



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

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

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

December 5, 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 US Bioservices  
Corporation

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 US Bioservices and the State of North Carolina.

The settlement resolves allegations that from August 2010 through March 31, 2012, US Bioservices participated in an arrangement with Novartis under which US Bioservices received additional patient referrals and related benefits in return for achieving a higher refill percentage for Exjade patients as compared to the refill percentages among Exjade patients at other "Exjade Patient Assistance and Support Services" pharmacies.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$111,769.86. Of that amount the federal government will receive \$77,917.47 for North Carolina's federal portion of Medicaid recoveries. The North Carolina Medicaid Program will receive \$31,750.34 as restitution and interest. Pursuant to G.S. § 1-608(c), the North Carolina Department of Justice will receive \$2,102.05 for investigative costs.

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: John Poteat, NCGA Fiscal Research Division

## STATE SETTLEMENT AGREEMENT

### I. PARTIES

This Settlement Agreement (the "Settlement Agreement") is entered into between the State of North Carolina ("the State") and U.S. Bioservices Corporation including its predecessors, successors, and assigns (US Bio), collectively, "the Parties."

### II. PREAMBLE

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

- A. At all relevant times, US Bio, a specialty pharmacy headquartered in Frisco, Texas and a wholly owned subsidiary of AmerisourceBergen Specialty Group, LLC, filled patient prescriptions for Exjade (deferasirox), a drug manufactured and distributed by Novartis Pharmaceuticals Corporation (Novartis). From on or about August 2010 to on or about to March 31, 2012, US Bio contracted with Novartis to dispense Exjade as part of Novartis' "Exjade Patient Assistance and Support Services" (EPASS) network. During this period, US Bio was one of three specialty pharmacies permitted to dispense Exjade as part of EPASS.
- B. On August 22, 2017 the United States filed an action (the "Civil Action") in the United States District Court for the Southern District of New York captioned *United States of America v. U.S. Bioservices, Corp.*, Civil Action No. 1:17-cv-06353 pursuant to the False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.*, alleging, inter alia, that

defendant US Bio violated the FCA and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (AKS), in connection with distributing Exjade and caused, in part, the federal Medicaid program to make improper payments to US Bio.

C. US Bio has entered into a separate civil settlement agreement with the United States of America (the "Federal Settlement Agreement").

D. The State contends that US Bio caused claims for payment to be submitted to the State's Medicaid Program (42 U.S.C. Chapter 7 Subchapter XIX).

E. The State contends that it has certain civil and administrative causes of action against US Bio for engaging in the following conduct (the "Covered Conduct"): From on or about August 2010 through on or about March 2012, US Bio violated the federal AKS, state anti-kickback statutes, and the State FCA, and/or similar state laws by submitting claims for Exjade to the State's Medicaid Program and by participating in an arrangement with Novartis under which US Bio could receive additional patient referrals and related benefits in return for achieving a higher refill percentage for Exjade patients as compared to the refill percentages among Exjade patients at the other EPASS pharmacies.

F. This Settlement Agreement is neither an admission of facts or liability by US Bio, nor a concession by the State that its allegations are not well founded.

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. US Bio agrees to pay to the United States and the Medicaid Participating States (as defined in Sub-paragraph (c) below), collectively, the sum of \$13,400,000 (Settlement Amount). 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, as defined therein 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) US Bio shall pay to the United States the sum of \$10,642,013 plus accrued interest on that amount at the rate of 2% per annum commencing on June 21, 2017 and continuing to the date of payment (the "Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.

(b) US Bio shall pay to the Medicaid Participating States the sum of \$2,757,987 plus accrued interest on that amount at the rate of 2% per annum commencing on June 21, 2017 and continuing to the date of payment of the Federal Settlement Amount (the "Medicaid State Settlement Amount"), subject to the non-participating state deduction provision of Sub-paragraph (d) below (the "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 (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 (the "State Team"), which written instructions shall be delivered to counsel for US Bio.

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

(d) The total portion of the amount paid by US Bio in settlement for the Covered Conduct for the State is \$111,658.28, 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 \$33,740.81 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 US Bio absent written agreement between counsel for US Bio and the State Team to extend the time-period for executing this Agreement.

2. Contingent upon receipt of the State Amount, the State agrees not to bring and to dismiss with prejudice any state law claims, which the State has the authority to dismiss currently pending against US Bio in State or Federal Courts for the Covered Conduct.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of US Bio set forth in this Agreement, and conditioned upon receipt by the State of the State Amount, the State agrees to release US Bio, its predecessors and current and former parents, divisions, direct and indirect subsidiaries, brother and sister corporations, current and former corporate owners, affiliates, successors, transferees, heirs, and assigns (collectively, the "US Bio Released Entities"), from any civil or administrative monetary cause of action that the State has for any claims submitted or caused to be submitted to the State's Medicaid Program as a result of 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 US Bio 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 to the State arising from the Covered Conduct for claims submitted or caused to be submitted to any "managed care entities" as defined by 42 U.S.C. § 1396u-2;

(f) any liability based upon obligations created by this Agreement;

(g) except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusions from the State's Medicaid Program;

(h) any liability for expressed or implied warranty claims or other claims for defective or deficient products and services, including quality of goods and services;

(i) any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

(j) any liability for failure to deliver goods or services due; or

(k) any liability of individuals.

5. In consideration of the obligations of US Bio set forth in this Agreement, 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 US Bio for the Covered Conduct, except as reserved in Paragraph 4 above. Nothing in this Agreement precludes the State from taking action against US Bio in the event that US Bio is excluded by the federal government, or for conduct and practices other than the Covered Conduct.

6. US Bio waive(s) 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 US Bio 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 US Bio 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 US Bio must pay to the State pursuant to Paragraph III.1. 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 US Bio 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. US Bio 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. US Bio 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. 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 the Parties do not release any liability as to 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, US Bio agrees to pay the State Team's reasonable expenses and fees, including travel costs, consultant expenses, and administrative fees. US Bio 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 US Bio 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 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. Hobgood

Dated: 9/14/2017

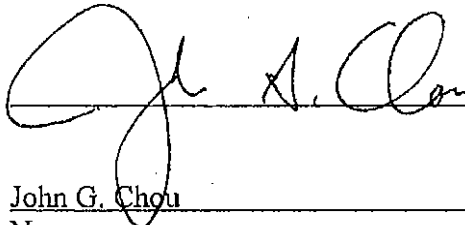
CHARLES H. HOBGOOD  
Director, Medicaid Investigations Division  
Office of the Attorney General

By: Dave Richard

Dated: 9/5/2017

DAVE RICHARD  
Deputy Secretary for Medical Assistance  
Division of Medical Assistance

US Bioservices Corp.

By:  Dated: 8/23/17  
John G. Chou  
Name

Executive Vice President & Chief Legal & Business Officer  
Title

AmerisourceBergen Corporation  
Organization

By: Eric W. Sitarchuk, <sup>PMO</sup> Dated: 8/23/17

Eric W. Sitarchuk

Morgan Lewis & Bockius LLP

Counsel to US Bioservices