

v.)	Civil Action No. A05CA375LY
)	
ALBERT HAWKINS, in his capacity as)	
EXECUTIVE COMMISSIONER)	
OF THE TEXAS HEALTH AND)	
HUMAN SERVICES COMMISSION)	
and THE TEXAS HEALTH AND)	
HUMAN SERVICES COMMISSION)	
Defendants.)	
_____)	

SETTLEMENT AGREEMENT AND RELEASE

Part I: Parties

This Settlement Agreement (the “Agreement”) is entered into by and between, on the one hand, the State of Texas (“State”), Ven-A-Care of the Florida Keys, Inc. (“Ven-A-Care”), Albert Hawkins, in his capacity as Executive Commissioner of the Texas Health and Human Services Commission and the Texas Health and Human Services Commission (collectively referred to as “Plaintiffs”); and, on the other hand, Roxane Laboratories, Inc. (“RLI”), Boehringer Ingelheim Roxane, Inc. (“BIRI”), Boehringer Ingelheim Pharmaceuticals, Inc. (“BIPI”), Ben Venue Laboratories, Inc. (“BVL”), and Boehringer Ingelheim Corporation (“BIC”) (collectively referred to as “Defendants”), through their authorized representatives. All of the parties are collectively referred to as the “Parties” herein.

Part II: Preamble

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

A. RLI is a corporation organized under the laws of Nevada; BIRI is a corporation organized under the laws of Delaware; BIPI is a corporation organized under the laws of Delaware; BVL is a corporation organized under the laws of Delaware; and BIC is a corporation organized under the laws of Nevada. RLI, BIRI, BIPI, and BVL are wholly owned subsidiaries of BIC. RLI,

BIRI, BIPI, and BVL manufacture and/or sell certain pharmaceutical products.

B. Plaintiffs contend that the State has civil claims against Defendants under the Texas Medicaid Fraud Prevention Act, TEX. HUM. RES. CODE ANN. chapter 36, for unlawful actions taken by Defendants through the date this Agreement is executed, pertaining to the inclusion of certain of Defendants' drugs on the Texas Drug Code Index ("TDCI"). Defendants' drugs that now are the subject of the settlement of the captioned lawsuit are collectively referred to hereafter as the Covered Drugs, and are listed on **Exhibit A**, attached hereto and in a CD that was reviewed by Plaintiffs on October 17, 2005 as part of the mediation process that led to the settlement of this case (referred to hereafter as the "CD").¹ Specifically, Plaintiffs contend that Defendants have committed unlawful acts, as defined by Tex. Hum. Res. Code Ann. § 36.002, in connection with the submission of pricing information to the Texas Vendor Drug Program ("VDP") for the purpose of including certain of Defendants' Covered Drugs on the TDCI. Plaintiffs also make alter ego contentions against Defendants. The acts and omissions sued upon and which are subject to the release language in this Agreement are set forth in Cause No. GV3-03079, *State of Texas, ex. rel. Ven-A-Care of the*

¹ It is the understanding of the parties that the Covered Drugs include all of the Defendants' drugs that were on the TDCI from January 1, 1995 through the present; however, if either the Plaintiffs or the Defendants discover that one or more of the Defendants' drugs were on the TDCI during that time period and were not listed on Exhibit A or the CD, the party discovering this omission shall notify all the other parties to this Settlement Agreement within 20 business days of the discovery. As to any omitted drug with a difference 15% or greater between its AMP and reported Price to Wholesaler and/or Distributor for any quarter, the Defendants shall promptly pay the State 100% of the difference between AMP and the reported Price to Wholesaler and/or Distributor (without interest or penalty) multiplied by the number of claims for reimbursement paid to pharmacy providers for the omitted drug during the quarter in which the 15% or greater discrepancy existed. The State shall accept the aforementioned payment in full and final satisfaction for all claims (including claims for damages, statutory treble damages, penalties, exemplary damages, interest, or exclusion) the State could assert on account of the Defendants' Covered Conduct related to the omitted drug or drugs.

Florida Keys, Inc., vs. Roxane Laboratories, Inc., Boehringer Ingelheim Pharmaceuticals, Inc., Ben Venue Laboratories, Inc. and Boehringer Ingelheim Corporation, (the “Lawsuit”), and are alleged in the FOURTH AMENDED PETITION filed in the Lawsuit on or about April 14, 2005.

C. Defendants' alleged conduct and transactions referenced in Paragraph II(B) are hereinafter referred to as the “Covered Conduct.” The Covered Conduct is expressly limited to: (i) conduct which has occurred prior to the date of the execution of this Agreement; (ii) conduct as expressly alleged, in the FOURTH AMENDED PETITION in the Lawsuit as though such conduct had been alleged with respect to all of the Covered Drugs; and (iii) conduct directly related to the Defendants' price reporting conduct expressly alleged in the FOURTH AMENDED PETITION in the Lawsuit as though such conduct had been alleged with respect to all of the Covered Drugs.

D. Defendants deny all of the Plaintiffs' claims and allegations and deny that they have any liability relating to such claims and allegations. Defendants vigorously defended themselves against Plaintiffs' allegations and continue to assert that the State's claims are without basis in fact or law.

E. RLI contends that the State has unlawfully excluded certain of RLI's pharmaceutical products from the TDCI. RLI contends that the Federal Medicaid Act preempts conflicting Texas Medicaid regulations regarding when a prescription drug will be eligible to be reimbursed under the Medicaid program. The acts and omissions sued upon and which are subject to the release language in this Agreement are set forth in RLI's counterclaims raised in Cause No. GV002327, *State of Texas, ex rel Ven-A-Care of the Florida Keys, Inc., v. Roxane Laboratories, Inc.* (the “Original Lawsuit”) and RLI's claims raised in Civil Action No. A05CA375LY; *Roxane Laboratories, Inc. v. Albert Hawkins, Executive Commissioner of the Health and Human Services Commission, et al.*;

in the United States District Court for the Western District of Texas, Austin Division. (the “Federal Declaratory Judgment Action”), and are alleged in RLI’s Original Complaint filed on or about May 24, 2005.

F. The State’s alleged conduct and transactions referenced in paragraph II(E) are hereinafter referred to as the “State’s Covered Conduct.” The State’s Covered Conduct is expressly limited to: (1) conduct which has occurred prior to the date of the execution of this Agreement; (2) conduct as expressly alleged in RLI’s counterclaims raised in the Original Lawsuit and RLI’s claims raised in the Original Complaint in the Federal Declaratory Judgment Action and (3) conduct which arises directly from conduct expressly alleged in RLI’s counterclaims raised in the Original Lawsuit and expressly alleged in the Original Complaint in the Federal Declaratory Judgment Action.

G. The State denies all of RLI’s claims and allegations and denies that it has any liability relating to such claims and allegations. The State has asserted various defenses to RLI’s claims.

H. In order to avoid the delay, uncertainty, inconvenience and expense of protracted litigation of these claims, and as a result of a mutual desire to settle their disputes, the Parties have reached a full and final settlement as set forth in this Agreement.

I. This Agreement does not constitute an admission of fault or liability by Defendants, nor does it constitute evidence of any liability or unlawful conduct on the part of Defendants, and the Plaintiffs will not urge or seek to admit this Agreement as evidence of any fault or liability of Defendants’ Released Parties (as defined below in Part III(4) of this Agreement) in any investigation, administrative proceeding, or federal or state court or arbitration proceeding.

J. Plaintiffs represent to Defendants, subject only to the Relator’s rights as a qui tam plaintiff under applicable state and federal law to participate in this Agreement and to receive a

percentage of the Settlement Amount, and to the rights possessed by the United States, that no interest in any claim herein released has been assigned by them to any third party.

K. The State has concluded that this settlement is in the public interest.

Part III: Terms and Conditions

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

Incorporation of Representations

1) The foregoing Preamble is incorporated herein.

The Settlement Payment

2) (a) Defendants agree to pay the State and the Relator the total sum of TEN MILLION ONE-HUNDRED THOUSAND DOLLARS (\$10,100,000), plus interest accruing at the rate then prevailing in Texas for Bank of America, N.A.'s "Business Interest Maximizer Account" on the sum of TEN MILLION DOLLARS (\$10,000,000) from October 14, 2005 to the date of payment and interest accruing at the same rate on the sum of ONE HUNDRED THOUSAND DOLLARS (\$100,000) from October 28, 2005 to the date of payment (the "Settlement Amount") in settlement and full satisfaction of any and all claims for restitution, damages and penalties of any kind related to the Covered Conduct. Defendants shall make payment of the Settlement Amount by wire transfer to the State of Texas. Payment of the Settlement Amount shall be delivered in accordance with instructions from Patrick J. O'Connell, Chief, Civil Medicaid Fraud Section, at the Office of the Attorney General of Texas. The Parties will cooperate to exchange wiring and routing instructions so that such payment can be promptly made. Defendants shall make payment not later than 5:00

p.m. (Central Daylight Time) on November 23, 2005.

(b) THIS PARAGRAPH CONTAINS AN INDEMNITY AND HAS BEEN READ CAREFULLY BY RELATOR. The Relator expressly INDEMNIFIES and holds Defendants' Released Parties (as defined below in Part III(4) of this Agreement) harmless from and against any claims by persons or entities who have represented or provided services to the Relator in connection with the claims released herein for: (1) attorneys fees, costs, and expenses; or (2) any portion of the Settlement Amount.

Defendants' Future Compliance With Price Reporting Obligations to the State of Texas

3) Concurrent with this Agreement, and as a part of the consideration therefor, Defendants are entering into a separate agreement with the State of Texas Health & Human Services Commission regarding the Defendants' future compliance with the price reporting requirements of the State of Texas. Defendants' agreement with the State of Texas Health & Human Services Commission is attached hereto and incorporated herein for all purposes as **Exhibit B**.

Plaintiffs: Release of Defendants

4) Subject to the exceptions in Paragraph III(10) below, in consideration of the obligations of Defendants set forth in this Agreement, and conditioned upon Defendants' payment in full of the Settlement Amount specified herein, the State (on behalf of itself, its officers, agents, agencies and departments), and the Relator (on behalf of itself, its officers, agents, employees, servants, and its attorneys) fully and finally release Defendants, their affiliates, parents, subsidiaries, predecessors, successors and assigns as well as their respective current and former directors, officers, employees, agents, shareholders and attorneys (collectively, the "Defendants' Released Parties") from any civil or administrative claim, action, suit or proceeding (including any claim for restitution, damages,

attorneys fees, penalties, punitive damages, sanctions, costs, and expenses of every kind and however denominated) the State and Relator have or may have or could assert in the future under any source of law for the Covered Conduct. The payment of this Settlement Amount fully discharges Defendants from any civil or administrative obligation to the State for the Covered Conduct. Neither the Office of the Attorney General of Texas nor the Relator shall initiate or prosecute litigation against Defendants on behalf of the United States based on the impact on Texas Medicaid as a result of the Covered Conduct. This release shall not release any accounts receivable unrelated to the Covered Conduct due to the State, or any agency or instrumentality of the State, from the Defendants.

5) In consideration of the obligations of Defendants set forth in this Agreement, conditioned upon Defendants' payment in full of the Settlement Amount specified herein, the State agrees to release and refrain from instituting, directing or maintaining any action seeking exclusion from the VDP or any other Texas Medicaid program against Defendants' Released Parties for the Covered Conduct as it relates to the Texas Medicaid program, except as reserved in Paragraph III(10), below.

6) In consideration of the obligations of Defendants set forth in this Agreement, and conditioned upon payment in full of the Settlement Amount specified herein, the Plaintiffs (on behalf of themselves and their counsel) fully discharge the Defendants' Released Parties from any obligations to the State or Relator under any Guaranties of Judgment related to the Original Lawsuit or the Lawsuit and fully and finally release Defendants' Released Parties from any claims the State or Relator have or may have or could assert in the future under any source of law based on any Guaranties of Judgment related to the Original Lawsuit or the Lawsuit. Upon payment of the

Settlement Amount, all Guaranties of Judgment related to the Original Lawsuit or the Lawsuit are irrevocably terminated and any rights or obligations under any Guaranties of Judgment are extinguished.

Defendants: Release of the State and the Relator

7) Defendants fully and finally release the State, its agencies, employees, servants, attorneys and agents from any claim, action, suit or proceeding based on events occurring prior to the date of this Agreement (including any claim for restitution, damages, attorneys fees, sanctions, costs, and 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, employees, servants, attorneys and agents, for the State's Covered Conduct, or related to the Covered Conduct and the Plaintiffs' investigation and prosecution of the Covered Conduct. RLI provides this release, in part, based on the representation of the State that the State has processed all of RLI's pending drug applications and placed the subject drugs on its Medicaid formulary. This release shall not release any accounts receivable unrelated to the Covered Conduct due from the State, or any agency or instrumentality of the State.

8) Defendants fully and finally release the Relator, its employees, officers, servants, attorneys and agents from any claims based on events occurring prior to the date of this Agreement (including attorneys fees, costs, and expenses of every kind and however denominated) which Defendants have asserted, could have asserted, or may assert in the future against the Relator, its employees, officers, servants, attorneys and agents, related to the Covered Conduct and the Plaintiffs' investigation and prosecution thereof.

Defendants' Pricing Information Maintained by the State's Vendor Drug Program

9) The State shall comply with the applicable provisions of Chapter 552 of the Texas Government Code (the Public Information Act) upon receipt of an open records request for the pricing information submitted by the Defendants to the Texas Vendor Drug Program.

Limitations on Release

10) Notwithstanding any other terms of this Agreement, including the release provisions in paragraphs III(4), (5), (6), and (7) above, specifically reserved and excluded from the scope and terms of this Agreement, and from the scope and terms of the releases, as to any entity or person (including Defendants), are any and all of the following:

- (a) Any claims based upon such obligations as are created by this Agreement;
- (b) Any express or implied product or service warranty claims or other claims for defective or deficient products or services, including quality of goods and services, provided by Defendants;
- (c) The subrogation rights to claims for personal injury or property damage arising from usage by a participant in the Medicaid program of any of the Covered Drugs;
- (d) Any claims based on a failure to deliver products or services due;
- (e) Any claims arising from Defendants's obligations to report and/or to pay rebates to the State under any law or contract, including, but not limited to under the provisions of the Omnibus Budget Reconciliation Act of 1990 ("OBRA 90");
- (f) Any claims that the Relator may have under any provision of 31 U.S.C.A. §§ 3729-3733 (the federal False Claims Act), excluding any claim related to any recovery attributable to the impact on Texas Medicaid of the Covered Conduct; or

- (g) Any claims that the Relator may have under the *qui tam* provisions of the laws of any state other than Texas.

Corporate Integrity Agreement

11) Should Defendants enter into a Corporate Integrity Agreement with the Office of the Inspector General of the United States Department of Health and Human Services (“OIG”), relating to the Covered Conduct, Defendants acknowledge that the OIG may share information provided under the Corporate Integrity Agreement with the State.

No Waiver or Release of Claims Against Other Persons

12) This Agreement is intended to be solely for the benefit of the Parties and persons and entities released and, except as stated herein, the Parties do not by this instrument release any claims against any other person or entity, including any individual or entity that purchased drugs or pharmaceutical products from Defendants. No word, term, phrase or definition in this Agreement is or may be used for the benefit of any person, entity or litigant who is not a signatory to, or released by this Agreement.

Claims for Physician Services and Medicare

13) The State and the Relator covenant not to sue or take any other civil or administrative action against Defendants: (i) for claims relating to reimbursement by Texas Medicaid for all Covered Drugs administered by physicians or incident to physicians’ services based upon any conduct, including the reporting of average wholesale price (“AWP”) to national data reporting services; or (ii) for co-payments for Covered Drugs made under Medicare Part B, occurring prior to the date of this Agreement. Notwithstanding anything stated herein to the contrary: 1) the State and the Relator shall not be precluded from participating or recovering in any federal action or national settlement

that results in a Texas recovery other than of the State's share of damages to the Texas Medicaid Program expressly arising from Defendants' price or cost representations used for determining reimbursement paid by the Texas Medicaid Program to pharmacies for the Covered Drugs, 2) The Relator shall not be precluded from participating or recovering in any action brought pursuant to the federal False Claims Act or a similar state statute, of a state other than Texas, that seeks recovery of damages other than the State's share of damages to the Texas Medicaid Program expressly arising from Defendants' price or cost representations used for determining reimbursement paid by the Texas Medicaid Program to pharmacies for the Covered Drugs.

Dismissal of Actions

14) Simultaneously with the execution of this Agreement and payment of the Settlement Amount, the Defendants, State and the Relator will execute agreed motions to dismiss and agreed orders (in the forms collectively attached hereto as **Exhibit C**) dismissing with prejudice the following lawsuits: Cause No. GV3-03079 (the Lawsuit), Cause No. GV002327 in the District Court, Travis County, Texas (the Original Lawsuit), and Civil Action No. A05CA375LY in the U.S. District Court for the Western District of Texas, Austin Division (the Federal Declaratory Judgment Action).

Existing Protective Orders

15) The parties shall continue to abide by the provisions of any protective orders entered with respect to documents, data and other information produced in discovery in the action(s) being settled; however, the State agrees to return to the Defendants the data and documents the Defendants produced to the State in the Original Lawsuit and the Lawsuit within 60 days of receipt of payment in full of the Settlement Amount. Further, the Defendants agree to return to the State the data and documents the State produced to the Defendants in the Original Lawsuit and the Lawsuit within 60

days of payment in full of the Settlement Amount. The Relator is not required to return discovery and will continue to abide by the provisions of any protective orders.

No Impairment or Creation of Rights

16) Nothing in this Agreement shall be construed to abrogate or alter any future obligation of Defendants pursuant to the law of the State.

No Waiver of Sovereign Immunity

17) Nothing in this Agreement shall be construed to create a waiver of the State's Sovereign Immunity.

Exclusive Venue for Enforcement of Agreement

18) Subject to paragraph 18, any party shall be entitled to enforce the terms of this Agreement in the District Courts of Travis County, Texas, which shall have exclusive jurisdiction and venue over any such action.

Notice of Breach and Requirement of Mediation

(19) In the event disputes arise between the Plaintiffs and Defendants in connection with the performance of this Agreement, the Parties shall be required to first provide notice and an opportunity to cure. The Parties shall provide notice of any alleged dispute or breach by delivering notice to the person or persons identified below in paragraph 23. The notice must set forth in reasonable detail the nature of the dispute or alleged breach, including a description of the alleged conduct and identification of the provision in the Agreement which allegedly requires contrary conduct. The responding party shall be given ten (10) business days to cure the alleged breach or otherwise respond to the notice (the ten-day cure period). If the dispute is not resolved by the responding party's response, the Parties shall promptly enlist the mediation services of John W.

Hughes, or another mediator agreeable to all parties, to seek an amicable resolution of disputes. The parties shall mediate any disputes within thirty (30) days of the expiration of the ten-day cure period. The Parties agree that no party shall file suit pursuant to Section III(18) above or seek relief from any court to enforce the terms of this Agreement until either (a) the Parties mediate or (b) the thirty (30) day deadline to mediate expires, whichever comes first.

Complete Agreement

20) This Agreement, including all exhibits, constitutes the complete agreement between the Parties and may not be amended except by written consent of the Parties.

Costs

21) Except as otherwise provided herein, each Party to this Agreement will bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

Choice of Law

22) This Agreement is governed by the laws of the State of Texas, except to the extent otherwise governed by federal law.

Notification

23) Unless otherwise stated in writing subsequent to the Effective Date of this Agreement, all notifications and communications made pursuant to this Agreement shall be submitted to the entities listed below:

(a) State for all purposes:

OFFICE OF THE ATTORNEY GENERAL
Civil Medicaid Fraud Section
Antitrust and Civil Medicaid Fraud Division
P O Box 12548
Austin, Texas 78711-2548

(b) RELATOR for all purposes:

James J. Breen, Esq.
3562 Old Milton Parkway
Alpharetta, GA 30005

(c) Defendants, Roxane Laboratories, Inc., Boehringer Ingelheim Pharmaceuticals, Inc., Ben Venue Laboratories, Inc. and Boehringer Ingelheim Corporation, for all purposes:

Steve McConnico
Scott, Douglass & McConnico
One American Center
600 Congress Avenue, 15th Floor
Austin, Texas 78701-2589

Office of the General Counsel
Boehringer Ingelheim Corporation
900 Ridgebury Road
P.O. Box 368
Ridgefield, Connecticut 06877-0368

Defendants: No Duress

24) Defendants represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

Relator: Agreement Reasonable

25) The Relator agrees that this Agreement is fair, adequate, and reasonable.

Authorization

26) The Parties have read the foregoing Agreement and accept and agree to the provisions contained herein and hereby have caused this Agreement to be signed as of the day and date adjacent to their respective signatures. The undersigned individuals signing this Agreement on behalf of Defendants represent and warrant that they are authorized by Defendants 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. The Relator's attorney, James J. Breen, and its president, T. Mark Jones represent that they are duly authorized to sign this Agreement on behalf of the Relator.

No Other Representations or Promises

27) The Parties represent and acknowledge that in entering into this Agreement they are not relying on any promises or representations other than those expressly set forth in this Agreement and its exhibits.

Counterparts

28) This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall be deemed to constitute one and the same Agreement.

Acts Necessary to Effectuate Agreement

29) Each Party agrees to perform such further acts and to execute and to deliver such further documents as may reasonably be necessary to carry out this Agreement.

Captions Are for Convenience Only

30) The bold-face paragraph captions in this Agreement are for convenience only and do not add to, detract from or change the substantive language or terms of this Agreement.

Effective Date

31) The Effective Date of this Agreement shall be the date upon which all of the Parties below have executed this Agreement or November 18, 2005, whichever is later.

**STATE of TEXAS
Office of the Attorney General**

**Relator, Ven-A-Care of the Florida Keys,
Inc.**

By: _____

By: _____

Date: _____

Date: _____

Printed Name: _____

James J. Breen, Esq.
The Breen Law Firm, P.A.
3562 Old Milton Parkway
Alpharetta, GA 30005

Title: _____

Office of the Attorney General of Texas
P.O. Box 12548
Austin, Texas 78711-2548

**Texas Health & Human Services
Commission**

**Relator, Ven-A-Care of the Florida Keys,
Inc.**

By: _____

By: _____

Date: _____

Date: _____

Printed Name: _____

T. Mark Jones
Title: President

Title: _____

Defendant Boehringer Ingelheim Corporation

By: _____

Date: _____

Printed Name: _____

Title: _____

Defendant Boehringer Ingelheim Pharmaceuticals, Inc.

By: _____

Date: _____

Printed Name: _____

Title: _____

Defendant Roxane Laboratories, Inc.

By: _____

Date: _____

Printed Name: _____

Title: _____

Defendant Ben Venue Laboratories, Inc.

By: _____

Date: _____

Printed Name: _____

Title: _____

Defendant Boehringer Ingelheim Roxane Inc.

By: _____

Date: _____

Printed Name: _____

Title: _____