# STATE SETTLEMENT AGREEMENT AND RELEASE

## I. PARTIES

This Settlement Agreement and Release ("Agreement") is entered into between the State of Michigan (hereinafter referred to as "the State") and Aventis Pharmaceuticals, Inc. ("API"). The State and API are hereinafter collectively referred to as "the Parties".

## II. PREAMBLE

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

A. From 1992 until December 1999, Rhône-Poulenc Rorer Pharmaceuticals Inc. ("RPR"), a Delaware corporation with its principal place of business in Collegeville, Pennsylvania, marketed and sold pharmaceutical products throughout the United States. In a series of corporate transactions beginning in December 1999, RPR became API. API's corporate parent then merged with Sanofi-Synthélabo in 2004, leading to the creation of sanofi-aventis U.S. Inc. and sanofi-aventis U.S. LLC.

B. Among the products marketed and sold by RPR at times during this period was the prescription drug product triamcinolone acetonide, a steroid-based anti-inflammatory nasal spray, sold under the brand name Azmacort®. RPR sold Azmacort®, and later Nasacort® and Nasacort AQ®, which are also steroid-based anti-inflammatory nasal sprays containing triamcinolone acetonide, to various customers, including, among others, Health Maintenance Organizations ("HMOs"), hospitals, long term care providers, and retail pharmacies.

C. During the period from October 1, 1995 through September 30, 2000, RPR and API at various times sold Azmacort®, Nasacort®, and Nasacort AQ® to the HMOs Kaiser Permanente Medical Care Program ("Kaiser") and its affiliate, Group Health Cooperative ("GHC") through "private label sales contracts." Under these private label sales contracts, RPR

and API manufactured, packaged, and shipped Azmacort®, Nasacort®, and Nasacort AQ® to Kaiser and GHC in special packaging that included the National Drug Code ("NDC") numbers obtained by the HMOs rather than the NDC numbers obtained by RPR for each product. Under the private label sales contracts, RPR and API sold Azmacort®, Nasacort®, and Nasacort AQ® to Kaiser and GHC at discounted prices

D. At all relevant times, RPR and API participated in the Medicaid Drug Rebate Program, 42 U.S.C. § 1396r-8, which is part of the federal Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. § 1396-1396v. Under the Medicaid Drug Rebate Program, RPR and API generally agreed: (i) to report quarterly to the Centers for Medicare and Medicaid Services ("CMS"), formerly the Health Care Financing Administration ("HCFA"), the Average Manufacturer Price and Best Price for their drug products, as defined by 42 U.S.C. §§ 1396r-8(k)(1) and 1396r-8(c)(1)(C); and (ii) to pay quarterly rebates to the states based on the product of (a) the units of each dosage form and strength paid for under the State Medicaid plan during the rebate period as reported by the state, and (b) the greater of the difference between the Average Manufacturer Price and Best Price, or a minimum rebate percentage of the Average Manufacturer Price, as further described in 42 U.S.C. § 1396r-8(c)(1)

E. The State contends that RPR and API knowingly made false statements to decrease obligations for payment, to the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v

F. The State contends that it has certain civil and administrative causes of action, as specified in paragraphs III.2 and 3, below, against API for engaging in the following conduct (hereinafter the "Covered Conduct"):

1. As set forth in Paragraph II.C, RPR and API entered into private label sales contracts with Kaiser and GHC in order to avoid including the discounted prices at which they sold privately labeled Azmacort®, Nasacort®, and Nasacort AQ® to Kaiser and GHC in their calculations of Best Price for those products.

2. From October 1, 1995 through September 30, 2000, RPR and API knowingly excluded the prices at which they sold, at various times, the privately labeled Azmacort®, Nasacort®, and Nasacort AQ® to Kaiser and GHC from their calculations of Best Price.

3. From October 1, 1995 through September 30, 2000, RPR and API reported to CMS false Best Prices for, at various times, Azmacort®, Nasacort®, and Nasacort AQ® to avoid paying higher quarterly drug rebates to the states.

4. From October 1, 1995 through September 30, 2000, RPR and API underpaid their Medicaid drug rebates by reporting to CMS, at various times, Best Prices for Azmacort®, Nasacort®, and Nasacort AQ® that excluded sales of the privately labeled Azmacort®, Nasacort®, and Nasacort AQ® sold to Kaiser and GHC.

G. The State contends that its Medicaid program was damaged as a result of the Covered Conduct.

H. API has entered into a separate civil settlement agreement (the "Federal Settlement Agreement") with the United States relating to the Covered Conduct.

I. RPR and API deny the contentions of the State and further deny any liability or wrongdoing related to those contentions.

J. This Agreement is neither an admission of liability by RPR or API, nor a concession by the State that its claims are not well founded.

K. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, the Parties mutually desire to reach a full and final settlement pursuant to the Terms and Conditions 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. (a) Pursuant to the Federal Settlement Agreement, API agrees to pay to the United States the sum of Forty Eight Million, Nine Hundred Fifty Four Thousand, Three Hundred Three Dollars ($48,954,303.00), plus interest accruing at a simple rate of 2.75 % per annum from December 29, 2008, through and including the effective date of the Federal Settlement Agreement, except that if the effective date of the Federal Settlement Agreement occurs after May 29, 2009, the interest rate shall accrue at a simple rate of 5.50 % per annum from May 29, 2009, through and including the effective date of the Federal Settlement Agreement (the "Federal Medicaid Settlement Amount"); and API agrees to pay the sum of Six Million, Four Hundred Ninety Two Thousand, One Hundred Seventy Six Dollars ($6,492,176.00), plus interest accruing in the same manner as described in this Paragraph, to Public Health Service entities (the "Federal PHS Settlement Amount"), as defined in 42 U.S.C. § 256b(a), that purchased Azmacort®, Nasacort® or Nasacort AQ® through the Drug Pricing Program, 42 U.S.C. § 256b, which is part of the Public Health Service Act, 42 U.S.C. §§ 201-300gg-92.

(b) Pursuant to the terms of Paragraph III. 1 (c) below, API agrees to pay to the States Forty Million, Fifty Three Thousand, Five Hundred Twenty One Dollars

($40,053,521.00) plus interest accruing at a simple rate of 2.75 % per annum from December 29, 2008, through and including the effective date of the Federal Settlement Agreement, except that if the effective date of the Federal Settlement Agreement occurs after May 29, 2009, the interest rate shall accrue at a simple rate of 5.50 % per annum from May 29, 2009, through and including the effective date of the Federal Settlement Agreement (the "Medicaid State Settlement Amount")

(c) API shall pay the Medicaid State Settlement Amount into an account designated by the National Association of Medicaid Fraud Control Units State Settlement Team (the "NAMFCU team") no later than three (3) business days after the effective date of the Federal Settlement Agreement and pursuant to written payment instructions from the NAMFCU team, or as otherwise agreed in writing by API and the NAMFCU team

(d) The Medicaid State Settlement Amount, to include interest, attributable to a state that chooses not to participate in this settlement, shall be returned to API.

(e) The portion of the total Medicaid Settlement Amount paid by API in settlement for the Covered Conduct on behalf of the Medicaid program of the State of Michigan is Two Million, Five Hundred Twenty Three Thousand, Seven Hundred Fifty Dollars and Three Cents ($2,523,750.03) plus applicable interest, consisting of a portion paid to the State under this Agreement and another portion paid to the Federal Government as part of the Federal Settlement Agreement. The individual portion of the Medicaid State Settlement Amount allocable and paid to the State of Michigan under this Agreement is the sum of One Million, One Hundred Seventy Five Thousand, Eight Dollars and Twenty Seven Cents ($1,175,008.27), plus applicable interest.

2. Subject to the exceptions in Paragraph 4 (concerning excluded claims), below, in consideration of the obligations of API in this Agreement, conditioned upon API's full payment of the Medicaid State Settlement Amount in accordance with Paragraph III.1 of this Agreement, the State on behalf of itself, and its officers, agents, agencies, political subdivisions and departments agrees to release API, its present and former affiliates, parents, subsidiaries and divisions, and each of its and their predecessors and successors, and each of their present and former officers, directors and employees (collectively the "Released Parties") from any civil or administrative monetary claim the State has or may have for any claims submitted or caused to be submitted to the State Medicaid Program for the Covered Conduct. The State does not release API from any claims or actions which may be asserted by private payers or insurers, including those that are paid by the State's Medicaid Program on a capitated basis.

3. In consideration of the obligations of API set forth in this Agreement and the Corporate Integrity Agreement between OIG-HHS and API, Aventis Inc., sanofi-aventis U.S. Inc. and sanofi-aventis U.S. LLC dated August 30, 2007 ("CIA") and the Addendum thereto ("CIA Addendum") and conditioned upon receipt by the State of its share of the Medicaid State Settlement Amount, the State agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the State's Medicaid program against API, Aventis Inc., sanofi-aventis U.S. Inc. and sanofi-aventis U.S. LLC for the Covered Conduct, except as reserved in Paragraph 4, below, and as reserved in this Paragraph. Nothing in this Agreement precludes the State from taking action against API, Aventis Inc., sanofi-aventis U.S. Inc. and sanofi-aventis U.S. LLC in the event any of those entities is excluded by the federal government, or for conduct and practices other than the Covered Conduct

4 Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including API) are the following claims of the State:

a. Any civil, criminal, or administrative liability arising under State revenue codes;

b. Any criminal liability;

c. Any liability to the State (or its agencies) for any conduct other than the Covered Conduct;

d. Any liability based upon such obligations as are created by this Agreement;

e. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from the State's Medicaid program;

f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services provided by API;

g. Any liability for failure to deliver goods or services due;

h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; or

i. Any civil or administrative liability of individuals (including current or former directors, officers, employees, agents, or shareholders of API) who receive written notifications that they are the target of a criminal investigation, are indicted, charged or convicted, or who enter into a plea agreement related to the Covered Conduct.

5 API waives and shall not assert any defenses API may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the State concerning the characterization of the Settlement Amount for purposes of the State revenue code.

6. In consideration of the obligations of the State set forth in this Agreement, API, on behalf of itself and its present and former affiliates, parents, subsidiaries, and divisions, and each of its and their predecessors and successors, fully and finally releases the State, its agencies, employees, servants, and agents from any claims (including attorney' s fees, costs, and expenses of every kind and however denominated) that API has asserted, could have asserted, or may assert in the future against the State, and its agencies, employees, servants, and agents, related to the Covered Conduct and the State's investigation and prosecution thereof

7. The amount that API must pay to the State pursuant to Paragraph 1, above shall 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 payer for the Covered Conduct; and API agrees not to resubmit to the State's Medicaid program or to any other state payer, any previously denied claims which denials were based on the Covered Conduct, and agrees not to appeal or cause the appeal any such denials of claims.

8. API agrees to cooperate fully and truthfully with the State's investigation (if any) of individuals and entities involved in the Covered Conduct but not released in this Agreement.

Upon reasonable notice, API shall encourage, and agrees not to impair, the cooperation of its directors, officers, agents and employees in any such investigation, and shall use its best efforts to make available and encourage the cooperation of former directors, officers, and employees for interviews and testimony in any such investigation, consistent with the rights and privileges of API and of such individuals. API agrees to produce to the State in a timely manner complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews and records in API's possession, custody or control as requested by the State in connection with any such investigation.

9. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against or waive any defense relating to any other person or entity, including any individual or entity that purchased Azmacort®, Nasacort® or Nasacort AQ® from API, except as specifically provided in this Agreement.

10. API agrees that it waives and shall not seek payment for any of the State Medicaid claims covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payers based upon the Covered Conduct.

11. API warrants that it has reviewed its financial situation and that it currently is 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 to the State of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to API, within the meaning of 11 U.S.C. § 547(c)(1), and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set

forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which API was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

12. Except as expressly provided to the contrary in this Agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

13. API represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

14. In addition to all other payments and responsibilities under this Agreement, API agrees to pay all reasonable travel costs and expenses of the NAMFCU Settlement Team. API will pay this amount by separate check or wire transfer made payable to the National Association of Medicaid Fraud Control Units.

15. This Agreement is governed by the laws of the State.

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

17. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

18. The individuals signing this Agreement on behalf of API represent and warrant that they are authorized by API to execute this Agreement. The 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 may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

20. This Agreement is binding on API's successors, transferees, heirs, and assigns.

21. All parties consent to the State's disclosure of this Agreement, and information about this Agreement, to the public.

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

THE STATE OF MICHIGAN

By: _____ Dated: June 24, 2009
[Name] ELIZABETH VALENTINE
[Title] Assistant Attorney General
[Office or Agency] Health Care Fraud Division
2860 Eyde Parkway
East Lansing, MI 48823

By: _____ Dated:
[Name]
[Title]
[Office or Agency]

By: _____ Dated: 6/23/09
[Name] JAMES R. BRANDELL
Title: Director, Bureau of Financial Management & Administrative Services
Medicaid Program:
Michigan Department of Community Health
201 Townsend Street
Lansing, MI 48913

AVENTIS PHARMACEUTICALS INC

DATED: 11/9/09 BY: _____
JOHN M. SPINNATO
Authorized Signatory
Aventis Pharmaceuticals Inc.

DATED: 11/9/09 BY: _____
LAURENT GILHODES
Authorized Signatory
Aventis Pharmaceuticals Inc.

DATED: 11/9/09 BY: _____
MICHAEL L. KOON
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