

# State of North Carolina

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October 3, 2013

North Carolina Senate President Pro Tempore Phil Berger North Carolina House of Representatives Speaker Thom Tillis Co-Chairs, Joint Legislative Commission on Governmental Operations

Senator Stan Bingham
Senator Thom Goolsby
Senator Buck Newton
Representative Jamie Boles
Representative N. Leo Daughtry
Representative John Faircloth
Representative Pat Hurley
Co-Chairs, Appropriations Subcommittee on Justice and Public Safety

North Carolina General Assembly Raleigh, North Carolina 27601-1096

Re: G.S. §114-2.5; Report on Settlement Agreement for Kmart Corporation G.S. §114-2.5; Report on Settlement Agreement for Wyeth Pharmaceuticals, Inc.

G.S. §114-2.5; Report on Settlement Agreement for Ranbaxy, Inc. G.S. §114-2.5; Report on Settlement Agreement for Amgen, Inc.

### Dear Members:

G.S. §114-2.5 requires the Attorney General to report to the Joint Legislative Commission on Governmental Operations and the Chairs of the Appropriations Subcommittees on Justice and Public Safety regarding all settlements and court orders which result in more than \$75,000.00 being paid to the State. Pursuant to that statute, I am writing regarding the settlement of claims for Medicaid reimbursement to the State and Federal governments in the above-referenced matters. Pursuant to federal law (42 C.F.R. § 433.320) recoveries in these cases are shared on a pro rata basis by the State and Federal governments.

# **Kmart Corporation**

A Settlement Agreement has been executed between Kmart and the State of North Carolina. Kmart is a Michigan corporation with its principal place of business in Hoffman Estates, Illinois. Kmart, within its retail stores, operated a national pharmacy chain in 46 states and 3 territories of the United States. The settlement resolves allegations that from January 1, 2004 through October 17, 2005, Kmart billed Medicaid for certain full prescriptions when those prescriptions were only partially dispensed.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$99,127.64. Of that amount the federal government will receive \$63,474.98 to satisfy North Carolina's obligation to return the federal portion of Medicaid recoveries to the federal government. The North Carolina Medicaid Program will receive \$25,039.14 as restitution and interest. In addition, pursuant to Article IX, Section 7 of the North Carolina Constitution and G.S. § 115C-457.1, the penalty portion of the settlement in the amount of \$9,205.34 will be paid to the Civil Penalty Forfeiture Fund for the support of North Carolina public schools. Pursuant to G.S. § 115C-457.2 and G.S. § 108A-70.12(b)(3), the North Carolina Department of Justice will receive \$1,408.18 for investigative costs and costs of collection.

## Wyeth Pharmaceuticals, Inc.

A Settlement Agreement has been executed between Wyeth Pharmaceuticals and the State of North Carolina. Wyeth Pharmaceuticals, Inc. is a Delaware corporation headquartered in Collegeville, Pennsylvania. In October 2009, Pfizer, Inc. acquired Wyeth and Wyeth became a wholly owned subsidiary of Pfizer, Inc. Wyeth distributed, marketed and sold pharmaceutical products in the United States, including one sold under the trade name Rapamune. The settlement resolves allegations that from September 1999 through December 2011, Wyeth knowingly promoted the sale and use of Rapamune for uses for which it had not been approved by the Food and Drug Administration, including for use in connection with solid organ transplant patients other than kidney transplant patients, which were not medically-accepted indications, and were not covered by Medicaid.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$1,284,729.11. Of that amount the federal government will receive \$853,811.38 to satisfy North Carolina's obligation to return the federal portion of Medicaid recoveries to the federal government. The North Carolina Medicaid Program will receive \$208,994.57 as restitution and interest. In addition, pursuant to Article IX, Section 7 of the North Carolina Constitution and G.S. § 115C-457.1, the penalty portion of the settlement in the amount of \$205,016.36 will be paid to the Civil Penalty Forfeiture Fund for the support of North Carolina public schools. Pursuant to G.S. § 115C-457.2 and G.S. § 108A-70.12(b)(3), the North Carolina Department of Justice will receive \$16,906.80 for investigative costs and costs of collection.

## Ranbaxy, Inc.

A Settlement Agreement has been executed between Ranbaxy, Inc. and the State of North Carolina. Ranbaxy is a Delaware corporation. Ranbaxy distributed and sold pharmaceutical products in the United States that were manufactured at its facilities in Paonta Sahib, India and Dewas, India. The settlement resolves allegations that from April 1, 2003 through September 16, 2010, Ranbaxy knowingly submitted false statements to the FDA and failed to comply with current Good Manufacturing Practices resulting in systematic deficiencies in manufacturing plants located in Paonta, India and Dewas, India.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$8,792,991.10. Of that amount the federal government will receive \$5,760,106.46 to satisfy North Carolina's obligation to return the federal portion of Medicaid recoveries to the federal government. Pursuant to G.S. § 1-610, the qui tam plaintiffs whose whistleblower actions brought this matter to the government's attention will receive \$626,875.38 of North Carolina's recovery. The North Carolina Medicaid Program will receive \$1,180,193.25 as restitution and interest. In addition, pursuant to Article IX, Section 7 of the North Carolina Constitution and G.S. § 115C-457.1, the penalty portion of the settlement in the amount of \$1,132,429.49 will be paid to the Civil Penalty Forfeiture Fund for the support of North Carolina public schools. Pursuant to G.S. § 115C-457.2 and G.S. § 108A-70.12(b)(3), the North Carolina Department of Justice will receive \$93,386.52 for investigative costs and costs of collection.

## Amgen, Inc.

A Settlement Agreement has been executed between Amgen, Inc. and the State of North Carolina. Amgen is a Delaware corporation with its principal place of business in California. Amgen developed, manufactured, distributed, marketed and sold biologic products in the United States, including Enbrel, Aranesp, Epogen, Neulasta, Neupogen and Sensipar. The settlement resolves allegations that from January 1, 2001 through September 30, 2011, Amgen engaged in various illegal marketing practices to promote sales of Aranesp, Enbrel, Epogen, Neulasta, Neupogen and Sensipar and inaccurately reported and manipulated prices for these drugs.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$370,524.18. Of that amount the federal government will receive \$248,593.39 to satisfy North Carolina's obligation to return the federal portion of Medicaid recoveries to the federal government. The North Carolina Medicaid Program will receive \$90,247.49 as restitution and interest. In addition, pursuant to Article IX, Section 7 of the North Carolina Constitution and G.S. § 115C-457.1, the penalty portion of the settlement in the amount of \$26,880.42 will be paid to the Civil Penalty Forfeiture Fund for the support of North Carolina public schools. Pursuant to G.S. § 115C-457.2 and G.S. § 108A-70.12(b)(3), the North Carolina Department of Justice will receive \$4,802.88 for investigative costs and costs of collection.

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We will be happy to respond to any questions you may have regarding this report.

Very truly yours,

Kristi Hyman Chief of Staff

cc: Kristine Leggett, NCGA Fiscal Research Division Christy Agner, NCDOJ, Legislative Liaison

Nels Roseland, NCDOJ, Deputy Chief of Staff

### STATE SETTLEMENT AGREEMENT

#### I. PARTIES

This Settlement Agreement ("Agreement") is entered into between the State of North Carolina ("the State") and Wyeth Pharmaceuticals Inc. ("Wyeth") and Pfizer Inc ("Pfizer") (collectively "Defendants"), hereinafter collectively referred to as "the Parties."

### II. PREAMBLE

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

- A. Wyeth Pharmaceuticals Inc. is a Delaware corporation headquartered in Collegeville, Pennsylvania. Pfizer Inc is a Delaware corporation headquartered in New York, New York. At all relevant times, Wyeth distributed, marketed, and sold pharmaceutical products in the United States, including an immunosuppressive drug sold under the trade name of Rapamune. In October 2009, Pfizer acquired Wyeth and Wyeth became a wholly owned subsidiary of Pfizer.
- B. On or about December 16, 2005, Marlene Sandler ("Sandler") and Scott Paris ("Paris") filed a *qui tam* action in the United States District Court for the Eastern District of Pennsylvania captioned <u>United States ex rel. Sandler, et al. v. Wyeth Pharmaceuticals, Inc.</u>, Civil Action No. 05-6609, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the "Civil Action"). On or about May 24, 2010, Relators Sandler and Paris amended their Complaint adding Pfizer as a defendant, and this Second Amended Complaint sets forth the current allegations in their *qui tam* action (the "Sandler Civil Action"). On or about January 16, 2007, Relator Mark

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Campbell ("Campbell") filed a *qui tam* action in the United States District Court for the Western District of Oklahoma captioned <u>United States ex rel. Campbell v. Wyeth, Inc.</u>, Civil Action No. 07-0051, pursuant to the *qui tam* provision of the False Claims Act, 31 U.S. C. § 3730(b). On or about April 20, 2009, Relator Campbell amended his complaint, and this Fourth Amended Complaint sets forth Relator Campbell's current allegations in his *qui tam* action (the "Campbell Civil Action"). On or about November 5, 2010, the Sandler Civil Action was transferred by Court Order to the Western District of Oklahoma to be handled together with the Campbell Civil Action. Together, the Sandler Civil Action and the Campbell Civil Action are the "Civil Actions."

- C. On such date as may be determined by the Court, Wyeth Pharmaceuticals Inc. will enter a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) (the "Plea Agreement") to an Information filed in *United States of America v. Wyeth Pharmaceuticals Inc.*, Criminal Action No. [to be assigned] (Western District of Oklahoma)(the "Criminal Action") that will allege a violation of Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f), namely, the introduction into interstate commerce of a misbranded drug, Rapamune, in violation of the Food, Drug, and Cosmetic Act (FDCA).
- D. Defendants have entered into a separate civil settlement agreement (the "Federal Settlement Agreement") with the United States of America (as that term is defined in the Federal Settlement Agreement), hereinafter referred to as the "United States."

- E. The State contends that Defendants caused claims for payment for Rapamune to be submitted to the State's Medicaid Program (see 42 U.S.C. §§ 1396-1396(v)).
- F. The State contends that it has certain civil and administrative causes of action against Defendants for engaging in the following conduct during the period September 1999 through December 2011 (referred to hereinafter as the "Covered Conduct"):

Wyeth (a) knowingly promoted the sale and use of Rapamune for uses for which it had not been approved by the United States Food and Drug Administration (FDA), including for use in connection with solid organ transplant patients other than kidney transplant patients, which were not medically-accepted indications (as defined in 42 U.S.C. §1396r-8(k)(6)), and were not covered by Medicaid; and (b) knowingly promoted the sale and use of Rapamune in treatment regimens that had not been approved by the FDA, including the use of Rapamune with transplant patients who used another immunosuppressant drug before using Rapamune and who did not receive Rapamune at or around the time of a kidney transplant and the use of Rapamune in combination with certain types of products other than cyclosporine and corticosteroids, resulting in claims being paid by the State Medicaid program.

As a result of the foregoing Covered Conduct, Wyeth knowingly caused the submission of false and fraudulent claims for Rapamune to the State's Medicaid program and Defendants obtained proceeds and profits to which they were not entitled.

G. This Agreement is neither an admission of facts or liability by Defendants, nor a concession by the State that its allegations are not well founded. Except for the

specific conduct for which Wyeth is pleading guilty as described in the plea agreement filed in the Federal Criminal Action, Defendants expressly deny the allegations of the State as set forth herein and in the Civil Actions. Wyeth contends that 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 Defendants, except as set forth in this Paragraph.

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

#### III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants and obligations set forth in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. Defendants agree to pay to the United States and the Medicaid
Participating States (as defined in sub-paragraph (c) below), collectively, the sum of
\$257,400,000.00, plus accrued interest on that amount of 1.375% per annum
commencing on October 17, 2012, and continuing and including the day before payment
is made under this Agreement (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 the Federal Settlement Agreement,

and subject to the terms of this Agreement. The debt shall forever be discharged by payments to the United States and the Medicaid Participating States, under the following terms and conditions:

- (a) Defendants shall pay to the United States the sum of \$230,112,596.00, plus accrued interest ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.
- (b) Defendants shall pay to the Medicaid Participating States the sum of \$27,287,404.00, plus accrued interest ("Medicaid State Settlement Amount"), subject to the non-participating state deduction provision of sub-paragraph (d) below ("Medicaid Participating State Settlement Amount"), no later than seven (7) business days after: (i) the expiration of the 60 day opt-in period for Medicaid Participating States described in sub-paragraph (c) below or, (ii) the Court accepts a Fed. R. Crim. P. 11(c)(1)(C) guilty plea in the Federal Criminal Action and imposes the agreed-upon sentence, whichever occurs later. The Medicaid Participating State Settlement Amount shall be paid by electronic funds transfer to the New York State Attorney General's National Global Settlement Account pursuant to written instructions from the State Negotiating Team ("State Team"), which written instructions shall be delivered to counsel for Defendants.
- (c) Defendants shall execute a State Settlement Agreement with any
  State that executes such an Agreement in the form to which Defendants and the State
  Team have agreed, or in a form otherwise agreed to by Defendants and an individual
  State. The State shall constitute a Medicaid Participating State provided the Agreement

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is fully executed by the State and delivered to Defendants' attorneys within 60 days of receiving this Agreement. If this condition is not satisfied within 60 days Defendants' offer to resolve this matter with the individual State shall become null and void absent written agreement between counsel for Defendants and the State Team to extend the 60 day period.

- (d) The total portion of the amount paid by Defendants in settlement for the Covered Conduct for the State is \$1,280,750.90, consisting of a portion paid to the State under this Agreement and another portion paid to the United States as part of the Federal Settlement Agreement. The amount allocated to the State under this Agreement is the sum of \$426,939.52, plus applicable interest (the "State Amount"). If the State does not execute this Agreement within 60 days of receiving this Settlement Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by Defendants absent written agreement between counsel for Defendants and the State Team to extend the time period for executing this Agreement.
- (e) If Wyeth'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 State or Defendants. If either the State or Defendants exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within five business days of the Court's decision, the Parties will not object and this Agreement will be rescinded. If this Agreement is rescinded, Defendants will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories, to any Page 6 of 14

civil or administrative claims, actions or proceedings arising from the Covered Conduct that are brought by the State within 90 calendar days of rescission, except to the extent such defenses were available on January 1, 2010, or as otherwise preserved by the filing of the Civil Actions, referenced in Preamble Paragraph B, which were served on the State.

- The State agrees to dismiss with prejudice any state law claims which the
   State has the authority to dismiss currently pending against Defendants in State or
   Federal Courts for the Covered Conduct.
- 3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Defendants set forth in this Agreement, and conditioned upon receipt by the State of its share of the Medicaid State Settlement Amount, the State agrees to release Defendants, their predecessors and current and former parents, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and former directors, officers, and employees, individually and collectively (collectively, the "Defendants' Released Entities"), from any civil or administrative monetary cause of action that the State has for any claims submitted or caused to be submitted to the State Medicaid Program as a result of the Covered Conduct.
- 4. Notwithstanding any term of this Agreement, the State specifically does not release any person or entity from any of the following liabilities:
- (a) any criminal, civil, or administrative liability arising under state revenue codes;
  - (b) any criminal liability not specifically released by this Agreement;

- (c) any civil or administrative liability that any person or entity, including any Released Entities, has or may have to the State or to individual consumers or state program payors under any statute, regulation or rule not expressly covered by the release in Paragraph 3 above, including but not limited to, any and all of the following claims: (i) State or federal antitrust violations; (ii) Claims involving unfair and/or deceptive acts and practices and/or violations of consumer protection laws;
- (d) any liability to the State for any conduct other than the Covered Conduct;
- (e) any liability which may be asserted on behalf of any other payors or insurers, including those that are paid by the State's Medicaid program on a capitated basis;
  - (f) any liability based upon obligations created by this Agreement;
- (g) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusions from the State's Medicaid program;
- (h) any liability for expressed or implied warranty claims or other claims for defective or deficient products and services provided by Defendants;
- (i) any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; or
  - (j) any liability based on a failure to deliver goods or services due.
- 5. This Agreement is expressly conditioned upon resolution of the Federal Criminal Action. In consideration of the acceptance of Wyeth's plea of guilty in the Federal Criminal Action, the State's Medicaid Fraud Control Unit agrees that it shall not further criminally investigate, prosecute, or refer for prosecution or criminal investigation

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to any agency, Defendants, their present and former parents, divisions, and subsidiaries and their predecessors, successors and assigns, for the Covered Conduct.

- 6. In consideration of the obligations of Defendants set forth in this
  Agreement, and the Corporate Integrity Agreement ("CIA") with the Office of the
  Inspector General of the United States Department of Health and Human Services to
  which both Pfizer and Wyeth are subject, and conditioned on receipt by the State of its
  share of the State Medicaid Settlement Amount, except as reserved in Paragraph 4 above,
  the State agrees to release and refrain from instituting, recommending, directing, or
  maintaining any administrative action seeking exclusion from the State's Medicaid
  program against Defendants for the Covered Conduct or for Wyeth's conviction in the
  Federal Criminal Action. Nothing in this agreement precludes the State from taking
  action against Defendants in the event that Defendants are excluded by the federal
  government, or for conduct and practices other than the Covered Conduct or Wyeth's
  conviction in the Federal Criminal Action.
- 7. Defendants waive and shall not assert any defenses they may have to criminal prosecution or administrative action for the Covered Conduct, which defenses may be based in whole or in part on a contention, under the Double Jeopardy Clause of the Fifth Amendment of the Constitution or the Excessive Fines Clause of the Eighth Amendment of the Constitution, that this Agreement bars a remedy sought in such criminal prosecution or administrative action.
- 8. In consideration of the obligations of the State set forth in this Agreement,
  Defendants waive and discharge the State, its agencies, political subdivisions, employees,
  servants, and agents from any causes of action (including attorneys' fees, costs, and

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expenses of every kind and however denominated) which Defendants have asserted, could have asserted, or may assert in the future against the State, its agencies, political subdivisions, employees, servants, and agents, arising from the State's investigation and prosecution of the Covered Conduct.

- 9. The amount that Defendants must pay to the State pursuant to Paragraph III.1. above will not be decreased as a result of the denial of claims for payment now being withheld from payment by the State's Medicaid program, or any other state payor, for the Covered Conduct. Defendants agree not to resubmit to the State's Medicaid program or any other state payor, any previously denied claims, which denials were based on the Covered Conduct, and agree not to appeal or cause the appeal of any such denials of claims.
- 10. Defendants shall not seek payment for any claims for reimbursement to the State's Medicaid Program covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors.
- 11. Defendants expressly warrant that they have reviewed their financial condition and that they are currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(B)(ii)(I), and shall remain solvent following payment of the Settlement Amount and compliance with this Agreement.
- 12. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.
- 13. Defendants agree to cooperate fully and truthfully with any State investigation of individuals or entities not released in this Agreement, stemming from the

Covered Conduct. Upon reasonable notice, Defendants shall facilitate, and agree not to impair, the cooperation of their directors, officers, employees or agents, for interviews and testimony, consistent with the rights and privileges of such individuals and of Defendants. Upon request, Defendants agree to furnish to the State complete and unredacted copies of all non-privileged documents and records in their possession, custody or control, concerning the Covered Conduct. Defendants shall be responsible for all costs they may incur in complying with this paragraph.

- 14. Except as expressly provided to the contrary in this Agreement, each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- 15. Except as otherwise stated in this Agreement, this Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any liability against any other person or entity.
- 16. Nothing in this Agreement constitutes an agreement by the State concerning the characterization of the amounts paid hereunder for purposes of the State's revenue code.
- 17. In addition to all other payments and responsibilities under this

  Agreement, Defendants agree to pay all reasonable expenses and travel costs of the State

  Team, including reasonable consultant fees and expenses. Defendants will pay this

  amount by separate check made payable to the National Association of Medicaid Fraud

  Control Units, after the Medicaid Participating States execute their respective

  Agreements, or as otherwise agreed by the Parties.

- 18. This Agreement is governed by the laws of the State, and venue for addressing and resolving any and all disputes relating to this Agreement shall be the state courts of appropriate jurisdiction of the State.
- 19. The undersigned Defendants signatories represent and warrant that they are authorized as a result of appropriate corporate action to execute this Agreement. The undersigned State signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement on behalf of the State through their respective agencies and departments.
- 20. The Effective Date of this Agreement shall be the date of signature of the last signatory to this Agreement. Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.
- 21. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.
- 22. This Agreement constitutes the complete agreement between the Parties with respect to this matter and shall not be amended except by written consent of the Parties.
- 23. This Agreement may be executed in counterparts, each of which shall constitute an original, and all of which shall constitute one and the same Agreement.

# STATE OF NORTH CAROLINA

Ву: _	CHARLES H. HOBGOOD Director, Medicaid Investigations Division Office of the Attorney General	Dated: <u>\$20\2013</u>
By: _	Cent	Dated:5/15/13

CAROL STECKEL, Director Division of Medical Assistance

# PFIZER INC AND WYETH PHARMAEUTICALS INC.

Ву:	Day 20 Dated: 7/23/13
	Pfizer Inc and Wyeth Pharmaceuticals Inc.
	Gary F. Granpetruzzi
	V.1. = Assistant General Counsel
Ву:	JOSHUA S. LEVY STEVEN S. GOLDSCHMIDT Ropes & Gray, LLP Counsel for Defendants Pfizer Inc and Wyeth Pharmaceuticals Inc.
Ву:	Dated:
	ROBERT G. McCAMPBELL Fellers, Snider, Blankenship, Bailey & Tippens, P.C. Counsel for Defendants Pfizer Inc and Wyeth Pharmaceuticals Inc.

# PFIZER INC AND WYETH PHARMAEUTICALS INC.

	Dated:
Pfizer Inc and Wye	eth Pharmaceuticals Inc.
	Dated:
JOSHUA S. LEV STEVEN S. GOI Ropes & Gray, L Counsel for Defe	LDSCHMIDT
Lokest	Mc Coybell Dated: 7/24
	CAMPBELL Blankenship, Bailey & Tippens, P.C. Endants Pfizer Inc and Wyeth Pharmaceuticals Inc.