

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

IN RE PFIZER INC. SHAREHOLDER  
DERIVATIVE LITIGATION

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**JURY TRIAL DEMANDED**

**ECF CASE**

**CONSOLIDATED, AMENDED AND VERIFIED  
SHAREHOLDER DERIVATIVE COMPLAINT**

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Lead Plaintiff Amalgamated Bank, as trustee for the LongView Largecap 500 Index VEBA Fund, LongView Largecap 500 Index Fund and LongView Quantitative Largecap Fund (“Lead Plaintiff”), and on behalf of additional named plaintiffs Skandia Life Insurance Company Ltd.; Louisiana Sheriffs’ Pension and Relief Fund; Port Authority of Allegheny County Retirement and Disability Allowance Plan for Employees represented by Local 85 of Amalgamated Transit Union; LIUNA Staff & Affiliates Pension Fund; Laborers’ International Union of North America National (Industrial) Pension Fund; and Ms. Henrietta Klein (collectively, “Additional Plaintiffs”), brings this action for the benefit of nominal defendant Pfizer Inc. (“Pfizer” or the “Company”).

The allegations in this consolidated, amended and verified shareholder derivative complaint (the “Complaint”) are made upon Lead Plaintiff’s personal knowledge with regard to its own acts and upon information and belief as to all other matters. Lead Plaintiff’s information and belief is based upon, among other things, the investigation by Court-appointed lead counsel Bernstein Litowitz Berger & Grossmann LLP and other counsel retained by Additional Plaintiffs, which includes review of filings with the U.S. Securities and Exchange Commission (“SEC”), interviews of former employees, review of materials obtained through requests for disclosure under the Freedom of Information Act, and review of other publicly available information. Based on the allegations in this Complaint, Lead Plaintiff asserts derivative claims for violations of Securities Exchange Act §14(a) and Rule 14a-9 promulgated thereunder, breach of fiduciary duty and unjust enrichment against certain current or former members of Pfizer’s board of directors (the “Board”) and certain Pfizer executives (collectively “Defendants”) during the period commencing on or about May 11, 2004 and ending September 2, 2009 (the “Relevant Period”).

## I. INTRODUCTION

1. This derivative action arises from the Pfizer Board's knowingly causing and permitting the Company to engage in nearly a decade of systematic illegal marketing and promotion of powerful pharmaceuticals. On September 2, 2009, the U.S. Department of Justice (the "DOJ") announced a \$2.3 billion settlement arising from Pfizer's fraudulent and criminal promotion of at least 13 different regulated drugs. The DOJ described the underlying misconduct as so pervasive and embedded in Pfizer's corporate culture that it required "the largest criminal fine ever imposed in the United States for any matter" and the "largest civil fraud settlement in history against a pharmaceutical company." In announcing the settlement, the U.S. Attorney for the District of Massachusetts attributed the severity of the fines to "Pfizer's recidivism," lamenting that "at the very same time Pfizer was in our office negotiating and resolving [prior] allegations of criminal conduct . . . Pfizer was itself in its other operations violating those very same laws. *Today's enormous fine demonstrates that such blatant and continued disregard of the law will not be tolerated.*"<sup>1</sup>

2. As explained herein and will be shown at trial, the criminal conduct warranting this unprecedented punishment is not the work of a rogue employee or business division outside the direct purview of the Board and senior management. Rather, the conduct was a policy of calculated violation of the drug marketing laws that was affirmatively adopted as Pfizer's business strategy, and was deeply embedded in the Company's regular practices and corporate culture. As John Kopchinski, a former Company sales representative whose "whistle-blower" complaint in part helped prompt the government's recent actions, said, "if you didn't sell drugs illegally, you were not seen as a team player."

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<sup>1</sup> Emphasis has been added unless otherwise indicated.

3. Pfizer's historic \$2.3 billion settlement follows numerous prior regulatory and enforcement actions well known to the Board and senior executives. This was at least Pfizer's fourth major fine, and third criminal guilty plea, for illegal marketing and sales practices since 2002. Indeed, settlements in 2002, 2004, and 2007 had already cost Pfizer a combined \$513 million in fines. Moreover, as a result of these earlier instances of misconduct, Defendants had specifically agreed—pursuant to “Corporate Integrity Agreements” reached with regulators—to establish and administer internal compliance mechanisms to directly inform the Board of the Company's compliance or non-compliance with the drug marketing laws. Nevertheless, despite repeated legal violations within the Company and the overwhelming “red flags” confronting the Board, the directors continued to look the other way.

4. In light of the multiple prior civil and criminal fines for off-label and other improper marketing practices, Pfizer's Board and senior executives knew that continued illegal conduct could subject the Company and its shareholders to grave consequences—including massive criminal and civil fines and penalties, as well as severe sanctions such as debarment from participation in Medicare and Medicaid. Despite these risks, the Board and senior management made a calculated bet that the negative consequences of getting caught would never become significant. Defendants lost that bet. Their conduct represents a direct breach of Defendants' fiduciary duties that caused significant harm to the Company and for which they must be held accountable.

5. In 2002, Pfizer and its wholly-owned subsidiary, the Warner Lambert Company (“Warner Lambert”), agreed to pay \$49 million to settle allegations concerning the payment of illegal kickbacks to health professionals for prescribing Pfizer's anti-cholesterol drug “Lipitor.” Regulators placed the responsibility for rectifying the Company's prior

practices squarely on Pfizer's Board and senior executives, insisting that Pfizer enter into the earliest "Corporate Integrity Agreement," whereby the Board was required to receive directly "periodic (at least semi-annual) reports regarding compliance matters" from a specifically designated Compliance Officer, and which provided that the Compliance Officer was also "authorized to report on such matters to the Board of Directors at any time." Notwithstanding the 2002 Corporate Integrity Agreement, and the specific responsibilities assumed by the Board in this agreement, Pfizer's use of illegal kickbacks and other systematic violations of the drug marketing laws continued unabated.

6. In 2004, another Pfizer subsidiary pled guilty to criminal charges for misbranding Pfizer drug "Neurontin," including the illegal and deceptive promotion of off-label uses and doses. This time, the government ratcheted up its demands, settling only when Pfizer agreed to pay a \$240 million criminal fine, which the DOJ noted at the time was "the second largest criminal fine ever imposed in a health care fraud prosecution." Pfizer also paid \$190 million to resolve related civil False Claims Act claims, for a total payment of \$430 million that necessarily alerted the Board to the risks presented by the Company's endemic pattern of unlawful marketing practices. Recognizing this fact, regulators once again placed responsibility for addressing the Company's pattern of illegal drug marketing with the Board, which agreed to a second "Corporate Integrity Agreement" aimed at preventing future violations. The 2004 Corporate Integrity Agreement—which imposed even more stringent obligations on the Board than its predecessor—was another empty promise.

7. Thus, by 2004, Pfizer's Board had agreed to adopt a specific mechanism whereby information concerning the Company's compliance or non-compliance with the drug marketing laws was reported directly to the Board on a regular and systematic basis.

Accordingly, the Relevant Period begins with the Board's execution (and prompt breach) of the 2004 Corporate Integrity Agreement.

8. The Board's continued compliance deficiencies following the 2004 Corporate Integrity Agreement and the nearly ten-fold increase in fines that accompanied it constitute inexcusable bad faith violations of fiduciary trust. Pfizer's widespread violations of federal law continued unabated under Defendants' direct supervision and management. The Company's deeply ingrained culture of unlawful drug marketing required Defendants' knowing involvement in or conscious disregard of reports and other information that Pfizer was breaking the law.

9. Sure enough, in 2007, Pfizer again faced criminal sanctions for illegal marketing. Pfizer subsidiary Pharmacia entered a criminal guilty plea for the illegal promotion and sales practices of Pfizer drug Genotropin, a human growth hormone (anabolic steroid). To settle the charges, Pfizer entered into a deferred prosecution agreement with the U.S. Attorneys' Office in Massachusetts and agreed to pay yet another \$34.6 million in criminal fines.

10. The fact that Pfizer has been operated with a systematic disregard for the laws governing its fundamental business was not hidden from the Board, which repeatedly and knowingly disregarded red flags demonstrating the Company's wrongdoing. In addition to receiving regular compliance reports as mandated by the 2002 and 2004 Corporate Integrity Agreements, the Board also received updates on complaints by current and former Pfizer employees of widespread illegal activities, which included 11 *qui tam* "whistleblower" lawsuits, as well as numerous formal governmental notices of violation informing Defendants of the very conduct covered by the \$2.3 billion settlement, including at least one formal FDA



Warning Letter sent directly to Pfizer's Chairman and CEO.

11. Pfizer's repeat-offender status, the numerous Pfizer drugs involved, and the habitual nature and similarity of its crimes have caused tremendous damage to the Company. This damage includes not only the record **\$2.3 billion** in fines and penalties, but also substantial exposure to damages and legal expenses from dozens of private consumer actions and state government consumer protection actions, personal injury actions, and whistleblower lawsuits, as well as the downgrading Pfizer's reputation from the world's preeminent pharmaceutical company to among the worst violators of federal law. Immediate intervention is needed because, as industry sources have explained, any continuing violations could require Pfizer's debarment from federal programs—a "death knell" for Pfizer.

12. At Pfizer's October 16, 2009 sentencing hearing, the Honorable Douglas P. Woodlock, District Judge for the United States Court for the District of Massachusetts, eloquently expressed the concerns at the heart of this matter. As Judge Woodlock explained:

[T]here is a substantial history here that cannot be ignored, and I recognize that the sentence is, according to the government, the largest criminal fine ever imposed.

But I am concerned about the individuals. This is a case in which no human being, apparently, is going to be held responsible for substantial criminal activity by a corporation. I have invoked before . . . the observation of the 19th Century British judge, that "The Problem with sentencing a corporation is that it has no soul to damn nor body to kick." That is ordinarily not within the sentencing guidelines, that is, kicking or damning, but in the sentencing guidelines is a recognition of real criminal culpability; and there is no, apparently, human being who did anything wrong here or at least the government is prepared to pursue.

\* \* \*

Nevertheless, suffusing the materials that I have been provided with is a lengthy pattern by persons, who may or may not still be with the corporation in its new incarnation, that are [consistent] with violations for which the corporation is pleading guilty. It seems to me that those are things, even if they are not winners from the government's point of view, which bear prosecution.

It has, I think, become something of a cost of doing business, a very high cost of doing business, for some of these corporations to shed their skin like certain animals and leave the skin behind and move on to the future without ultimately giving the public what it is entitled to, which is the satisfaction of knowing that there has been a full evaluation of the criminal responsibility of the individuals who occupied that skin.

13. This litigation on behalf of Pfizer seeks to rectify the conduct of the individuals bearing ultimate responsibility for the corporation's criminal conduct—the directors on the Board and senior management—and to impose appropriate responsibility upon those individuals.

## **II. JURISDICTION AND VENUE**

14. This Court has jurisdiction of this action under federal question jurisdiction pursuant to 28 U.S.C. § 1331 because this action arises under the laws of the United States. This Court has exclusive jurisdiction, pursuant to Section 27 of the Securities Exchange Act, 15 U.S.C. §§ 78aa, because this action asserts claims under Section 14(a) of the Exchange Act, 15 U.S.C. §78n(a), and has supplemental jurisdiction over the non-federal claims asserted herein under 28 U.S.C. § 1367(a). This is not a collusive action designed to confer jurisdiction on a court of the United States that it would not otherwise have.

15. Venue is proper in this District pursuant to 28 U.S.C. §1391(a). Substantial acts in furtherance of the alleged wrongdoing and/or their effects have occurred within this District, and nominal defendant Pfizer, Inc.'s headquarters are in New York, New York.

## **III. THE PARTIES**

### **A. Lead Plaintiff and Additional Named Plaintiffs**

16. Lead Plaintiff Amalgamated Bank, as trustee for the LongView Largecap 500 Index VEBA Fund, LongView Largecap 500 Index Fund and LongView Quantitative Largecap Fund, is referred to herein as "Amalgamated." Amalgamated, which the Court

appointed as “Lead Plaintiff” on November 4, 2009, is a current shareholder of the Company, was a shareholder at the time of the misconduct complained of herein, and intends to continue to hold Pfizer shares at least through the resolution of this action.

17. Additional named plaintiff Skandia Life Insurance Company Ltd., is a current shareholder of the Company, was a shareholder at the time of the misconduct complained of herein, and intends to continue to hold Pfizer shares at least through the resolution of this action.

18. Additional named plaintiff Louisiana Sheriffs’ Pension and Relief Fund is a current shareholder of the Company, was a shareholder at the time of the misconduct complained of herein, and intends to continue to hold Pfizer shares at least through the resolution of this action.

19. Additional named plaintiff Port Authority of Allegheny County Retirement and Disability Allowance Plan for Employees represented by Local 85 of Amalgamated Transit Union is a current shareholder of the Company, was a shareholder at the time of the misconduct complained of herein, and intends to continue to hold Pfizer shares at least through the resolution of this action.

20. Additional named plaintiff LIUNA Staff & Affiliates Pension Fund is a current shareholder of the Company, was a shareholder at the time of the misconduct complained of herein, and intends to continue to hold Pfizer shares at least through the resolution of this action.

21. Additional named plaintiff Laborers’ International Union of North America National (Industrial) Pension Fund is a current shareholder of the Company, was a shareholder at the time of the misconduct complained of herein, and intends to continue to

hold Pfizer shares at least through the resolution of this action.

22. Additional named plaintiff Ms. Henrietta Klein is a current shareholder of the Company, was a shareholder at the time of the misconduct complained of herein, and intends to continue to hold Pfizer shares at least through the resolution of this action.

**B. The Nominal Corporate Defendant**

23. Nominal defendant Pfizer is a Delaware corporation headquartered in New York, New York. According to its public filings, Pfizer describes itself as “the world’s largest research-based biomedical and pharmaceutical company.” The Company employs more than 80,000 people in over 150 countries. At all relevant times herein, Pfizer distributed or directed the distribution of pharmaceuticals to all fifty states and the District of Columbia, as well as in numerous countries around the world. Pfizer conducts its business directly, as well as through over 350 subsidiary entities, such as Warner Lambert and Pharmacia.

**C. The Board of Directors**

24. Pfizer’s Board maintains several standing committees on which the directors serve. These standing committees include the Executive Committee (the “Executive Committee”), the Audit Committee (the “Audit Committee”), the Corporate Governance Committee (the “Corporate Governance Committee”), and the Compensation Committee (the “Compensation Committee”).

25. Defendant Dennis A. Ausiello (“Ausiello”) has served as a director of the Company since December 2006. In addition, defendant Ausiello served as a member of the Corporate Governance Committee during the Relevant Period. Further, defendant Ausiello had received more than \$573,000 for his service as a director of the Company.

26. Defendant Michael S. Brown (“Brown”) has served as a director of the

Company since 1996. In addition, defendant Brown served as a member of the Corporate Governance Committee during the Relevant Period. Since 2002, Brown received more than \$1,200,000 for his service as a director of the Company.

27. Defendant M. Anthony Burns (“Burns”) has served as a director of the Company since 1998. In addition, defendant Burns has served as a member of both the Executive Committee and the Audit Committee during the Relevant Period. Since 2002, Burns received more than \$1,000,000 for his service as a director of the Company.

28. Defendant Robert N. Burt (“Burt”) has served as a director of the Company since 2000. During the Relevant Period, defendant Burt served as a member of the Audit Committee and the Compensation Committee. Since 2002, defendant Burt received more than \$1,000,000 for his service as a director of the Company.

29. Defendant W. Don Cornwell (“Cornwell”) has served as a director of the Company since 1997. In addition, defendant Cornwell has served as a chair of the Audit Committee during the Relevant Period. Since 2002, defendant Cornwell received more than \$1,000,000 for his service as a director of the Company.

30. Defendant William H. Gray III (“Gray”) has served as a director of the Company since 2000. In addition, defendant Gray served as a member of the Corporate Governance Committee during the Relevant Period. Since 2002, defendant Gray received more than \$975,000 for his service as a director of the Company.

31. Defendant Constance J. Horner (“Horner”) has served as a director of the Company since 1993. In addition, defendant Horner served as a chair of the Corporate Governance Committee and a member of the Executive Committee during the Relevant Period. Since 2002, defendant Horner received more than \$1,000,000 for her service as a

director of the Company.

32. Defendant James M. Kilts (“Kilts”) has served as a director of the Company since September 2007. In addition, defendant Kilts served as a member of the Compensation Committee during the Relevant Period. In 2007 and 2008, defendant Kilts received more than \$365,000 for his service as a director of the Company.

33. Defendant Jeffrey B. Kindler (“Kindler”) has served as the Company’s Chief Executive Officer (“CEO”) since July 31, 2006. Before becoming Pfizer’s CEO, defendant Kindler served as the Company’s General Counsel and Chief Compliance Officer for part of the Relevant Period. Defendant Kindler has served as a director of the Company since July 2006 and as Chairman of the Board since December 2006. In addition, defendant Kindler served as a member of the Executive Committee during part of the Relevant Period. In 2008, defendant Kindler received more than \$13 million for his service to the Company, including a salary of \$1,575,000, stock awards of \$4,715,947, stock options worth \$3,281,916, non-equity incentive compensation of \$3,000,000, and non-qualified deferred compensation earnings of \$759,298. Since 2006, defendant Kindler has received more than \$33,000,000 from Pfizer.

34. Defendant George A. Lorch (“Lorch”) has served as a director of the Company since 2000. During the Relevant Period defendant Lorch served as a member of the Compensation Committee. Since 2002, defendant Lorch received more than \$1,000,000 for his service as a director of the Company.

35. Defendant Suzanne Nora Johnson (“Johnson”) has served as a director of the Company since September 2007. In addition, defendant Johnson has served as a member of the Audit Committee during the Relevant Period. In 2007 and 2008, defendant Johnson received more than \$375,000 for her service as a director of the Company.

36. Defendant Dana G. Mead (“Mead”) has served as a director of the Company since 1998. During the Relevant Period, defendant Mead served as Chair of the Compensation Committee. Since 2002, defendant Mead received more than \$1,000,000 for his service as a director of the Company.

37. Defendant William C. Steere, Jr. (“Steere”) has served as a director of the Company since 1987. In addition, defendant Steere has served as Chairman Emeritus of the Company since July 2001, as Chairman of the Board from 1992 to April 2001, and CEO from 1991 to 2000. As Chairman Emeritus, Steere earns director fees of at least \$275,000 per year. During the Relevant Period defendant Steere also served on the Corporate Governance Committee. Since 2002, defendant Steere received more than \$840,000 for his service to the Company.

38. Defendant Stephen W. Sanger (“Sanger”) has served as a director of the Company since February 2009. Defendant Sanger signed and caused the 2009 Proxy Statement (as defined herein) to be issued. Defendant Sanger is named as a defendant herein only with respect to claims arising from the disclosures constituting the 2009 Proxy Statement.

39. Defendants Ausiello, Brown, Burns, Burt, Cornwell, Gray, Horner, Kilts, Kindler, Lorch, Mead, Johnson, Sanger and Steere comprise the current directors on the Board, and are collectively referred to as the “Director Defendants” (except that, with respect to the 2007 and 2008 Proxy Statements (as defined herein), the term “Director Defendants” excludes defendant Sanger).

#### **D. Former Board Members**

40. Defendant William R. Howell (“Howell”) served as a director of the Company

from 2000 to 2009. In addition, defendant Howell served as a member of the Audit Committee from 2000 to 2009, including as the Committee's Chair in 2005 and 2006. Since 2002, defendant Howell received more than \$1,000,000 for his service as a director of the Company.

41. Defendant Henry A. McKinnell ("McKinnell") served as a director of the Company from June 1997 to February 2007. In addition, defendant McKinnell was Pfizer's Chairman of the Board from May 2001 to December 2006 and served as Chief Executive Officer of the Company from January 2001 to July 2006. Further, defendant McKinnell served as President, Pfizer Pharmaceuticals Group, from January 1997 to April 2001; as Chief Operating Officer from May 1999 to December 2000; as Executive Vice President from 1992 to 1999; and at various other positions within the Company from 1971 to 1992. In 2007, defendant McKinnell received more than \$15,800,000 for his service to the Company and between 2002 and 2007 received more than \$216,000,000 in compensation from Pfizer.

42. Defendant Stanley O. Ikenberry ("Ikenberry") served as a director of the Company from 1982 to 2007. In addition, defendant Ikenberry served as a member of the Corporate Governance Committee from at least 2001 through 2004; as a member of the Compensation Committee from 2005 to 2006; as a member of the Science and Technology Committee from 2003 to 2006; and as a member of the Executive Committee from 2003 through 2006. Between 2002 and 2007, defendant Ikenberry received more than \$660,000 for his service as a director of the Company.

43. Defendant Ruth J. Simmons ("Simmons") served as a director for the Company from January 1997 to April 2007. In addition, defendant Simmons served as a member of the Corporate Governance Committee from 2002 to 2006 (including as its Chair



from 2004 to 2005), as well as a member of the Audit Committee from 1997 to 2001. Between 2002 and 2007, defendant Simmons received more than \$600,000 for her service as a director of the Company.

44. Defendants Howell, McKinnell, Ikenberry, and Simmons are collectively referred to as the “Former Director Defendants.”

#### **E. Senior Executives**

45. Pfizer has an “Executive Leadership Team” that functions as the senior-most leadership, management and decision-making body of the company. During the Relevant Period, Pfizer’s Executive Leadership Team included defendants Kindler, Allen P. Waxman, Ian Read, and Joseph M. Feczko.

46. Defendant Frank A. D’Amelio (“D’Amelio”) has served as Chief Financial Officer (“CFO”) of the Company since September 2007. D’Amelio is a current member of Pfizer’s Executive Leadership Team and responsible for both the financial and business operations of the Company. In 2008, D’Amelio received more than \$8.1 million for his service to the Company.

47. Defendant Joseph M. Feczko (“Feczko”) served as the Company’s Chief Medical Officer from 2006 until 2009. During this time, Feczko was a member of Pfizer’s Executive Leadership Team and responsible for all aspects of Pfizer’s medical affairs, including regulatory matters and developing relationships with key medical opinion leaders.

48. Defendant Douglas M. Lankler (“Lankler”) has served as Senior Corporate Counsel, Senior Vice President and Chief Compliance Officer of Pfizer during part of the Relevant Period. In addition, defendant Lankler is a signatory to the 2004 and 2009 Corporate Integrity Agreements.

49. Defendant Ian Read (“Read”) is a senior vice president, a current member of Pfizer’s Executive Leadership Team, and group president of Pfizer’s worldwide pharmaceutical business. According to Pfizer’s website, this Pfizer operating unit is “the world’s largest organization devoted to developing, marketing and selling prescription pharmaceutical medicines, with approximately \$61 billion in global revenues.” In 2008, defendant Read received more than \$6.8 million for his service to the Company.

50. Defendant Allen P. Waxman joined Pfizer in 2003 as senior assistant general counsel and was later named senior vice president and associate general counsel with responsibility for, among other things, regulatory compliance. In 2006, Waxman was promoted to be Pfizer’s general counsel and became a member of Pfizer’s Executive Leadership Team. As Pfizer’s general counsel, Waxman was responsible for leading Pfizer’s legal department with respect to, among other things, corporate governance and compliance with legal requirements of healthcare programs such as Medicaid and Medicare, the federal anti-kickback statute and other laws and regulations. Waxman resigned in 2008.

51. Defendants D’Amelio, Feczko, Kindler, Lankler, Read and Waxman are collectively referred to as the “Executive Defendants.”

\* \* \*

52. The Director Defendants, the Former Director Defendants, and the Executive Defendants are collectively referred to as “Defendants.”

#### **IV. FACTUAL BACKGROUND**

##### **A. Background on Pfizer’s Marketing Machine**

53. Pfizer is one of the world’s largest pharmaceutical companies. Pfizer engages in the business of manufacturing, marketing and selling prescription drugs and other products

for the prevention, diagnosis and treatment of illness and afflictions in the United States and worldwide. During the Relevant Period, Pfizer's core products included Aricept, Bextra, Lipitor, Lyrica, Norvasc, Relpax, Viagra, Zithromax, Zoloft, Zyrtec and Zyvox. A number of those products are so-called "blockbuster drugs," meaning that they each earned Pfizer more than \$1 billion per year in revenue. Examples are Neurontin (\$1.7 billion in 2001), Bextra (\$1.3 billion in 2003), Celebrex (\$2.4 billion in 2008), Viagra (\$1.9 billion in 2008) and Lipitor (\$12.4 billion in 2008), all of which achieved the coveted blockbuster status through pervasive illegal marketing efforts. During fiscal year 2008, Pfizer's business generated \$8.1 billion in profit.

54. Pfizer's core business rests upon the marketing of its drugs, not only to consumers, but also to doctors. To assist in the marketing of its drugs, Pfizer collects detailed information regarding the behavior of prescribing doctors, the number of prescriptions, and the general usage for which those prescriptions were written with respect to its own drugs and for competitor drugs. This is commonly referred to as "prescription data mining." *Dr. Drug Rep.*, Daniel Carlat, N.Y. Times Magazine (Nov. 25, 2007). Among Pfizer's purposes for prescription data mining is the identification of doctors who are supportive of Pfizer drugs over competitors' drugs and who may be incentivized to convince other doctors to prescribe Pfizer drugs as well. Within Pfizer, this identification process was at times referred to as "influence mapping." In essence, Pfizer collects extensive data for the specific purpose of targeting physicians likely to be susceptible to unlawful off-label promotion of Pfizer pharmaceuticals.

55. Defendants have caused and permitted Pfizer to openly violate and evade the legal marketing restrictions applicable to its products. Pfizer employs and trains numerous

“pharmaceutical sales representatives” (“sales reps” or “PSRs”) to visit and persuade identified doctors to prescribe Pfizer drugs to patients. Doctors understand that Pfizer sales reps visit them to promote Pfizer drugs. Certain doctors, including many of whom Pfizer has identified through the influence mapping process as “thought leaders” or “key opinion leaders,” refuse to meet with sales reps. Pfizer therefore also employs medical liaisons or “regional medical and research specialists” (“RMRS”). As explained in an October 20, 2009 job advertisement in the New Scientist, Pfizer medical liaisons are expected to “establish relationships with regional and national [Key Opinion Leaders], medical leaders in the regions including academicians, medical directors, directors of pharmacy and other health care professionals.”

56. Using the information collected via Pfizer’s marketing efforts, including prescription data mining, influence mapping, and the employment of sales reps and medical liaisons, Pfizer formulates multi-billion dollar marketing and promotion budgets and strategic plans that are approved by the highest levels of management. These budgets include hundreds of millions of dollars to organize or sponsor meetings with doctors, teleconferences, advisory panels, and continuing medical education seminars. In addition, Pfizer has one of the largest advertising budgets in the United States.

## **B. The Extensive Regulation of Pfizer’s Business**

57. Pfizer’s business is the focus of extensive regulation and regulatory oversight by the Food and Drug Administration (“FDA”). The Federal Food, Drug and Cosmetics Act (“FDCA”), 21 U.S.C. §301 *et seq.*, regulates the development, manufacturing, and distribution of all drugs in the United States.

58. Prior to 1962, pharmaceutical companies were permitted to promote drugs for

any use in the United States. Congress banned the practice in 1962, however, after the disastrous consequences of the drug Thalidomide, a sedative that was widely prescribed to thousands of women suffering from morning sickness during pregnancy. The drug caused tragic birth defects in thousands of babies. As a result of this calamity, and in a legislative effort to prevent similar occurrences, the FDCA was enacted, requiring drug companies to scientifically establish that their drugs are safe and effective for specified intended uses and prohibiting the marketing of drugs for any use other than as specifically approved.

59. Under the FDCA, drug companies are not allowed to market a drug until the drug has been approved by the FDA. Even once approved, the marketing of the drug must be confined to the approved use and dosage, as described on the drug's label. Drug companies may not engage in marketing or promoting unapproved or "off label" uses or dosages, *i.e.* uses or dosages for which the drug has not been approved by the FDA and that are not on the label, because such off-label uses or dosages have not been proven safe and effective.

60. The FDCA also prohibits the marketing or promotion of any drug that is misbranded. A drug is misbranded if the labeling or the advertising for the drug is false or misleading, or if the labeling or the advertising contains inadequate directions for the drug's intended use. Because the FDA will not approve labels with directions for off-label uses or dosages, off-label marketing also violates the FDCA's prohibition on the marketing or promotion of drug that are misbranded.

61. Proving that a specific use or dosage is safe and effective for large numbers of patients requires lengthy clinical trials and is very expensive. On the other hand, drug companies derive immediate and substantial profits from off-label prescriptions. As a result, drug companies have a substantial short-term financial incentive to break the law by

marketing and promoting their drugs for uses and dosages that are not proven to be medically safe and effective in treating large numbers of patients. For the same reasons, drug companies have a short-term financial incentive to improperly provide gifts, money and other kickbacks to doctors to induce and encourage off-label prescriptions. The resulting improper prescriptions are frequently reimbursed by federal healthcare programs such as Medicaid and Medicare, which in turn subjects the perpetrator to liability under the False Claims Act and Federal anti-kickback statute.

62. Drug companies that violate the FDCA prohibition against misbranding or introducing drugs, uses or dosages without FDA approval are also subject to criminal prosecution and, if convicted, face exclusion or “debarment” from Federal healthcare programs. Such federal debarment would result in catastrophic damage to the Company and its shareholders because Medicaid and Medicare would no longer cover the costs of any Pfizer drug and most patients would therefore find an alternative drug sold by a competitor or would forego treatment altogether.

### **C. The Specific Fiduciary Duties of Pfizer’s Management and Board**

63. Under Delaware law, Pfizer’s senior management and directors on the Board have fiduciary duties to the Company and its shareholders, including the duties of loyalty, good faith, and candor. In addition, Pfizer’s foundational corporate documents (such as Board committee charters and the Board’s Code of Conduct and Ethics) also expressly detail the requirements of the Board’s duties, requiring, *inter alia*, that the Board must actively identify and root out unlawful and/or unethical business practices within the Company, must report and prevent such misconduct, and must disclose any deviation from strict performance of these obligations.

64. Pfizer and its shareholders depend and rely on Board members to carry out their fiduciary duties. As stated on Pfizer's website: "***The Pfizer Board understands and acts on the fundamental principle that good corporate governance is critical to organizational success and the protection of shareholder value.***"

65. To implement this philosophy, the Company maintains, and directors are obligated to follow, formal Corporate Governance Principles, which are articulated by the Corporate Governance Committee of the Board. The Corporate Governance Principles place ultimate decision-making authority for the Company with the Board and explicitly require and establish mechanisms for the Board to be continuously informed with respect to the Company's important business affairs. As stated in the Corporate Governance Principles:

The Board of Directors, which is elected by the shareholders, is the ultimate decision-making body of the Company, except with respect to those matters reserved to the shareholders. . . Having selected the senior management team, the Board acts as an advisor and counselor to senior management and ultimately monitors its performance. The function of the Board to monitor the performance of senior management is facilitated by the presence of outside Directors of stature who have substantive knowledge of the Company's business.

66. Pfizer's Corporate Governance Principles recognize that the members of the Board must be kept fully informed in order to meet their fiduciary duties. They therefore require the establishment of an ongoing "Director Orientation and Continuing Education" program, which "includes extensive materials, meetings with key management and visits to Company facilities." Moreover, Pfizer's "Board members have free access to all other members of management and employees of the Company and, as necessary and appropriate, Board members may consult with independent legal, financial, accounting and other advisors to assist in their duties to the Company and its shareholders."

67. In addition to the express Corporate Governance Principles, Pfizer also

maintains a “Code of Business Conduct and Ethics for Members of the Board of Directors” (the “Code of Conduct and Ethics”) that “is intended to focus the Board and each director on areas of ethical risk” and to “provide mechanisms to report unethical conduct . . . and help foster a culture of honesty and accountability.” As stated in the Company’s 2009 Corporate Responsibility Report: “Ethical conduct starts with the Board of Directors at Pfizer, who follow the Code of Conduct and Ethics.”

68. Pfizer’s Code of Conduct and Ethics imposes specific duties on the Board to comply and ensure compliance with laws and regulations and to report any suspected violations so that they may be investigated and acted upon. As set forth in the Code of Conduct and Ethics:

**COMPLIANCE WITH LAWS, RULES AND REGULATIONS; FAIR DEALING.**

Directors must comply, and oversee compliance by employees, officers and other directors, with laws, rules and regulations applicable to the Company, including insider trading laws.

Directors must deal fairly, and must oversee fair dealing by employees and officers, with the Company’s customers, suppliers, competitors and employees.

\* \* \*

**ENCOURAGING THE REPORTING OF ANY ILLEGAL OR UNETHICAL BEHAVIOR.**

Directors should promote ethical behavior and take steps to ensure the Company:

- (a) Encourages employees to talk to supervisors, managers and other appropriate personnel when in doubt about the best course of action in a particular situation;
- (b) Encourages employees to report violations of laws, rules, regulations or the Company's Code of Conduct to appropriate personnel;
- (c) Informs employees that the Company will not allow retaliation for reports made in good faith.

\* \* \*



## COMPLIANCE STANDARDS

Directors should communicate any suspected violations of this Code promptly to the Chairman of the Audit Committee. Violations will be investigated by the board or by persons designated by the board, and appropriate action will be taken in the event of any violations of the Code.

69. The Board's Code of Conduct and Ethics is nondiscretionary and not aspirational. Rather, the directors on the Board are required to follow the Code of Conduct and Ethics and may only deviate from its terms upon an explicit waiver, which is formally required to be disclosed to shareholders. As set forth in the Code of Conduct and Ethics:

Any waiver of this Code may be made *only* by the Board of Directors and must be promptly disclosed to the Company's shareholders. (emphasis in original).

70. Notably, and as discussed in Section IV.E.2, *infra*, the Code of Conduct and Ethics (and the specific duties of the Board thereunder) was expressly incorporated into the 2004 Corporate Integrity Agreement. Thus, not only were the directors on the Board responsible to the Company and to its shareholders to comply with the Code of Conduct and Ethics; they had also specifically agreed with regulators to perform this function as the direct result of the Company's repeated previous instances of misconduct and consequent settlement of government investigations.

71. The Board has several committees to monitor specific aspects of Pfizer's business. These committees have their own, supplemental charters setting forth additional express duties for their respective members. For example, the charter of the Audit Committee provides that its members have a special obligation to monitor the Company's compliance with the law. It states that Audit Committee members must:

Review: (a) the status of compliance with laws, regulations, and internal procedures; and (b) the scope and status of systems designed to promote Company compliance with laws, regulations and internal procedures, through

review of reports from management, legal counsel and third parties as determined by the Audit Committee.

72. The Audit Committee is also specifically charged with risk management responsibilities, including identifying risks and contingent liabilities facing the Company. Specifically, Audit Committee members are required to:

Discuss Company policies with respect to risk assessment and risk management, and review contingent liabilities and risks that may be material to the Company.

73. In addition, the directors on the Audit Committee are affirmatively obligated under the terms of the Audit Committee Charter to monitor legal and regulatory developments which may materially affect Pfizer. Specifically, the Audit Committee is obligated to “review major legislative and regulatory developments which could materially impact the Company’s contingent liabilities and risks.” Such developments necessarily included the Company’s previous regulatory settlements in 2002, 2004, and 2007. As such, the Audit Committee was required to review these settlements and assess how the type of conduct at issue could affect Pfizer’s contingent liabilities and risks going forward.

74. Pfizer’s Corporate Governance Committee is expressly charged with ensuring that the members of the Board and the Company’s senior executives are complying with their fiduciary duties and the Corporate Governance Principles, described above. In this regard, the Corporate Governance Committee charter provides that members of the committee must stay informed regarding Pfizer’s corporate governance and to “monitor emerging issues potentially affecting the reputation of the pharmaceutical industry and the Company.” Furthermore, the members of the Corporate Governance Committee must “review annually with the Chairman and Chief Executive Officer the job performance of elected corporate officers and other senior executives,” and must “review the functions of senior officers to make recommendations on

changes.” Moreover, the Corporate Governance Committee is obligated to review matters of corporate governance and to maintain an informed status on Company issues related to corporate social responsibility.

75. Pfizer’s misconduct resulting in the largest criminal fine in history and the largest civil fine in the history of the pharmaceutical industry is completely inconsistent with the fiduciary duties that all Pfizer directors and senior management undertake as a condition to accepting their prestigious and well-paying positions with the Company.

**D. Pfizer’s Long-Standing Culture of Off-Label Marketing, Kickbacks and Other Unlawful Drug Sales Methods**

**1. Pfizer’s Illegal Marketing And Sales Strategy**

76. Before and during the Relevant Period, Defendants knowingly caused and/or permitted a Company-wide, multifaceted strategy to promote off-label prescriptions for numerous Pfizer drugs through illegal off-label marketing and payment of illegal kickbacks, including for Bextra, Caduet, Celebrex, Depo-Provera, Detrol L.A., Glucotrol XL, Geodon, Lipitor, Lyrica, Neurontin, Norvasc, Relpax, Viagra, Zithromax, Zoloft, Zyrtec, and Zyvox.

77. Using the nationwide information from “prescription data mining” efforts and the results from “influence mapping” analyses, Defendants caused Pfizer to select specific doctors to be targeted for Pfizer’s marketing efforts encouraging off-label prescribing behavior. Selected doctors would be visited by Pfizer’s sales reps, who were provided with specific prescription quotas for doctors within their geographic territory. As former Pfizer sales rep Mark Westlock explained in a sealed whistleblower complaint,<sup>2</sup> the quotas provided by Pfizer’s headquarters included doctors whose practices did not typically give rise to a need

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<sup>2</sup> Unless otherwise indicated, the whistleblower complaints referenced herein were only recently unsealed.

to prescribe the promoted drugs for FDA-approved uses.<sup>3</sup> Moreover, according to Westlock, Pfizer's sales reps, district managers, regional managers, and vice-presidents of sales all had a financial incentive to maximize prescribing behavior without regard to whether prescriptions were on-label or off-label.<sup>4</sup> Former Pfizer sales representatives Robert Wilson, Richard Ehlers, and Craig Watkins stated in a separate whistleblower complaint that Pfizer's marketing plan expressly included the marketing of certain Pfizer painkiller drugs with limited approved uses "to doctors who did not treat [approved uses for those drugs], such as emergency room doctors, podiatrists, oncologists, and even psychiatrists for any and all kinds of pain."<sup>5</sup> Former Pfizer sales representatives David Wetherholt, and Marci Dimer also confirmed in their whistleblower complaint that Pfizer gave strong financial incentives to its sales force to promote off-label prescriptions.<sup>6</sup>

78. In order to influence prescribing behavior and assist Pfizer's sales force in promoting off-label prescriptions, numerous free samples of the Company's drugs were provided for distribution to doctors, including to doctors who had no FDA-approved use for the drug. Former Pfizer sales representative and "institutional health representative" Blair Collins and former Pfizer sales representatives John Kopchinski, David Farber, Casey Schildhauer, Robert Wilson, Richard Ehlers, and Craig Watkins all detailed this prevalent

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<sup>3</sup> Complaint, *United States ex rel. Mark R. Westlock, et al. v. Pfizer, Inc., et al.*, Civ. No. 08-CA-11318 DPW (D. Mass. Aug. 22, 2008).

<sup>4</sup> *Id.* at ¶¶217-222.

<sup>5</sup> Complaint at ¶14, *United States ex rel. Robert Willson, Richard Ehlers and Craig Watkins v. Pfizer, Inc., et al.*, Civ. No. 07-11115 RGS (D. Mass. June 15, 2007).

<sup>6</sup> See Complaint at ¶27, *United States ex rel. David Wetherholt and Marci Dimer v. Pfizer, Inc.*, Civ. No. 06-10240-DPW, (D. Mass. Feb. 2, 2006).

practice in their whistleblower complaints.<sup>7</sup> Because of the size and scale of these companywide promotion efforts involving free samples, and due to their positions at the Company, Pfizer's chief medical officer, defendant Feczko, and Pfizer's president of pharmaceutical operations, defendant Read, must have known about the use of free samples to influence the prescribing behavior of doctors. Because of regulations governing the distribution of medication, Pfizer's general counsel – defendant Kindler until 2006 and defendant Waxman from 2006 until 2008 – also must have known about the companywide promotion efforts involving free samples. Similarly, Pfizer's chief financial officer defendant D'Amelio must have known of these efforts because of the budgets and expenses involved.

79. Before and during the Relevant Period, the Company's own medical liaisons (or RMRSs) assisted Pfizer's sales force with promoting off-label prescriptions. In a sealed whistleblower complaint, former Pfizer district manager Ronald Rameiro explained that Pfizer had developed a marketing scheme known as the "Scientific Ambassador Program" in which "Pfizer scientists are used to promote Pfizer drugs off-label and to enable representatives to gain access to difficult to influence physicians."<sup>8</sup> According to Rainero, Pfizer's senior sales management received bonuses predicated on the number of Scientific Ambassador programs implemented in their region.<sup>9</sup> Whistleblowers David Farber, Casey Schildhauer and Mark Westlock similarly confirmed the use of Pfizer's medical liaisons to promote off-label

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<sup>7</sup> See Complaint at ¶45, *United States ex rel. Blair Collins, et al. v. Pfizer, Inc.*, Civ. No. 04-11780 DPW (D. Mass. Aug. 13, 2007); Complaint at ¶¶111-13, *United States ex rel. John Kopchinski v. Pfizer, Inc. et al.*, Civ. No. 05-cv-12115 RCL (D. Mass. Dec. 12, 2008); Complaint at ¶14, *United States ex rel. Robert Willson, Richard Ehlers and Craig Watkins v. Pfizer, Inc., et al.*, Civ. No. 07-11115 RGS (D. Mass. June 15, 2007).

<sup>8</sup> Complaint at ¶¶20, 180, *United States et al. ex rel. Ronald Rainero v. Pfizer, Inc.*, Civ. No. 07-CA-11728 DPW (D. Mass. June 19, 2008).

<sup>9</sup> *Id.* at ¶179.

prescriptions in their complaints.<sup>10</sup> Because of their positions at the Company, Pfizer’s chief medical officer, defendant Feczko, and Pfizer’s president of pharmaceutical operations, defendant Read, must have known about the Scientific Ambassador Program, and the concerted use of Pfizer medical liaisons to assist the Pfizer sales force in convincing doctors to prescribe Pfizer drugs off-label.

80. Indeed, this strategy—using Pfizer’s own purportedly independent scientists to manipulate the prescription habits of physicians—was a global effort. In 2002, the *British Medical Journal* reported, for example, that Pfizer had been given a “rare public reprimand” by the Association of the British Pharmaceutical Industry because the British Prescription Medicines Code of Practice Authority, which monitors complaints about drug companies, had discovered that “Pfizer had been using a team of medical liaison executives to promote unlicensed medicines and to promote off-licence indications for other products.”<sup>11</sup>

81. During their visits with targeted doctors, Pfizer’s sales reps and medical liaisons would habitually make false and misleading statements about the available evidence regarding the safety and/or efficacy of off-label prescriptions with respect to specific Pfizer drugs. For example, former Pfizer sales rep Robert Liter stated in a sealed whistleblower complaint that during a national sales meeting in September 2005, “Pfizer instructed and encouraged me and other sales representatives to employ the following illegal promotional tactics to promote the sale of Lyrica: ... [m]aking false statements to physicians and

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<sup>10</sup> Complaint at ¶127, *United States ex rel. David Farber and Casey Schildhauer v. Pfizer, Inc.*, Civ. No. 07-10304 (D. Mass. June 12, 2007); Complaint at ¶184, *United States ex rel. Mark R. Westlock, et al. v. Pfizer, Inc., et al.*, Civ. No. 08-CA-11318 DPW (D. Mass. Aug. 22, 2008).

<sup>11</sup> See BMJ 2002 March 30; 324(7340): 753, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1122697/>, last viewed on November 7, 2009.

pharmacists concerning the efficacy and safety of Lyrica for ‘off-label’ uses” and “[a]ctively concealing its promotional scheme from the FDA to avoid that agency’s enforcement mechanisms.”<sup>12</sup> Former Pfizer sales reps Wetherholt, Dimer and Westlock independently substantiated Liter’s account in other whistleblower complaints.<sup>13</sup>

82. Defendants intentionally supported Pfizer’s sales force and medical liaisons in making such false and misleading statements by commissioning articles in medical journals that ostensibly supported off-label prescriptions of Pfizer drugs and by distributing such articles to its sales force. On November 12, 2009, researchers from the John Hopkins Bloomberg School of Health and from the Department of Clinical Pharmacy and Institute of Health Policy from the University of California at San Francisco published an article in the *New England Journal of Medicine* examining the reporting practices for clinical trials that were funded by Pfizer about off-label uses of Neurontin (generic name gabapentin).<sup>14</sup> Specifically, the researchers reviewed the reporting practices for 20 separate clinical trials that were funded by Pfizer to evaluate the effectiveness of prescribing Neurontin off-label for migraine, prophylaxis, bipolar disorders, neurophatic pain, or nociceptive pain. The study found that out of 20 clinical trials, 8 trials were never reported at all. Comparing the published trial results for the remaining 12 trials with internal, non-disclosed research

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<sup>12</sup> Complaint at ¶32, *United States ex rel. Robert A. Liter v. Pfizer, Inc.*, Civ. No. 06-176 WOB (E.D. Ky. Nov. 21, 2007).

<sup>13</sup> See Complaint at ¶27, *United States ex rel. David Wetherholt and Marci Dimer v. Pfizer, Inc.*, Civ. No. 06-10240-DPW, (D. Mass. Feb. 2, 2006); Complaint at ¶137, *United States ex rel. Mark R. Westlock, et al. v. Pfizer, Inc., et al.*, Civ. No. 08-CA-11318 DPW (D. Mass. Aug. 22, 2008).

<sup>14</sup> *Outcome Reporting in Industry-Sponsored Trials of Gabapentin for Off-Label Use*, S. Swaroop Vedula, M.D., M.P.H., Lisa Bero, Ph.D., Roberta W. Scherer, Ph.D., and Kay Dickersin, Ph.D., *N. Engl. J. Med.* 361; 20 (Nov. 12, 2009).

documents from Pfizer, the study further found that in 8 of those 12 published trials, the publication inaccurately reported the efficacy of using Neurontin for off-label uses. This inaccurate reporting, the researchers stated, led to “a more favorable presentation in the medical literature of gabapentin’s efficacy for unapproved indications.”<sup>15</sup> Reviewing these results, the researchers stated they were “concerned that the reporting practices observed in our analysis do not meet the ethical standards for clinical research or maintain the integrity of scientific knowledge.”<sup>16</sup> The director of the University of Pennsylvania’s Center for Bioethics, Arthur Caplan, reviewed this study and told the *Associated Press* that it was “***one of the most ethically disturbing papers I’ve read in some time.***”

83. Former Pfizer sales representative Glenn DeMott explained that Pfizer’s sales force would receive the biased studies that were commissioned and funded by Pfizer for distribution among prescribing doctors to promote off-label prescriptions.<sup>17</sup> According to John Kopchinski’s whistleblower complaint, this practice was a “cornerstone” of Pfizer’s marketing strategy.<sup>18</sup> Because of their positions at the Company, defendants Feczko and Read (respectively the Pfizer’s chief medical officer and president of pharmaceutical operations) must have known about Pfizer’s practice of commissioning studies about the off-label uses of Pfizer drugs and the distribution of such studies to Pfizer’s sales representatives.

84. Pfizer’s sales force also was provided with substantial financial means to

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<sup>15</sup> *Id.* at 1969.

<sup>16</sup> *Id.*

<sup>17</sup> Amended Complaint at ¶4, *United States, et al. ex rel. Glenn DeMott v. Pfizer, Inc.*, Civ. No. 05-12040 RWZ (D. Mass. Apr. 17, 2009).

<sup>18</sup> Complaint at ¶103, *United States ex rel. John Kopchinski v. Pfizer, Inc. et al.*, Civ. No. 05-cv-12115 RCL (D. Mass. Dec. 12, 2008).



promote off-label prescribing behavior. As explained by former Pfizer sales rep. John Kopchinski in his whistleblower complaint, doctors who were identified as suitable marketing targets would, for example, be invited for “consultant meetings” and were “frequently paid money to attend on the pretence that they would provide ‘consulting information.’”<sup>19</sup> According to Kopchinski, hundreds of such consultant meetings were organized across the country, to which between fifty and several hundred doctors would typically be invited and paid to attend.<sup>20</sup> Kopchinski reported that, in addition to travel expenses and accommodations in luxury hotels, physician participants were paid “between \$250 and \$1,500 each to simply attend a single consultant meeting” and that they were typically “not required to do anything but show up to receive his or her payment.”<sup>21</sup> According to Kopchinski, these conferences were simply pretexts for paying unlawful kickbacks.<sup>22</sup> Wilson, Ehlers, and Watkins substantially confirmed this practice in another whistleblower complaint.<sup>23</sup>

85. In addition to paying doctors to attend Pfizer’s marketing meetings, Defendants also caused doctors, including identified key opinion leaders, to be paid to speak at ostensibly “independent” continuing medical education meetings, roundtables and other meetings with colleagues to promote off-label prescribing behavior for Pfizer drugs. According to whistleblower Westlock, “Pfizer recruited a nationwide network of paid speakers to promote Geodon, maintained lists of these speakers, tracked each speaker’s

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<sup>19</sup> *Id.* at ¶114.

<sup>20</sup> *See id.* at ¶124.

<sup>21</sup> *Id.* at ¶125.

<sup>22</sup> *Id.*

<sup>23</sup> *See* Complaint at ¶14, *United States ex rel. Robert Willson, Richard Ehlers and Craig Watkins v. Pfizer, Inc., et al.*, Civ. No. 07-11115 RGS (D. Mass. June 15, 2007).

effectiveness, including each speaker's off-label presentations, and provided these lists to its sales force."<sup>24</sup> One of those speakers was reportedly paid up to \$4,000 per day plus expenses and "became such a frequent speaker that he used his own private helicopter to fly to various locations throughout the United States, all at Pfizer's expense."<sup>25</sup> Whistleblowers Glenn DeMott, David Farber, Casey Schildhauer, Robert Wilson, Richard Ehlers, and Craig Watkins (all former Pfizer PSRs) and Stefan Kruszewski (a board-certified physician) confirmed Pfizer's use of paid medical speakers to promote off-label prescriptions in their complaints.<sup>26</sup> As Pfizer's chief medical officer, responsible for fostering and maintaining relationships with such key opinion leaders, defendant Feczko must have known about Pfizer's practice of paying physicians to speak at meetings with other doctors about off-label uses of Pfizer drugs.

86. Defendants carefully tracked their investment in encouraging off-label prescriptions in the form of number of prescriptions and revenues. According to Collins, this was accomplished by the use of accounting software called the "Budgets and Education Tracking System" or "BETSY" and, based on this tracking, "Pfizer expected to get a \$10 return on investment (*i.e.*, sale of its drugs) for every \$1 spent through marketing budgets."<sup>27</sup> The amounts involved were staggering. The government's October 9, 2009 sentencing

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<sup>24</sup> Complaint at ¶160, *United States ex rel. Mark R. Westlock, et al. v. Pfizer, Inc., et al.*, Civ. No. 08-CA-11318 DPW (D. Mass. Aug. 22, 2008).

<sup>25</sup> *Id.* at ¶165.

<sup>26</sup> See Complaint at ¶ 42, *United States ex rel. David Farber and Casey Schildhauer v. Pfizer, Inc.*, Civ. No. 07-10304 (D. Mass. June 12, 2007); Complaint at ¶ 14, *United States ex rel. Robert Wilson, Richard Ehlers and Craig Watkins v. Pfizer, Inc., et al.*, Civ. No. 07-11115 RGS (D. Mass. June 12, 2007); Complaint at ¶92, *United States ex rel. Stefan Kruszewski v. Pfizer, Inc.*, Civ. No. 07-CV-4106 (E.D. Pa. Aug. 21, 2009)

<sup>27</sup> Complaint at ¶¶43, 150, *United States ex rel. Blair Collins, et al. v. Pfizer, Inc.*, Civ. No. 04-11780 DPW (D. Mass. Aug. 13, 2007).

memorandum in the Bextra criminal action stated that off-label prescriptions of Bextra alone generated more than \$1 billion in sales (\$1,021,000,000), including an estimated \$664,000,000 that was directly attributable to the illegal sales and promotion practices (as *conceded* by Pfizer). As Pfizer's Chief Financial Officer, Defendant D'Amelio must have known about Pfizer's multifaceted, multibillion dollar marketing and promotion strategy, including the tracking of payments and other incentives to doctors, and the expected, company-wide rate of return on those "investments."

87. Rather than creating a culture that encouraged regulatory compliance, the Board and senior management viciously retaliated against the many Pfizer employees who reported internally that Pfizer's marketing practices and payment of kickbacks to promote off-label prescriptions were illegal and put the welfare and future of the Company at risk (not to mention the health of Pfizer's patients). Despite often lengthy employment histories with many commendations and promotions, such employees were retaliated against and forced out of the Company.<sup>28</sup> In his whistleblower complaint, Mark Westlock stated, for example, that he was the subject of retaliation after he informed defendant Read (Pfizer's Worldwide Pharmaceuticals Operations President and a member of Pfizer's Executive Leadership Team) and other members of Pfizer's management in 2007 of the illegal off-label promotion of Geodon. Retaliation from the upper levels of Pfizer in response to reports of wrongdoing was

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<sup>28</sup> See Complaint at ¶8, *United States ex rel. John Kopchinski v. Pfizer, Inc. et al.*, Civ. No. 05-cv-12115 RCL (D. Mass. Dec. 12, 2008); Amended Complaint at ¶243, *United States, et al. ex rel. Glenn DeMott v. Pfizer, Inc.*, Civ. No. 05-12040 RWZ (D. Mass. Apr. 17, 2009); Complaint at ¶145-54, *United States ex rel. David Farber and Casey Schildhauer v. Pfizer, Inc.*, Civ. No. 07-10304 (D. Mass. June 12, 2007); Complaint at ¶¶ 269-272, *United States ex rel. Mark R. Westlock, et al. v. Pfizer, Inc., et al.*, Civ. No. 08-CA-11318 DPW (D. Mass. Aug. 22, 2008).

so frequent and so widely known among Pfizer employees that they invented an acronym to describe it. As explained in the government's October 9, 2009 sentencing memorandum in the criminal action involving the illegal marketing of Bextra (discussed in more detail in Section IV.F, *infra*), to report illegal off-label marketing to senior management was "considered a 'CLM' or 'Career Limiting Move'," that is "an action that possibly ended his/her promotion potential or led to being disfavored by management and, ultimately, fired."

**2. 2002 – Pfizer Pays A Multimillion Dollar Settlement And Accepts The First Corporate Integrity Agreement**

88. Lipitor is a medication that reduces low-density lipoprotein cholesterol and overall cholesterol in the blood. Lowering cholesterol can help prevent heart disease, strokes and vascular disease. Financially, Lipitor has been one of Pfizer's most successful drugs, ranking among the world's most profitable drugs of the past decade.

89. In 2002, Pfizer subsidiary Warner Lambert settled charges under the civil False Claims Act alleging that, prior to its 2001 acquisition by Pfizer, it had illegally concealed cash discounts given to a managed care organization in New Orleans called the Ochsner Health Plan ("Ochsner"). In exchange for these concealed discounts, Ochsner agreed to extend an unlawful *quid pro quo* in the form of an "unrestricted formulary status to Lipitor in order to encourage Ochsner plan doctors to write Lipitor prescriptions for Ochsner plan beneficiaries," meaning that doctors who were part of the Ochsner plan knew that there were few restrictions on plan coverage for Lipitor prescriptions. As a result of the illegal non-disclosure of those discounts, Warner Lambert was alleged to have retained \$20 million in Medicaid rebates that it owed to the Medicaid program. Although prior to the acquisition by Pfizer, this misconduct took place under the auspices of a Lipitor marketing agreement between Pfizer and its soon-to-be subsidiary Warner Lambert.

90. To settle the charges that Warner Lambert had improperly overcharged the Medicaid program, Pfizer agreed to pay \$49 million. In addition, Pfizer entered into a five-year corporate integrity agreement (the “2002 CIA”) with the Office of the Inspector General of the Department of Health and Human Services (“OIG HHS”) to ensure that Pfizer would not pay illegal kickbacks in the future. Under the 2002 CIA, the Board was required to directly preside over a compliance mechanism designed to elevate information concerning legal compliance or non-compliance directly to the Board. Accordingly, the Board was directly aware of the improper activities that had led to the Company’s entry into the 2002 CIA and the Board assumed affirmative duties designed to ensure that such conduct would not continue. The terms of the 2002 CIA are more fully discussed in Section IV.E.1, *infra*.

91. Notably, the 2002 CIA’s requirement that the Board adopt a direct and ongoing role in the Company’s marketing activities was highly significant (and unusual) in that it reflected the government’s view that Pfizer’s senior management could not be relied upon to ensure lawful conduct by Pfizer and that direct involvement by the Board was necessary. In other words, the Board was made directly responsible for implementing the terms of the 2002 CIA because the government did not trust Company management to address Pfizer’s recurrent compliance problems and, instead, relied on the Board to prevent further violations by the Company.

**3. 2004 – Pfizer Pays The Second Largest Criminal Fine Ever Imposed In A Healthcare Fraud Prosecution And Enters Into Another Corporate Integrity Agreement**

92. Neurontin is an anticonvulsant medication that affects chemicals and nerves in the body that cause seizures. In the U.S., Neurontin is manufactured and sold by Warner Lambert, a wholly-owned subsidiary of Pfizer.

93. The FDA approved the use of Neurontin for the management of post-herpetic neuralgia (pain resulting from damage caused by shingles or herpes zoster) in adults and to control epileptic seizures of adults if used in conjunction with another drug. The FDA approved doses ranging from 900 mg to 1800 mg per day. Neurontin is a drug with dangerous side effects, even when it is administered for an approved use and at an approved dosage.<sup>29</sup>

94. In 1997, Warner Lambert formally applied to the FDA to change Neurontin's labeling to include a stand-alone treatment (*i.e.*, treatment without simultaneous use of other medication or "mono-therapy") for epilepsy seizures. The FDA rejected this application and declined to approve the prescription of Neurontin for use as a general pain medication or for the treatment of bipolar disorder, depression, migraine, or attention deficit disorder. Warner Lambert nevertheless began to promote Neurontin for off-label uses and dosages, without knowing whether it was medically safe to do so, for: (i) off-label dosages exceeding 1800 mg per day; (ii) use as an epilepsy monotherapy; (iii) use as a general pain medication; and (iv) use as treatment of bipolar disorder, depression, migraine, and attention deficit disorder.

95. On May 19, 2003, a former medical liaison of Warner Lambert, Dr. David

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<sup>29</sup> On January 31, 2008, the FDA sent out an alert entitled "Serious Health Risks with Antiepileptic Drugs" to alert health care professionals and consumers that a review of 11 antiepileptic drug studies showed that patients taking anti-epileptics such as Neurontin "have about twice the risk of suicidal thoughts and behaviors, compared with patients receiving an inactive substance (placebo)."

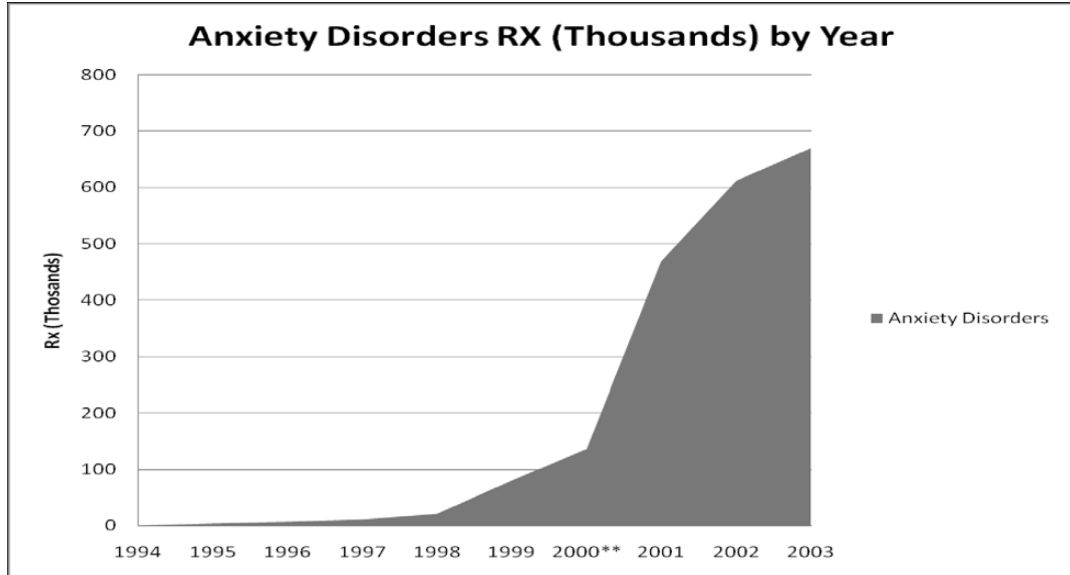
Franklin, filed a whistleblower lawsuit under the federal civil False Claims Act and a sworn affidavit detailing the illegal off-label marketing strategy, including how medical liaisons were “trained and instructed to misrepresent the amount of clinical evidence available to support the use of Neurontin” and to “ignore and conceal any negative information about Neurontin.” Warner Lambert’s promotion campaign showed blatant disregard for the safety or legality of its drug sales. The Associate Director of Medical Affairs for the Northeastern region of the United States was quoted as instructing medical liaisons who visited doctors to promote Neurontin for off-label uses as follows:

Medical liaisons, this is Phil. I am calling in regard to the – you know, there’s a Neurontin push that’s supposed to be on. What we’d like to do is, anytime you’re called out, just make sure that your main focus out of what you are doing is on Neurontin.... When we get out there, we want to kick some ass on Neurontin, we want to sell Neurontin on pain. All right? ***And monotherapy and everything we can talk about, that’s what we want to do.***

96. Dr. Franklin further described in his affidavit that he was “trained and instructed to use a number of misleading abstracts and case reports” to promote Neurontin for “a variety of medically unacceptable uses.” According to Dr. Franklin, Pfizer’s subsidiary also trained medical liaisons like himself to make offers of paid consultancy engagements, offers of paid participation in “studies,” offers of junkets to first class resorts or hotels paid for by Warner Lambert, and offers of cash payments in order to induce physicians to prescribe Neurontin for off-label uses, and at higher doses than approved by the FDA.

97. Warner Lambert’s illegal off-label promotion strategies were very successful and substantially increased the number of off-label Neurontin prescriptions. The following chart shows, for example, the increase in Neurontin off-label prescriptions for anxiety

disorders from the start of defendants' off-label campaign in 1994 until 2003:<sup>30</sup>



98. Following the submission of Dr. Franklin's affidavit, the federal government opened a criminal investigation. In 2004, Warner Lambert pled guilty to criminal and civil charges that it had fraudulently promoted the uses of Neurontin to treat a wide array of ailments for which the drug was not approved, in violation of the FDCA. As the DOJ noted on May 15, 2004, Pfizer's subsidiary "promoted Neurontin even when scientific studies had shown it was not effective."

99. In the government's June 2, 2004 sentencing memorandum, the prosecutor set out a number of "key tactics" that were used to increase off-label use of Neurontin, including: (i) "Encouraging sales representatives to provide one-on-one sales pitches ('details') to physicians about off-label uses;" (ii) "Utilizing medical liaisons, who represented themselves, often falsely, as neutral scientific experts in the area of a particular drug, to promote off-label

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<sup>30</sup> See Memorandum and Order, *In re Neurontin Mrktg. and Sale Practices Litig.*, MDL Docket No. 1629, Civ. Action No. 04-10981 (D. Mass. Aug. 29, 2007).



uses for Neurontin, working in tandem with sales representatives;” (iii) “Paying physicians, through both direct payments, and the provisions of trips, hotel rooms, dinners and other benefits, to attend a variety of ‘consultant’ or ‘advisory’ meetings or ‘speaker bureau trainings’ in which doctors received presentations about off-label uses of Neurontin;” and (iv) “Sponsoring ostensibly independent medical education’ events on off-label Neurontin uses ...”<sup>31</sup> In calculating the culpability score, the sentencing memorandum noted that this marketing scheme *was implemented with knowledge and approval of senior management.*<sup>32</sup> According to the DOJ May 15, 2004 release, “[t]hese tactics were part of a widespread, coordinated national effort to implement an off-label marketing plan.”

100. To settle the charges, Pfizer’s subsidiary pled guilty to two felony counts of violating the FDCA and Pfizer agreed to pay a \$240 million criminal fine. The DOJ explained at the time that this fine was *“the second largest criminal fine ever imposed in a health care fraud prosecution.”* Pfizer agreed to pay an additional \$190 million to resolve related claims under the civil False Claims Act, including allegations of violations of the Federal anti-kickback statute, that Warner Lambert’s conduct had caused doctors to write prescriptions for Medicaid patients when those medications were not eligible for Medicaid reimbursement because those prescriptions were fraudulently obtained through false statements to doctors and by payment of illegal kickbacks, including so-called “consulting fees” and paid trips for doctors.

101. In addition to paying the then-second largest criminal fine ever imposed in a

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<sup>31</sup> See United States’ Sentencing Memorandum to the Federal District Court of Massachusetts, 26-27, *United States v. Warner Lambert Company LLC*, Case Number 04-cr-10150 RGS(D. Mass. June 2, 2004).

<sup>32</sup> See *id.* at 51.

health care fraud prosecution and millions of dollars in civil fines to atone for past transgressions, Defendants caused Pfizer to also enter into another, more extensive corporate integrity agreement to prevent similar practices in the future (the “2004 CIA”). Once again, the Board was at the center of the compliance obligations imposed by the 2004 CIA. The 2004 CIA again required the Board to directly preside over a mechanism designed to elevate information concerning legal compliance or non-compliance directly to the Board, and, in addition, placed significantly more stringent obligations on the Board than the 2002 CIA. Accordingly, the Board was yet again aware of the improper activities that led to the Company’s entry into the 2004 CIA and the Board once again assumed affirmative duties designed to ensure that such misconduct would not continue. The DOJ itself stated on May 15, 2004 its expectation and understanding that the 2004 CIA would ensure that “any future off-label marketing conduct is detected and corrected on a timely basis.” The terms of the 2004 CIA are more fully discussed in Section IV.E.2, *infra*. Once again, the Board’s integral role in the 2004 CIA was the government’s *de facto* expression of reliance on the Board to take control of the situation and to ensure that Pfizer marketed its drugs in a lawful manner.

#### **4. 2007 – Pfizer Pays Yet Another Criminal Fine**

102. Genotropin is a human growth hormone (anabolic steroid) that was approved by the FDA for the limited use of treating children who suffer from growth failure. In the U.S., Genotropin is manufactured and sold by Pharmacia, a wholly-owned subsidiary of Pfizer. Genotropin can pose substantial risks to human health, particularly for teenagers, when it is prescribed for off-label uses or dosages. In the August 2004 edition of “Endocrine News,” Dr. Linn Goldberg of the Hormone Foundations’ Hormone Abuse Program Advisory Council noted for example that “[y]oung developing bodies are likely more sensitive to the

*adverse health effects of steroids, some of which can be irreversible* such as stunting of height in males and voice and body/facial hair changes in females.”

103. The FDCA also recognizes the substantial health risks posed by the use of human growth hormones like Genotropin for uses that are not approved by the FDA. Under the provisions of this statute, whoever knowingly distributes or possesses with intent to distribute human growth hormones for any use that is not approved by the FDA faces up to 5 years in prison, and up to 10 years in prison if the offense involves a minor.

104. Pfizer subsidiary Pharmacia did not seek approval from the FDA for use of Genotropin for athletic performance enhancement, anti-aging, or cosmetic use. Pharmacia also did not submit information to the FDA asserting that such other uses would be safe, and the FDA never approved such other uses. Knowing that it was illegal to do so, and with the intent to defraud and mislead, Pharmacia nevertheless marketed Genotropin for unapproved uses, including athletic performance enhancement, anti-aging, and cosmetic use.

105. The illegal off-label marketing and sales promotion of Genotropin was very successful—Pfizer’s revenues from Genotropin increased from \$481 million in 2003 to \$843 million in 2007.<sup>33</sup> Similarly, the August 2004 edition of “Endocrine News” noted that a number of national studies had concluded that during 2001, when Pharmacia had already begun its efforts to illegally market the off-label use of Genotropin, “lifetime use of anabolic steroids was at a new high of 3.7 percent among 12th graders.”

106. In or about March 2007, Pharmacia entered into criminal guilty plea for the illegal promotion and sales practices of Genotropin. Pfizer’s subsidiary admitted that during

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<sup>33</sup> See Pfizer Form 10-K for 2003 and Pfizer Form 10-K for 2007 filed with the U.S. Securities and Exchange Commission.

visits to anti-aging doctors and clinics, “Pharmacia made misleading representations about the effectiveness of Genotropin as an anti-aging medication,” that it “knew it was illegal to promote Genotropin for Unapproved Uses such as anti-aging,” and that it had “earned millions of dollars in gross revenue from selling Genotropin for various Unapproved Uses.” Moreover, Pfizer’s subsidiary admitted that “[s]ome of the reasons that individuals took Genotropin had nothing to do with any medical condition, but instead were to obtain better skin tone, better skin elasticity, better general appearance, and better ability to lift more weights at the gym.”

107. In or about March 2007, Pharmacia also pleaded guilty to intentionally violating the Federal anti-kickback statute. Pharmacia admitted that it had knowingly and willfully offered excess payments on a contract with a drug distribution company to induce that company into recommending purchasing or ordering Pharmacia’s pharmaceutical products that were eligible for payment under a Federal health care program.

108. To settle the charges regarding the illegal promotion and sales practices of Genotropin and the charges related to the Federal anti-kickback statute, Pfizer entered into a deferred prosecution agreement with the U.S. Attorneys’ Office in Massachusetts. In addition, Pfizer agreed to pay \$34.6 million in criminal fines.<sup>34</sup>

#### **E. Defendants’ Obligations Under The 2002 and 2004 CIAs**

109. As noted above, as a result of the 2002 and 2004 settlements, Pfizer was required to implement “Corporate Integrity Agreements” mandating, among other things, the creation of an internal compliance mechanism specifically designed to report and elevate any

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<sup>34</sup> The criminal fine consisted of \$15 million for the illegal promotion and sales practices of Genotropin and \$19.6 million for intentional violations of the Federal anti-kickback statute.

non-compliance issues directly to the Board.

### **1. The 2002 CIA**

110. The 2002 CIA was signed on October 24, 2002 by various Pfizer lawyers, including by Pfizer deputy corporate compliance officer defendant Lankler. In the preamble, Pfizer represented that it had already voluntarily implemented compliance measures, including “the appointment of a Compliance Committee, a Disclosure Program ... and regular training” of “all employees of the Pfizer Pharmaceuticals Group located in the United States whose job responsibilities directly related to the promotion of prescription drug products to managed care facilities” and “those persons of Pfizer’s contract sales force whose job responsibilities directly related to Managed Care Contracting.”

111. The 2002 CIA required Pfizer to “implement written policies and procedures regarding the operation of Pfizer’s Compliance Program, and its compliance with Federal health care program requirements.” Those policies and procedures were required to address, among other things, “promotional practices that conform with all applicable Federal health care program requirements, including but not limited to, the Federal anti-kickback statute, codified at 42 U.S.C. § 1320a-7b.”

112. The 2002 CIA also required the Company to establish an internal mechanism for directly reporting compliance violations to the Board and required active involvement by the Board in policing Pfizer’s compliance with the FDCA and the federal anti-kickback statute. For example, the 2002 CIA specifically required Pfizer’s Compliance Officer “*make periodic (at least semi-annual) reports regarding compliance matters directly to the Board of Directors of Pfizer (or its designated subcommittee, in such form or manner as the Board of Directors determines), and shall be authorized to report on such matters to the Board of*

*Directors any time.*” From 2002 until his appointment as Pfizer’s Chief Executive Officer in 2006, defendant Kindler was the “Compliance Officer” who had the obligation to make those periodic (at least semi-annual) reports to the Board.

113. Documents prepared by Pfizer personnel show the clear understanding of Pfizer’s senior management and the Board that the 2002 CIA required the Board to be actively involved in policing Pfizer’s compliance with the FDCA and the Federal anti-kickback statute. For example, on June 9, 2003, defendant Lankler gave a presentation at the 2003 Pharmaceutical Congress entitled “Living With a Corporate Integrity Agreement” that included bullet points stating: “*Make sure everyone knows about the CIA and understands its impact,*” “*Frequent reminders,*” “*Involve Board; keep them involved,*” and “*Document everything.*”

## **2. The 2004 CIA**

114. As with the 2002 CIA, the 2004 CIA was signed by Pfizer deputy compliance officer Defendant Lankler and required the establishment of mechanisms to ensure direct reporting to senior management and the Board concerning compliance or non-compliance with the FDCA, the federal anti-kickback statute, and federal healthcare program requirements. The 2004 CIA required Pfizer to maintain a disclosure program to enable employees to report violations of federal health care law and FDA regulations to senior management and the compliance department. It further required the Compliance Officer to maintain a disclosure log to record a summary of each received disclosure, the status of any review, and any corrective action taken in response. The disclosure program was required to “emphasize a nonretribution, nonretaliation policy” and to “include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained.”

115. The 2004 CIA emphasized the required monitoring and oversight role of the Board in ensuring that Pfizer would not again engage in illegal marketing and sales promotions of its drugs. It provided that Pfizer's Chief Compliance Officer and Pfizer's Deputy Compliance Officer—defendants Kindler and Lankler, both members of senior management—“shall make periodic (at least semi-annual) reports regarding compliance matters directly to the Board of Directors of Pfizer (or its designated subcommittee, in such form or manner as the Board of Directors determines), and both shall be authorized to report on such matters to the Board of Directors at any time.” The 2004 CIA required that “these periodic reports” inform “the Directors . . . of Pfizer's continuing activities and obligations under the [2004 CIA].”

116. The 2004 CIA also noted that “the Directors have agreed to abide by a Code of Conduct which they adopted.” As described above, the Code of Conduct and Ethics required the Board, among other things, to “comply, and oversee compliance by employees, officers and other directors, with laws, rules and regulations applicable to the Company.” The 2004 CIA further required “all officers directly involved in Pfizer's US Pharmaceutical operations” to certify that they “read, received, understood and shall abide by Pfizer's [Code of Conduct and Ethics],” including the requirement that they would be “expected to comply with all Federal health care program requirements and FDA requirements.” As president of Pfizer's pharmaceutical operations, defendant Read must have certified that he received, read, understood, and would abide by Pfizer's Code of Conduct and Ethics.

117. Defendants also agreed to implement written policies and procedures regarding the operation of Pfizer's compliance program and that those policies would, among other things, address:

- (i) The methods for selling, marketing, promoting, advertising, and disseminating information about off-label uses of Pfizer's products in compliance with all FDA requirements;
- (ii) Policies designed to ensure that speaker meetings, advisory board meetings and all other consulting arrangements would be used for legitimate purposes in accordance with applicable Federal health care program requirements and with FDA requirements relating to the dissemination of information about off-label uses of products;
- (iii) Policies designed to ensure that Pfizer's sponsorship or funding of grants, research or related activities (including clinical trials, market research or authorship of other articles) comply with all applicable Federal health care program and FDA requirements; and
- (iv) The methods for selling, marketing, and promoting Pfizer products in compliance with all applicable Federal health care program requirements, including, but not limited to, the Federal anti-kickback statute.

118. Pfizer's senior management and the Board understood the key role of the compliance department and the Board in protecting the Company and its shareholders from potentially ruinous consequences of any future noncompliance with the requirements of the FDCA and the federal anti-kickback statute. For example, as stated in Pfizer's 2009 Corporate Responsibility Report:

Pfizer's Corporate Ethics and Compliance Program, established under the direction of our Board of Directors, supports the company's unyielding commitment to high standards of legal and ethical conduct. Through the program, our Corporate Compliance Officer and staff provide oversight and guidance to ensure compliance with applicable laws, regulations and company policies, and foster a positive, ethical work environment for all employees.

119. As another example, on April 20, 2005, Defendant Lankler (then assistant general counsel and Pfizer's deputy compliance officer) gave a presentation at the 2005 HCCA Annual Compliance Institute stating that Defendant Kindler (then Pfizer's general counsel) had the "overall responsibility of company-wide compliance," that "everyone with compliance responsibility has dotted-line reporting to General Counsel," that Pfizer's



Corporate Compliance Committee reviewed “Hotline matters quarterly,” and that the Compliance Officer, “*reports to Board of Directors and Audit Committee* of Board as necessary.”

120. In 2005, defendant Kindler was both the General Counsel and the Compliance Officer discussed in defendant Lankler’s presentation. In his role as General Counsel and Pfizer’s Chief Compliance Officer, defendant Kindler was specifically charged under the 2004 CIA as the primary individual at the Company “responsible for developing and implementing policies, procedures, and practices designed to ensure compliance” with the federal health care laws, FDA regulation and the CIAs and for “monitoring the day-to-day compliance activities engaged in by Pfizer as well as for any reporting obligations created” under the CIA. The Board elevated defendant Kindler to the position of Pfizer’s CEO in 2006. At that time, defendant Waxman was promoted to become Pfizer’s general counsel and undertook an affirmative responsibility to ensure that Pfizer would obey the FDCA, FDA regulations regarding the promotion of off-label prescriptions, the federal anti-kickback statute, and the requirements of federal healthcare programs.

**F. September 2009 - The Government Imposes History’s Largest Criminal Fine And Largest Civil Fine For Any Healthcare Fraud**

**1. The Criminal Promotion of Bextra**

121. Bextra, also known under its generic name “valdecoxib,” is a drug that inhibits an enzyme that is responsible for transmitting inflammation and pain. The enzyme is called cyclooxygenase-2 and commonly referred to as “COX-2.” Bextra is therefore frequently referred to as a “COX-2 inhibitor.”

122. In or about October 2001, Pfizer entered into an alliance with Pharmacia to market Bextra together with Pfizer’s COX-2 inhibitor Celebrex, and to position both products

against another COX-2 inhibitor that was produced by competitor Merck (VIOXX). Pfizer acquired Pharmacia approximately one year later. As part of their pre-acquisition marketing alliance, Pfizer and Pharmacia shared information about sale and promotion strategies for both Bextra and Celebrex.

123. Prior to the acquisition by Pfizer, a New Drug Application (“NDA”) for approval of Bextra was submitted to the FDA seeking approval for Bextra to be used for the treatment of “acute pain” (including in connection with surgeries) and “dysmenorrhea” (severe uterine pain during menstruation) by administering 40 milligram (“mg”) of Bextra/valdecoxib per day. In addition, the NDA sought FDA approval for Bextra to be used for the treatment of chronic symptoms of arthritis at a dose of 10 mg per day, with the possibility to prescribe an additional 10 mg per day for certain patients.

124. In or about November 2001, the FDA denied the majority of applications of Bextra for which approval was sought in the NDA, in part because of concerns regarding the adverse health consequences of Bextra. In particular, the FDA rejected Bextra for use in treating “acute pain” because of safety concerns identified in a study of Bextra showing an increase of serious risks, including death, for certain patients who were given 40 mg of the drug per day.

125. According to the FDA the serious adverse events associated with Bextra included an increased risk of the formation of blood clots that could break loose and be carried by the blood stream to plug another vessel. If carried to the lungs, blood clots can lead to a potentially lethal pulmonary embolism. If carried to the brain, blood clots can lead to a potentially lethal stroke; if carried to the heart, blood clots can result in a potentially lethal heart attack.

126. In addition, the FDA concluded that the findings of this study warranted “further investigation before [Bextra] can be considered safe and effective for the treatment of pain, particularly multidose therapy in the perioperative setting,” or before, during or after surgery.

127. Ultimately, the FDA only approved Bextra “for the indications of osteoarthritis and rheumatoid arthritis at a dose of 10mg/day and dysmenorrhea at a dose of 20-mg bid as needed.”

128. Despite the FDA’s limited approval of Bextra, and the serious health concerns expressed by the FDA with respect to the other proposed uses of the drug, Defendants immediately created plans to market Bextra to a broad range of patients whose medical problems did not involve FDA-approved uses Bextra. Based on those plans, Defendants caused and permitted Pfizer and Pharmacia to: (i) illegally promote Bextra with false and misleading safety and comparative claims; (ii) create sham doctor requests for medical information about unapproved uses in order to send unsolicited information about unapproved uses and dosages of Bextra; (iii) distribute promotional samples with unapproved dosages to surgeons and other doctors who had no FDA-approved use for those samples; (iv) fund purportedly “independent” continuing medical education programs to promote Bextra for unapproved uses, including acute pain and surgical pain; and (v) employ a publication strategy by funding, sponsoring and sometimes drafting articles about Bextra for unapproved uses and dosages in order to promote such unapproved uses and dosages.<sup>35</sup>

129. There are numerous specific instances of improper and unlawful Bextra

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<sup>35</sup> See Criminal Information at ¶¶55-75, *United States v. Pharmacia*, 09-CR-10258 (DPW) (D. Mass. Sept. 2, 2009).

marketing and related evidence of misconduct that illustrate Pfizer's institutionalized attitude toward violating the law. For example:

- On or about March 12, 2002, Pfizer senior corporate counsel Heidi Chen and assistant general counsel Debbie Walters gave a presentation about the market for COX-2 inhibitors, including the "Pfizer/Pharmacia alliance," "COX-2 Portfolio Positioning" and "special COX-2 Challenges." Despite the FDA's express denial of approval for use of Bextra to treat acute pain in November 2001, the March 2002 presentation stated that Bextra would "pursue" acute pain and that the market "positioning message" of Bextra would be: "Meet All Arthritic & Pain Relief Needs." Elsewhere the presentation stated that, in 2001, the size of the "Arthritis and Pain Market" was \$9 billion in sales and that Bextra was projected to generate \$1 billion in sales by 2004 "or sooner!!";
- On October 28, 2002, Pfizer's Michael J. Langan sent an email to two colleagues discussing his visit to discuss Bextra with prescribing doctors who had no FDA-approved use for it. Although the FDA had expressly warned that further investigation was needed before Bextra "can be considered safe and effective for the treatment of pain, particularly multidose therapy in the perioperative setting," Langan reported the results of a meeting with the "Anesthesia Department the other day to discuss the role of COX II's in the Multi Modal Approach to Pain Surgical Management." Langan stated that during the meeting, one of the doctors remarked that sleep apnea (breathing pauses or shallow breathing during sleep) is "a major and common concern for patients under anesthesia for surgery." According to Langan, promoting Bextra and Celebrex for the non FDA-approved use of treating sleep apnea presented an excellent opportunity to promote Bextra and Celebrex for a new off-label use, stating "I can assure you that Merck is not targeting this market." Moreover, Langan offered to "expand on this during the [Institutional Health Representatives] conference call." On November 6, 2002, Pfizer's South Florida district manager Matthew Lustig forwarded Langan's email to numerous Pfizer sales representatives and institutional health representatives specializing in hospital visits.
- Between late 2001 and late 2003, Pharmacia held almost 100 consultant meetings (including over 5,000 health care professionals) to promote unapproved uses and dosages of Bextra.<sup>36</sup> For example, the 2003 Bextra and Celebrex Medical Education Plan showed that Pfizer and Pharmacia formulated an illegal strategy to "[e]nhance the value proposition to support broader utility" by focusing on the off-label promotion of Bextra for "(peri-op) dosing, multimodal therapy & emergency medicine" during ostensibly non-promotional continuing medical education meetings:



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<sup>36</sup> *Id.* at ¶¶37, 38.

**Strategies for Medical Education**

**Enhance the value proposition to support broader utility:**

- Utilize brand specific health economic & outcomes data
- Differentiate CELEBREX and BEXTRA by disseminating full extent of data (efficacy, GI, CV, neuronal plasticity)
- Educate physicians, NPs & PAs on the extent of OTC product use, and highlight the efficacy and safety benefits of COXIB portfolio over OTC brands
- Educate on concept of multi-modal therapy and differing pain models to penetrate the non narcotic & opioid/combo market
- Drive increased hospital utilization of portfolio through focus on pre-op (peri-op) dosing, multi-modal therapy & emergency medicine

130. The strategy of off-label marketing and promotion of Bextra for acute pain and use in the perioperative setting continued after Pfizer completed the acquisition of Pharmacia in 2003.<sup>37</sup> During this time, Defendants continued to position Bextra as a competitor for VIOXX—which was used by physicians to treat acute pain.<sup>38</sup> In this regard, for example, Pfizer’s 2003 Bextra and Celebrex Medical Education Plan included the illegal suggestion to use continuing medical education meetings to “[p]ioneer new opportunities beyond arthritis and pain” and to “leverage oncology and other emerging areas.” At no time was there an FDA-approved use for Bextra in the treatment of cancer.

131. Throughout this time, the 2002 CIA was in effect. In May 2004, the 2004 CIA—with its enhanced provisions concerning compliance reporting to the Board—went into effect. Nevertheless, Defendants caused Pfizer’s unlawful Bextra marketing and promotion to

<sup>37</sup> See Information at ¶¶23-32, 39-51, *United States v. Pharmacia*, 09-CR-10258 (DPW) (D. Mass. Sept. 2, 2009).

<sup>38</sup> *Id.* at ¶24.

continue unabated, despite numerous red flags and other indications that this misconduct was ongoing and that it presented a threat to the Company.

132. On October 6, 2004, the European Medicines Agency (“EMA”) announced that it had safety concerns about COX-2 inhibitors such as Bextra, and that it would “review available long term data on cardiovascular safety for all licensed COX-2 inhibitors” within two weeks.<sup>39</sup> In October 2004, Pfizer also learned the results of a second study of Bextra in coronary artery bypass graft surgery (the “Second CABG study”). This study showed a statistically significant increase in thrombotic cardiovascular events in patients taking Bextra following the administration of another Pfizer drug called parecoxib.<sup>40</sup> Defendants were thus once again placed on notice that Bextra could pose serious health risks for patients, even if solely prescribed for FDA approved use and dosage. Defendants nevertheless turned a blind eye to the Company-wide illegal practice of promoting Bextra off-label for uses and dosages other than the uses and dosages approved by the FDA.

133. On January 10, 2005, the FDA sent a letter informing Robert B. Clark, Pfizer’s Vice-President for U.S. Regulatory Affairs, that certain Pfizer promotional materials contained misleading safety claims regarding Bextra, including safety claims that were “inconsistent with the Warning in the Bextra [FDA approved labeling] regarding serious and life-threatening ... side effects, including bleeding in the stomach and intestines.” The FDA letter also stated that a 27 minute Pfizer TV infomercial for Bextra was “misleading.” Pursuant to the terms of the 2004 CIA, the Compliance Officer and the Deputy Compliance Officer

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<sup>39</sup> See Doc. Ref. EMEA/97949/2004

<sup>40</sup> See Information at ¶20, *United States v. Pharmacia*, 09-CR-10258 (DPW) (D. Mass. Sept. 2, 2009).

informed the Pfizer Board of this FDA letter.

134. On February 17, 2005, the EMEA issued a public statement announcing regulatory action on all COX-2 inhibitors and stating that the EMEA's Committee for Medicinal Products for Human Use had concluded that "the available data show an increased risk of cardiovascular events for COX-2 inhibitors as a class."<sup>41</sup> The EMEA therefore announced a series of "interim measures" and recommended that "[g]iven the association between cardiovascular risk and exposure to COX-2 inhibitors, *doctors are advised to use the lowest effective dose for the shortest possible duration of treatment.*" Because of the exceptional financial importance to Pfizer, it is reasonable to infer that the Board and senior management were on notice of the EMEA's regulatory action. Despite the EMEA's findings and express recommendation to use the lowest effective dose for the shortest possible duration of treatment, Defendants continued to turn a blind eye to the illegal practice in the U.S. of promoting Bextra "off-label" for uses and dosages other than the uses and dosages approved by the FDA.<sup>42</sup>

135. On or about April 7, 2005, the FDA requested that Pfizer voluntarily withdraw Bextra from the U.S. market. The FDA explained that Bextra had been "been demonstrated to be associated with an increased risk of serious adverse [cardiovascular] events in two short-term trials." Defendants agreed to do so, and ceased all sales and promotion activities in the U.S., including the illegal promotion of off-label use for Bextra.

136. In June 2009, one of Pfizer's regional sales managers, Mary Holloway, was

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<sup>41</sup> See Doc. Ref. EMEA/62838/2004

<sup>42</sup> See Information at ¶22, *United States v. Pharmacia*, 09-CR-10258(DPW) (D. Mass. Sept. 2, 2009).

sentenced for her role in the off-label promotion of Bextra by the United States District Court for the District of Massachusetts to a fine and two years of probation. But Holloway was not acting on her own, in isolation or without the knowledge of her superiors at Pfizer. As Ms. Holloway's sentencing memorandum submitted to the United States District Court for the District of Massachusetts stated:

Ms. Holloway's region dutifully reported Bextra protocols attained for orthopedic, podiatry, urology, ob/gyn, ENT and dental indications, where much of the usage was off-label. *Corporate tracked this information, and at no time did it inform Ms. Holloway that any of the reported protocols were inappropriate.*<sup>43</sup>

137. On or about August 2009, Pfizer's subsidiary Pharmacia agreed to plead guilty to a criminal felony charge of violating the FDCA, admitting that it intentionally, and with the intent to deceive and defraud, marketed Bextra for uses and dosages that were not approved by the FDA. The deceptive sales conduct regarding Bextra took place from February 2002 through April 2005. During this time, Defendants knew that Bextra was dangerous to human life. As noted by the DOJ on September 2, 2009, "*Pfizer promoted the sale of Bextra for several uses and dosages that the FDA specifically declined to approve due to safety concerns.*"

## 2. Pfizer's Pays \$1.3 Billion In Criminal Fines And Forfeitures

138. To settle the pending criminal charges, Pfizer agreed to pay a fine of \$1.195 billion, which, according to the DOJ, is "*the largest criminal fine ever imposed in the United States for any matter.*" The calculation of the fine was set forth in an August 31, 2009 letter from the prosecuting attorney to Pfizer's counsel. The letter documented the agreement with Pfizer's subsidiary to pay a \$1.195 billion fine and \$105 million in criminal forfeitures in part

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<sup>43</sup> See Mary Holloway's Sentencing Memorandum to the Federal District Court of Massachusetts at 7, Case Number 09-cr-10089-JGD (D. Mass. June 12, 2009).



because:

[T]he organization had 5,000 or more employees, and an individual within the high level personnel of the unit participated in or condoned the offense and/or *tolerance of the offense by substantial authority personnel was pervasive throughout the organization.*

139. According to the government's prosecuting attorney, the size of the punishment of Pfizer reflected "*the seriousness and scope of Pfizer's crimes.*" The government's prosecuting attorney added that "Pfizer violated the law over an extensive time period" and that "at the same time Pfizer was in our office negotiating and resolving the allegations of criminal conduct by its then newly acquired subsidiary, Warner Lambert, Pfizer was itself in its other operations violating those very same laws. Today's enormous fine demonstrates that such blatant and continued disregard of the law will not be tolerated."

### **3. Pfizer's \$1 Billion Civil Settlement**

140. In addition to paying \$1.3 billion in criminal fines regarding the illegal promotion and sales practices of Bextra, Pfizer agreed to pay another \$1 billion to settle civil claims by the government that the Company had violated the False Claims Act, including prohibited off-label use and dosage promotions, and violations of the Federal anti-kickback statute, with respect to 13 different drugs. According to the DOJ, this is "*the largest civil fraud settlement in history against a pharmaceutical company.*" Further, as Assistant Attorney General Tony West commented in connection with the announcement of the settlement, "[t]his civil settlement and plea agreement by Pfizer represent yet another example of what penalties will be faced when a pharmaceutical company *puts profits ahead of patient health.*"

141. Pfizer's charged illegal conduct, which spanned almost eight years, between January 1, 2001 and October 31, 2008, involved Company-wide marketing practices and some

of Pfizer's most material and important products. Of Pfizer's nine most important pharmaceutical products—those so-called “blockbuster” drugs generating over \$1 billion per year in revenue each (representing 60 percent of the Company's total pharmaceutical revenues in 2008)—*seven* (Lipitor, Norvasc, Lyrica, Celebrex, Viagra, Geodon and Zyvox) were included in the \$2.3 billion settlement as drugs that were promoted for off-label uses and/or through illegal kickbacks and other improper means. Indeed, Defendants have admitted in Pfizer's SEC filings that if any of those drugs “become subject to problems such as...regulatory proceedings,” it could have a “significant” impact on the Company's revenues.

142. Pfizer's violations were plainly not isolated incidents, or the work of a small number of “rogue” employees. Rather, the \$1 billion payment to settle those charges was the punishment for a deliberate general business strategy designed, implemented and approved at the highest levels of the Company to illegally promote off-label drug use. The settlement agreement, which identifies four major Pfizer pharmaceuticals that were extensively promoted for off-label uses, summarizes some of this misconduct as follows:

- (1) **Bextra:** During the period February 1, 2002, through April 30, 2005, Pfizer:
  - (a) illegally promoted the sale and use of Bextra for a variety of conditions (including acute pain and various types of surgical pain) and at dosages other than those for which its use was approved by the Food and Drug Administration (“FDA”) (*i.e.*, “off-label” uses), in violation of the FDCA, 21 U.S.C. § 331, *et seq.*, and which were not medically-accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6) for which the United States and state Medicaid programs provided coverage for Bextra;
  - (b) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Bextra, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); and
  - (c) made and/or disseminated unsubstantiated and/or false representations or statements about the safety and efficacy of Bextra. As a result of the

foregoing conduct, Pfizer knowingly caused false or fraudulent claims for Bextra to be submitted to, or caused purchases by, Medicaid and the other Federal Health Care Programs.

(2) **Geodon:** During the period from January 1, 2001, through December 31, 2007, Pfizer:

- (a) illegally promoted the sale and use of Geodon for a variety of off-label conditions (including depression, bipolar maintenance, mood disorder, anxiety, aggression, dementia, attention deficit hyperactivity disorder, obsessive compulsive disorder, autism and post-traumatic stress disorder), and for patients (including pediatric and adolescent patients) and dosages that were off-label, in violation of the FDCA, 21 U.S.C. § 331, *et seq.*, and which were not medically-accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6) for which the United States and state Medicaid programs provided coverage for Geodon;
- (b) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Geodon, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); and
- (c) made and/or disseminated unsubstantiated and/or false representations or statements about the safety and efficacy of Geodon. As a result of the foregoing conduct, Pfizer knowingly caused false or fraudulent claims for Geodon to be submitted to, or caused purchases by, Medicaid, Medicare and the other Federal Health Care Programs.

(3) **Zyvox:** During the period January 1, 2001, through February 28, 2008, Pfizer:

- (a) illegally promoted the sale and use of Zyvox for a variety of off-label conditions (including infections caused by methicillin-resistant *Staphylococcus aureus* (“MRSA”) generally, rather than only those types of MRSA infections for which Zyvox was FDA-approved), in violation of the FDCA, 21 U.S.C. § 331, *et seq.*, and which were not medically-accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6) for which the United States and state Medicaid programs provided coverage for Zyvox;
- (b) made and/or disseminated unsubstantiated and/or false representations or statements about the safety and efficacy of Zyvox (including that Zyvox was superior to vancomycin, its primary competitor drug for these indications); and
- (c) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Zyvox, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320-7b(b). As a result of the foregoing conduct, Pfizer knowingly caused false or fraudulent claims for

Zyvox to be submitted to, or caused purchases by, Medicaid, Medicare and the other Federal Health Care Programs.

- (4) **Lyrica:** During the period September 1, 2005, through October 31, 2008, Pfizer:
- (a) illegally promoted the sale and use of Lyrica for a variety of off-label conditions (including chronic pain, neuropathic pain, perioperative pain, and migraine), in violation of the FDCA, 21 U.S.C. § 331, et seq., and which were not medically-accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6) for which the United States and state Medicaid programs provided coverage for Lyrica;
  - (b) made and/or disseminated unsubstantiated and/or false representations or statements about the safety and efficacy of Lyrica, including claims that it was superior to Neurontin and its generic equivalent, gabapentin; and
  - (c) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Lyrica, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320-7b(b). As a result of the foregoing conduct, Pfizer knowingly caused false or fraudulent claims for Lyrica to be submitted to, or caused purchases by, Medicaid, Medicare and the other Federal Health Care Programs.
- (5) **Kickbacks:** From January 2001, through December 2004, Pfizer paid illegal remuneration for speaker programs, mentorships, preceptorships, journal clubs, and gifts (including entertainment, cash, travel and meals) to health care professionals to induce them to promote and prescribe the drugs Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zolofit, and Zyrtec, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). As a result of the foregoing conduct, Pfizer caused false claims to be submitted to Medicaid and TRICARE.

143. In the course of resolving these allegations against the Company, Defendants made significant admissions evincing a shocking disregard for the health and safety of the millions of patients who took Pfizer's drugs. Defendants admitted, for example, that the illegal promotion of Bextra described in Section IV.F.1, *supra*, continued on its watch long after the Company acquired Pharmacia in 2003, and despite repeated warnings that to do so would jeopardize human life.

144. Defendants have also admitted specific facts regarding the illegal marketing of

Zyvox—an antibacterial agent that is approved by the FDA to treat certain types of infections, including nosocomial pneumonia caused by methicillin-resistant staphylococcus aureus (“MRSA”)—that underscore the cavalier attitude Defendants took in ensuring compliance with Pfizer’s legal obligations and the obligations specifically imposed upon them by the 2004 CIA. In this regard, Defendants have admitted that, under their management and leadership, Pfizer continued to illegally misbrand Zyvox even after the FDA issued a Warning Letter to Pfizer’s Chairman and CEO on July 20, 2005 expressly warning that such conduct violated federal law.

145. After receiving the FDA Warning Letter, Defendants agreed, at the FDA’s request, to publish a corrective advertisement noting the FDA’s objection to Pfizer’s earlier superiority claims and to take steps to ensure that the advertisement and similarly objectionable promotional would not be used by sales representatives. But, as Defendants admitted in papers filed in connection with the 2009 settlement, the Company—with the knowledge and encouragement of headquarters-based executives—continued to promote Zyvox through the very unsubstantiated claims that the FDA identified as false, misleading and unlawful. In particular, Defendants admitted that that this misconduct continued even after its Chairman and CEO received the FDA warning letter:

Pfizer’s sales representatives thereafter continued to make claims to physicians that Zyvox was superior to [competitor drug] vancomycin for certain patients with MSRA, which included the claim that Zyvox would have a higher cure rate, and would save more lives, despite the fact that these claims were inconsistent with the FDA’s Warning Letter and Zyvox’s FDA approved label, and which were inconsistent with the manner in which Pfizer, after receipt of the Warning Letter, agreed to present the clinical data cited by the FDA.

#### **4. The 2009 CIA**

146. In addition to paying the largest criminal fine and the largest civil fraud

settlement in history, the government imposed on Pfizer's Board yet another Corporate Integrity Agreement (the "2009 CIA"). The 2009 CIA supersedes the 2004 CIA and includes additional, enhanced compliance requirements that directly reflect the government's loss of faith in the ability of Pfizer's senior management and the Board to ensure Pfizer's compliance with the FDCA, the federal anti-kickback statute and other healthcare regulations. In large measure, the 2009 CIA reflects a government takeover of monitoring and ensuring corporate governance at Pfizer because of the repeated and knowing refusal of senior management and the Board to do so.

147. *First*, the 2009 CIA imposes new obligations on the Audit Committee, requiring the Audit Committee to meet quarterly to review and oversee the Company's compliance activities and evaluate their effectiveness. Moreover, upon each quarterly review, the Audit Committee must adopt a resolution summarizing its inquiry into and oversight of Pfizer's compliance with federal health program requirements, FDA regulations and the Company's obligations under the CIA. The resolution—which must be signed by each individual member of the Audit Committee—must verify that Pfizer's compliance program has been effective to "meet Federal health care program requirements, FDA requirements, and the obligations of the CIA." If an Audit Committee member is unable to provide such an affirmation, the Audit Committee must include a written explanation of the reasons "why it is unable to provide the conclusion and the steps it is taking to assure implementation by Pfizer of an effective Compliance Program at Pfizer."

148. *Second*, the 2009 CIA mandates similar compliance measures for management, requiring that the presidents and finance directors of each business unit involved in pharmaceutical sales complete a certification affirming that they have taken appropriate

steps to ensure compliance, that the relevant business unit's leadership team has not directly or indirectly encouraged policy violation, and that controls are operating effectively. Similar to the verifications required of the Audit Committee members, the management certifications must also affirm that the certifying individual has reviewed 1) internal reports addressing promotional quality assessments; 2) reports of speaker programs, advisory boards, consultant payments, travel and entertainment expenses; 3) sales compensation exclusion criteria; and 4) corporate compliance group statistics. In addition, the certifying executive must verify that no violation of law, regulation, Pfizer policy or the CIA has occurred, or if an issue has been identified, affirm that the potential violations have been referred to the Corporate Compliance Group or a member of the Pfizer legal division.

149. *Third*, the 2009 CIA requires the Board to review compliance measures on a more frequent basis, requiring that the Chief Compliance Officer submit reports to the Board's Audit Committee on at least a quarterly basis. Further, the Chief Compliance Officer—who can no longer be the same individual who acts as general counsel for the Company—cannot be subordinate to the General Counsel or the CEO, but must be a member of senior management who reports directly to the Chief Executive Officer. This significant change will require that defendant Douglas M. Lankler, who currently serves as Pfizer's Chief Compliance Officer and who signed the 2002 and 2004 CIAs, be replaced, and represents a significant departure from the practice under the 2004 CIA, under which defendant Kindler acted as both Pfizer's General Counsel and its Chief Compliance Officer.

**G. The Largest Criminal Fine Ever And The Largest Civil Fine For Any Healthcare Fraud In History Were The Result Of The Defendants' Conscious Breach of Their Duties**

150. Under the 2002 and 2004 CIAs, Defendants agreed to implement and monitor

a comprehensive compliance mechanism that would ensure that Pfizer would not commit criminal violations under the FDCA and the federal anti-kickback statute. In stepping forward and agreeing to preside over the compliance apparatus installed as a result of the CIAs, Defendants—and the directors on the Board in particular—created the impression that they had *acted* and taken control of the situation with a full appreciation of the prior wrongdoing and risks for the Company, and that they were actively involved in remedying the Company’s culture of chronic legal violations. In reality, however, they consciously failed to carry out these affirmative obligations, thereby perpetuating and encouraging the Company’s widespread misconduct

151. The 2002 and 2004 CIAs contained extensive reporting requirements to make senior management and the Board aware of non-compliance with and violation of the relevant drug marketing laws. Between 2002 and April 2009, Pfizer’s Chief and Deputy Compliance Officers thus informed the Compliance Committee, the Audit Committee and other members of the Board repeatedly of allegations that numerous Pfizer employees were violating the FDCA, FDA regulations, Federal healthcare program regulations and the Federal anti-kickback statute with regard to numerous drugs. Among other red flags, the members of the Board were informed of:

- ***July 1, 2002 FDA violation notice regarding Neurontin:*** informing Pfizer that it violated the FDCA by using a model that was “misleading because it suggests that Neurontin is useful for a broader range of [Central Nervous System] conditions than has been demonstrated by substantial evidence.” The FDA therefore requested that Pfizer “immediately discontinue the use of this model and of any promotional material with the same or similar issues.”
- ***August 12, 2002 FDA violation notice regarding Lipitor:*** informing Pfizer that it violated the FDCA by placing a print ad in magazines with a national distribution such as Time that “misleadingly suggests that Lipitor is safer than [competitor drugs].” The FDA therefore requested that Pfizer “immediately discontinue this ad and all other promotional materials and activities for Lipitor that contain claims the



same or similar violative presentations.”

- **September 3, 2002 FDA violation notice regarding Geodon:** informing Pfizer that it violated the FDCA by engaging in the promotion of Geodon “in a manner that is misleading and lacking fair balance because it minimizes important risk information regarding the greater capacity of Geodon to cause QT prolongation, and the potential to cause torsade de pointes-type arrhythmia and sudden death.” The FDA therefore requested that Pfizer “immediately discontinue the use of these and any other promotional materials and activities with the same or similar issues” and “to respond to this letter within ten days,” including “a list of all promotional materials with the same or similar issues.”
- **2003 anti-kickback statute violation reports regarding Lipitor, Viagra, Zyrtec, Norvasc, Zithromax, Zoloft, Glucotrol:** by Pfizer employee Blair Collins to compliance personnel. Collins alleged that he was improperly forced to resign in retaliation for making these reports, and he commenced a *qui tam* action in 2004.
- **October 24, 2003 FDA violation notice regarding Covera-HS** (a calcium channel blocker relaxing the muscles of the heart and blood vessels): informing Pfizer that it violated the FDCA by using a sales aid that “misleadingly overstates the efficacy of Covera-HS and minimizes its risks.” The violation notice explained that the sales aid continued a number of unsubstantiated claims, including superiority claims, based on a single study that suffered from “design flaws.” The FDA therefore requested that Pfizer “immediately cease the use of this sales aid and of any other promotional materials for Covera-HS that contain claims the same or similar to those described above.”
- **November 17, 2003 FDA violation notice regarding Camptosar** (a cancer medication): informing Pfizer that it violated the FDCA by including a visual aid in its promotional materials that “omits material facts with respect to potentially life-threatening adverse event for Camptosar and contains inaccurate information related to important dose modifications that are needed to manage potentially serious adverse events.” The FDA further concluded that the visual aid “misbrands Camptosar within the meaning of 21 U.S.C. §§ 321(n) and 352(a) because the presentation and omission of risk information misleadingly suggest the drug is safer than has been demonstrated by substantial evidence or substantial clinical experience.” The FDA therefore requested that Pfizer “immediately cease the dissemination of this sales aid and of any other promotional materials for Camptosar that contain claims the same or similar to those described above.”
- **2003-2004 misleading promotion reports regarding Geodon, Bextra, Celebrex, Relpax, and Lyrica:** by Pfizer employee Glenn Demott to Pfizer’s national compliance office in New York about the illegal use of unreliable and flawed studies to improperly promote the drugs’ efficacy. Demott alleged that he was improperly forced to resign in retaliation to making these reports, and he commenced a *qui tam* action in 2005.

- **2004 Neurontin Settlement:** including (i) the facts and circumstances leading to the second largest criminal fine that was ever imposed in a health care fraud prosecution before 2004, such as illegal promotion of off-label uses, dissemination of misleading information to doctors, and improper offers of remuneration to doctors to induce prescription of a Pfizer drug; and (2) the 2004 CIA, including the obligations of Pfizer employees, officers and directors.
- **April 22, 2004 FDA violation notice regarding Zyrtec-D:** that it illegally misbranded Zyrtec-D by using a professional sales aid and making promotional statements on a Pfizer website that omitted “information concerning the risks of Zyrtec-D.” The FDA noted that “the omission of this risk information is a public health concern because Zyrtec-D is contraindicated for several patient populations, and the ingestion ... may cause serious adverse health consequences.” The FDA therefore requested that Pfizer “immediately cease the dissemination of promotional materials for Zyrtec-D the same or similar to those described above.”
- **November 10, 2004 FDA violation notice regarding Viagra:** informing Pfizer that it illegally misbranded Viagra by claiming in two television advertisements that “Viagra is intended for sex” while the advertisements “omit the indication of the drug (namely, treatment of erectile dysfunction) and fail to provide information relating to major side effects and contraindications of the drug.” The FDA therefore requested that Pfizer “immediately cease the dissemination of promotional materials for Viagra the same or similar to those described above.”
- **January 10, 2005 FDA violation notice regarding Bextra and Celebrex:** informing Pfizer that the FDA had reviewed five promotional pieces and that those materials variously “omit material facts, including the indication and risk information; fail to make adequate provision for the dissemination of the FDA-approved product labeling; and make misleading safety, unsubstantiated superiority, and unsubstantiated effectiveness claims.” The FDA noted that Bextra and Celebrex were “associated with a number of serious risks” and requested that Pfizer immediately cease the dissemination of violative promotional materials. The FDA further noted that “[t]he seriousness of the violations concerning your promotion of Celebrex described above would generally have warranted a Warning Letter; however, in light of your recent agreement to voluntary suspension on all consumer promotion for Celebrex, we do not feel that is appropriate at this time. You should be aware, however, of the serious nature of the violations described above and act to avoid disseminating similarly misleading promotion materials for your products in the future.”
- **April 13, 2005 FDA Warning Letter:** directly sent to the attention of Pfizer’s Chief Executive Officer to inform Pfizer of misbranding of Zyrtec distributing direct to consumer print advertisements that “make superiority claims about Zyrtec by suggesting it is clinically superior to some other allergy medicines” while “these claims have not been demonstrated by substantial evidence or substantial clinical experience.” The FDA noted that it had sent three previous violation notices to Pfizer

about Zyrtec and that the FDA and the FTC had also sent a joint letter to Pfizer expressing concerns about Zyrtec promotion materials making unsubstantiated claims. The FDA therefore requested that Pfizer “immediately cease the dissemination of violative promotional materials for Zyrtec that contain claims the same or similar to those described above.”

- **May 6, 2005 FDA violation notice regarding Zoloft:** informing Pfizer that it violated the FDCA by misbranding Zoloft when it placed a false or misleading advertisement in the New York Times Magazine that omitted “important information relating to the risk of suicidality in patients taking Zoloft.” The FDA noted that “[t]his ad is concerning from a public health perspective because it fails to include a serious risk associated with the drug.” The FDA therefore requested that Pfizer “immediately cease the dissemination of promotional materials for Zoloft the same or similar to those described above.”
- **July 20, 2005 FDA Warning Letter:** directly sent to the attention of Pfizer’s Chief Executive Officer to inform Pfizer of serious violations of the FDCA and FDA implementation regulations regarding advertising for ZYVOX by: (i) improperly claiming that ZYVOX was superior to another drug without medical evidence supporting the claim; (ii) improperly suggesting off-label use of ZYVOX by claiming, without substantial evidence or substantial clinical experience, that ZYVOX could be used to treat a broader range of infections than the use approved by the FDA; and (iii) failing to reveal important risk information that may result from the use of ZYVOX.
- **2006 off-label promotion reports regarding Lyrica:** by Pfizer PSR Robert Liter to Pfizer compliance personnel, to Pfizer’s corporate counsel Lisa Shroyer, and to Pfizer’s outside counsel from Davis Polk & Wardwell LLP about the illegal off-label promotion of Lyrica, including by producing unsolicited “medical inquiries”—requests from doctors for information about a drug that are intended to help doctors determine whether or not a drug will be effective.
- **2006 and 2007 off-label promotion reports regarding improper marketing of Lyrica:** by Pfizer sales representatives David Farber and Casey Schildhauer who reported these improper and illegal marketing activities to Pfizer management. Farber and Schildhauer alleged that they were improperly forced to resign or terminated in retaliation to making these reports and commenced a *qui tam* action in 2007.
- **2006-2007 off-label promotion reports regarding Geodon:** by Pfizer sales representative Mark Westlock to compliance personnel, human resources, Pfizer district manager Cheryl Shaughnessy, Pfizer regional manager Curt McAllister, Pfizer vice-president Amy Pitts, and Pfizer president of U.S. pharmaceutical operations, Defendant Ian Read, regarding Pfizer’s illegal practice of promoting Geodon for the dangerous off-label use of treating agitated dementia in the elderly. Westlock alleged that he was improperly forced to resign in retaliation for making these reports, and he commenced a *qui tam* action in 2008.

- **2007 Genotropin settlement and deferred prosecution agreement:** of criminal charges regarding the promotion of off-label use of Pfizer's human growth hormone (steroids) Genotropin for athletic performance enhancement, anti-aging, or cosmetic use, and charges related to the Federal anti-kickback statute.
- **July 16, 2007 FDA violation notice regarding Geodon:** informing Pfizer that the FDA had reviewed a professional journal advertisement for Geodon that was "false or misleading because it omits important risk information and contains unsubstantiated superiority claims." The FDA stated that although the ad discussed some risk information the "journal ad fail[ed] to communicate other serious warnings and precautions associated with Geodon..." The FDA further stated that the ad was misleading because it implied that Gedeon was more effective than a competitor in a particular use "when this has not been demonstrated by substantial evidence or substantial clinical experience." The FDA requested that Pfizer "immediately cease dissemination of violative promotional materials for Gedeon..."
- **2008 qui tam lawsuit regarding allegations of off-label promotion of Zyvox:** filed by Pfizer District Manager Ronald Rainero and detailing allegations of improper off-label promotion, including management's encouragement of sales representatives to use misleading and unsubstantiated claims to promote the drug.
- **April 16, 2008 FDA Warning Letter:** directly sent to the attention of Pfizer's Chief Executive Officer, Defendant Kindler, to inform Pfizer of serious violations of the FDCA regarding advertising for VIAGRA because Pfizer's promotional material "raises public health and safety concerns through its complete omission of risk information for Viagra by suggesting that Viagra is safer than has been demonstrated." The FDA further stated that "Viagra is associated with headaches, flushing, dyspepsia and abnormal vision" and asked Pfizer to "immediately cease dissemination of violative promotional materials for Viagra that are the same as or similar to those described above."
- **March 26, 2009 FDA violation notice regarding Aromasin, Caduet, Chantix, Detrol, Lyrica, and Celebrex:** informing Pfizer that it violated the FDCA by sponsoring links on Internet search engines about these drugs that "fail to communicate any risk information associated with the use of these drugs." (Emphasis in original.) The FDA requested that Pfizer "immediately cease dissemination of violative promotional materials for Aromasin, Caduet, Chantix, Detrol, Lyrica, and Celebrex, such as those described above."

152. A majority of the Director Defendants (Defendants Burns, Burt, Cornwell, Gray, Horner, Lorch, Mead, and Steere) served on the Board at the time that each and every one of these regulatory issues was brought to the Board's attention. Further as noted above, defendant Kindler, the Company's current CEO and a director on the Board, was on the front

lines for many of these communications as he served as the Company's General Counsel and Chief Compliance and/or CEO at the time they occurred.

153. Time and again, the Board looked the other way, consciously ignoring these red flags and their express duty to intervene for almost eight years. Instead, Defendants retaliated against a number of the employees who had made the reports of illegal behavior. Defendants thereby violated their fiduciary duties of loyalty and good faith, and actively permitted and encouraged the lawbreaking employees to continue their illegal behavior. Defendants' breaches of fiduciary duty placed the Company and its shareholders at serious risk, and subjected the Company to the largest government fines in history.

#### **H. Another Criminal Conviction Could Have Catastrophic Consequences For Pfizer And Its Shareholders**

154. The Board's decision to allow a large part of Pfizer's business to be run as a *de facto* criminal enterprise has put (and if not stopped will continue to put) Pfizer and its shareholders at risk. On September 4, 2009, a *Bloomberg* article entitled "AIG of Drugmakers Pfizer Is Too Big to Be Guilty" noted that "Pfizer is fortunate to avoid criminal prosecution" and that "[g]iven the scope of the alleged misconduct, potential harm to the public, mistreatment of employees who insisted on following the law and its history as a repeat offender (excuse me, make that a repeat-settler), *it got off lightly.*"

155. In a December 2009 report of *Bloomberg Markets*, professor Lon Schneider of the University of Southern California's Keck School of Medicine in Los Angeles said that drug companies like Pfizer have an "unwritten business plan" that involves breaking the law and that they "regard the risk of multimillion-dollar penalties as just another cost of doing business." However, Pfizer may not get off so lightly if it were convicted of another crime. According to the September 4, 2009 *Bloomberg* article, "if Pfizer were convicted of a crime, it

would face debarment from federal programs” resulting in ruinous consequences for Medicaid and Medicare patients who “would have to either somehow pay pocket for vital medicines the company produces or go without.” As many millions of patients would not be able to afford Pfizer products, federal debarment would also lead to ruinous consequences for Pfizer and its shareholders.

156. There is good reason to believe that, notwithstanding recent events, Defendants are continuing on its path of widespread illegal marketing practices. Just two months after the Company informally agreed to the \$2.3 billion settlement in January 2009, Pfizer received a letter from the FDA informing Pfizer that it was violating Federal law by misbranding various drugs on the Internet by failing to provide any risk information. This even included one of the drugs covered by the \$2.3 billion settlement, Lyrica. The FDA stated that “the sponsored links misleadingly suggest that Aromasin, Caduet, Chantix, Detrol LA, Lyrica, and Celebrex are safer than has been demonstrated,” and demanded that Pfizer cease this illegal activity “immediately.”

V. **DEFENDANTS CAUSE PFIZER TO DISSEMINATE MATERIALLY INNACCURATE PROXY STATEMENTS**

157. Pfizer’s Annual Proxy Statements filed on SEC form DEF 14A on or about March 15, 2007 (the “2007 Proxy Statement”), March 14, 2008 (the “2008 Proxy Statement”), and March 13, 2009 (the “2009 Proxy Statement”) each were materially inaccurate in that they failed to disclose numerous highly material facts and circumstances. The materially inaccurate Proxy Statements caused direct harm to the Company in that, among other things, Defendants’ omissions perpetuated the systematic legal violations within the Company, which brought about the severe fines, penalties, and other liabilities to which the Company was ultimately subjected, as well as through the creation of compensation obligations by the

Company that would not have existed but for the materially inaccurate and incomplete Proxy Statements.

158. Each of these Proxy Statements included, as Appendix A, the Pfizer “Financial Report” for the previous year. Specifically, the 2007 Proxy Statement included Pfizer’s 2006 Financial Report (the “2006 Financial Report”) as Appendix A thereto; the 2008 Proxy Statement included Pfizer’s 2007 Financial Report (the “2007 Financial Report”) as Appendix A thereto; and the 2009 Proxy Statement included Pfizer’s 2008 Financial Report (the “2008 Financial Report,” and with the 2006 Financial Report and the 2007 Financial Report, the “Financial Reports”) as Appendix A thereto. Pfizer’s Financial Reports are published annually and are the principal documents through which information concerning the Company’s operations and financial condition are publicly disclosed. Each of the Financial Reports included, *inter alia*, a detailed narrative concerning Pfizer’s ongoing business operations (including specific annual sales figures for each Pfizer drug), the Company’s consolidated financial statements, and the notes to the Company’s consolidated financial statements. These disclosures thus formed a part of the Proxy Statements and were a critical element of the solicitation embodied in the Proxy Statements.

159. Each of the Proxy Statements was intended to, and did, procure Pfizer’s shareholders’ votes with respect to matters materially affecting the Company that legally required shareholder approval. All three Proxy Statements sought and obtained election of the Director Defendants by shareholder vote, in each case upon the Board’s explicit recommendation as to which directors should be elected. In addition, the 2009 Proxy Statement, sought and obtained shareholder approval for the Amended and Restated Pfizer Inc. 2004 Stock Plan (the “Restated Stock Plan”), which authorized a \$425,000,000 increase

in the stock available for grants to executives, outside directors (*i.e.*, all except defendants Kindler and Steere), and other Pfizer employees for as little as one year of positive performance. Defendants portrayed the Restated Stock Plan as a necessary increase in potential compensation to reward high-performing employees, officers and outside directors.

160. Each director on the Board was duty-bound—pursuant to their general fiduciary duties under Delaware law, the specific duties applicable of directors set forth in the Company’s foundational corporate documents, and by the clear provisions of the federal securities laws—to fully disclose all information material to shareholders’ decision concerning how to cast their votes in connection with the election of Board members in 2007, 2008 and 2009, and with respect to their decision whether to vote to approve the massive compensation increases embodied in the Restated Stock Plan.

161. The Board was also subject to an explicit affirmative disclosure duty under the Code of Conduct and Ethics governing the Board’s discharge of its duties. As described in Section IV.C, *supra*, pursuant to the Code of Conduct and Ethics, the Board was required to, among other things, ensure legal compliance within Pfizer, report any suspicions of non-compliance, and ensure that there were effective mechanisms in place so that misconduct would be reported to the Board. The Code of Conduct and Ethics further required that the Board was obligated to disclose to shareholders any waiver of or deviation from the terms of the Code of Conduct and Ethics, As set forth in the Code of Conduct and Ethics:

Any waiver of this Code may be made *only* by the Board of Directors and must be promptly disclosed to the Company’s shareholders. (emphasis in original)

162. The meaning, purpose, and intent of this express disclosure provision is clear: to ensure that the Board was either performing the specific functions set forth in the Code of Conduct and Ethics, or directly informing shareholders that the Board was declining to do so.



Indeed, the explicit inclusion in the Code of Conduct and Ethics of this affirmative disclosure obligation demonstrates that the other provisions of the Code—*e.g.*, those requiring the Board to report any suspicions of legal compliance—were highly material to shareholders, such that any deviation therefrom required express disclosure. This disclosure provision also demonstrates the significant reliance placed by shareholders on the Board’s discharge of the duties articulated in the Code of Conduct and Ethics. In other words, the Board’s obligations under the Code of Conduct and Ethics were regarded as so important that the Board could not deviate from them in any way without specifically informing shareholders of that decision.

163. Despite its obligations under fiduciary duty, the federal securities laws, and the Code of Conduct and Ethics, the Board caused the Company to file and disseminate the materially inaccurate Proxy Statements. Specifically, in Pfizer’s definitive Proxy Statements, Defendants provided materially similar information and disclosures concerning the Company (including its financial statements), the general responsibilities of the Board and its Committees, and the basis upon which the members of the Board (or prospective members of the Board) were seeking election to another (or initial) term of office. However, in the Proxy Statements, Defendants uniformly failed to disclose material information to shareholders concerning critical aspects of the Board’s responsibilities and activities—such as the Board’s obligation to assure compliance with applicable drug marketing laws and regulations, or the fact that the financial and operating metrics disclosed in the Proxy Statements were the result of widespread criminal misconduct within Pfizer that the Board was duty-bound to prevent.

164. Pfizer’s unique history of recurring corporate misconduct and ensuing regulatory troubles—embodied in its prior failures to comply with the federal drug marketing laws—also made specific information about the Board’s role in and oversight of the

Company's compliance efforts particularly material to Pfizer shareholders. Indeed, federal regulators had made a specific decision to place internal responsibility to improve and assure compliance with the law squarely upon the Board. In agreeing to the CIAs, the Board affirmatively and expressly accepted this responsibility, a fact that the Company, its shareholders, and the relevant federal regulators relied upon. The existence of the CIAs, their very real and serious implications for the conduct of the Board, and any actions taken by the Board to comply with the CIAs, were each material facts concerning the decision whether or not to elect or re-elect (as the case may be) the director-candidates proposed and recommended by the then-current members of the Board.

165. The 2007 through 2009 Proxy Statements were materially inaccurate and incomplete because, among other things, Defendants omitted to disclose:

- (i) The extent to which the Company's impressive disclosed financial performance depended on the Company's off-label marketing of Pfizer drugs—including seven of Pfizer's nine most important pharmaceutical products responsible for over a \$1 billion in revenue per year each—which exposed the Company and its shareholders to tremendous regulatory, reputational and financial risk;
- (ii) The nature of the Board's responsibilities pursuant to the CIAs. Defendants disclosed no information concerning the implementation (or failure to implement) the duties and procedures required by the 2002 and 2004 CIAs, including what Board members and/or committees, if any, were responsible for receiving the regular required reports; the nature and content of any reports made pursuant to the CIAs; what actions, if any, they took based on these reports; the identity and responsibilities of third parties or outside consultants, if any, retained in connection with carrying out the duties of the Board under the CIAs, including their precise duties, their level and manner of compensation, and the existence of any potential conflicts of interest; and numerous other details relevant to shareholders' decisions with respect to whether to elect or re-elect individuals to the Board;
- (iii) The circumstances surrounding the Board's waiver or constructive waiver of explicit provisions of the Code of Conduct and Ethics—including with respect to Defendants' duties to ensure legal compliance, to ensure the reporting of legal violations, and to themselves report suspected non-compliance—even though the Board had waived or otherwise determined to deviate from these clear

requirements;

- (iv) The nature of the Board's performance of their duties under the charters of the Board's various committees, including the reason for the then-current Directors' decision to allow continued off-label and otherwise improper marketing despite the risks to the Company, its shareholders, or its patients;
- (v) The numerous instances in which the Board was informed of legal compliance violations concerning the unlawful marketing of Pfizer drugs.

166. In light of Defendants' highly material omissions from the Proxy Statements, the votes and the consequent election of directors to the Board were obtained on the basis of inaccurate disclosures. Had shareholders been provided with complete and accurate information concerning the Board's performance of its duties—including with respect to presiding over the Company's extensive criminal violations—the members of the Board would not have been elected (or reelected).

167. The election (or reelection) of the Director Defendants inflicted significant harm on the Company. In essence, the Board—by ostensibly taking control of the Company's legal compliance system established by the CIAs while, in reality, declining to actually perform the affirmative legal and compliance obligations—directly caused and perpetuated the Company's continued violation of the drug marketing rules. In this regard, the Board's assumption of affirmative compliance duties under the CIAs was directly relied upon by others—such as federal regulators and the Company's shareholders—who, based on that reliance, refrained from taking action to terminate the Company's systematic legal violations. This reliance on the Board's assumption of duty caused direct detriment of the Company, which, in the absence of the Board's fulfillment of its obligations, was left helpless to prevent the misconduct occurring in its name. The consequent criminal and civil penalties levied upon the Company, as well as the numerous other liabilities to patients and other third parties,

were a direct result of the Board's perpetuation of the Company's misconduct, which was only made possible by the materially inaccurate and incomplete statements that caused Defendants' election to the Board. But for the Board's assumption in the CIAs of duties vis-à-vis the compliance program, followed by the Board's refusal to carry out those very duties, the harm that befell the Company would not have occurred.

168. Further, shareholders would not have voted in favor of the Restated Stock Plan but for the materially misleading 2009 Proxy Statement. Had they been provided with complete and accurate disclosures, Pfizer shareholders would have chosen not to increase the compensation of employees, officers, and directors who participated in illegal marketing misconduct, and thereby reward them for their illegal activity. Rather, Pfizer's shareholders would have instead demanded that appropriate legal action be taken against those employees, officers and outside directors who participated in this widespread misconduct. Shareholders' approval of the Restated Stock Plan likewise harmed the Company by drawing off \$425,000,000 worth of stock directly from the Company in order to offer lavish compensation to senior executives and others at Pfizer—including the outside directors—in return for engaging in extensive criminal misconduct in Pfizer's name.

169. Accordingly, Pfizer has been damaged by the materially inaccurate statements and omissions in the 2007 through 2009 Proxy Statements that procured the reelection of Defendants to the Board, thus perpetuating their misconduct, as well as shareholders' approval for an increase in compensation for employees, officers, and outside directors who had been involved in wide-ranging criminal conduct—a proposal that would have been rejected had the true facts been disclosed to shareholders.

## **VI. DEMAND ON THE BOARD OF DIRECTORS WOULD BE FUTILE**

170. Lead Plaintiff brings this action derivatively in the right and for the benefit of Pfizer to redress the breaches of fiduciary duty and other violations of law by Defendants as alleged herein.

171. Lead Plaintiff will adequately and fairly represent the interests of Pfizer and its shareholders in enforcing and prosecuting its rights, and it has retained counsel experienced in prosecuting this type of action.

172. Lead Plaintiff incorporates by reference all preceding and subsequent paragraphs as though they were fully set forth herein.

173. At the time this action was initiated, the Board was comprised of fourteen (14) directors: defendants Ausiello, Brown, Burns, Burt, Cornwell, Gray, Horner, Kilts, Kindler, Lorch, Mead, Johnson, Sanger and Steere (defined earlier as the “Director Defendants”). Lead Plaintiff did not issue a demand upon the Director Defendants prior to instituting this action because a majority of the Director Defendants either: (a) engaged in conduct that is not a legitimate exercise of judgment and/or is *ultra vires* and, therefore, cannot enjoy the protections of the business judgment rule; and/or (b) would have been “interested” in (and therefore conflicted from and unable to fairly consider) a demand because they face a substantial likelihood of liability for their role in Pfizer’s improper conduct.

### **A. Demand Is Excused Because The Director Defendants’ Conduct Is Not A Valid Exercise Of Business Judgment**

174. The Director Defendants’ challenged misconduct at the heart of this case constitutes the direct facilitation of criminal activity, including knowingly and consciously presiding over the Company’s systematic violations of the drug marketing laws and regulations, as well as actively covering up this misconduct through the Director Defendants’

participation in and assurances with respect to the CIAs. In essence, as the “ultimate decision-making body” of the Company, the Board affirmatively adopted, implemented, and condoned a business strategy based on deliberate, widespread, and often criminal violations of law. Breaking the law is not a legally protected business decision and such conduct can in no way be considered a valid exercise of business judgment. Accordingly, demand on the Board is excused.

175. A derivative claim to recoup damages for harm caused to the Company by unlawful activity represents a challenge to conduct that is outside the scope of the Board’s business judgment—conduct for which the Board should face potential personal liability. Simply put, committing crimes, approving the commission of crimes by others, or looking the other way while refusing to prevent others under the Board’s control from committing crimes are all forms of misconduct that cannot under any circumstances be examples of legitimate business conduct. The protections of the “business judgment rule” do not extend to such malfeasance. Nor can such malfeasance ever constitute the “good faith” required of corporate fiduciaries.

176. Significantly, Pfizer’s unique history of non-compliance with the drug marketing laws and the consequent warnings, public reprimands, and imposition of the CIAs render the basis of this derivative action distinct from the case of virtually every other corporate board in the United States. A typical corporate board might plausibly claim ignorance concerning compliance failures in general. In this case, the Pfizer Board was made specifically and uniquely accountable and responsible under the CIAs for monitoring, ensuring, and enforcing the Company’s compliance with the drug marketing laws. Further, as discussed below, a majority of the current members of the Board served as directors while the

CIAAs were in effect and were, therefore, explicitly obligated to carry out these specific responsibilities. Their decision not to do so, and to instead knowingly cause Pfizer to undertake violation of the drug marketing laws as an intentional business strategy, cannot be regarded as a valid exercise of business judgment.

177. Moreover, this action does not arise from an anomalous incident of misconduct within the Company or from the acts of a rogue employee or division within the Company. Rather, as alleged herein, serious violations of the drug marketing laws occurred systematically and at every level of the Company as a direct result of the Board's decision to embrace a policy of calculated legal violations as the Company's deliberate business strategy. There is no legitimate "business judgment" involved in devising or carrying out such an unlawful policy. Accordingly, demand on the Board is futile and excused.

**B. Demand is Excused Because A Majority Of The Current Board Members Are Conflicted By A Substantial Likelihood Of Liability Arising From Their Misconduct**

178. Even if knowingly presiding over criminal misconduct could somehow fall within the ambit of the business judgment rule (which it does not), demand is also futile and excused because a majority of the members of the current Board are not disinterested or independent and cannot, therefore, properly consider any demand.

179. Specifically, nine (9) of the current members of the Board (defendants Brown, Burns, Burt, Cornwell, Gray, Horner, Lorch, Mead, and Steere) face a substantial likelihood of liability because they each served on the Board since at least 2002 (when Pfizer entered into the first CIA and well before the Relevant Period alleged herein).

180. As alleged herein (in Section IV.E, *supra*), pursuant to the CIAAs, each of these current Board members was required to be a direct participant in managing, implementing,

and overseeing the Company's compliance program and was systematically and repeatedly informed concerning the Company's widespread violations of the drug marketing laws, including through regular reports by the Compliance Officer.

181. As alleged herein (in Section IV.C, *supra*)—and pursuant to the Company's Corporate Governance Principles, Code of Business Conduct and Ethics, and Delaware law, as well as the compliance reporting required under the CIAs—these current Board members were also awash in other “red flags” that necessarily informed them of the rampant legal violations taking place within the Company.

182. Given these duties placed on the directors on the Board, to the extent any of these Director Defendants did not have actual knowledge of the extensive violations of the drug marketing laws taking place within Pfizer, such lack of knowledge could only be the product of willful blindness that constitutes a bad faith breach of their duties.

183. These Defendants were, moreover, required to act upon this information to protect the Company from continued legal violations being committed in its names. Rather than doing so, these Defendants, in violation of their legal obligations, consciously ignored the information presented to them and about which they were otherwise made aware concerning the Company's extensive legal violations. As a result, defendants Brown, Burns, Burt, Cornwell, Gray, Horner, Lorch, Mead, and Steere—constituting a nine (9) member majority of the current Board—face a substantial likelihood of liability for their conduct and demand is, therefore, excused.

184. Defendant Kindler is also currently a Board member and likewise faces a substantial likelihood of liability arising from his conduct. Although defendant Kindler was not on the Board at the time the Company entered into the 2002 and 2004 CIA's, he served as



the Company's General Counsel and Chief Compliance Officer at the time they were agreed to and for periods thereafter. Defendant Kindler was thus personally responsible for reporting to the Board concerning the Company's compliance or non-compliance with the relevant drug marketing laws and was, therefore, personally aware of the Company's extensive legal violations. Defendant Kindler, therefore, bears a substantial risk of personal liability as a result of his conduct and is fundamentally disabled from impartially considering a demand or to vigorously prosecute this action. Of course, Kindler brought all of his prior knowledge to the Board when he joined it in 2006 and is, therefore, just as culpable as the nine (9) Director Defendants discussed *supra*.

185. The Director Defendants are likewise conflicted from and unable to pursue the Company's claims against the Executive Defendants. Any effort to directly prosecute such claims against the Executive Defendants for their direct roles in the off-label marketing and other marketing improprieties carried out in Pfizer's name would necessarily expose the Board's own culpability for the very same conduct. In other words, given that the Board was required to be regularly informed concerning the Company's compliance or non-compliance with the drug marketing laws, any effort by the Director Defendants to hold the Executive Defendants liable would surely lead the Executive Defendants to defend on the ground that their own conduct was consistent with corporate policy and practice, as established and by and known to the Board.

186. Indeed, the treatment that the Director Defendants have extended to certain of the Executive Defendants in the time since Pfizer's guilty plea itself demonstrates the inability and/or unwillingness of the current Board to impartially consider demand or to vigorously prosecute this action. In particular, on October 28, 2009, Pfizer announced that the Board had

approved discretionary windfall payments of \$1.2 million and \$1 million, respectively, to defendants D'Amelio and Read. As stated in the Company's press release announcing these payments, the awards were ostensibly intended "to recognize their performance and leadership in connection with the successful completion of the acquisition of Wyeth on October 15, 2009." The current Board's willingness to shower financial rewards on these defendants, rather than seeking to punish and hold these individuals accountable for their misconduct, demonstrates the Board's utter inability and/or unwillingness to fairly consider demand or to vigorously prosecute this action.

187. Further, although half of these awards to defendants D'Amelio and Read were paid in cash (two days prior to the announcement), the other half of the awards was paid in stock-based compensation, using shares authorized by the Restated Stock Plan. As discussed in Section V, *supra*, the Restated Stock Plan was itself authorized pursuant to a shareholder vote based on the inaccurate and incomplete 2009 Proxy Statement. Thus, not only has the Board extended significant financial benefits to individuals against whom it should rightfully be taking legal action, but it has also done so using shares obtained by means of an inaccurate and incomplete solicitation that did not disclose, among other things, the very facts that should be prompting the Board to file suit against these defendants and that led to the criminal prosecution of the Company. In light of their continued willingness to provide substantial financial rewards to these Executive Defendants, and their use of improperly authorized stock-based compensation to do so, the members of the Board are clearly unable to impartially consider demand or to vigorously prosecute this action.

188. In addition to the foregoing, a majority of the Board's current members face a substantial likelihood of liability arising from their conduct on specific committees of the

Board.

189. Defendants Burns, Burt, Cornwell, and Johnson are conflicted from considering a demand because they each face a substantial likelihood of liability as a result of their conduct on the Audit Committee. Defendants Burns, Burt, and Cornwell have each served as directors on the Board since at least 2000 and have also served as members of the Audit Committee at various times during the Relevant Period. Defendant Johnson has served as a member of the Audit Committee since September 2007. As set forth in Section IV.C, *supra*, the Audit Committee's charter imposes specific duties on members of this committee to ensure compliance with laws, regulations, and internal procedures.

190. Moreover, the Audit Committee Charter also provides that the Audit Committee was responsible for reviewing major legislative and regulatory developments which could materially impact the Company's contingent liabilities and risks. Such developments necessarily included the 2002 and 2004 CIAs. As such, the Audit Committee was required to review these settlements and assess how the type of misconduct at issue could affect Pfizer's contingent liabilities and risks going forward. The Audit Committee Defendants violated their fiduciary duties to act in good faith to address the violations complained of herein. Accordingly, defendants Burns, Burt, Cornwell, and Johnson face a substantial likelihood of liability and cannot appropriately consider a demand, and therefore demand is excused with respect to these Defendants.

191. Further, Defendants Brown, Burns, Gray, Horner, and Ausiello are conflicted from considering a demand because they each face a substantial likelihood of liability as a result of their conduct on the Corporate Governance Committee. Defendants Brown, Burns, Gray, and Horner have each served as directors on the Board since at least 2000 and have also

served as members of the Corporate Governance Committee at various times during the Relevant Period. Defendant Ausiello has served as a member of the Corporate Governance Committee since 2007.

192. As noted previously (in Section IV.C, *supra*), pursuant to the Corporate Governance Committee's charter, the members of the Corporate Governance Committee are specifically charged with reviewing matters of corporate governance and maintaining an informed status on Company issues related to corporate social responsibility and its "visibility as a global corporate citizen." In addition, the members of the Corporate Governance Committee are required to "monitor emerging issues potentially affecting the reputation of the pharmaceutical industry and the Company." Defendants Brown, Burns, Gray, Horner, and Ausiello breached their fiduciary duties of due care, loyalty, and good faith, as they permitted a Company-wide scheme to repeatedly violate the laws and regulations as discussed above, despite the fact that they were on notice of the Company's illicit marketing activities and the consequences thereof to the Company. The repeated Company-wide conduct described above, which included the fraudulent promotion of drugs and the paying of kickbacks—placed profits ahead of patients, ultimately resulting in a record \$2.3 billion in fines and untold damage to the Company's reputation.

193. Moreover, the additional obligations imposed upon these Defendants pursuant to their membership on the Corporate Governance Committee—which mandated heightened vigilance to matters affecting Pfizer's standing as a "global corporate citizen," including the potentially devastating effect the further violation of the CIA (or other health regulations) would have on the Company's reputation (indeed, Pfizer's very ability to continue operating as a business)—underscores the severity of their breach of fiduciary duties in failing to in

good faith address the Company's rampant violations of law. The facts alleged herein clearly demonstrate that the Corporate Governance Committee failed to fulfill its duties and to ensure that the Company acted in a "socially responsible" manner. As a result, Pfizer now bears the dubious distinction of having received the largest criminal fine ever imposed on a public company for any legal violation. Accordingly, defendants Brown, Burns, Gray, Horner, and Ausiello face a substantial likelihood of liability and cannot appropriately consider a demand, and therefore demand is excused with respect to these Defendants.

194. The Board has also conceded, in Company financial filings, that defendants Kindler and Steere are not independent directors of the Company. Defendant Kindler's principal occupation is as Pfizer's CEO, and, as such, he lacks independence from the numerous interested directors referenced *supra*, rendering him incapable of impartially considering a demand to commence and vigorously prosecute this action. Along similar lines, Defendant Steere is currently the Chairman Emeritus of the Company. This position is his principal professional occupation, for which he receives materially higher fees than is typical for a director. Accordingly, defendants Kindler and Steere are incapable of considering a demand to commence and vigorously prosecute this action.

195. Finally, all the Director Defendants bear a substantial likelihood of liability arising from their violation of the federal securities laws in connection with their issuance of the Proxy Statements. The Proxy Statements constituted solicitations by the Director Defendants, as applicable, for which they may be held personally liable under the federal securities laws. As set forth in Section V, *supra*, the Proxy Statements were materially inaccurate and incomplete, which caused significant harm to the Company. As a result, the Director Defendants each bear a substantial likelihood of liability for their violations of the

federal securities laws, are conflicted and not disinterested with respect to such claims, and are, fundamentally disabled from impartially considering a demand to impose liability on themselves for violating their own statutory disclosure obligations.

### COUNT I

**DERIVATIVE CLAIM FOR VIOLATIONS OF SECTION 14(a) OF THE  
EXCHANGE ACT AND RULE 14a-9 PROMULGATED THEREUNDER BASED UPON  
MATERIAL MISSTATEMENTS IN AND OMISSIONS FROM  
PFIZER'S 2007-2009 PROXY STATEMENTS  
(Against the Director Defendants and the Former Director Defendants  
(the "Proxy Defendants"))**

196. Lead Plaintiff incorporates by reference and realleges each and every allegation above as though fully set forth herein.

197. The Proxy Defendants caused Pfizer to issue the 2007 Proxy Statement, the 2008 Proxy Statement, and the 2009 Proxy Statement to solicit shareholder votes for the election of directors and, with respect to the 2009 Proxy Statement, for approval of the Restated Stock Plan.

198. As alleged in detail above, these Proxy Statements contained materially inaccurate and incomplete disclosures, including by omitting to disclose:

- (i) the extent to which the Company's impressive disclosed financial results depended on the Company's off-label marketing of Pfizer drugs—including seven of Pfizer's nine most important pharmaceutical products responsible for over a \$1 billion in revenue per year each—which exposed the Company and its shareholders to tremendous regulatory, reputational and financial risk;
- (ii) the nature of the Board's responsibilities pursuant to the CIAs and the fact that its directors were not fulfilling them. Defendants disclosed no information concerning the implementation (or failure to implement) the duties and procedures required by the 2002 and 2004 CIAs, including what Board members and/or committees, if any, were responsible for receiving the regular required reports; what actions, if any, they took based on these reports; the identity and responsibilities of third parties or outside consultants, if any, retained in connection with carrying out the duties of the Board under the CIAs, including their precise duties, their level and manner of compensation, and the existence of

any potential conflicts of interest; and numerous other details relevant to shareholders' decisions with respect to whether to elect or re-elect individuals to the Board;

- (iii) the circumstances surrounding the Board's waiver or constructive waiver of explicit provisions of the Code of Conduct and Ethics—including with respect to Defendants' duties to ensure legal compliance, to ensure the reporting of legal violations, and to themselves report suspected non-compliance—even though the Board had waived or otherwise determined to deviate from these clear requirements;
- (iv) the nature of the Board's performance of their duties under the charters of the Board of Directors' various committees, including the reason for the then-current Directors' decision to allow continued off-label and otherwise improper marketing despite the risks to the Company, its shareholders, or its patients;
- (v) the numerous instances in which the Board was informed of legal compliance violations concerning the unlawful marketing of Pfizer drugs.
- (vi) the numerous instances in which the Board was informed of legal compliance violations concerning the unlawful marketing of Pfizer drugs.

199. The inaccuracies and omissions in each Proxy Statement concerned matters of material importance to the Company and were material to shareholders in response to the solicitations embodied in each Proxy Statement. The Proxy Statements were an essential link in Defendants' conscious disregard for Pfizer's known illegal sales and promotion practices, as disclosure to the shareholders of the truth would have brought an end to shareholders' endorsement of the Proxy Defendants as fiduciaries and termination of the Company's compensation policies.

200. The Proxy Defendants' failure to include these material facts in the 2007 through 2009 Proxy Statements rendered the Proxy Statements materially inaccurate and incomplete, in violation of Section 14(a) of the Exchange Act and Rule 14a-9 thereunder.

201. As a direct and proximate result of the issuance of materially inaccurate and incomplete Proxy Statements, Pfizer suffered direct and significant damages in the form of,

*inter alia*, the perpetuation of the widespread misconduct committed in the Company's name, substantial fines and penalties inflicted on the Company for this misconduct, and substantial additional liabilities related to numerous qui tam "whistleblower suits," consumer class actions, and other lawsuits and investigations, as well as significant expenses related thereto. The Company was also directly damaged by the enactment of the Restated Stock Plan, which enactment was likewise solicited by the materially inaccurate and incomplete 2009 Proxy Statement. Accordingly, the harm to the Company included:

- a. The largest criminal fine ever imposed in history in any matter against Pfizer, \$1.2 billion, for the illegal off-label marketing of Bextra, and a \$105 million criminal forfeiture of Bextra proceeds, the guilty plea of Pharmacia to a felony violation of the FDCA, and Pfizer's agreement to a non-prosecution agreement subjecting it to severe restrictions and potential future sanctions;
- b. The largest DOJ civil fraud settlement in the history of the United States, \$1 billion, for the illegal off-label promotion of Bextra, Lyrica, Geodon, and Zyvox and for illegal kickbacks to healthcare professionals to prescribe Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft, and Zyrtec;
- c. Damages and the costs of legal expenses to defend against 11 Qui Tam "Whistleblower" suits arising from current and former employees reporting Pfizer's widespread illegal conduct and asserting allegations against Pfizer;
- d. Damages and the costs of legal expenses from numerous consumer fraud actions alleging deceptive and illegal marketing of Pfizer drugs covered by the settlement, including an \$89 million charge the Company announced on October 17, 2008 to pay for the settlement of consumer fraud lawsuits regarding the illegal marketing of Bextra and Celebrex, and consumer fraud class actions such as Caltieri v. Pfizer Inc., et al., Civil Action No. 09-11480-DPW, (D. Mass., filed September 4, 2009), which challenge the deceptive marketing of the 11 other Pfizer drugs illegally marketed as set forth herein;
- e. Damages and legal expenses Pfizer has had to pay to settle State consumer protection actions regarding the illegal marketing alleged herein, including the \$33 million settlement Pfizer announced on September 2, 2009, with 42 States and the District of Columbia regarding the illegal marketing of Geodon;
- f. Damages and the costs of legal expenses to defend against numerous product liability suits by patients and consumers harmed by Pfizer's improper marketing of its drugs for off-label uses and dosages, including a \$745 million charge Pfizer announced on



October 17, 2008 to settle product liability claims by plaintiffs who suffered injuries after falling victim to deceptive marketing of Bextra and Celebrex; and

- g. Loss of Pfizer's market value due to its lost reputation and goodwill.

202. In connection with the improper acts alleged under this Count, the Proxy Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the United States mail, interstate telephone communications, or the facilities of a national securities exchange.

203. This count is only alleged against the Proxy Defendants as to those proxies that were issued during their terms as directors on the Board.

## **COUNT II**

### **DERIVATIVE CLAIM FOR BREACH OF FIDUCIARY DUTIES FOR DISSEMINATING MATERIALLY INNACCURATE AND INCOMPLETE STATEMENTS (Against all Defendants)**

204. Lead Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

205. As alleged in detail herein, each of the Defendants (and particularly the Audit Committee Defendants) had a duty to ensure that Pfizer disseminated accurate, truthful and complete information to its shareholders.

206. Defendants violated their fiduciary duties of care, loyalty, and good faith by causing or allowing the Company to disseminate to Pfizer shareholders materially inaccurate and incomplete information through, inter alia, the Proxy Statements and the Financial Reports included therein. These actions could not have been a good faith exercise of prudent business judgment.

207. As a direct and proximate result of Defendants' foregoing breaches of

fiduciary duties, the Company has suffered significant damages, as alleged herein.

### **COUNT III**

#### **DERIVATIVE CLAIM FOR BREACH OF FIDUCIARY DUTY FOR CAUSING THE COMPANY TO ENGAGE IN UNLAWFUL CONDUCT AND/OR CONSCIOUSLY DISREGARDING WIDESPREAD VIOLATIONS OF LAW (Against the Director Defendants)**

208. Lead Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

209. The Director Defendants all owed and owe fiduciary duties to Pfizer and its shareholders. By reason of their fiduciary relationships, Defendants specifically owed and owe Pfizer the highest obligation of good faith and loyalty in the administration of the affairs of Pfizer, including the oversight of Pfizer's compliance with federal laws governing the marketing of pharmaceuticals. Moreover, the Board had specific fiduciary duties as defined by the Company's key corporate governance documents and principles that, had they been discharged in accordance with the Board's obligations, would have necessarily prevented the misconduct and consequent harm to the Company alleged herein.

210. Defendants were also duty-bound to abide by the CIAs—which caused the Director Defendants to be regularly informed concerning the Company's compliance or non-compliance with the drug marketing laws--and expressly agreed to abide by the Code of Conduct and Ethics requiring compliance with federal laws against improper promotion and sales practices for off-label use and dosages, and against improper payment of kickbacks to healthcare professionals to induce the prescription of Pfizer's drugs.

211. The Director Defendants consciously violated their corporate responsibilities in at least the following ways:

- a. Affirmatively and repeatedly declining to stop and prevent Pfizer's illegal marketing of off-label uses and/or dosages of Bextra, Lyrica, Geodon, and Zyvox after receiving reports of such illegal activity and numerous red flags indicating such widespread illegality, and/or consciously disregarding such reports and activity;
- b. Deciding not to act to stop and prevent Pfizer's illegal kickbacks to health professionals for prescribing at least nine other Pfizer drugs, including Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft, and Zyrtec in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and/or consciously disregarding such reports and activity; and
- c. Approving and/or consciously disregarding Pfizer's business plan of marketing its drugs through the widespread illegal promotion of off-label uses and dosages and through illegal kickbacks to healthcare professionals in order to maximize Pfizer's short-term profit but at the expense of shareholder's long-term interests and Pfizer's reputation and goodwill.

212. As a direct and proximate result of the Director Defendants' conscious failure to perform their fiduciary obligations, Pfizer has sustained significant damages, not only monetarily, but also to its corporate image and goodwill. Such damage included, among other things, the substantial penalties, fines, liabilities and expenses described herein.

213. As a result of the misconduct alleged herein, the Director Defendants are liable to the Company.

#### **COUNT IV**

##### **DERIVATIVE CLAIMS FOR BREACH OF FIDUCIARY DUTY (Against the Executive Defendants)**

214. Lead Plaintiff incorporate by reference and reallege each and every allegation contained above as though fully set forth herein.

215. By reason of their positions as fiduciaries of the Company, the Executive Defendants owed duties of good faith, loyalty, and truthful disclosure. The Executive Defendants were all aware of and educated concerning the relevant laws and regulations concerning pharmaceutical marketing and were duty-bound to abide by the laws and

regulations and to enforce compliance therewith.

216. The Executive Defendants consciously violated and breached these duties by causing Pfizer to employ a deliberate and systematic business plan of artificially increasing sales by engaging in unlawful sales and promotion practices by numerous Pfizer employees for a prolonged period of time in violation of FDA requirements, Federal healthcare program requirements and/or the Federal anti-kickback statute.

217. The Executive Defendants authorized and implemented Pfizer policies and practices of encouraging the widespread illegal marketing and promotion of off-label uses and dosages of Pfizer drugs, as well as the payment of illegal kickbacks to healthcare professionals to induce the prescription of Pfizer's drugs, and retaliation against employees who reported such illegal practices to management.

218. As a direct and proximate result of the Executive Defendants' breaches of fiduciary duty, the Company has sustained, and will continue to sustain, substantial harm, including the damages set forth herein.

219. The Executive Defendants are liable to the Company as a result of the acts alleged herein.

## **COUNT V**

### **DERIVATIVE CLAIM FOR UNJUST ENRICHMENT (Against All Defendants)**

220. Lead Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though full set forth herein.

221. By their wrongful acts and omissions, Defendants were unjustly enriched at the expense of and to the detriment of Pfizer.

222. Lead Plaintiff, as a shareholder and representative of Pfizer, seeks restitution,

damages, an order of this Court disgorging all profits, benefits and other compensation obtained by these Defendants from their wrongful conduct and fiduciary breaches, and other relief for the Company, in an amount to be proven at trial.

**RELIEF REQUESTED**

WHEREFORE, Lead Plaintiff demands judgment as follows:

- (a) Determining that this action is a proper derivative action maintainable under law and demand is excused;
- (b) Awarding, against all Defendants and in favor of Pfizer, the damages sustained by the Company as a result of Defendants' breaches of fiduciary and contractual duties;
- (c) Awarding to Pfizer restitution from Defendants, and from each of them, and ordering disgorgement of all profits, benefits and other compensation obtained by the Defendants during the Relevant Period;
- (d) An Order invalidating the election of directors to the Board pursuant to the 2009 Proxy Statement;
- (e) An Order invalidating the authorization of the Restated Stock Plan, which was solicited and obtained by means of the 2009 Proxy Statement;
- (f) Directing Pfizer to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with the Company's existing governance obligations and all applicable laws and to protect the Company and its shareholders from a recurrence of the damaging events described herein;
- (g) Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and
- (h) Granting such other and further relief as the Court deems just and proper.

**JURY DEMAND**

Lead Plaintiff demands a trial by jury.

Dated: November 18, 2009

**BERNSTEIN LITOWITZ BERGER &  
GROSSMANN LLP**

A handwritten signature in black ink, appearing to read "Mark Lebovitch" with a stylized flourish at the end.

Gerald H. Silk

Mark Lebovitch

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*Counsel for additional plaintiff Henrietta Klein*



**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

IN RE PFIZER INC. SHAREHOLDER  
DERIVATIVE LITIGATION

Master File No. 09-CV-7822 (JSR)

**JURY TRIAL DEMANDED**

**ECF CASE**

**VERIFICATION FOR CONSOLIDATED, AMENDED AND VERIFIED  
SHAREHOLDER DERIVATIVE COMPLAINT**

I, Scott Zdrazil, verify that:

1. I am First Vice President and Director of Corporate Governance for Amalgamated Bank, as Trustee for the LongView Largecap 500 Index VEBA Fund, LongView Largecap 500 Index Fund and LongView Quantitative Largecap Fund (“Amalgamated”), which is Court-appointed lead plaintiff in this action.

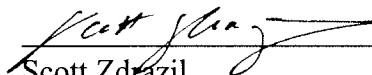
2. Amalgamated has been a shareholder of Pfizer Inc. (“Pfizer”) both before and during the period of misconduct complained of in the Consolidated, Amended and Verified Shareholder Derivative Complaint (the “Amended Complaint”), and has continuously held Pfizer common stock since such time, continues to hold such shares, and intends to continue to hold Pfizer shares until at least the resolution of this action.

3. I have reviewed the allegations made in the Amended Complaint, and as to those of which I have personal knowledge I believe those allegations to be true. As to those allegations of which I do not have personal knowledge, I rely on my counsel and their investigation and

believe them to be true. Having received a copy of this Complaint and having reviewed it with my counsel, I hereby authorize its filing on behalf of Amalgamated.

I verify under penalty of perjury that the foregoing is true and correct.

Executed this 8 day of November 2009 in New York, New York.

  
\_\_\_\_\_  
Scott Zdrzil  
First Vice President  
Director of Corporate Governance  
Amalgamated Bank  
275 Seventh Avenue  
New York, NY 10001

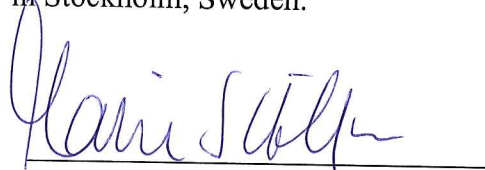
## VERIFICATION

I, Marie Schöllin, verify that:

I am the Head of Administration of Skandia Life Insurance Company Ltd. ("Skandia"), a plaintiff in this action. I hereby verify that Skandia has been a shareholder of Pfizer Inc. ("Pfizer") both before and during the period of misconduct complained of in the Consolidated, Amended and Verified Shareholder Derivative Complaint (the "Complaint"), and has continuously held Pfizer common stock since such time, continues to hold such shares, and intends to continue to hold Pfizer shares until at least the resolution of this action. Additionally, I have reviewed the allegations made in the Complaint and to those of which I have personal knowledge I believe those allegations to be true. As to those allegations which I do not have personal knowledge, I rely on my counsel and their investigation and believe them to be true. Having received a copy of this Complaint and having reviewed it with my counsel, I hereby authorize its filing on behalf of Skandia.

I declare that the foregoing is true and correct to the best of my knowledge.

Executed this 18th day of November, 2009 in Stockholm, Sweden.

A handwritten signature in blue ink, appearing to read "Marie Schöllin", is written over a horizontal line.

Marie Schöllin

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

IN RE PFIZER INC. SHAREHOLDER  
DERIVATIVE LITIGATION

Master File No. 09-CV-7822 (JSR)

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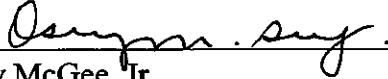
I, Osey McGee, Jr., verify that:

I am the Executive Director of Louisiana Sheriffs' Pension and Relief Fund ("Louisiana Sheriffs"), a plaintiff in the above action. I hereby verify that Louisiana Sheriffs has been a shareholder of Pfizer Inc. ("Pfizer") both before and during the period of misconduct complained of in the Consolidated Amended and Verified Shareholder Derivative Complaint (the "Amended Complaint"), and has continuously held Pfizer common stock since such time, continues to hold such shares, and intends to continue to hold Pfizer shares until at least the resolution of this action. Additionally, I have reviewed the allegations made in the Amended Complaint and as to those of which I have personal knowledge I believe those allegations to be true. As to those allegations of which I do not have personal knowledge, I rely on my counsel and their investigation and believe them to be true. Having received a copy of this Amended Complaint

and having reviewed it with my counsel, I hereby authorize its filing on behalf of Louisiana Sheriffs.

I declare that the foregoing is true and correct to the best of my knowledge.

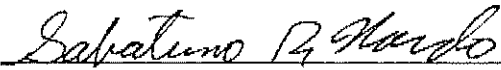
Executed this 18<sup>th</sup> day of November, 2009 in Baton Rouge, Louisiana.

  
\_\_\_\_\_  
Osey McGee, Jr.  
Executive Director  
Louisiana Sheriffs' Pension and Relief Fund

VERIFICATION

I, Sabatino DiNardo, Financial Secretary and Treasurer of the Amalgamated Transit Union Local 85 and a trustee of the Port Authority of Allegheny County Retirement and Disability Allowance Plan for Employees Represented by Local 85 of the Amalgamated Transit Union ("ATU 85"), plaintiff in the foregoing action, do hereby declare that I am authorized to make this verification on behalf of the plaintiffs; that I have read the consolidated complaint, and that the facts therein are true to my own knowledge, except as to matters stated therein to be alleged upon information and belief, and as to those matters, I believe them to be true and correct to the best of my knowledge, information and belief.

Dated: Pittsburgh, Pennsylvania  
November 18, 2009

  
\_\_\_\_\_  
Sabatino DiNardo

VERIFICATION

I, Mark W. Speakes, Fund Administrator of the LIUNA Staff & Affiliates Pension Fund, and the Laborers' International Union of North America National (Industrial) Pension Fund, plaintiffs in the foregoing action, do hereby declare that I am authorized to make this verification on behalf of the plaintiffs; that I have read the amended complaint, and that the facts therein are true to my own knowledge, except as to matters stated therein to be alleged upon information and belief, and as to those matters, I believe them to be true and correct to the best of my knowledge, information and belief.


Dated: Washington, D.C.  
November 18, 2009

  
\_\_\_\_\_  
Mark W. Speakes

**PFIZER INC. CONSOLIDATED AND AMENDED VERIFICATION**

I, Henrietta Klein, hereby verify that I am familiar with the allegations in the Consolidated and Amended Shareholder Derivative Complaint, that I have authorized the filing of the Consolidated and Amended Shareholder Derivative Complaint, and that the foregoing is true and correct to the best of my knowledge, information, and belief.

Date: November 18, 2009

  
Henrietta Klein