



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

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

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

February 10, 2021

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 Danny Earl Britt, Jr.  
Senator Warren Daniel  
Representative James Boles, Jr.  
Representative Allen McNeill  
Representative Carson Smith  
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 Shire Regenerative  
Medicine, LLC

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 Shire Regenerative Medicine, LLC and the State of North Carolina.

The settlement resolves allegations that from January 1, 2007 through January 16, 2014, Shire Regenerative Medicine paid kickbacks and off-label marketed its drug Dermagraft.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$1,192,185.48. Of that amount the federal government will receive \$826,982.44 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 \$72,649.27 of North Carolina's recovery. The North Carolina Medicaid Program will receive \$114,708.03 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 \$150,949.38 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 \$26,896.36 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: William Childs, NCGA Fiscal Research Division  
Mark White, NCGA Fiscal Research Division  
Morgan Weiss, NCGA Fiscal Research Division

## **STATE SETTLEMENT AGREEMENT**

### **I. PARTIES**

This Settlement Agreement ("Agreement") is entered into between the State of North Carolina ("the State") and Shire Holdings US AG ("SHUSAG"), Shire Pharmaceuticals LLC ("Shire Pharmaceuticals"), and Shire Regenerative Medicine LLC ("SRM") (collectively, "Shire") (hereinafter collectively referred to as "the Parties").

### **II. PREAMBLE**

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

A. SHUSAG, a Delaware corporation with its principal place of business in Pennsylvania, through its direct and indirect subsidiaries, is a biotechnology company conducting business throughout the United States. SRM, a Delaware company with a principal place of business in Massachusetts, is a subsidiary of Shire plc, an international biotechnology company headquartered in Ireland. Shire Pharmaceuticals LLC, formerly Shire Pharmaceuticals, Inc., is a Delaware company with its principal place of business in Massachusetts. At the time of the Covered Conduct (defined below), SHUSAG was a parent company of SRM and Shire Pharmaceuticals.

B. Advanced BioHealing, Inc. ("ABH") was a biotechnology company formed in January 2006, headquartered in La Jolla, California, which marketed and sold "Dermagraft®," a human skin substitute approved by the United States Food and Drug Administration as a medical device for the treatment of certain diabetic foot ulcers. In June 2011, Shire Pharmaceuticals, Inc. acquired ABH. ABH subsequently became SRM

and continued to market and sell Dermagraft®. In January 2014, Shire sold assets associated with Dermagraft® to another company.

C. The following qui tam actions have been brought:

(1) On November 21, 2012, E. Daniel Petty, Christopher Allen Bell, Kyle Lee Richardson, and Tara Lyn Denney (each a “Relator” and collectively, “Relators”) filed a *qui tam* action in the United States District Court for the Eastern District of Pennsylvania, that was subsequently transferred to the United States District Court for the Middle District of Florida, captioned *United States of America et al., ex rel. Petty, et al. v. Shire Regenerative Medicine, Inc. f/k/a Advanced BioHealing, Inc., Shire Pharmaceuticals Inc., and Shire plc*, Civil Action No. 8:14-cv-969-T-30TBM (M.D. Fla.) (the “Petty Action”).

(2) On February 14, 2014, Antonio S. Montecalvo (“Relator”, or “Relators” collectively with Relators in the Petty Action) filed a *qui tam* action in the United States District Court for the District of Columbia that was subsequently transferred to the United States District Court for the Middle District of Florida, captioned *United States of America, et al., ex rel. Montecalvo v. Shire Regenerative Medicine, Inc., f/k/a/ Advanced BioHealing, Inc.* (Civil Action No. 8:16-cv-268-T-30TBM (M.D. Fla.) (the “Montecalvo Action”). The Petty Action and the Montecalvo Action will be referred to collectively as the “Civil Actions.”

D. Shire 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) hereinafter referred to as the “United States.”

E. The State contends that from January 1, 2007 through January 16, 2014, ABH and SRM caused claims for payment to be submitted to the State's Medicaid Program (see 42 U.S.C. §§ 1396-1396(v)). Claims may be submitted to the State's Medicaid Program directly or through an intermediary, including through a managed care organization (MCO) which may be under contract with the State's Medicaid Program and which included coverage for Dermagraft®. The submission of claims for payment to an MCO constitutes the submission of claims to the State's Medicaid Program.

F. The State contends that it has certain civil and administrative causes of action against Shire for engaging in the following conduct:

From January 1, 2007 through January 16, 2014, ABH and SRM, marketed and sold Dermagraft® to the State's Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 ("Medicaid"); in the course of marketing and selling Dermagraft® during this time period, ABH and SRM knowingly submitted or caused to be submitted false or fraudulent claims for Dermagraft® and related services to Medicaid by: (1) paying or offering to pay kickbacks to induce the purchase, use and/or overutilization of Dermagraft®; (2) marketing Dermagraft® for uses outside the FDA-approved indication (*i.e.*, "off-label" uses); (3) making false statements to inflate the price of Dermagraft®; and (4) causing improper coding, verification, and/or certification of claims for Dermagraft® and related services.

The actions, transactions, occurrences, and alleged wrongdoing set forth in this Paragraph F are herein collectively referred to as the "Covered Conduct."

G. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of facts or liability by Shire or any related person or entity, nor a concession by the State that its allegations are not well founded. Shire and related persons and entities expressly deny the allegations of the State as set forth herein and in the Civil Actions and deny that they engaged in any wrongful conduct in connection with the Covered Conduct.

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. Shire agrees to pay to the United States and the Medicaid Participating States (as defined in sub-paragraph (c) below), collectively, the sum of three hundred and fifty million dollars (\$350,000,000) (the "Settlement Amount"), plus accrued interest as set forth below. 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) Shire shall pay to the United States the sum of three hundred and forty-three million, eight-hundred and ninety-six thousand dollars (\$343,896,000.00), plus accrued interest on that amount at the rate of one and one-half percent (1.5%) per annum commencing on October 1, 2016 ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.

(b) Shire shall pay to the Medicaid Participating States the sum of six million, one hundred four thousand dollars (\$6,104,000.00), plus accrued interest on that amount at the rate of one and one-half percent (1.5%) per annum commencing on October 1, 2016 ("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 fourteen (14) business days after the expiration of the 45 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 Shire. After making the Medicaid Participating State Settlement Amount payment to the New York State Attorney General's National Global Settlement Account, Shire shall have no continuing obligations with respect to payment of the State Amount (defined below).

(c) Shire shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which Shire and the State Team have agreed,

or in a form otherwise agreed to by Shire and an individual State. The State shall constitute a Medicaid Participating State provided this Agreement is fully executed by the State and delivered to counsel for Shire within 45 days of receiving this Agreement. If this condition is not satisfied within 45 days, Shire's offer to resolve this matter with the individual State shall become null and void absent written agreement between counsel for Shire and the State Team to extend the 45 day period.

(d) The total portion of the amount paid by Shire in settlement for the Covered Conduct for the State is \$1,190,717.95, 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 \$363,735.51, plus applicable interest (the "State Amount"). If the State does not execute this Agreement within 45 days of receiving this Settlement Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by Shire absent written agreement between counsel for Shire and the State Team to extend the time period for executing this Agreement.

2. Upon receipt of the State Amount described above, the State agrees to dismiss with prejudice any state law claims which the State has the authority to dismiss currently pending against the Released Parties (as defined in Paragraph 3 below) in State or Federal Courts for the Covered Conduct, including any supplemental state law claims asserted in the Civil Actions. Contingent upon the receipt of its respective State Amount, the State, if served with either of the Civil Actions and liable to pay a Relator's share, agrees to pay a Relator's share in the amount to be agreed upon, plus applicable interest.



This amount is to be paid through the State Team and 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 Shire set forth in this Agreement, and conditioned upon receipt by the State of its share of the Medicaid State Settlement Amount, the State on behalf of itself, and its officers, agents, agencies, political subdivisions and departments to the extent authorized by law, agrees to release Shire, together with its current and former direct and indirect parent corporations; current and former direct and indirect subsidiaries; current and former brother or sister corporations, divisions, and affiliates; and the predecessors, successors, transferees and assigns of any of them (the "Released Parties"), from any civil or administrative monetary cause of action that the State and its officers, agents, agencies, political subdivisions and departments to the extent authorized by law, has or may have for any claims submitted or caused to be submitted to the State Medicaid Program or its contracted MCOs as a result of the Covered Conduct. The payment of the Medicaid Participating State Settlement Amount fully discharges the Released Parties from any obligation to pay Medicaid restitution, Medicaid damages, and/or Medicaid civil fines or Medicaid civil penalties to the State 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;
- (c) any civil or administrative liability that any person or entity, including any of the Released Parties, 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 or permissive exclusion 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. The Released Parties waive and shall not assert any defenses they 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 United States Constitution or the Excessive Fines

Clause of the Eighth Amendment of the United States Constitution, that this Agreement bars a remedy sought in such criminal prosecution or administrative action.

6. In consideration of the obligations of the State set forth in this Agreement, the Released Parties waive and discharge the State, its agencies, employees, and agents from any causes of action (including attorneys' fees, costs, and expenses of every kind and however denominated) that the Released Parties have against the State, its agencies, employees, and agents arising from the State's investigation and prosecution of the Covered Conduct.

7. The amount that Shire must pay to the State pursuant to Paragraph III.1(d) 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, any MCO which may be under contract to the State Medicaid Program or any other state payor, for the Covered Conduct; and the Released Parties agree not to resubmit to the State's Medicaid program, any MCO which may be under contract to the State Medicaid Program, or any other state payor, any previously denied claims, which denials were based on the Covered Conduct, and agree to withdraw the appeal of or not to appeal or cause the appeal of any such denials of claims.

8. Shire shall not seek payment for any claims for reimbursement to the State Medicaid Program covered by this Agreement or any MCOs which may be under contract to the State Medicaid Program, and attributable in any way to the Covered Conduct, from any healthcare beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors.

9. The Released Parties expressly warrant that they have reviewed their financial condition and that they are 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.

10. The Released Parties agree 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, the Released Parties shall encourage, and agree not to impair, the cooperation of their directors, officers, and employees, and shall use their best efforts to make available, and encourage, the cooperation of such former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals.

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

12. 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.

13. 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.

14. 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.

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

16. 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.

17. The undersigned Shire 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.

18. The Effective Date of this Agreement shall be the date of signature of the last signatory to this Agreement. Facsimiles and electronic transmission of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

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. 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. Hobergood

Dated: 1/24/2017

CHARLES H. HOBGOOD  
Director, Medicaid Investigations Division  
Office of the Attorney General

By: Dave Richard

Dated: 1/18/2017

DAVE RICHARD  
Deputy Secretary for Medical Assistance  
Division of Medical Assistance

**SHIRE HOLDINGS US AG, SHIRE PHARMACEUTICALS LLC, AND SHIRE  
REGENERATIVE MEDICINE LLC:**

By: Jason Baranski Dated: 2-28-17

**JASON BARANSKI**  
Corporate Secretary

*Authorized to execute on behalf of Shire Holdings US AG,  
Shire Pharmaceuticals LLC and Shire Regenerative Medicine LLC*

By: Mark Jensen Dated: 2-28-17

**J. SEDWICK SOLLERS III, ESQ.**  
**MARK A. JENSEN, ESQ.**  
**BRANDT LEIBE, ESQ.**  
King & Spalding LLP  
1700 Pennsylvania Avenue, NW  
Washington, DC 20006

*Counsel for Shire Holdings US AG, Shire Pharmaceuticals LLC,  
and Shire Regenerative Medicine LLC*