

SETTLEMENT AGREEMENT AND RELEASE

I. PARTIES

This Settlement Agreement and Release (“Agreement”) is entered into as of the “Effective Date,” defined in paragraph 26 below, by and among the STATE of TEXAS (“STATE”) and Fougera Pharmaceuticals Inc. (“FOUGERA”). The STATE and FOUGERA are each individually referred to as a “Party” and collectively referred to as the “Parties” in this Agreement.

II. PREAMBLE

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

A. FOUGERA is a wholly-owned subsidiary of Sandoz Inc., organized under the laws of New York with its principal place of business in Melville, New York. FOUGERA develops, manufactures, markets and sells generic and brand pharmaceuticals in the United States.

B. All pharmaceutical products manufactured, marketed, distributed and/or sold by FOUGERA using the labeler code **00168** for the time period September 1, 1995 to the Effective Date are hereinafter referred to as the “Covered Drugs”;

C. The STATE contends that between September 1, 1995 and the Effective Date, FOUGERA knowingly set, reported and/or maintained, or caused to be set, reported and/or maintained false, fraudulent, and/or inflated pricing information for certain of the Covered Drugs, including the pricing information reported directly to the Texas Vendor Drug Program (“VDP”). The STATE further contends that FOUGERA submitted or caused to be submitted, false claims to the VDP for certain of the Covered Drugs based on that false and/or inflated

reported pricing information. The STATE contends these false and/or inflated prices resulted in overpayments to Texas pharmacies. The STATE contends that FOUGERA committed unlawful acts, as defined by Tex. Hum. Res. Code Ann. § 36.002 in connection with the submission of pricing information to the VDP, including for the purpose of including certain of FOUGERA's Covered Drugs on the Texas Drug Code Index ("TDCI"). This Agreement covers all conduct that has occurred prior to the Effective Date in connection with FOUGERA's submission or failure to submit pricing information to the Texas VDP for the Covered Drugs including those acts or omissions described in this paragraph. All such conduct is hereinafter referred to as the "Covered Conduct";

D. This Agreement is the result of a compromise of disputed issues of law and fact and is neither an admission of facts or liability by FOUGERA, nor a concession by the STATE that the STATE's allegations and claims are not well-founded.

E. FOUGERA has a number of defenses to the STATE's allegations and claims concerning the Covered Conduct, and has denied and continues to deny the STATE's allegations and/or any wrongdoing as may be alleged by the STATE.

F. As a result of a mutual desire to settle their disputes, and to avoid the delay, expense, inconvenience and uncertainty of protracted litigation of the STATE's claims, the Parties have reached a full and final settlement as set forth in this Agreement; and

G. The STATE has concluded that this settlement is in the public interest, and is fair, adequate, and reasonable under all the circumstances.

III. AGREEMENT

NOW, THEREFORE, 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. The foregoing Preamble is incorporated herein.

2. Within ten (10) business days following the Effective Date, in full settlement of all claims by the STATE arising from or relating to the Covered Conduct, including claims for attorneys' fees, penalties, treble, multiple, or other damages, costs or expenses of every kind and however denominated, FOUGERA shall pay the STATE and the United States of America the aggregate sum of **TWENTY-TWO MILLION SEVEN HUNDRED AND FIFTY THOUSAND UNITED STATES DOLLARS (\$22,750,000)** (the "Final Settlement Payment") in accordance with the wire instructions set forth in Exhibit 1. The Parties further agree that all amounts payable to the United States shall be paid out of the Final Settlement Payment, and that FOUGERA will have no liability or obligation to make any such payment. The payment of the Final Settlement Payment shall satisfy FOUGERA's obligation to make any and all payments required under this Agreement.

3. In no way does entering into this Agreement entitle FOUGERA or its counsel to direct or influence the allocation of the Final Settlement Payment. FOUGERA expressly acknowledges that it is not entitled to direct or influence the manner in which the Final Settlement Payment is allocated by Texas. The STATE will allocate and distribute the attorneys' fees and costs, as well as the United States' pro rata share of the net recovery, in accordance with state and federal law.

4. Subject to the exceptions in Paragraph 7 below, in consideration of the obligations of FOUGERA set forth in this Agreement, and conditioned upon FOUGERA's payment in full of the Final Settlement Payment, the STATE (on behalf of (i) itself, its past and present officers, agents, entities, divisions, agencies and departments and (ii) any insurers and reinsurers of those identified in subclause (i)) shall, fully and finally, and to the greatest extent allowed by law, release FOUGERA and (i) its past and present holding companies, predecessors, successors, parents, subsidiaries, entities and divisions; (ii) all past and present officers, directors, members, partners and/or limited partners, principals, assigns, representatives, employees, agents, servants, shareholders and attorneys of FOUGERA and those identified in subclause (i); (iii) all heirs, executors, administrators, spouses, agents and assigns of those identified in subclauses (i) and (ii); and (iv) any insurers and reinsurers of FOUGERA and those identified in subclauses (i) and (ii) (collectively, the "FOUGERA Released Parties") from any civil or administrative claim, action, suit or proceeding (including those for attorneys' fees, penalties, treble, multiple, or other damages, costs, and expenses of every kind and however denominated) that the STATE has asserted, could assert, or may assert in the future on behalf of itself or any other person or entity under any source of law or in equity against the FOUGERA Released Parties arising from or relating to the Covered Conduct. In addition, the Parties agree that the payment of the Final Settlement Payment fully discharges the FOUGERA Released Parties from any civil or administrative obligation to the STATE to pay restitution, damages, penalties or fines to the STATE for the Covered Conduct. In addition, the STATE, including the Office of the Attorney General of Texas, agrees that it shall not initiate or prosecute litigation or any other civil or administrative action, including by way of example and not limitation, civil investigative demands, against the FOUGERA Released Parties or any of them, related to the Covered

Conduct, on behalf of itself or the United States. This provision is not intended to release claims or causes of action unrelated to the Covered Conduct.

5. In consideration of the obligations of FOUGERA set forth in this Agreement and conditioned upon FOUGERA's payment in full of the Final Settlement Payment, the STATE agrees to release and refrain from instituting, directing or maintaining any action seeking exclusion, suspension, or disbarment from the VDP or any other Texas Medicaid program against the FOUGERA Released Parties based on or relating to the Covered Conduct.

6. FOUGERA fully and finally releases the STATE, its agencies, employees, servants, attorneys and agents from any claims based on events occurring prior to the date of this Agreement (including those for attorney's fees, costs, and expenses of every kind and however denominated) which FOUGERA has asserted, could have asserted, or may assert in the future against the STATE, its agencies, employees, servants, attorneys and agents, related to the Covered Conduct and the STATE's investigation and prosecution thereof. This provision is not intended to release claims or causes of action unrelated to the Covered Conduct.

7. Notwithstanding any other terms of this Agreement, including the release provisions in Paragraphs 4, 5, and 6 above, specifically reserved and excluded from the definition of Covered Conduct, and thus the scope and terms of this Agreement, and from the scope and terms of the releases, as to any entity or person (including FOUGERA and the STATE), are the following, for the time period September 1, 1995 through and including the Effective Date:

- (a) Any claims based upon such obligations 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 FOUGERA;

(c) Any civil or administrative liability that any person or entity has or may have to individual consumers involving unfair and/or deceptive acts and practices and/or violations of consumer protection laws;

(d) Any civil or administrative liability that any person or entity, including the FOUGERA Released Parties, has or may have to the State for state or federal antitrust violations;

(e) Any civil or administrative liability that any person or entity has or may have related to marketing or promotion of any of the Covered Drugs, including but not limited to off-label marketing, product misbranding, or misrepresentations or concealment of information about the safety, efficacy, or appropriate use of any of the Covered Drugs, unrelated to the Covered Conduct;

(f) Any civil or administrative liability that any person or entity has or may have regarding inducement of healthcare providers to prescribe any of the Covered Drugs, unrelated to the Covered Conduct;

(g) The subrogation rights to claims for personal injury or property damage arising from usage of Fougera products by a participant in the Medicaid Program;

(h) Any claims based on a failure to deliver products or services due;

(i) Any claims arising from FOUGERA's obligation 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");

(j) Any claims that a Relator may have under the *qui tam* provisions of the laws of any state other than Texas except for any claim for Medicaid overpayments by the Texas Medicaid program or the United States, but only with respect to the Texas Medicaid program arising from or relating to the Covered Conduct (such claims having been expressly released in paragraphs 4 and 5, above);

(k) Any civil, criminal, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code) or any state tax or revenue law;

(l) Any criminal liability; and

(m) Any liability for any conduct other than the Covered Conduct.

8. Should FOUGERA 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, FOUGERA acknowledges that the OIG may share information provided under the Corporate Integrity Agreement with the STATE.

9. The STATE hereby agrees that this Agreement, and any and all negotiations, documents and discussions associated with this Agreement shall not be deemed or construed to be an admission or evidence of any violation of any statute or law, of any liability or wrongdoing by the FOUGERA Released Parties or of the truth or the infirmity of any of the claims or allegations of the STATE, and evidence thereof shall not be discoverable or used directly or indirectly by the STATE in any way (except that the provisions of this Agreement may be used by the Parties to enforce its terms), whether in Texas or in any other forum. The STATE agrees it will not urge or seek to admit this Agreement as evidence of any fault or liability of the FOUGERA Released Parties in any investigation, administrative claim, action, suit or proceeding, or federal or state court or arbitration proceeding unless ordered to do so by

a state court, federal court, or arbitration panel in which case it will provide notice to FOUGERA, pursuant to the terms of this Agreement, no later than five (5) business days after its receipt of such order and prior to admitting the Agreement as evidence in any proceeding whatsoever.

10. Within ten (10) business days of the Effective Date, the STATE shall withdraw that certain Civil Investigative Demand (“CID”), dated May 22, 2012, directed to FOUGERA related to the Covered Conduct and release FOUGERA from any and all obligations, responsibilities and demands contained therein.

11. The STATE represents to FOUGERA that no interest in any claim herein released has been assigned by the STATE to any third party.

12. Nothing in this Agreement shall be construed to create a waiver of the STATE’s Sovereign Immunity except as to a proceeding to enforce this Agreement.

13. 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.

14. This Agreement, including all exhibits, constitutes the complete agreement between the Parties with regard to the settlement of all claims and/or liability arising from or relating to the Covered Conduct. This Agreement may not be amended except by a writing signed by all Parties.

15. Each Party will bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

16. This Agreement shall be governed by the laws of the State of Texas.

17. This Agreement shall be construed and interpreted to effectuate the Parties' intent, which is to resolve completely the STATE's claims and allegations in connection with the Covered Conduct with respect to the FOUGERA Released Parties.

18. None 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.

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

20. Unless otherwise stated in writing subsequent to the Effective Date, 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 Division
P O Box 12548
Austin, Texas 78711-2548

(b) FOUGERA, for all purposes:

Fougera Pharmaceuticals Inc.
c/o Sandoz Inc.
506 Carnegie Center, Suite 400
Princeton, New Jersey 08540
Attn: General Counsel

21. 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 individual signing this Agreement on

behalf of FOUGERA represents and warrants that he is authorized by FOUGERA 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 and to compromise the claims of the STATE. The Texas Health and Human Services Commission (“HHSC”) Executive Commissioner concurs with the aspects of the agreement that are within his authority.

22. 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. The Parties understand, acknowledge and agree that (i) they have each performed an independent investigation of the allegations of fact and law made in connection with the Covered Conduct and (ii) they each may hereafter discover facts in addition to, or different from, those that they now know or believe to be true with respect to the subject matter of this Agreement. Nevertheless, it is the Parties’ intention to resolve their disputes pursuant to the terms of this Agreement and, thus, in furtherance of their intentions, the Agreement shall remain in full force and effect notwithstanding the discovery of any additional facts or law, or changes in law, and the Agreement shall not be subject to rescission or modification by reason of any change or difference in facts or law.

23. The waiver of any rights conferred by this Agreement shall be effective only if made in writing by the waiving Party. The waiver of any Party of any breach of this Agreement shall not be deemed or construed as a waiver of any other breach, whether prior to, subsequent to, or contemporaneously with this Agreement.

24. 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. A facsimile or PDF

copy of a signature shall constitute an acceptable binding signature for purposes of this Agreement.

25. 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.

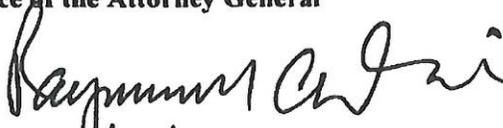
26. The Effective Date of this Agreement shall be the first date upon which all of the Parties below have executed the Agreement.

EXECUTION OF RELEASE

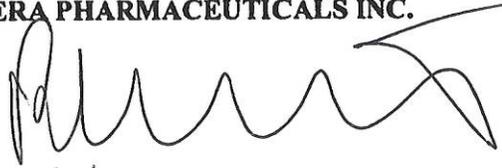
**STATE of TEXAS
Office of the Attorney General**

FOUGERA PHARMACEUTICALS INC.

By:



By:



Date:

9/10/13

Date:

10/4/13

Raymond C. Winter
Chief, Civil Medicaid Fraud Division
Assistant Attorney General
Office of the Attorney General of Texas
P.O. Box 12548
Austin, Texas 78711-2548

[Name] Peter Goldschmidt
[Title] President

Texas Health & Human Services Commission

By:



Date:

9/18/13

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Executive Commissioner
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