

## SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into by and among the United States of America, acting through the United States Department of Justice on behalf of the Office of Inspector General of the United States Department of Health and Human Services (“OIG-HHS”), the TRICARE Management Activity (“TMA”), and the United States Office of Personnel Management (“OPM”) (collectively the “United States”), Relators identified in the cases listed in Paragraph B of the Preamble to this Agreement (“Relators”), and Pfizer Inc (“Pfizer”), through their authorized representatives. Collectively, all of the above will be referred to as “the Parties.”

### PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. Pfizer is a Delaware corporation with its principal place of business in New York.

At all relevant times, Pfizer developed, manufactured, distributed, marketed and sold pharmaceutical products in the United States, including drugs sold under the trade names of: Bextra, Geodon, Zyvox, Lyrica, Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft, and Zyrtec (collectively the “Covered Drugs”).

B. The Relators listed herein have filed the following qui tam actions against Pfizer (collectively the “Civil Actions”):

- (1) United States et al. ex rel. Blair Collins v. Pfizer, Inc.,  
Civ. No. 04-11780-DPW (D. Mass.);
- (2) United States et al. ex rel. John Kopchinski v. Pfizer, Inc. et al.,  
Civ. No. 05-CV-12115 (D. Mass.);

- (3) United States ex rel. Dana Spencer v. Pfizer, Inc., Civ. No. 05-12326 (D. Mass.);
- (4) United States et al. ex rel. Glenn DeMott v. Pfizer, Civ. No. 05-12040 (D. Mass.);
- (5) United States et al. ex rel. David Farber and Casey Schildhauer v. Pfizer, Civ. No. 07-10304 (D. Mass.);
- (6) United States et al. ex rel. Ronald Rainero v. Pfizer, Civ. No. 07-11728 (D. Mass.);
- (7) United States et al. ex rel. Mark Westlock v. Pfizer, Inc. et al., Civ. No. 08-11318 (D. Mass.);
- (8) United States ex rel. Robert A. Liter v. Pfizer, Civ. No. 06-00176 (E.D. Ky.); and
- (9) United States et al. ex rel. Stefan Kruszewski v. Pfizer, Inc., Civ. No. 07-4106 (E.D. Pa.).

C. On such date as may be determined by the Court, Pfizer subsidiary Pharmacia & Upjohn Company, Inc. ("Pharmacia") will enter a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) (the "Plea Agreement") to an Information to be filed in United States of America v. Pharmacia & Upjohn Company, Inc., Criminal Action No. [to be assigned] (District of Massachusetts) (the "Criminal Action") that will allege a violation of Title 21, United States Code, Sections 331(a), and 333(a), namely, the introduction into interstate commerce of a misbranded drug, Bextra, in violation of the Food, Drug and Cosmetic Act ("FDCA").

D. Pfizer has entered into or will be entering into separate settlement agreements, described in Paragraph 1(b) below (hereinafter referred to as the "Medicaid State Settlement Agreements") with certain states and the District of Columbia in settlement of the Covered

Conduct. States with which Pfizer executes a Medicaid State Settlement Agreement in the form to which Pfizer and the National Association of Medicaid Fraud Control Units (“NAMFCU”) Negotiating Team have agreed, or in a form otherwise agreed to by Pfizer and an individual State, shall be defined as “Medicaid Participating States.”

E. The United States alleges that Pfizer caused to be submitted claims for payment for the Covered Drugs to the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v. The United States further alleges that Pfizer caused claims for payment for the Covered Drugs to be submitted to the TRICARE program, 10 U.S.C. §§ 1071-1109; the Federal Employees Health Benefits Program (“FEHBP”), 5 U.S.C. §§ 8901-8914; the Federal Employees Compensation Act Program, 5 U.S.C. § 8101, *et seq.*; and caused purchases of the Covered Drugs by the Department of Veterans’ Affairs (“DVA”) and the Bureau of Prisons (“BOP”) (collectively, the “other Federal Health Care Programs”). The United States further alleges that Pfizer caused certain claims for payment for certain of the Covered Drugs to be submitted to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh.

F. The United States contends that it and the Medicaid Participating States have certain civil claims, as specified in Paragraph 2, below, against Pfizer for engaging in the following conduct (hereinafter referred to as the “Covered Conduct”):

- (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, Zoloft, 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.

G. The United States also contends that it has certain administrative claims against Pfizer as specified in Paragraphs 4 through 6, below, for engaging in the Covered Conduct.

H. This Agreement is made in compromise of disputed claims. This Agreement is not an admission of facts or liability by Pfizer, and Pfizer expressly denies the allegations of the United States and the Relators as set forth herein and in the Civil Actions and denies that it

engaged in any wrongful conduct in connection with the Covered Conduct except as to: 1) such admissions as Pharmacia makes in connection with any guilty plea and as provided herein; and 2) the facts set forth in Attachment A as to Zyvox. This Agreement is not a concession by the United States that its claims are not well-founded. Neither this Agreement, nor the performance of any obligation arising under it, including any payment, nor the fact of settlement is intended to be, or shall be understood as, an admission of liability or wrongdoing, or other expression reflecting on the merits of the dispute by Pfizer, except as set forth in this Paragraph.

I. To avoid the delay, expense, inconvenience and uncertainty of protracted litigation of these claims, the Parties mutually desire to reach a final settlement as set forth below.

#### **TERMS AND CONDITIONS**

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

1. Pfizer agrees to pay to the United States and the Medicaid Participating States, collectively, the sum of one billion dollars (\$1,000,000,000), plus (a) interest at the rate of 3.75% per annum on \$502,524,316 from May 15, 2008, and continuing until and including the day before payment is made under this Agreement and, (b) interest at the rate of rate of 2.125% per annum on the remaining \$497,475,684 from January 23, 2009, and continuing until and including the day before payment is made (collectively, the "Settlement Amount"). The Settlement Amount shall constitute a debt immediately due and owing to the United States and

the Medicaid Participating States on the Effective Date of this Agreement. This debt shall be discharged by payments to the United States and the Medicaid Participating States, under the following terms and conditions:

(a) Pfizer shall pay to the United States the sum of \$668,514,830 plus accrued interest ("Federal Settlement Amount"). The Federal Settlement Amount shall consist of: (1) \$343,339,991, plus interest accrued on this amount at the rate of 3.75% per annum from May 15, 2008, continuing until and including the day before payment is made; and, (2) \$325,174,839 plus interest accrued on this amount at the rate of 2.125% per annum from January 23, 2009, continuing until and including the day before payment is made. The Federal Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the United States no later than seven (7) business days after (i) this Agreement is fully executed by the Parties and delivered to Pfizer's attorneys; or (ii) the Court accepts a Fed. R. Crim. P. 11(c)(1)(C) guilty plea as described in Preamble Paragraph C in connection with the Criminal Action and imposes the agreed upon sentence, whichever occurs later.

(b) Pfizer shall pay to the Medicaid Participating States the sum of \$331,485,170, plus accrued interest ("Medicaid State Settlement Amount"). The Medicaid State Settlement Amount shall consist of: (1) the sum of \$159,184,326, plus interest accrued thereon at the rate of 3.75% per annum from May 15, 2008, continuing until and including the day before payment is made; and, (2) the remaining \$172,300,844, plus interest accrued thereon from January 23, 2009, at the rate of 2.125% per annum until and including the day before payment is made. The Medicaid State Settlement Amount shall be paid no later than seven (7) business days after (i)

this Agreement is fully executed by the Parties and delivered to Pfizer's attorneys; or (ii) the Court accepts a Fed. R. Crim. P. 11(c)(1)(C) guilty plea as described in Preamble Paragraph C in connection with the Criminal Action and imposes the agreed upon sentence, whichever occurs later. The Medicaid State Settlement Amount shall be paid by electronic funds transfer to an interest bearing account pursuant to written instructions from the NAMFCU Negotiating Team and under the terms and conditions of the Medicaid State Settlement Agreements that Pfizer will enter into with the Medicaid Participating States.

(c) Contingent upon the United States receiving the Federal Settlement Amount from Pfizer, the United States agrees to pay, as soon as feasible after receipt, the following Relators the following amounts plus their proportionate share of the interest accrued on the Federal Settlement Amount described in (a) above as Relators' share of the proceeds pursuant to 31 U.S.C. §3730(d):

- (1) John Kopchinski: \$51,500,999
- (2) Dana Spencer: \$2,743,637
- (3) Blair Collins: \$2,354,582
- (4) Glenn DeMott: \$7,431,505
- (5) Stefan Kruszewski: \$29,013,420
- (6) Ronald Rainero: \$9,321,369

No other relator payments shall be made by the United States with respect to the matters covered by this Agreement. All Relators in the Civil Actions listed in Preamble Paragraph B, above, represent that they will abide by the terms of any written and executed separate agreements that



they may have entered into with one or more of the other Relators concerning the allocation of the Relators' share among themselves.

(d) If Pharmacia's agreed-upon guilty plea pursuant to Fed. R. Crim. P. 11(c)(1)(C) in the Criminal Action described in Preamble Paragraph C is not accepted by the Court or the Court does not impose the agreed-upon sentence for whatever reason, this Agreement shall be null and void at the option of either the United States or Pfizer. If either the United States or Pfizer exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within five (5) business days of the Court's decision, the Parties will not object and this Agreement will be rescinded. If this Agreement is rescinded, Pfizer will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims, actions or proceedings arising from the Covered Conduct that are brought by the United States within 90 calendar days of rescission, except to the extent such defenses were available on the day on which the qui tam complaints listed in Preamble Paragraph B, above, were filed.

2. Subject to the exceptions in Paragraph 7 below (concerning excluded claims), in consideration of the obligations of Pfizer set forth in this Agreement, conditioned upon Pfizer's payment in full of the Settlement Amount, the United States (on behalf of itself, its officers, agencies, and departments) agrees to release Pfizer, its predecessors, and its current and former divisions, parents, subsidiaries, successors and assigns and their current and former directors, officers, and employees from any civil or administrative monetary claim that the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733;

the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; any statutory provision creating a cause of action for civil damages or civil penalties for which the Civil Division of the Department of Justice has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part O, Subpart I, 0.45(d) and common law claims for fraud, payment by mistake, breach of contract, disgorgement and unjust enrichment.

3. Subject to the exceptions in Paragraph 7 (concerning excluded claims), below, in consideration of the obligations of Pfizer in this Agreement, conditioned upon Pfizer's full payment of the Settlement Amount, Relators, for themselves and for their heirs, successors, attorneys, agents, and assigns, agree to release Pfizer and its predecessors, and its current and former divisions, parents, subsidiaries, successors and assigns and their current and former directors, officers, and employees from any civil monetary claim the United States has or may have under the False Claims Act, 31 U.S.C. §§ 3729-3733, for the Covered Conduct; provided, however, that Relators do not release Pfizer for any claims under 31 U.S.C. §§ 3730(d) and (h), nor from any other claims that Relators have or may have, whether asserted in their Civil Actions or not asserted therein.

4. In consideration of the obligations of Pfizer set forth in this Agreement and the Corporate Integrity Agreement ("CIA") entered into between OIG-HHS and Pfizer, conditioned upon Pfizer's full payment of the Settlement Amount, OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the Medicare, Medicaid and other Federal health care programs (as defined in 42 U.S.C. § 1320a-

7b(f) against Pfizer under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 7 (concerning excluded claims), below, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Pfizer from the Medicare, Medicaid and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

5. In consideration of the obligations of Pfizer set forth in this Agreement and, conditioned upon Pfizer's payment in full of the Settlement Amount, TMA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program against Pfizer, under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 7 below (concerning excluded claims), and as reserved in this Paragraph. TMA expressly reserves authority to exclude Pfizer under 32 C.F.R. §§ 199.9(f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii), based upon the Covered Conduct. Nothing in this Paragraph precludes TMA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

6. In consideration of the obligations of Pfizer set forth in this Agreement and conditioned upon Pfizer's full payment of the Settlement Amount, OPM agrees to release and

refrain from instituting, directing, or maintaining any administrative action against Pfizer under 5 U.S.C. § 8902a or 5 C.F.R. Part 970 for the Covered Conduct, except as reserved in Paragraph 7 below (concerning excluded claims), except if required by 5 U.S.C. § 8902a(b). Nothing in this Paragraph precludes OPM from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7 below.

7. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Pfizer and the Relators) are the following claims of the United States:

- (a) Any civil, criminal, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);
- (b) Any criminal liability;
- (c) Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;
- (d) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- (e) Any liability based upon such obligations as are created by this Agreement;
- (f) Any liability for express or implied warranty claims or other claims for defective or deficient products and services, including quality of goods and services;

- (g) Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;
- (h) Any liability for failure to deliver items or services due; or
- (i) Any liability of individuals (including current or former directors, officers, employees, or agents of Pfizer) who receive written notification that they are the target of a criminal investigation, are criminally indicted or charged, or are convicted, or who enter into a criminal plea agreement.

8. Each Relator, and his/her respective heirs, successors, attorneys, agents, and assigns agree not to object to this Agreement and agree and confirm that this Agreement and the allocation of amounts to their respective claims as set forth in Paragraph 12 are fair, adequate and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B), and expressly waive the opportunity for a hearing on any objection to this Agreement pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon payment by the United States of the amounts set forth in Paragraph 1(c), above, Relators for themselves individually, and for their heirs, successors, agents, and assigns, fully and finally release, waive, and forever discharge the United States, its officers, agents, and employees, from any claims arising from or related to 31 U.S.C. § 3730 for any claims arising from the Covered Conduct and/or for any claims in the Civil Actions; and from any other claims for a share of the Settlement Amount, and in full settlement of any claims Relators may have against the United States under this Agreement. This Agreement does not resolve or in any manner affect any claims the United States has or may have against the

Relators arising under Title 26, U.S. Code (Internal Revenue Code), or any claims arising under this Agreement.

9. Conditioned upon the United States' receipt of the payments described in Paragraph 1(a), above, Relators, for themselves, and for their respective heirs, successors, attorneys, agents, and assigns, agree to release Pfizer, its predecessors, subsidiaries, successors and assigns and its current and former directors, officers, agents, and employees, from any liability to Relators arising from the allegations in Relators' Civil Actions that are being resolved pursuant to this Agreement by payment by Pfizer of the Federal Settlement Amount for the Covered Conduct. Relators' release of Pfizer does not extend to allegations in their Civil Actions that are not within the Covered Conduct, including Relators' claims for reasonable attorneys' fees, expenses and costs pursuant to 31 U.S.C. § 3730(d), Relators' claims under 31 U.S.C. § 3730(h), Relators claims for a Relator's Share under the Medicaid State Settlement Agreements, nor to any other claims Relators may have or had against Pfizer that are not expressly resolved herein.

10. Pfizer waives and shall not assert any defenses it may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by

the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

11. Pfizer fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) which Pfizer has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct or arising from the United States' investigation and prosecution of the Civil Actions and the Criminal Action.

12. Should this Agreement be challenged by any person as not fair, adequate or reasonable pursuant to 31 U.S.C. § 3730(c)(2)(B), Pfizer agrees that it will take all reasonable and necessary steps to defend this Agreement. Pfizer and the United States agree that the following allocation of the Settlement Amount to the Covered Conduct identified in Preamble Paragraph (F) is fair, adequate and reasonable under the circumstances:

- (1) For the Covered Conduct referenced in Preamble paragraph F(1) regarding Bextra: \$502,524,316;
- (2) For the Covered Conduct referenced in Preamble paragraph F(2) regarding Geodon: \$301,462,065;
- (3) For the Covered Conduct referenced in Preamble paragraph F(3) regarding Zyvox: \$97,945,019;
- (4) For the Covered Conduct referenced in Preamble paragraph F(4) regarding Lyrica: \$48,223,886
- (5) For the Covered Conduct referenced in Preamble paragraph F(5) regarding other specified kickbacks: \$49,844,714.

13. In consideration of the obligations of the Relators set forth in this Agreement, Pfizer, on behalf of itself, its predecessors, and its current and former divisions, parents, subsidiaries, agents, successors, assigns, and their current and former directors, officers and employees, fully and finally release, waive, and forever discharge the Relators and their respective heirs, successors, assigns, agents, and attorneys from any claims or allegations Pfizer has asserted or could have asserted, arising from the Covered Conduct, except as they relate to a statutory claim by Relators for reasonable attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d) and as to any claims Relators may have under 31 U.S.C. § 3730(h).

14. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary or any state payer, related to the Covered Conduct; and Pfizer agrees not to resubmit to any Medicare carrier or intermediary or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

15. Pfizer agrees to the following:

(a) Unallowable Costs Defined: that all costs (as defined in the Federal Acquisition Regulations (FAR) 48 C.F.R. § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Pfizer, its present or former officers, directors, employees, shareholders, and agents in connection with the following shall be "Unallowable Costs" on government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, and FEHBP:



- (1) the matters covered by this Agreement and the related plea agreement;
- (2) the United States' audit and civil and criminal investigation of the matters covered by this Agreement;
- (3) Pfizer's investigation, defense, and any corrective actions undertaken in response to the United States' audit and civil and criminal investigation in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement, the plea agreement, and the Medicaid State Settlement Agreements;
- (5) the payments Pfizer makes to the United States or any State pursuant to this Agreement, the plea agreement, or the Medicaid State Settlement Agreements and any payments that Pfizer may make to Relators (including costs and attorneys' fees);
- (6) the negotiation of, and the obligations undertaken pursuant to the CIA to:
  - (i) retain an independent review organization and outside reviewer to perform annual reviews as described in Section III of the CIA; and
  - (ii) prepare and submit reports to the OIG-HHS. However, nothing in this paragraph 15(a)(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Pfizer.

(All costs described or set forth in this paragraph 15(a) are hereafter "Unallowable Costs")

(b) Future Treatment of Unallowable Costs: These Unallowable Costs shall be separately determined and accounted for by Pfizer, and Pfizer shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid Program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Pfizer or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

(c) Treatment of Unallowable Costs Previously Submitted for Payment: Pfizer further agrees that within 90 days of the Effective Date of this Agreement, it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid Program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Pfizer or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Pfizer agrees that the United States, at a minimum, shall be entitled to recoup from Pfizer any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice, and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Pfizer or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Pfizer's or any of its subsidiaries' or affiliates' cost reports, cost statements, or information reports.

(d) Nothing in this Agreement shall constitute a waiver of the rights of the United States to examine or reexamine Pfizer's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

16. Pfizer agrees to cooperate fully and truthfully with the United States' investigation relating to the Covered Conduct of individuals and entities not released in this Agreement. Upon reasonable notice, Pfizer shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Pfizer agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by its counsel or other agent.

17. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 18 below (waiver for beneficiaries paragraph).

18. Pfizer agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

19. Pfizer expressly warrants that it has reviewed its financial situation and that it is currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and will remain solvent following payment of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants and obligations set forth herein constitute a contemporaneous exchange for new value given to Pfizer, within the meaning of 11 U.S.C. § 547(c)(1); and (b) conclude that these mutual promises, covenants and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which Pfizer was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

20. On the Effective Date of this Agreement or any date thereafter:

(a) The United States shall intervene in the Civil Actions as to the Covered Conduct and decline or consent to the voluntary dismissal as to all other defendants and all other allegations set forth in the Civil Actions.

(b) Following payment of the Settlement Amount, the Parties shall file a stipulation of dismissal in each of the Civil Actions as follows:

(1) each stipulation of dismissal shall be with prejudice as to the United States' and Relators' claims as to Pfizer as to the Covered Conduct in each Civil Action pursuant to and consistent with the terms and conditions of this Agreement;

(2) each stipulation of dismissal shall be without prejudice as to the United States and with prejudice as to Relators as to all other entities and individuals and as to all other claims, or without prejudice to Relators if agreed to by Relators and Pfizer in any separate written agreement(s) entered into by Relators and Pfizer;

(3) provided, however, that the following claims against Pfizer shall not be dismissed, unless they are settled, adjudicated, or otherwise resolved, and any required consent by the United States is obtained, and the Court is so informed: (a) all claims against Pfizer reserved by any Relator for claims not resolved herein, including for allegations in their Civil Actions that are not within the Covered Conduct; (b) Relators' claims for reasonable attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d); (c) Relators' claims under § 3730(h); (d) Relators' claims for a Relator's Share under the Medicaid State Settlement Agreements; and (e) any other claims Relators may have or had against Pfizer that are not expressly resolved herein.

21. Except as provided in Paragraph 20, each party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement, except Relators reserve their rights against Pfizer to seek attorneys' fees, costs and expenses under § 3730(d).

22. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

23. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement, including any dispute regarding payment of Relator's attorneys' fees, expenses and costs, shall be the district court in which the Civil Action was pending on the Effective Date of this Agreement, except as otherwise agreed by the parties to the dispute, and except that any disputes arising under the CIA shall be resolved exclusively through the dispute resolution provisions set forth in the CIA.

24. For purposes of construction, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any party for that reason in any dispute.

25. This Agreement constitutes the complete agreement between the Parties with respect to the issues covered by the Agreement. This Agreement may not be amended except by written consent of all the Parties.

26. The individuals signing this Agreement on behalf of Pfizer represent and warrant that they are authorized by Pfizer to execute this Agreement. The individuals signing this

Agreement on behalf of each Relator represent and warrant that they are authorized by that Relator to execute this Agreement. The United States' signatories represent that they are signing this Agreement in their official capacities and they are authorized to execute this Agreement.

27. This Agreement may be executed in counterparts, each of which constitutes an original and all of which shall constitute one and the same Agreement.

28. This Agreement is binding on Pfizer's successors, transferees, heirs and assigns.

29. This Agreement is binding on Relators' successors, transferees, heirs, attorneys and assigns.

30. All parties consent to the disclosure of this Agreement, and information about this Agreement, to the public after it has been finally executed.

31. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

UNITED STATES OF AMERICA

MICHAEL K. LOUCKS  
Acting United States Attorney

By:  \_\_\_\_\_

SARA MIRON BLOOM  
SUSAN M. POSWISTILO  
ZACHARY A. CUNHA  
Assistant United States Attorneys  
District of Massachusetts

Dated: 8/31/09



By:

  
\_\_\_\_\_

MICHAEL L. LEVY  
United States Attorney  
United States Attorney's Office  
Eastern District of Pennsylvania

Dated: 8/28/08

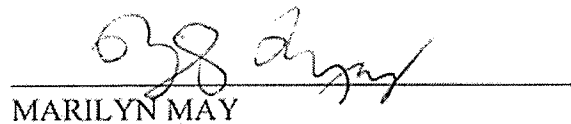
By:

  
\_\_\_\_\_

MARGARET L. HUTCHINSON  
Chief, Civil Division  
United States Attorney's Office  
Eastern District of Pennsylvania

Dated: 8/28/08

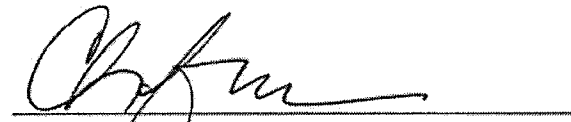
By:

  
\_\_\_\_\_

MARILYN MAY  
Assistant U.S. Attorney  
United States Attorney's Office  
Eastern District of Pennsylvania

Dated: 8/28/08

By:

  
\_\_\_\_\_

CHARLENE KELLER FULLMER  
Assistant U.S. Attorney  
United States Attorney's Office  
Eastern District of Pennsylvania

Dated: 8/28/08

JAMES A. ZERHUSEN  
United States Attorney

By: Robin Gwinn  
ROBIN GWINN  
CHERYL MORGAN  
Assistant United States Attorneys  
Eastern District of Kentucky

Dated: 8/28/09

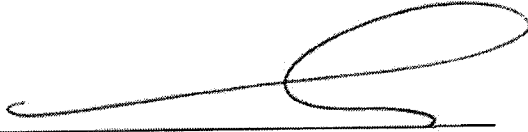
TONY WEST  
Assistant Attorney General

By: Sanjay M. Bhambhani

Dated: 8/31/2009

JOYCE R. BRANDA  
Director  
JAMIE ANN YAVELBERG  
SANJAY BHAMBHANI  
PATRICIA L. HANOWER  
COLIN M. HUNTLEY  
Trial Attorneys  
Civil Division  
United States Department of Justice

By:

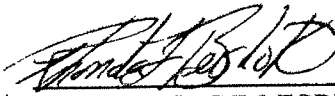


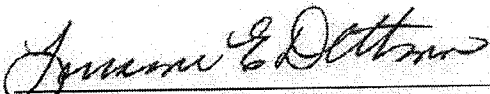
GREGORY E. DEMSKE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services

Dated:


8/31/09

Civil Settlement - Pfizer

By:  (Acting Deputy General Counsel) Dated: 28. Aug 2009  
for LAUREL C. GILLESPIE  
Deputy General Counsel  
TRICARE Management Activity  
United States Department of Defense

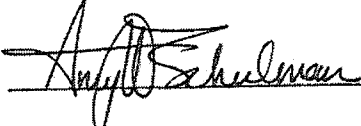
By:   
LORRAINE E. DETTMAN  
Assistant Director  
for Insurance Services Programs  
Center for Retirement & Insurance Services  
United States Office of Personnel Management

Dated: 8/31/09

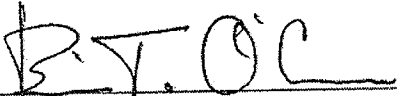
By:   
J. DAVID COPE  
Assistant Inspector General for Legal Affairs  
United States Office of Personnel Management

Dated: 8/31/09

PFIZER INC

By:   
[Its Officer]  
Pfizer Inc

Dated: 31 August 2009

By:   
BRIEN O'CONNOR  
JOSHUA LEVY  
Ropes & Gray LLP  
Counsel to Pfizer Inc and Pharmacia & Upjohn Company, Inc.

Dated: 8/31/09

RELATOR JOHN KOPCHINSKI

By: *John Kopchinski*  
JOHN KOPCHINSKI

Dated: *August 27, 2009*

By: *Erika A. Kelton*  
ERIKA KELTON  
Phillips & Cohen LLP  
Counsel to Relator John Kopchinski

Dated: *8/28/09*



**RELATOR DANA SPENCER**

By: Dana T. Spencer  
DANA SPENCER

Dated: Aug 28, 2009

By: William V. Hoyle, Jr.  
WILLIAM V. HOYLE, Jr.  
The Law Offices of William V. Hoyle, Jr., PC  
Counsel to Relator Dana Spencer

Dated: Aug. 28, 2009

**RELATOR BLAIR COLLINS**

By: Blair M. Collins  
BLAIR COLLINS

Dated: 8/28/2009

By: Suzanne E. Durrell / RMT  
Robert M. Thomas Jr.  
SUZANNE E. DURRELL  
Durrell Law Office  
ROBERT M. THOMAS, JR  
ROYSTON H. DELANEY.  
Thomas & Associates  
Counsel to Relator Blair Collins

Dated: 8/28/09

**RELATOR GLENN DEMOTT**

By: *Glenn DeMott*  
GLENN DEMOTT

Dated: 08/28/2009

By: \_\_\_\_\_  
ANN LUGBILL  
Murphy Anderson PLLC  
Counsel to Relator Glenn DeMott

Dated: \_\_\_\_\_

By: \_\_\_\_\_  
JOHN C. KAIRIS  
Grant & Eisenhofer, PA  
Counsel to Relator Glenn DeMott

Dated: \_\_\_\_\_

By: \_\_\_\_\_  
REUBEN GUTTMAN  
Grant & Eisenhofer, PA  
Counsel to Relator Glenn DeMott

Dated: \_\_\_\_\_

**RELATOR GLENN DEMOTT**

By: \_\_\_\_\_  
GLENN DEMOTT

Dated: \_\_\_\_\_

By: Ann Lughbell (MCA)  
ANN LUGBILL  
Murphy Anderson PLLC  
Counsel to Relator Glenn DeMott

Dated: 8/28/09

By: \_\_\_\_\_  
JOHN C. KAIRIS  
Grant & Eisenhofer, PA  
Counsel to Relator Glenn DeMott

Dated: \_\_\_\_\_

By: \_\_\_\_\_  
REUBEN GUTTMAN  
Grant & Eisenhofer, PA  
Counsel to Relator Glenn DeMott

Dated: \_\_\_\_\_

**RELATOR GLENN DEMOTT**

By: \_\_\_\_\_  
GLENN DEMOTT

Dated: \_\_\_\_\_

By: \_\_\_\_\_  
ANN LUGBILL  
Murphy Anderson PLLC  
Counsel to Relator Glenn DeMott

Dated: \_\_\_\_\_

By: John C. Kairis (CAJ)  
JOHN C. KAIRIS  
Grant & Eisenhofer, PA  
Counsel to Relator Glenn DeMott

Dated: 8/28/2008

By: Reuben J. Guttman  
REUBEN GUTTMAN  
Grant & Eisenhofer, PA  
Counsel to Relator Glenn DeMott

Dated: 8/28/2008

**RELATOR ROBERT LITER**

By: Robert Liter  
ROBERT LITER

Dated: 8/28/09

By: BARBARA BONAR  
BARBARA BONAR  
The Law Offices of B. Dahlenburg Bonar  
Counsel to Relator Robert Liter

Dated: Aug. 28<sup>th</sup>, 2009

**RELATOR CASEY SCHILDHAUER**

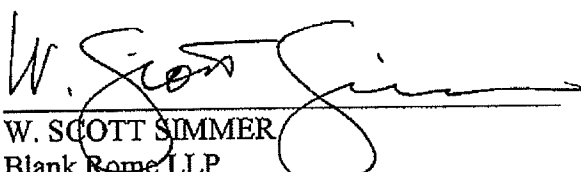
By: \_\_\_\_\_  
CASEY SCHILDHAUER

Dated: \_\_\_\_\_

**RELATOR DAVID FARBER**

By: \_\_\_\_\_  
DAVID FARBER

Dated: \_\_\_\_\_

By:   
W. SCOTT SIMMER  
Blank Rome LLP  
Counsel to Relators Casey Schildhauer and David Farber

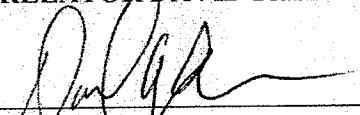
Dated: 8/28/2009

**RELATOR CASEY SCHILDHAUER**

By: \_\_\_\_\_  
CASEY SCHILDHAUER

Dated: \_\_\_\_\_

**RELATOR DAVID FARBER**

By:   
\_\_\_\_\_  
DAVID FARBER

Dated: 8/28/2009

By: \_\_\_\_\_  
W. SCOTT SIMMER  
Blank Rome LLP  
Counsel to Relators Casey Schildhauer and David Farber

Dated: \_\_\_\_\_



**RELATOR CASEY SCHILDHAUER**

By:   
CASEY SCHILDHAUER

Dated: 8/28/2009

**RELATOR DAVID FARBER**

By: \_\_\_\_\_  
DAVID FARBER

Dated: \_\_\_\_\_

By: \_\_\_\_\_  
W. SCOTT SIMMER  
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Counsel to Relators Casey Schildhauer and David Farber

Dated: \_\_\_\_\_

**RELATOR STEFAN KRUSZEWSKI**

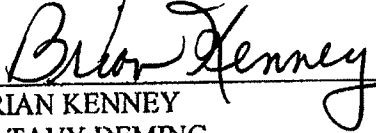
By:

  
\_\_\_\_\_  
STEFAN KRUSZEWSKI

Dated:

8/31/2009

By:

  
\_\_\_\_\_  
BRIAN KENNEY  
M. TAVY DEMING  
Kenney Egan McCafferty & Young  
Counsel to Relator Stefan Kruszewski


Dated:

8/31/2009

**RELATOR MARK WESTLOCK**

By: \_\_\_\_\_  
MARK WESTLOCK

Dated: \_\_\_\_\_

By:  \_\_\_\_\_  
W. SCOTT SIMMER  
Blank Rome LLP  
Counsel to Relator Mark Westlock

Dated: 8/28/2009

**RELATOR MARK WESTLOCK**

By: Mark Westlock  
MARK WESTLOCK

Dated: 8/20/09

By: \_\_\_\_\_  
W. SCOTT SIMMER  
Blank Rome LLP  
Counsel to Relator Mark Westlock

Dated: \_\_\_\_\_

**RELATOR RONALD RAINERO**

By:   
RONALD RANEIRO

Dated: 8/28/09

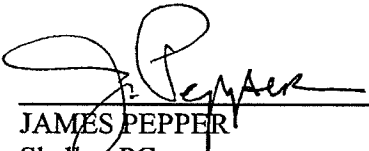
By: \_\_\_\_\_  
JAMES PEPPER  
Sheller, PC  
Counsel to Relator Ronald Rainero

Dated: \_\_\_\_\_

**RELATOR RONALD RAINERO**

By: \_\_\_\_\_  
RONALD RANEIRO

Dated: \_\_\_\_\_

By:  \_\_\_\_\_  
JAMES PEPPER  
Sheller, PC  
Counsel to Relator Ronald Rainero

Dated: 8/28/09

## ATTACHMENT A

This statement reflects facts as to which Pfizer and the United States agree are true and accurate. It does not contain all of the United States' factually-based contentions regarding Pfizer's marketing of Zyvox, nor does it contain all of Pfizer's responses to those allegations:

1. Zyvox (linezolid) is an antibacterial agent that is approved by the FDA to treat certain types of infections including, among other approved indications, nosocomial pneumonia caused by methicillin-resistant *Staphylococcus aureus* ("MRSA") and complicated skin and skin structure infections ("CSSSIs") due to MRSA.
2. Although Zyvox is approved to treat these indications, it has not been demonstrated by substantial evidence to be superior to the primary competitor drug for those indications: vancomycin, an antibiotic that has been on the market for nearly fifty years.
3. On July 20, 2005, the FDA sent Pfizer a Warning Letter ("Warning Letter") regarding a journal advertisement for Zyvox. In this Warning Letter, the FDA stated that Pfizer's advertisement misbranded Zyvox by making misleading and unsubstantiated implied superiority claims, claims that broadened the indications of Zyvox, and omitted important safety information.
4. The FDA stated in the Warning Letter that the journal advertisement implied that Zyvox is superior to vancomycin for the treatment of nosocomial pneumonia caused by MRSA. Specifically, the FDA Warning Letter objected to the advertisement's use of certain retrospective analyses of head-to-head clinical trials of linezolid and vancomycin. The FDA stated that these analyses were not prospectively designed or sufficiently powered to demonstrate statistically significant differences in treatment groups. Thus, the FDA stated that the superiority of Zyvox for the treatment of nosocomial pneumonia caused by MRSA had not been demonstrated by substantial evidence and that the advertisement was therefore misleading.
5. The FDA stated that Pfizer's advertisement misbranded Zyvox in violation of 21 U.S.C. 352(n) & 321(n) and FDA implementing regulations and requested that Pfizer cease dissemination of the journal advertisement and other promotional materials containing similar statements.
6. After receiving the Warning Letter, Pfizer responded to the FDA, taking the position that it did not believe that the journal advertisement made an improper superiority claim. However, Pfizer informed the FDA that, in response to the FDA's concerns, Pfizer would cease use of the journal advertisement in question. Further, Pfizer informed the FDA that all other Zyvox promotional materials had been reviewed to identify other items that could raise similar concerns, and that steps had been taken to discontinue or appropriately revise any promotional materials that could potentially be misinterpreted in a similar manner. Pfizer also

informed the FDA that it was instructing its sales force that materials containing information that the FDA stated constituted an implied superiority claim could no longer be used. Pfizer also advised its sales force to discontinue using certain identified promotional materials and that sales representatives would be provided with replacement pieces.

7. In addition, at the FDA's request, Pfizer agreed to publish a corrective advertisement in February 2006, which was entitled "IMPORTANT CORRECTION OF DRUG INFORMATION ZYVOX." In this corrective advertisement, Pfizer noted that the FDA had objected to the presentation, in its previous advertisement, of clinical data that showed a more favorable comparison of Zyvox to vancomycin than was shown in the data included in the the Zyvox label, which states that 57% of Zyvox patients and 60% of vancomycin patients in the clinically evaluable population were cured of MRSA. Further, the label reflects that 59% (13/22) of Zyvox patients and 70% (7/10) of vancomycin patients with microbiologically-confirmed MRSA at baseline were clinically cured.
8. Despite notifying its sales force that it should cease using promotional materials that raised concerns of the type identified in the FDA Warning Letter, Pfizer did not provide adequate guidance to its sales force regarding what statements were permissible concerning data from head-to-head trials and retrospective analyses and what promotional statements were not permitted.
9. As a result, Pfizer's sales personnel thereafter continued to make claims to physicians that Zyvox was superior to vancomycin for certain patients with MRSA, 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 the receipt of the Warning Letter, agreed to present the clinical data cited by the FDA.
10. Moreover, certain Pfizer sales managers, including a regional manager and a headquarters-based vice president, were aware of and, in certain cases, encouraged a sales message that Zyvox was superior to vancomycin for certain patients, despite their knowledge of the FDA Warning Letter and the issues it raised.