



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

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

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

December 17, 2019

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  
Senator Norman W. Sanderson  
Representative James Boles, Jr.  
Representative Ted Davis, Jr.  
Representative Allen McNeill  
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 Avanir  
Pharmaceuticals, Inc.

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 Avanir and the State of North Carolina.

The settlement resolves allegations that from October 29, 2010 through December 31, 2016, Avanir off-label marketed its drug Nuedexta and provided remuneration to health care providers to induce those providers to prescribe Nuedexta.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$660,979.18. Of that amount the federal government will receive \$369,448.86 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 \$53,268.63 of North Carolina's recovery. The North Carolina Medicaid Program will receive \$102,614.28 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 \$126,358.00 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 \$9,289.41 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: John Poteat, NCGA Fiscal Research Division

## STATE SETTLEMENT AGREEMENT

### I. PARTIES

This Settlement Agreement (the "Agreement") is entered into between the State of North Carolina ("the State") and Avanir Pharmaceuticals, Inc.; collectively, "the Parties."

### II. PREAMBLE

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

A. Avanir Pharmaceuticals, Inc. (Avanir), headquartered in Aliso Viejo, California, is wholly owned by Otsuka Pharmaceutical Co., Ltd. At all relevant times, Avanir distributed, marketed and sold a pharmaceutical product in the United States sold under the trade name of Nuedexta. Nuedexta is approved by the U.S. Food and Drug Administration (FDA) for the treatment of pseudobulbar affect (PBA). According to the FDA-approved label for Nuedexta, "PBA occurs secondary to a variety of otherwise unrelated neurologic conditions, and is characterized by involuntary, sudden, and frequent episodes of laughing and/or crying. PBA episodes typically occur out of proportion or incongruent to the underlying emotional state. PBA is a specific condition, distinct from other types of emotional lability that may occur in patients with neurological disease or injury." Nuedexta is not approved for any other uses.

B. On April 17, 2015, Duane R. Arnold and Mark A. Shipman (the "Relators") filed a *qui tam* action in the United States District Court for the Northern District of Georgia captioned *United States of America et al., ex. rel Arnold and Shipman and California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Washington, Wisconsin,*

*Massachusetts, Virginia, and the District of Columbia v. Avanir Pharmaceuticals, Inc.*, case number 1:15-cv-01250. This *qui tam* action will be referred to as the “Civil Action.”

C. Avanir has entered into a separate civil settlement agreement (the “Federal Settlement Agreement”) with the “United States of America” (“United States”) as that term is defined in the Federal Settlement Agreement.

D. Avanir has entered into a Deferred Prosecution Agreement (“DPA”) with the United States Attorney’s Office for the Northern District of Georgia, as referenced in the Federal Settlement Agreement.

E. The State contends that Avanir caused claims for payment to be submitted to the State’s Medicaid Program (42 U.S.C. Chapter 7 Subchapter XIX), including “managed care entities” as defined by 42 U.S.C. § 1396u-2.

F. The State contends that it has certain civil and administrative causes of action against Avanir for engaging in the following conduct between October 29, 2010 and December 31, 2016 (the “Covered Conduct”):

1. Avanir provided remuneration in the form of money, honoraria, travel, and food to certain physicians and other health care professionals (HCPs) to induce those certain HCPs to write prescriptions for Nuedexta. One form of remuneration included Avanir’s payment to certain HCPs to give talks (commonly known as “speaker’s programs”) about Nuedexta based on the willingness of the HCPs to prescribe Nuedexta.

One example of such remuneration involved a physician who gave 55 speaker programs for Avanir from July 2015 through February 2016. These 55 programs however, only had 42 unique attendees, the vast majority of whom were not physicians, according to the sign-in sheets for the events. The sign-in sheets, however, also contain signatures that the Avanir sales

representative either manufactured or obtained under false pretenses. Restaurants also adjusted the number of attendees on the final bill to make it appear as though there were more attendees for these speaker program events than were actually present, at the request of the Avanir sales representative. These events were primarily social, with no educational value. This physician was one of Avanir's top prescribers; in addition to the remuneration for the speaker programs, he received other inducements from certain Avanir employees, such as dinner and, on at least one occasion, liquor.

2. Avanir implemented a strategy to market Nuedexta to HCPs treating patients in long-term care (LTC) facilities for uses other than PBA. Non-PBA uses are not FDA approved and are also not medically accepted indications as defined by the statutes and regulations governing the Federal health care programs. Specifically, to counter the objection by certain HCPs that they had few, if any, patients that exhibited signs of PBA in their facilities, Avanir instructed sales representatives to provide false and misleading information that PBA patients could be exhibiting a wide variety of "behaviors" such as crying without tears, moaning, or making other inarticulate sounds, without sufficiently distinguishing patients who have dementia without PBA from patients who have dementia with PBA.

In addition, Avanir sought to capitalize on efforts by the Centers for Medicare and Medicaid Services (CMS) to reduce the use of anti-psychotics on dementia patients in LTC facilities, based in part on CMS's concern that anti-psychotics can be and have been used as a form of chemical restraint for residents. In announcing a reduction initiative in 2012, CMS stated that it was "emphasizing non-pharmacological alternatives for nursing home residents," and, as one component of the initiative, CMS began publishing data on the use of anti-psychotics in nursing homes. Considering this initiative "an opportunity," Avanir sent a marketing

communication to HCPs “express[ing] its support” for the CMS initiative, which stated that “[d]ementia patients may be on an anti-psychotic to treat the symptoms of [PBA]” and emphasized that Nuedexta “is not categorized as an anti-psychotic medication.” In one example, an Avanir sales representative asked to speak to staff at a facility about PBA and Nuedexta, presenting Nuedexta as “alternate solution” to psychotropics for nursing home residents. Similarly, in 2015, when CMS took further steps to reduce anti-psychotic use, Avanir instructed its sales force to “leverage” the opportunity in LTC facilities to initiate discussions regarding anti-psychotic use and how Nuedexta could be used to reduce a LTC facility’s reliance on anti-psychotics even though Avanir’s own studies demonstrated that the actual population of patients with PBA is limited; those studies posited that the prevalence of PBA across the six most commonly associated underlying neurologic conditions is estimated to be approximately ten percent. This strategy worked, and Nuedexta utilization in LTC facilities increased.

In one example, an Avanir employee reported that one doctor, who was also a paid speaker for Nuedexta, had “entire units” of patients on Nuedexta at the LTC facility where he worked, which contained a large number of dementia patients with behavioral issues. And while another doctor – a geriatrician – who also worked in the same LTC facility routinely discontinued Nuedexta for patients, the doctor paid by Avanir “constantly re-initiat[ed]” the treatment.

The State contends that Avanir knowingly submitted or caused to be submitted false and/or fraudulent claims to the State’s Medicaid Program.

G. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of liability by Avanir nor a concession by State that their claims are not well founded.

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. Avanir agrees to pay to the United States and the Medicaid Participating States (as defined in sub-paragraph (c) and subject to the non-participating state deduction provision of sub-paragraph (d) below), collectively, the sum of \$103,000,000.00 plus accrued interest at a rate of 2.75% from March 22, 2019 and continuing until and including the date of payment (the "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) Avanir shall pay to the United States the sum of \$95,972,017.00, plus accrued interest pursuant to the terms of the Federal Settlement Agreement.

(b) The total Medicaid recovery for the Covered Conduct is \$15,175,950.00, consisting of \$7,027,983.00 for the states pursuant to this Agreement and \$8,147,967.00 for the United States pursuant to the Federal Settlement Agreement. Avanir shall pay to the Medicaid Participating States the sum of \$7,027,983.00 plus accrued interest on that amount of 2.75% per annum commencing on from March 22, 2019 and continuing to and include the day payment is



made under this Agreement (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 and immediately deposited 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 Avanir. This electronic funds transfer shall constitute tender and negotiation of the State Amount as defined in Paragraph III. 1. (d) below.

(c) Avanir shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which Avanir and the State Team have agreed, or in a form otherwise agreed to by Avanir and an individual State. The State shall constitute a Medicaid Participating State provided this Agreement is fully executed by the State and delivered to Avanir’s attorneys within 60 days of receiving this Agreement. Avanir’s offer to resolve this matter with the State shall become null and void absent written agreement between counsel for Avanir and the State Team to extend the 60-day period.

(d) The total portion of the amount paid by Avanir in settlement for the Covered Conduct for the State is \$657,387.38 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 \$287,938.52 plus applicable interest (the “State Amount”), of which \$130,869.25 is restitution. 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 Avanir absent written agreement between counsel for Avanir and the State Team to extend the time period for executing this Agreement.

(e) If the Court does not accept the DPA, this Agreement shall be null and void at the option of either the State or Avanir. If either the State or Avanir exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within ten (10) business days of the Court's order, the Parties will not object and this Agreement will be rescinded. If this Agreement is rescinded, Avanir will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims, actions or proceedings arising from the Covered Conduct that are brought by the State within 90 calendar days of rescission, except to the extent such defenses were available on the day on which the *qui tam* complaint listed in Preamble Paragraph B, above, was filed.

2. Contingent upon receipt of the State Amount, the State agrees to dismiss with prejudice any state law claims which the State has the authority to dismiss currently pending against Avanir in State or Federal Courts for the Covered Conduct, including any supplemental state law claims asserted in the Civil Action. The State further agrees to dismiss without prejudice all other claims against the Avanir Released Entities (as defined below) in the Civil Action. Contingent upon receipt of the State Amount, the State, if served with the Civil Action and otherwise liable to pay a relator's share, agrees to pay the Relator(s) the amount of \$53,268.63 plus applicable interest. This amount is to be paid through the State Team and has been addressed via side letter(s) with the Relator(s) in the Civil Action(s).

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Avanir set forth in this Agreement, and conditioned upon tender and negotiation of the State Amount, the State, on behalf of itself, and its officers, agents, agencies, political subdivisions to the extent authorized by law, and departments, agrees to release Avanir, together with its current and former direct and indirect parent corporations and limited liability companies (the “Parents”), its and their affiliates, direct and indirect subsidiaries, brother and sister corporations, and divisions, and its and their respective current and former corporate owners, and the predecessors, successors, transferees, and assigns of any of them (collectively, the “Avanir Released Entities”) from any civil or administrative monetary cause of action that the State, its officers, agents, agencies, political subdivisions to the extent authorized by law, and departments have or may have for any claims submitted or caused to be submitted to the State’s Medicaid Program for the Covered Conduct. The payment of the amounts required hereunder fully discharges the Avanir Released Entities from any obligation to pay Medicaid restitution, Medicaid damages, and/or any Medicaid civil fine or civil penalty 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 by this Agreement:

- (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 Avanir 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 based upon obligations created by this Agreement;
- (f) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusions 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 provided by the Avanir Released Entities, 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. In consideration of the obligations of Avanir set forth in this Agreement, and the Corporate Integrity Agreement (the "CIA") that Avanir has entered into with the Office of the Inspector General of the United States Department of Health and Human Services in connection with this matter, 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 the Avanir Released Entities for the Covered Conduct, except as reserved in Paragraph 4 above. Nothing in this Agreement precludes the State from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 4, above.

6. Avanir 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 Avanir 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 Avanir 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 Avanir 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 Avanir 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. Avanir 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. Avanir expressly warrants that it has reviewed its financial condition and that it is currently solvent, meaning that a fair valuation of its property (exclusive of exempt property) exceeds the sum of its debts.

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

12. Avanir agrees to cooperate fully and truthfully with any State investigation of individuals or entities not released in this Agreement. Upon reasonable notice of such an investigation, Avanir shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available and encourage the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals and of Avanir. Upon request, Avanir agrees to furnish to the State complete and unredacted copies of all non-privileged documents including, but not limited to, reports, memoranda of interviews, and records in its possession, custody or control, concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf, as well as complete and unredacted copies of any other non-privileged documents in its possession, custody, or control relating to the Covered Conduct. Avanir shall be responsible for all costs it may incur in complying with this paragraph.

13. 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.

14. Except as otherwise stated in this Agreement, this Agreement is intended to be for the benefit of the Parties only, and by this Agreement the Parties do not release any liability as to any other person or entity.

15. 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.

16. In addition to all other payments and responsibilities under this Agreement, Avanir agrees to pay the State Team's reasonable expenses and fees, including travel costs, consultant expenses, and administrative fees. Avanir 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.

17. This Agreement is governed by the laws of the State, except disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions of the CIA, 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.

18. The undersigned Avanir 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.

19. 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.

20. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.

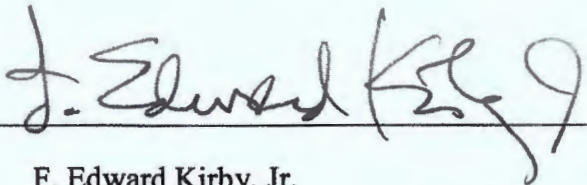
21. This Agreement constitutes the complete agreement between the Parties with respect to this matter and shall not be amended except by written consent of the Parties.

22. 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.

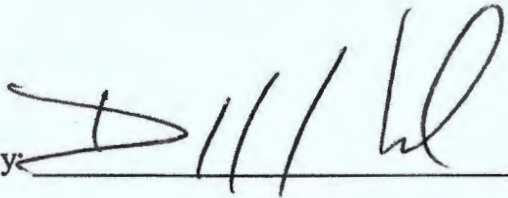
23. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by the Parties to this Agreement and shall not, therefore, be construed against any of the Parties for that reason.



STATE OF NORTH CAROLINA

By:   
F. Edward Kirby, Jr.  
Director, Medicaid Investigations Division  
Office of the Attorney General

Dated: 10-7-19

By:   
DAVE RICHARD  
Deputy Secretary, NC Medicaid  
Division of Health Benefits

Dated: 10/1/2019

AVANIR PHARMACEUTICALS, INC.

By: Aneta Ferguson

Dated: Nov 14, 2019

Aneta Ferguson  
Executive Director, Acting General Counsel  
Avanir Pharmaceuticals, Inc.

By: Matthew F. Dunn

Dated: 11/14/2019

Matthew J. O'Connor  
Matthew F. Dunn  
Covington & Burling LLP  
Counsel for Avanir Pharmaceuticals, Inc.