



State of North Carolina

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July 17, 2014

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 Astellas Pharma

Dear Members:

Section 114-2.5 of the North Carolina General Statutes 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 matter. 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.

A Settlement Agreement has been executed between Astellas Pharma US., Inc. and the State of North Carolina. Astellas Pharma US, Inc. is a pharmaceutical company based in Northbrook, Illinois. Astellas Pharma US, Inc. is an indirect subsidiary of its affiliate Astellas Pharma, Inc., based in Tokyo, Japan. At all relevant times, Astellas Pharma distributed, marketed, and sold pharmaceutical products in the United States,

including Mycamine.

The settlement resolves allegations that from January 1, 2005 through December 31, 2010, Astellas Pharma marketed and promoted the sale and use of Mycamine for pediatric patients, when the drug had not been approved as safe and effective by the Food and Drug Administration ("FDA") for such patients.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$165,528.55. Of that amount the federal government will receive \$112,099.14 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 \$9,042.58 of North Carolina's recovery. The North Carolina Medicaid Program will receive \$21,438.14 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 \$21,200.39 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 \$1,748.30 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

KH:ng

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 Astellas Pharma US, Inc. (“Defendant”), hereinafter collectively referred to as “the Parties.”

II. PREAMBLE

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

A. Astellas Pharma US, Inc. is a pharmaceutical company based in Northbrook, Illinois. Astellas Pharma US, Inc. is an indirect subsidiary of its affiliate, Astellas Pharma Inc., based in Tokyo, Japan. At all relevant times, Astellas Pharma US, Inc. distributed, marketed and sold pharmaceutical products in the United States, including Mycamine® (NDC Nos. 00469321110, 00469325010).

B. Mycamine® is a sterile, lyophilized antifungal agent that contains micafungin sodium and is administered through intravenous infusion. In 2005, Mycamine® was approved to treat adult patients with esophageal candidiasis and for prophylaxis of Candida infections in patients undergoing hematopoietic stem cell transplantations. In 2008, Mycamine® was also approved to treat adult patients with Candidemia, Acute Disseminated Candidiasis, Candida Peritonitis and Abscesses. From 2005 to June 23, 2013, Mycamine® was not approved to treat pediatric patients for any use.

C. On March 8, 2010, Relator filed a *qui tam* action in the United States District Court for the Eastern District of Pennsylvania captioned *United States ex rel. Frank Smith, et al. v. Astellas Pharma US, Inc., et al.*, Civil No. 10-999, pursuant to the *qui tam* provisions of the

False Claims Act, 31 U.S.C. § 3730(b) (the "Civil Action"). Relator filed his Third Amended Complaint on November 21, 2012.

D. Defendant has entered into a separate civil settlement agreement (the "Federal Settlement Agreement") with the United States (as that term is defined in the Federal Settlement Agreement) hereinafter referred to as the "United States."

E. The State contends that Defendant knowingly submitted or caused to be submitted false or fraudulent claims for payment to the State's Medicaid Program (see 42 U.S.C. §§ 1396-1396w-5).

F. The State contends that it has certain civil and administrative causes of action against the Defendant arising from the marketing, promotion, and sale of Mycamine® as follows (referred to throughout this agreement as the "Covered Conduct"):

Between January 1, 2005 through December 31, 2010, the Defendant knowingly marketed and promoted the sale and use of Mycamine® for pediatric patients, when the drug had not been approved as safe and effective by the Food and Drug Administration ("FDA") for such patients, and such use was not a medically-accepted indication as defined by 42 U.S.C. 1396r-8(k)(6) and the State's Medicaid program did not provide coverage for such use of Mycamine®. The State contends that Defendant knowingly submitted or caused to be submitted false or fraudulent claims to the State's Medicaid program.

G. This Agreement is neither an admission of facts or liability by Defendant, nor a concession by the State that its allegations are not well founded. Defendant expressly denies the allegations of the State as set forth herein and in the Civil Action.

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. Defendant agrees to pay to the United States and the Medicaid Participating States (as defined in sub-paragraph (c) below), collectively, the sum of \$7,300,000, plus accrued interest on that amount of 1.25% per annum commencing on December 18, 2013 and continuing and including the day 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) Defendant shall pay to the United States the sum of \$4,169,723.50, plus accrued interest on that amount at the rate of 1.25% per annum commencing on December 18, 2013 ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.

(b) Defendant shall pay to the Medicaid Participating States the sum of \$3,130,276.50 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 the expiration of the 60 day opt-in period for Medicaid Participating States described in sub-paragraph (c) below. 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 Defendant.

(c) Defendant shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which Defendant and the State Team have agreed, or in a form otherwise agreed to by Defendant and an individual State. The State shall constitute a Medicaid Participating State provided the Agreement is fully executed by the State and delivered to Defendant's attorneys within 60 days of April 14, 2014. If this condition is not satisfied within 60 days, Defendant's offer to resolve this matter with the individual State shall become null and void absent written agreement between counsel for Defendant and the State Team to extend the 60 day period.

(d) The total portion of the amount paid by Defendant in settlement for the Covered Conduct for the State is \$165,290.80, 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 \$53,191.66, plus applicable interest (the "State Amount"). If the State does not execute this Agreement within 60 days of April 14, 2014, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by Defendant absent written agreement between counsel for Defendant and the State Team to extend the time period for executing this Agreement.

2. The State agrees to promptly dismiss with prejudice any state law claims which the State has the authority to dismiss currently pending against Defendant in State or Federal Courts for the Covered Conduct, including any supplemental state law claims asserted in the Civil Action. Contingent upon the receipt of their respective State Amounts, the State, if served with

the Civil Action and liable to pay a Relator's share, agrees to pay the Relator the amount of \$9,042.58, plus applicable interest. This amount is to be paid through the State Team and has been addressed via a side letter with the Relator in the Civil Action.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Defendant set forth in this Agreement, and conditioned upon receipt by the State of the State Amount, the State agrees to release Defendant, together with its current and former direct and indirect parent corporations and limited liability companies (the "Parents"); its and their affiliates, direct and indirect subsidiaries, brother and sister companies, and divisions; and its and their respective current and former owners, officers, directors and employees; and the predecessors, successors, transferees, heirs, and assigns of any of them (collectively, the "Defendant Released Entities"), from any civil or administrative monetary cause of action that the State has for 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 Defendant 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 Defendant;
- (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. The States expressly reserve all rights to institute, direct, or to maintain any administrative action (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7(a) (mandatory exclusion), or 42 U.S.C. § 1320a-7a (permissive exclusion) against Astellas Pharma US, Inc. and/or its officers, directors, and employees for the covered conduct.

6. Defendant waives and shall not assert any defenses it 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.

7. In consideration of the obligations of the State set forth in this Agreement, Defendant waives and discharges the State, its agencies, political subdivisions, employees, servants, and agents from any causes of action (including attorneys' fees, costs, and expenses of

every kind and however denominated) which Defendant 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 and prosecution of the Covered Conduct.

8. The State Amount 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 Defendant 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.

9. Defendant 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.

10. Defendant 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 and compliance with this Agreement.

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

12. Defendant agrees to cooperate fully and truthfully with any State investigation of individuals or entities not released in this Agreement. Upon reasonable notice, Defendant shall facilitate, and agree not to impair, the cooperation of its directors, officers, employees or agents, for interviews and testimony, consistent with the rights and privileges of such individuals and of Defendant. Upon request, Defendant agrees to furnish to the State complete and unredacted

copies of all non-privileged documents including, but not limited to, reports, memoranda of interviews, and records in its possession, custody or control, concerning the Covered Conduct. Defendant shall be responsible for all costs it may incur in complying with this paragraph.

13. 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.

14. 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.

15. 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.

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

17. 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.

18. The undersigned Defendant signatory represents and warrants that he/she is 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.

19. 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.

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


21. 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.

22. 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: *5/8/2014* 

By: *Sandy Terrell*


SANDY TERRELL, RN, MS, Acting Director
Division of Medical Assistance

Dated: *4/28/14*

ASTELLAS PHARMA US, INC. - DEFENDANT

By:  Dated: 6/13/14

LINDA F. FRIEDMAN
Astellas Pharma US, Inc.
Secretary

By:  Dated: 6/13/14

THOMAS M. GALLAGHER
Pepper Hamilton LLP
Counsel for Defendant Astellas Pharma US, Inc.