Ex. B-M, 09/19/14 McKinnell Tr. at 47:8-49:9, 51:11-65:5, 88:19-91:16.)

46. McKinnell believed there was appropriate disclosure to all parties involved in the process of all relevant facts concerning the DOJ investigation. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 282:8-24; Musoff Ex. B-M, 09/19/14 McKinnell Tr. at 28:16-30:18, 47:8-49:9, 51:11-65:5, 88:19-91:16.)

47. The disclosures made in the financial statements signed by McKinnell during the Class Period were approved by Fox and Block, the Disclosure Committee and the individuals who attended the certification meeting. (Pfizer Rule 56.1 Statement, Section I; *see also* Petrosinelli Ex. B-4 at PFE-JONES 00036401-02 & PFE-JONES 00036468-69.)

48. McKinnell believed the Sarbanes-Oxley certification that he signed on March 1, 2006 to be accurate and truthful. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 295:10-296:17.)

49. McKinnell believed the Sarbanes-Oxley certification that he signed on May 8, 2006 to be accurate and truthful. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 295:10-296:17.)

50. Before McKinnell signed the March 1, 2006 certification (i) he was informed that KPMG had concluded that Pfizer maintained effective internal control over financial reporting and (ii) the individuals responsible for Pfizer's internal controls signed their own certifications and sub-certifications assuring that there were no material issues with Pfizer's internal controls. (Petrosinelli Ex. B-1, Pfizer's March 1, 2006 Form 10-K, Exhibit 23; Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 295:14-297:9; Petrosinelli Ex. B-4 at PFE-JONES 00036401-02.)

51. Before McKinnell signed the May 8, 2006 certification (i) KPMG did not identify any control issues as part of its quarterly review and (ii) McKinnell's direct reports informed him that the 10-Q was accurate and complete, that the disclosure controls were effective and that no other compliance issues needed to be disclosed. (Petrosinelli Ex. C-1, Pfizer's May 8, 2006 Form 10-Q at 20; Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 295:14-296:17; Petrosinelli Ex. B-4 at PFE-JONES 00036468-69.)

52. McKinnell believed that KPMG was fully informed of all relevant developments concerning Pfizer's internal controls. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 295:10-300:14.)

53. In signing the March 1, 2006 certification, McKinnell relied on his own experience, input from internal audit and KPMG's advice. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 295:10-300:14.)

54. In signing the May 8, 2006 certification, McKinnell relied on his own experience, input from internal audit and KPMG's advice. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 295:10-300:14.)

55. McKinnell believed that Pfizer's reserve decisions were correct and that Pfizer's disclosures regarding reserves were accurate. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 232:16-236:12, 236:13-239:10, 245:6-18, 278:11-279:12.)

56. McKinnell's belief in the correctness of Pfizer's reserve decisions and disclosures was based on (i) his personal knowledge of the Bextra investigation, (ii) Pfizer's robust and comprehensive process for evaluating the reserves decisions, (iii) input from Pfizer's Finance Group (led by Loretta Cangialosi, Pfizer's Controller) and numerous senior executives and (iv) his reliance on the work of KPMG. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 232:16-236:12, 236:13-239:10, 245:6-18, 278:11-279:12.)

57. McKinnell believed that the individuals involved in the process for evaluating Pfizer's reserve decisions, including the KPMG auditors, were fully informed of the relevant facts concerning the DOJ investigation and Pfizer's internal investigation. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 232:16-24, 246:18-247:18, 278:11-279:12.)

58. At the end of the process for evaluating Pfizer's reserve decisions, KPMG determined each quarter that Pfizer's reserving decisions were reasonable and compliant with Generally Accepted Accounting Principles. (Petrosinelli Ex. S-1, 06/21/13 Cangialosi Tr. at 380:19-382:15.)

F. McKinnell's August 2006 Cashless Exercise and February 2006 Compensation

59. On or about August 2, 2006, McKinnell engaged in a "cashless exercise" of stock options whereby he sold \$6.4 million of Pfizer stock to pay for the cost of acquiring Pfizer shares and as part of tax withholding. (Musoff Ex. A-M, 11/11/13 McKinnell Tr. at 331:10-332:22.)

60. Pfizer's Compensation Committee, composed of independent directors, set McKinnell's salary in 2006 based on the performance of both Pfizer and McKinnell in 2005. (Musoff Ex. E-M, 03/16/06 Pfizer Form 14A at 59-60.)

61. The Compensation Committee further awarded McKinnell stock options, restricted stock units and performance shares in early 2006 based on the performance of both Pfizer and McKinnell in 2005. (Musoff Ex. E-M, 03/16/06 Pfizer Form 14A at 59-60.)

Dated: New York, New York
October 30, 2014

Respectfully submitted,

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