



**JOSH STEIN**  
**ATTORNEY GENERAL**

**STATE OF NORTH CAROLINA**  
**DEPARTMENT OF JUSTICE**

**SETH DEARMIN**  
**CHIEF OF STAFF**

October 31, 2017

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

Senator Warren Daniel  
Senator Shirley Randleman  
Senator Norman W. Sanderson  
Representative James Boles, Jr.  
Representative Ted Davis, Jr.  
Representative Allen McNeill  
Representative Rena W. Turner  
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 Mylan, Inc.

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 has been executed between Mylan and the State of North Carolina.

The settlement resolves allegations that from July 29, 2010 through March 31, 2017, Mylan knowingly submitted false statements to CMS and/or state governments that incorrectly classified Epipen as a "noninnovator multiple source" drug, as opposed to a "single source" or "innovator multiple source" drug. This settlement also resolves allegations that Mylan did not report its Best Price to CMS.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$21,490,740.77. Of that amount the federal government will receive \$14,043,534.28 for North Carolina's federal portion of Medicaid recoveries. Pursuant to G.S. § 1-610, the qui tam plaintiffs whose whistleblower actions brought this matter to the government's attention will receive \$1,214,512.93 of North Carolina's recovery. The North Carolina Medicaid Program will receive \$4,408,970.83 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 \$1,517,950.70 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. § 1-608(c), the North Carolina Department of Justice will receive \$305,772.03 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,



Seth Dearmin  
Chief of Staff

SD:ng

cc: Kristine Leggett, NCGA Fiscal Research Division

## STATE SETTLEMENT AGREEMENT

### I. PARTIES

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

### II. PREAMBLE

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

A. At all relevant times, Mylan Inc., a Pennsylvania corporation with its principal place of business in Canonsburg, Pennsylvania, manufactured, distributed, marketed and/or sold pharmaceutical products in the United States through its wholly-owned subsidiaries. Mylan Inc. acquired Dey Pharma, L.P. ("Dey") as a wholly-owned subsidiary in 2007, and changed Dey's name to Mylan Specialty L.P. in 2012 (collectively referred to hereafter as "Mylan Specialty"). Mylan Specialty L.P. is a Delaware limited partnership with its principal place of business in Morgantown, West Virginia, and is a wholly-owned subsidiary of Mylan Inc. At all relevant times, Mylan Specialty has owned the exclusive rights to sell EpiPen® and EpiPen Jr.® products, identified by National Drug Codes ("NDCs") 49502-0500-01, 49502-0500-02, 49502-0501-01, and 49502-0501-02 (collectively, "EpiPen"), in the United States.

B. On July 29, 2016, sanofi-aventis US LLC ("Relator sanofi") filed a *qui tam* action in the United States District Court for the District of Massachusetts captioned *United States ex rel. sanofi-aventis US LLC v. Mylan Inc., et al.* (No. 16cv11572-ADB), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b), and filed

an amended *qui tam* complaint on August 4, 2016 (the “sanofi Action”) that asserted claims under state false claims acts. On December 8, 2016, Ven-a-Care of the Florida Keys, Inc. (“Relator Ven-a-Care”) filed a *qui tam* action in the United States District Court for the Southern District of New York captioned *United States, et al., ex rel. Ven-a-Care of the Florida Keys, Inc. v. Mylan Inc., et al.* (No. 16cv9484-JGK), pursuant to the *qui tam* provisions of the False Claims Act and state false claims acts, and filed an amended *qui tam* complaint on January 3, 2017 (the “Ven-a-Care Action”). On January 19, 2017, the Ven-A-Care’s Action was transferred to the District of Massachusetts under the same caption and later assigned Case No. 17-10140-ADB. Collectively, the sanofi Action and Ven-a-Care Action shall be referred to as the “Civil Actions,” and Sanofi and Ven-A-Care collectively shall be referred to as the “Relators.”

C. Mylan has 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 (the “United States”).

D. The State contends that: (1) under 42 U.S.C. § 1396r-8 (the “Rebate Statute”) and its Rebate Agreement with the Secretary of the Department of Health and Human Services (“HHS”), Mylan Specialty had obligations to pay quarterly rebates to the State Medicaid Program (42 U.S.C. Chapter 7 Subchapter XIX), per unit of EpiPen dispensed to State Medicaid Program participants; (2) pursuant to the Rebate Statute, Mylan Specialty was required to classify EpiPen as an “innovator” or “noninnovator” drug to the Centers for Medicare and Medicaid Services (“CMS”) and to submit pricing information to CMS regarding EpiPen; and (3) Mylan submitted or caused to be



submitted statements to CMS that were material to Mylan's obligations to pay rebates to the State's Medicaid Program for EpiPen.

E. The State contends that it has certain civil and administrative monetary claims against Mylan for the following conduct from July 29, 2010 to March 31, 2017:

Mylan Specialty knowingly submitted false statements to CMS and/or the State governments that incorrectly classified EpiPen as a "noninnovator multiple source" drug, as opposed to a "single source" or "innovator multiple source" drug, as those terms are defined in the Rebate Statute and Rebate Agreement. Mylan Specialty also did not report a Best Price to CMS, as that term is defined in the Rebate Statute and Agreement, for EpiPen which it was required to do for all "single source" and "innovator multiple source" drugs. As a result, the State asserts that Mylan (1) submitted or caused to be submitted false statements to the States relating to EpiPen for Medicaid rebate purposes; and (2) knowingly underpaid EpiPen rebates to the State Medicaid Programs. The alleged conduct set forth in this Paragraph constitutes the "Covered Conduct" for purposes of this Agreement. No statements by Mylan prior to the Effective Date of the Federal Settlement Agreement as to the settlement of this matter shall be construed as denying the Covered Conduct.

F. The United States contends that Mylan overcharged certain entities (hereinafter known as the 340B Covered Entities) that participated in the 340B Drug Pricing Program, 42 U.S.C. § 256b, which is part of the federal Public Health Service (PHS) Act, 42 U.S.C. § 201-300ggg-92, which conduct is part of the Covered Conduct in the Federal Settlement Agreement.

G. 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. Mylan agrees to pay to the United States, the Medicaid Participating States (as defined in sub-paragraph (b) below), and the 340B Covered Entities, collectively, the sum of four hundred sixty-five million dollars (\$465,000,000), plus accrued interest on that amount of 1.625% per annum commencing on October 6, 2016 and continuing and including the day payment is made under this Agreement (collectively, the "Settlement Amount") as specified in subparagraphs (a) through (c) below. The Settlement Amount shall constitute a debt immediately due and owing to the United States, the Medicaid Participating States, and the 340B Covered Entities 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, the Medicaid Participating States, and the 340B Covered Entities under the following terms and conditions:

(a) Mylan shall pay to the United States the sum of \$231,764,000 plus accrued interest on that amount at the rate of 1.625% per annum commencing on October 6, 2016 ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.



(b) Mylan shall pay to the Medicaid Participating States the sum of \$213,936,000 plus accrued interest on that amount at the rate of 1.625% per annum commencing on October 6, 2016 ("Medicaid State Settlement Amount"), subject to the non-participating state deduction provision of Sub-paragraph (e) 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 (d) 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 Settlement Team ("State Team"), which written instructions shall be delivered to counsel for Mylan.

(c) Mylan shall pay into an escrow account with a national banking institution (the "340B Deposit Account"), pursuant to written instructions provided by the United States, the sum of \$19,300,000 plus accrued interest ("340B Settlement Amount"). The 340B Payment Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.

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



(e) The total portion of the amount paid by Mylan in settlement for the Covered Conduct for the State is \$21,404,218.68, 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 \$7,360,684.40 plus applicable interest (the "State Amount"). If the State does not execute this Agreement within 60 days of receiving this Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by Mylan absent written agreement between counsel for Mylan and the State Team to extend the time period for executing this Agreement.

2. Contingent upon receipt of the State Amount, the State agrees to dismiss with prejudice any state law claims which the State has the authority to dismiss currently pending against Mylan in State or Federal Courts for the Covered Conduct, including any supplemental state law claims asserted in the Civil Actions. Contingent upon receipt of the State Amount, the State, if served with the Civil Actions and otherwise liable to pay a relator's share, agrees to pay the Relators the amount of \$1,214,512.93 plus applicable interest. This amount is to be paid through the State Team and has been addressed via side letters with the Relators in the Civil Actions.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Mylan set forth in this Agreement, and conditioned upon receipt by the State of the State Amount, the State agrees to release Mylan, its predecessors and current and former parents, divisions, subsidiaries, affiliates, successors, transferees, heirs, and assigns (collectively, the "Mylan Released Entities"), from any civil or administrative monetary cause of action that the State has for the Covered Conduct.

4. Notwithstanding the releases given in Paragraph 3 of this Agreement, or any other term of this Agreement, the following claims of the State are specifically reserved and are not released:

- (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 the Mylan 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; and (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) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusions from the State's Medicaid Program;
- (g) any liability for expressed or implied warranty claims or other claims for defective or deficient products and services, including quality of goods and services;
- (h) any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;
- (i) any liability for failure to deliver goods or services due; or
- (j) any liability of individuals.

5. In consideration of the obligations of Mylan set forth in this Agreement, and the Corporate Integrity Agreement (the "CIA") that Mylan has entered into with the Office of the Inspector General of the United States Department of Health and Human Services in connection with this matter, and conditioned on receipt by the State of the State Amount, 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 Mylan for the Covered Conduct, except as reserved in Paragraph 4 above. Nothing in this Agreement precludes the State from taking action against Mylan in the event that Mylan is excluded by the federal government, or for conduct and practices other than the Covered Conduct.

6. Mylan 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 U.S. Constitution or the Excessive Fines Clause of the Eighth Amendment of the U.S. 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, the Mylan Released Entities waive and discharge the State and any of its agencies, departments, and personnel including, but not limited to, officials, employees, and agents, whether current or former in their official and individual capacities from any causes of action (including attorneys' fees, costs, and expenses of every kind and however denominated) which the Mylan Released Entities have against the State and any of its



agencies, departments, and personnel as previously referenced arising from the State's investigation and prosecution of the Covered Conduct.

8. The amount that Mylan must pay to the State pursuant to Paragraph III.1.b above will not be decreased as a result of the denial of any claims for payment now being withheld from payment by the State's Medicaid Program, or any other state program payor, for the Covered Conduct; and Mylan agrees not to resubmit to the State's Medicaid Program or any other state program payor, any previously denied claims, which denials were based on the Covered Conduct, and agrees to withdraw the appeal of, or not to appeal or cause the appeal of, any such denials of claims.

9. Mylan 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. Mylan 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)(1)(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. Mylan agrees to cooperate fully and truthfully with any State investigation relating to the Covered Conduct of individuals or entities not released in this Agreement. Upon reasonable notice of such an investigation, Mylan 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 and of Mylan. Upon request, Mylan 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 any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf, as well as complete and unredacted copies of any other non-privileged documents in its possession, custody, or control relating to the Covered Conduct. Mylan 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 the Parties do not release any liability as to 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, Mylan agrees to pay the State Team's reasonable expenses and fees, including travel costs, consultant expenses, and administrative fees. Mylan 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, except disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions of the CIA, 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 Mylan 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.

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

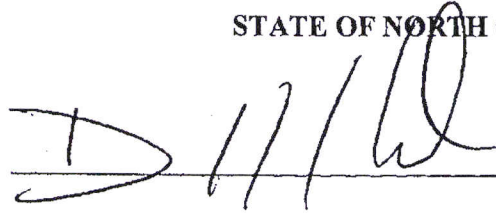
20. This Agreement constitutes the complete agreement between the Parties with respect to this matter and shall not be amended except by written consent of the Parties.

21. 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.

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:



Dated: 8/21/17

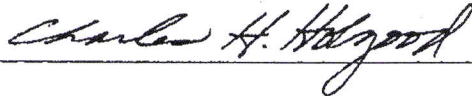
Dave Richard

Name

Deputy Secretary for  
Title medical Assistance

NC DHHS DMA  
Organization

By:



Dated: 8/23/2017

Charles H. Hobgood

Name

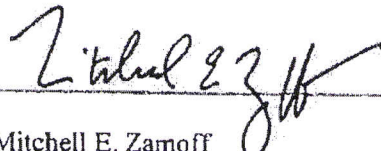
Director, Medicaid Investigations Division  
Title

Office of the Attorney General  
Organization

MYLAN

By:  Dated: 8/15/17

Brian S. Roman  
Global General Counsel  
Mylan Inc.

By:  Dated: 8/16/17

Mitchell E. Zamoff  
Hogan Lovells US LLP  
Counsel to Mylan