



## State of North Carolina

ROY COOPER  
ATTORNEY GENERAL

Department of Justice  
PO Box 629  
Raleigh, North Carolina  
27602

Phone: (919) 716-6400  
Fax: (919) 716-6750

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.

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 AWP SETTLEMENT AGREEMENT**

### **I. PARTIES**

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

### **II. PREAMBLE**

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

1. Amgen Inc. is a biotechnology company organized under the laws of the State of Delaware and headquartered in Thousand Oaks, California. Amgen Inc. develops, manufactures, markets and sells biologic products in the United States. Immunex Corporation is a wholly-owned subsidiary of Amgen Inc. and, until its acquisition by Amgen Inc. in July 2002, similarly was involved in the development, manufacturing, marketing and sale of biologic products in the United States. Immunex Corporation is organized under the laws of the State of Washington, and has its principal place of business in Thousand Oaks, California. Unless otherwise noted, Amgen Inc. and all of its subsidiaries, including but not limited to Amgen USA and Immunex Corporation, are collectively referred to herein as "Amgen."

2. At all times relevant to this Agreement, Amgen developed, manufactured, distributed, marketed and sold biologic products including without limitation biologics under the trade names Aranesp, Enbrel, Epogen, Neulasta, Neupogen and Sensipar. The biologic products manufactured, marketed, distributed and/or sold by Amgen and covered by this Agreement include all products which were produced, marketed, reimbursed or sold by Amgen including all products under Labeler Codes 55513 and 58406 and are referred to herein as the "Covered Drugs."

3. The State is one of several participating states investigating potential civil claims against Amgen arising out of its business and/or marketing practices in connection with the Covered Drugs, including, without limitation, possible claims on the states' behalf for submission of claims for payment to the states' Medicaid Programs. For purposes of this Agreement, "Medicaid Participating States" shall include: Arkansas; California; Colorado; Connecticut; Delaware; Florida; Georgia; Hawai'i; Idaho; Indiana; Maine; Maryland; Massachusetts; Michigan; Minnesota; Missouri; Nebraska; New Hampshire; New Jersey; New Mexico; New York; North Carolina; North Dakota; Ohio; Oklahoma; Oregon; Rhode Island; South Carolina; South Dakota; Tennessee; Utah; Vermont; Washington; West Virginia; Wyoming; and the District of Columbia.

4. The State contends that Amgen engaged in the conduct described in this Paragraph relating to the Covered Drugs which shall constitute the "Covered Conduct." The State further contends that it has certain potential civil, administrative, or other claims or causes of action against Amgen arising out of the Covered Conduct as a result of which it contends that Amgen directly or indirectly caused misleading, unfair, false, fraudulent or otherwise incorrect or inaccurate claims to be submitted to Medicaid for the Covered Drugs.

(a) The State contends that between 1991 and the Effective Date of this Agreement, Amgen engaged in conduct, events, transactions and practices, directly or indirectly, to set, report, publish and/or maintain, or caused to be used, set, reported, published and/or maintained, or failed to object to the use, setting, reporting, publication and/or maintenance of misleading, unfair, false, fraudulent, incorrect, inaccurate or inflated benchmark prices for certain of the Covered Drugs, including benchmark prices reported to various commercial price reporting services, including First DataBank and Red Book, and upon which the State and others

relied in setting Medicaid reimbursement rates and in making Medicaid reimbursements for the purchase of Amgen products. These reported prices included but were not limited to Average Wholesale Price (“AWP”), Wholesale Acquisition Cost (“WAC”), Wholesale Acquisition Price (“WAP”), Wholesaler Price, Wholesaler (Distributor) Price, Suggested AWP, List Price, Suggested List Price, and Direct Price (the “Reported Prices”).

(b) The State further contends that the difference between Amgen’s Reported Prices upon which Medicaid reimbursements were made for the Covered Drugs and the actual transaction price at which Covered Drugs were sold created excessive or otherwise improper profit margins for pharmacists, medical providers and others.

(c) The State further contends that Amgen unlawfully sold, marketed or otherwise promoted the “spread,” or difference, between the Reported Prices or reimbursement rates that the State contends were determined in part on the basis of the Reported Prices and the actual transaction prices for the Covered Drugs in order to induce or increase sales of the Covered Drugs – that is, that Amgen sold, marketed or otherwise promoted the profit margins between the prices upon which the State and others based Medicaid reimbursements for Covered Drugs and the transaction prices at which the Covered Drugs were actually sold. The State further contends that the Reported Prices were higher than they should have been and that Amgen knew or should have known that its Reported Prices would be used and/or relied upon by the State Medicaid Program to set reimbursement rates for the Covered Drugs.

5. The United States has requested the Medicaid Participating States accept payment of the federal share (the “Federal Share”) of each Medicaid Participating State’s settlement with Amgen and has, by separate letter agreement dated March 7, 2013, a copy of which is attached

hereto as an Exhibit and made a part hereof, requested that the State offset the federal recovery pursuant to the Social Security Act, 42 U.S.C. § 1396b(d)(2)(A).

6. This Agreement is made in compromise of disputed issues of law and fact and is neither an admission of facts or liability by Amgen nor a concession by the State that its allegations are not well-founded. Amgen has a number of defenses to the State's potential claims and has denied and continues to deny the allegations of the State or that it has engaged in any wrongful conduct in connection with the Covered Conduct. Neither this Agreement, nor its execution, nor the performance of any obligation 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 upon the merits of the dispute by Amgen. The allegations that are described herein are not intended to constitute evidence admissible in a court of law.

7. As a result of their mutual desire to settle their disputes, and to avoid the delay, expense, inconvenience and uncertainty of protracted litigation of these disputed issues of fact and law, the Parties have reached a full and final settlement as set forth below.

8. The State has further determined that this settlement is in the public interest.

### **III. AGREEMENT**

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

1. Amgen agrees to pay to the Medicaid Participating States the total sum of \$10,945,425.09, Ten Million Nine Hundred Forty-Five Thousand, Four Hundred and Twenty-Five Dollars and Nine cents including accrued interest at the rate of 1.25% per annum



commencing on September 10, 2012, and continuing until March 11, 2013(the "Settlement Amount"). Amgen shall, within 10 (ten) days of the Effective date of this Agreement, pay the Settlement Amount by electronic funds transfer to a fund established by the New York State Attorney General's Office ("NY State Account") and as directed pursuant to written instructions from the State Negotiating Team ("State Team"), which written instructions shall be delivered to counsel for Amgen. The Settlement Amount comprises both payment to the Medicaid Participating States and the Federal Share of those payments due and owing from the States to the United States. The Settlement Amount shall constitute a debt immediately due and owing to the Medicaid Participating States on the Effective Date of this Agreement, subject to the terms of this Agreement. The debt shall forever be discharged by payments to the Medicaid Participating States, under the following terms and conditions:

(a) Payment of the Federal Share. It is expressly understood that the Medicaid Participating States shall be solely responsible for the calculation and payment of the Federal Share of the Settlement Amount (including interest thereon), and that the Federal Share shall be paid from the total Settlement Amount with no further obligation on the part of Amgen. The State Team shall be solely responsible for allocating the Federal Share to each of the Medicaid Participating States, and the Medicaid Participating States shall be responsible for reporting and refunding that amount by offsetting the Federal Medical Assistance Percentage on the next appropriate quarterly expenditure report (Form CMS-64), as directed and authorized by the United States in the attached Exhibit.

(b) The total portion of the Settlement Amount paid by Amgen in settlement for the Covered Conduct for the State is \$368,304.24 , consisting of the State's portion of the Medicaid State Settlement Amount and its portion of the Federal Share, as determined by the State Team plus applicable interest. The individual portion of the Medicaid State Settlement Amount allocated to the State under this Agreement is \$121,284.70 , plus applicable interest (the "State Amount").

2. The State expressly agrees to dismiss with prejudice any lawsuit currently pending against the Amgen Released Entities (as defined below) in any State or Federal Court asserting allegations or claims as a result of the Covered Conduct in which the State has intervened or which the State has the authority to dismiss.

3. Subject to the exceptions set forth in Paragraph III.4 below, and in consideration of the obligations of Amgen set forth in this Agreement, conditioned upon payment of the Settlement Amount in the manner set forth herein, the State on behalf of itself, and its officers, agents, agencies, and departments, fully and finally, and to the greatest extent allowed by law, releases Amgen, its predecessors and current and former parents, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and former directors, officers, employees, and related corporate entities, individually and collectively (collectively, the "Amgen Released Entities"), from any civil or administrative claim, action, damages, suit or proceeding that the State, its officers, agents, and agencies and departments have or may have or could assert in the future against the Amgen Release Entities 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;

(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 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 anti-trust 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 based upon obligations created by this Agreement;

(f) 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;

(g) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusions from the State's Medicaid program, except for administrative liability, including mandatory exclusion based on the Covered Conduct;

(h) any express or implied warranty claims or other liability for defective or deficient products and services provided by Amgen;

(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 items or services due.

5. In consideration of Amgen's obligations as set forth in this Agreement, and conditioned on payment of the Settlement Amount in the manner set forth herein, except as reserved in Paragraph III.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 the Amgen Released Entities for the Covered Conduct. The State further agrees to refrain from recommending, causing or attempting any administrative action or sanction, including debarment for the Covered Conduct. Nothing in this Agreement precludes the State from taking action against Amgen in the event that Amgen is excluded by the federal government, or for conduct and practices other than the Covered Conduct, except as may otherwise be agreed upon by the parties.

6. In consideration of the obligations of the State as set forth in this Agreement, Amgen waives and discharges the State, its agencies, political subdivisions, employees, servants, and agents from any causes of actions (including any action for attorneys' fees, costs, and expenses of every kind and however denominated) which Amgen has 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 of the Covered Conduct.

7. The amount that Amgen 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; and, if applicable, Amgen agrees 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 agrees not to appeal or cause the appeal of any such denials of claims.

8. Amgen shall not seek payment for any of the claims for reimbursement to Medicaid covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors.

9. Amgen expressly warrants that it has reviewed its financial condition and that it is 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 due hereunder. Further, the Parties expressly warrant that, in evaluating whether to execute this Agreement, the Parties (a) have intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Amgen within the meaning of 11 U.S.C. § 547(c)(1), and (b) have concluded that these mutual promises, covenants and obligations do, in fact, constitute such a contemporaneous exchange.

10. Neither of the Parties to this Agreement shall be considered the drafter of this Agreement or of any included provision for the purpose of any statute, case law or rule of construction that would or might cause any provision to be construed against the drafter.

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

12. 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.

13. 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 person or entity, other than as may be released by Paragraph III.3, III.5 and III.6 above.

14. 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.

15. In addition to all other payments and responsibilities under this Agreement, Amgen agrees to pay all reasonable expenses and travel costs of the State Team, including reasonable consultant fees. Amgen 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.

16. 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.

17. The undersigned Amgen signatories represent and warrant that they are authorized 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.

18. 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.

19. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.

20. This Settlement 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.

21. 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

By: Charles H. Hobbgood

CHARLES H. HOBGOOD  
Director, Medicaid Investigations Division  
Office of the Attorney General


Dated: 3/22/2013

By: Carol

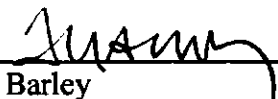
CAROL STECKEL, Director  
Division of Medical Assistance

Dated: 3/21/2013

AMGEN INC.

By:   
Name: Jill L. Korpe  
Title: Associate General Counsel

Dated: 4/17/13

By:   
Steven F. Barley  
Joseph H. Young  
HOGAN LOVELLS US LLP  
100 International Drive, Suite 2000  
Baltimore, MD 21202  
Attorneys for Amgen Inc.

Dated: 4/15/13