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17 **UNITED STATES DISTRICT COURT**
18 **FOR THE CENTRAL DISTRICT OF CALIFORNIA**

19 MSP RECOVERY CLAIMS, SERIES
20 LLC, a Delaware entity,

21 Plaintiff,

22 v.

23 AVANIR PHARMACEUTICALS, INC.,

24 Defendant.
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Case No. _____

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

1 Plaintiff, MSP Recovery Claims, Series LLC, (“MSPRC”), for itself and on behalf
2 of a Class of similarly situated third-party payers (“TPP”), brings this action against
3 Defendant Avanir Pharmaceuticals, Inc., (“Avanir”) and states the following:

4 **INTRODUCTION**

5 1. Avanir manufactures, markets, and sells a drug product containing
6 dextromethorphan hydrobromide and quinidine sulfate, which markets under the trade
7 name Nuedexta (“Nuedexta”). The U.S. Food and Drug Administration (“FDA”)
8 approved Nuedexta for one use—the treatment of pseudobulbar affect (“PBA”)—an
9 extremely rare condition affecting 0.5% to 2% of Americans characterized by episodes of
10 sudden and uncontrollable laughing or crying that do not reflect a person’s actual
11 emotions.

12 2. While the FDA approved Nuedexta for the treatment of PBA arising from
13 multiple sclerosis (“MS”) and amyotrophic lateral sclerosis (“ALS”), it did not approve
14 prescribing Nuedexta for patients with other types of emotional liability than can
15 commonly occur in patients with Alzheimer’s disease and other dementias.

16 3. Despite the FDA’s limited approval, Avanir aggressively marketed and
17 promoted Nuedexta by expanding the drug’s application to include treating PBA-like
18 symptoms. To bolster its marketing strategy, Avanir funded a “study” linking Nuedexta
19 to a decrease in PBA-like symptoms in patients. Four of the five doctors who authored the
20 study were paid by Avanir, and the other author was an Avanir employee.

21 4. Avanir used the study to further its scheme to promote and market Nuedexta
22 beyond actual PBA diagnoses, in turn driving up Nuedexta’s sales. But that’s not all.
23 Avanir also provided illegal kickbacks and incentives to doctors to prescribe Nuedexta,
24 which ultimately led to the U.S. Department of Justice (the “DOJ”) filing a criminal action
25 against Avanir. Avanir ultimately agreed to enter into a Deferred Prosecution Agreement
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1 (“DPA” or “Agreement”), whereby Avanir admitted its scheme. The DPA is attached as
2 **Exhibit A.**

3 5. Plaintiff’s TPP assignors, which provide benefits under Medicare Part C or
4 D, and the TPP Class Members, were the ultimate targets and victims of Avanir’s scheme.
5 Patient accessibility to Nuedexta was a central part of Avanir’s unlawful scheme. Through
6 its scheme, Avanir induced Plaintiff’s assignors and the Class Members to include
7 Nuedexta in their formularies largely without any prior authorizations or restrictions.
8 Further, Avanir kept the price of Nuedexta fairly low to ensure the drug was predominately
9 paid by the TPPs like Plaintiff’s assignors and the Class Members. Thus, Avanir caused
10 Plaintiff’s assignors and the Class Members to pay more for Nuedexta than they otherwise
11 would have had they known of Avanir’s scheme to push off-label Nuedexta and provide
12 kickbacks to physicians.

13 **JURISDICTION AND VENUE**

14 6. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1331
15 because this action arises under the laws of the United States. This Court has supplemental
16 jurisdiction pursuant to 28 U.S.C. § 1367(a) for each of the non-federal claims.

17 7. This Court also has subject-matter jurisdiction pursuant to 28 U.S.C. §
18 1332(d) because at least one member of the class is a citizen of a different state than the
19 Defendant and the aggregate amount in controversy exceeds \$5,000,000.00, exclusive of
20 interest and costs.

21 8. This Court has personal jurisdiction over Defendant because it is (i)
22 authorized and licensed to conduct business in California, (ii) has its principal place of
23 business in this judicial district, (iii) maintains and carries on systematic and continuous
24 contacts in this judicial district, (iv) regularly transacts business within this judicial
25 district, and (v) regularly avails itself of the benefits of this judicial district.

26 9. Venue is proper in this District under 28 U.S.C. § 1391(b)(1)-(2).
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PARTIES

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2 10. Plaintiff MSPRC Recovery Claims, Series LLC (“MSPRC”) is a Delaware
3 series limited liability company with its principal place of business at 2701 S. Lejeune
4 Road, 10th Floor, Coral Gables, Florida 33134. MSPRC’s limited liability company
5 agreement provides for the establishment of one or more specific series. All records of all
6 series are maintained together with all assets of MSPRC.

7 11. Plaintiff is the assignee of claims arising from the payments of prescription
8 drugs on behalf of Medicare beneficiaries. Plaintiff’s assignors paid for Nuedexta at all
9 relevant times. Pursuant to its operating agreement, MSPRC has the right and authority to
10 pursue claims assigned to its series limited liability companies.

11 12. Certain healthcare benefit providers have assigned their recovery rights to
12 assert the claims alleged in this Class Complaint to Series LLCs of MSPRC. Pursuant to
13 MSPRC’s limited liability agreement, all rights arising from the assignment to its series,
14 along with the right to bring any lawsuit in connection with that assignment, belong to
15 MSPRC. As such, MSPRC has the right and power to sue defendants to recover the
16 payments at issue in this action.

17 13. Certain series of MSPRC have executed irrevocable assignments of any and
18 all rights to recover payments made on behalf of their assignors’ health plan members and
19 enrollees. These assignments authorize the series and, in turn MSPRC through its
20 operating agreement, to pursue and enforce all legal rights of recovery and reimbursement
21 for health care services and Medicare benefits. For example, and only to serve to further
22 demonstrate standing, MSPRC alleges the following assignment below:

23 14. On May 12, 2017, Summacare, Inc. (“Summacare”) irrevocably assigned all
24 its rights and claims to recovery against any liable entity (including defendants) for
25 payments made on behalf of its enrollees under Medicare Parts A, B, and D to MSP
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1 Recovery, LLC (“MSP Recovery”). Specifically, the assignment provides the following
2 language:

3 [Summacare] hereby irrevocably assigns, transfers, conveys, sets over
4 and delivers to MSP Recovery, and any of its successors and assigns,
5 any and all of [Summacare’s] right, title, ownership and interest in and
6 to all Claims existing on the date hereof, whether based in contract, tort,
7 statutory right, and any and all rights (including, but not limited to,
8 subrogation) to pursue and/or recover monies for [Summacare] that
9 [Summacare] had, may have had, or has asserted against any party in
10 connection with the Claims and all rights and claims against primary
11 payers and/or third parties that may be liable to [Summacare] arising
12 from or relating to the Claims, including claims under consumer
13 protection statutes and laws, and all information relating thereto, all of
14 which shall constitute the “Assigned Claims”.

15 15. On June 12, 2017, MSP Recovery irrevocably assigned all rights acquired
16 under the Summacare Assignment to Series 16-11-509, a designated series of MSPRC:

17 [Assignor] irrevocably assigns, sells, transfers, conveys, sets over and
18 delivers to Assignee and its successors and assigns, any and all of
19 Assignor’s right, title, ownership and interest in and to the [claims] (and
20 all proceeds and products thereof) as such terms are defined in the
21 Recovery Agreement dated May 12, 2017, by and among [Summacare]
22 . . . and [MSP Recovery]

23 16. Summacare consented to, acknowledged, approved, and ratified the
24 assignment from MSP Recovery to Series 16-11-509, which is memorialized in a letter
25 dated September 5, 2018.

26 17. Defendant, Avanir Pharmaceuticals, Inc. (“Avanir”) is a biopharmaceutical
27 incorporated in Delaware with its principal place of business at 30 Enterprise, Suite 200,
Aliso Viejo, California 92656.

FACTUAL ALLEGATIONS

I. Nuedexta, a Drug Approved by the FDA to Treat Pseudobulbar Affect, a Rare Neurological Condition

18. Pseudobulbar affect is a condition characterized by episodes of sudden and uncontrollable laughing or crying that is not indicative of a person’s actual emotional state.¹ PBA is the resulting cause of a neurological disease, including a stroke, dementia, traumatic brain injury, and Parkinson’s disease.²

19. PBA is rare. It is estimated that only 0.5% to 2% of Americans suffer from PBA.³

20. There is no cure for PBA. To address PBA, doctors prescribe treatments to manage PBA’s symptoms to improve the patient’s quality of life. PBA is managed through regular, recurring treatments over the course of a patient’s life.

21. Pharmacological treatment for PBA is not appropriate for all patients with this condition. As such, treatment for PBA is equally targeted to the underlying disease that gave rise to PBA, as opposed to pharmacological treatment of PBA alone i.e., dementia drugs.

22. On October 29, 2010, the FDA approved the drug Nuedexta for a single use: treatment of PBA. At that time, and at all relevant times thereafter, Avanir’s primary marketed product was Nuedexta. Avanir commercially launched Nuedexta to the public in February 2011. Avanir currently has patent exclusivity over Nuedexta until 2026.

¹ *Pseudobulbar Affect*, Nat’l Center for Advancing Translational Sciences, https://rarediseases.info.nih.gov/diseases/12012/pseudobulbar-affect#ref_7191 (last visited Apr. 20, 2022).

² *Pseudobulbar Affect Infographic*, Am. Stroke Ass’n, <https://www.stroke.org/en/help-and-support/support-group-leader-resources/lesson-modules/pseudobulbar-affect/pseudobulbar-affect-infographic> (last visited Apr. 20, 2022).

³ *Pseudobulbar Affect (PBA)*, Cleveland Clinic, <https://my.clevelandclinic.org/health/diseases/17928-pseudobulbar-affect-pba> (last visited Apr. 20, 2022).

1 23. The FDA’s approval for Nuedexta for PBA was limited to patients with a
2 PBA diagnosis arising from MS or ALS. The FDA did not approve—and the prescription
3 label warned against—prescribing Nuedexta for patients with other types of emotional
4 liability than can commonly occur in patients with Alzheimer’s disease and other
5 dementias.

6 24. Despite the low prevalence of PBA among the general population, Avanir
7 aggressively marketed Nuedexta and shoved it into the market by any means necessary,
8 including broadening the scope of what Nuedexta can treat and redefining what PBA is to
9 the medical community, e.g., marketing non-PBA symptoms as PBA.

10 25. Avanir funded and provided editorial support for the manuscript preparation
11 of the study titled “PRISM: A Novel Research Tool to Assess the Prevalence of
12 Pseudobulbar Affect Symptoms Across Neurological Conditions” (the “PRISM study”).
13 Although the PRISM study was published by a group of five doctors, a closer inspection
14 reveals that each of these doctors received separate funding from Avanir for the study, and
15 one of the doctors was an Avanir employee.

16 26. The PRISM study focused on the prevalence of the symptoms of PBA—not
17 the prevalence of a PBA diagnosis. Avanir used the PRISM study through its salesforce
18 to promote Nuedexta as a treatment for symptoms of PBA and not PBA itself, the only
19 FDA-approved use of Nuedexta.

20 27. Avanir directed its sales representatives to distribute *summaries* of the
21 PRISM study to physicians. Thus, Avanir was promoting Nuedexta as a treatment for
22 patients experiencing symptoms of PBA, even though this went beyond the FDA’s
23 approval of Nuedexta.

24 28. By redefining PBA to include other diagnoses and unfoundedly touting its
25 increased prevalence, Avanir was broadening the market of people who would be eligible
26 for Nuedexta. Because PBA is secondary to an underlying neurological disorder, Avanir
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1 began marketing Nuedexta for patients with disorders more common than PBA, including
2 Alzheimer’s and dementia. Most patients with Alzheimer’s and dementia tend to be 65
3 years old and older whom Medicare provides with health and prescription drug insurance.

4 29. Avanir induced doctors to prescribe Nuedexta to more patients through
5 kickbacks and fraudulent marketing.

6 30. Plaintiff’s assignors and the Class Members were the intended victims of the
7 kickback scheme because they had to pay for the influx of prescriptions for Nuedexta.

8 **II. Nuedexta Coverage Under Medicare and Medicaid**

9 31. For a drug to qualify for Medicare Part D reimbursement, the Medicare
10 Prescription Drug Benefit Manual requires that the drug be provided only for “medically
11 accepted indications.” A medically accepted indication includes FDA approved uses or
12 off-label uses supported by one or more of three compendia specified in Section
13 1927(g)(1)(B) of the Social Security Act. None of the compendia listed any approved off-
14 label uses for Nuedexta. As such, Nuedexta qualified for Medicare Part D reimbursement
15 only when provided for its FDA-approved use—the treatment of PBA.

16 **A. Off-label Marketing**

17 32. Further, it is illegal for a drug company to market or knowingly sell its
18 products for off-label use.

19 33. Nonetheless, Avanir illegally marketed Nuedexta for off-label use. Through
20 its illegal marketing of Nuedexta, Avanir misrepresented PBA thereby expanding the
21 potential patient population and misleading prescribers into believing that their patients
22 had PBA when they did not. Thus, prescribers wrote prescriptions for people who were
23 not diagnosed with, and did not have, PBA.

24 34. For its scheme to work, Avanir needed to ensure that Nuedexta was
25 accessible to patients under their health insurance plan, whether under a commercial health
26 insurance policy or Medicare. Avanir considered Nuedexta’s pricing and the relation to
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1 formulary placement throughout its scheme to increase prescriptions. By purposely
2 keeping prices lower, Nuedexta remained in a lower tier in a plan’s formulary; thus,
3 avoiding detection of proliferation and further scrutiny.

4 35. Avanir’s aggressive marketing scheme touting the PRISM study and blurring
5 the lines between PBA symptoms and a PBA diagnosis also induced Plaintiff’s assignors
6 and the Class Members to largely eliminate formulary restrictions on Nuedexta.
7 According to Avanir’s internal documents, 66% of commercial health plans and 65% of
8 Medicare Part D plans included Nuedexta in their formularies as a preferred drug without
9 any restrictions in May 2015. Avanir touted the fact that nearly 9 million additional seniors
10 had unrestricted access to Nuedexta from 2014 to 2015.

11 36. Plaintiff’s assignors alone paid over \$5.2 million for Nuedexta prescriptions
12 throughout the time that Avanir engaged in an illegal kickback scheme with prescribers to
13 increase prescriptions of Nuedexta.

14 **III. Otsuka Pharmaceuticals Joins the Scheme to Increase Nuedexta Prescriptions**

15 37. In December 2014, Otsuka Pharmaceutical Co., Ltd.’s (“Otsuka
16 Pharmaceutical”) announced the acquisition of Avanir through a \$3.5 billion all-cash
17 tender offer. On January 13, 2015, the transaction closed, making Avanir a wholly owned
18 subsidiary of Otsuka America, Inc. (“Otsuka America”). Otsuka America is a subsidiary
19 of Otsuka Pharmaceutical.

20 38. Prior to the acquisition, Avanir was comprised of approximately 500
21 employees. Of those 500 employees, 330 were pharmaceutical sales representatives who
22 were tasked with promoting Nuedexta, which, at the time, was Avanir’s only FDA
23 approved prescription drug.

24 39. However, Avanir’s acquisition fortified the Nuedexta sales force with an
25 additional 300 Otsuka sales representatives at a minimum.

1 40. This expanded sales force of Nuedexta would result in “[m]ore noise, more
2 adoption, [and] more patients being helped!”

3 41. During a company-wide presentation on March 11, 2015, at Avanir’s
4 National Sales Meeting, Eric Benevich (Avanir’s Vice President for Marketing)
5 announced Otsuka’s reinforcement initiative. The following week, Otsuka’s sales
6 representatives were trained on the misinformation about Nuedexta by Avanir employees,
7 using Avanir training material. Shortly thereafter, Otsuka representatives were peddling
8 misinformation and kickbacks alongside Otsuka’s Avanir counterparts.

9 **IV. Placing Profits Over Medical Independence and Patient Safety**

10 42. Doctors take a Hippocratic Oath to treat patients to the best of their abilities
11 and put patients first. Once in bed with Avanir, however, the line between doing what’s
12 best for a patient and obtaining profits for personal gain begins to blur.

13 **A. Outlining the Kickback Scheme**

14 43. Avanir promotes Nuedexta through a speaker’s bureau program. Through the
15 speaker’s program, Avanir engaged doctors to promote Nuedexta to other medical
16 professionals using fraudulent marketing materials.

17 44. Upon information and belief, typical speaking engagements were held in
18 restaurants where Avanir would pay the physician a standard fee for each engagement,
19 pay for the physician’s meal, and reimburse the physician’s travel expenses. In addition,
20 Avanir held speaking engagements in a physician’s own office. Attendance at the speaking
21 engagements is generally small, often five (5) to ten (10) physicians.

22 45. Further, for the speaking engagements, Avanir limited a physician’s
23 presentation to materials prepared by Avanir and required the physician not deviate from
24 the focus on the prevalence of PBA, the PRISM study, and off-label use of Nuedexta.

1 46. Avanir approves an annual speaker program budget, which is distributed to
2 its sales representatives for them to use to pay prescribers of Nuedexta to appear at
3 speaking engagements.

4 47. Upon information and belief, Avanir evaluates employee performance solely
5 on the amount of prescriptions written, including refills, in each of the sales
6 representatives' respective territories—not the amount of new prescribers in the sales
7 representatives' assigned territory. To further fuel employee performance, Avanir creates
8 a competitive environment between the sales representatives by ranking them based on
9 the number of prescriptions written in each of their territories and providing end of year
10 incentives to the highest ranked employees.

11 48. Avanir employees were tasked with maximizing the number of prescriptions
12 in each of their territories and with minimal to indifferent oversight.

13 49. One way that Avanir sales representatives increased the number of
14 prescriptions in their territories was by leveraging Avanir's speaker engagement budget.

15 50. Avanir sales executives intended for speaker fees to be used to induce
16 prescribers to increase prescriptions of Nuedexta.

17 51. Avanir induced prescribers to become high prescribers of Nuedexta to
18 beneficiaries of federal healthcare programs, offered prescribers financial incentives to
19 write Nuedexta prescriptions for beneficiaries of federal healthcare programs, and induced
20 prescribers to recommend that other prescribers prescribe Nuedexta to beneficiaries of
21 federal healthcare programs, regardless of the patient's diagnosis.

22 52. Avanir provided speaking engagements to physicians who constantly
23 prescribed Nuedexta.

24 53. The kickbacks were not limited to speaking engagements though. Executives
25 and other employees at Avanir agreed to use payments to prescribers, including speaker
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1 fees and honoraria, to induce the prescribers to maintain and increase their Nuedexta
2 prescribing volume.

3 **B. Avanir Paid the Highest Prescribers of Nuedexta Thousands of Dollars**

4 54. Over the years, Avanir has paid millions of dollars to prescribers of
5 Nuedexta.⁴ For example, the allegations below involving two doctors illustrate how the
6 scheme played out.

7 55. From October 2011 through around February 2016, Avanir paid Dr. Deepak
8 Raheja (“Dr. Raheja”) over \$330,000 in honoraria for speaking engagements related to
9 Nuedexta. Dr. Raheja gave approximately 211 speaking presentations, which Avanir paid
10 approximately \$1,500 for each presentation. During this time, Dr. Raheja was the highest
11 prescribing doctor and wrote approximately 10,088 Nuedexta prescriptions.

12 56. According to CMS Open Payments, from 2014 to 2020, Avanir paid Dr. Idan
13 Sharon (“Dr. Sharon”) 329 times, resulting in more than \$260,000. Upon information and
14 belief, Dr. Sharon is one of Nuedexta’s highest prescribing doctors. Plaintiff’s assignor
15 has paid for at least 30 claims for Nuedexta from Dr. Sharon, resulting in Plaintiff’s
16 assignors paying at least \$12,512.05 for Nuedexta.

17 **THE NEUDEXTA ENTERPRISE**

18 57. Avanir and the co-conspirators conducted or actively participated in conduct
19 of an enterprise through a pattern of racketeering activity in violation of 18 U.S.C. §
20 1962(c). Additionally, and in the alternative, Avanir and the co-conspirators, through an
21 agreement to commit two or more predicate acts, conspired to conduct or participate in
22 the conduct of an enterprise through a pattern of racketeering activity in violation of 18
23 U.S.C. § 1962(d). Avanir’s and the co-conspirators’ actions (otherwise known as the
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26 _____
27 ⁴ Open Payments, <https://openpaymentsdata.cms.gov/company/100000005729> (last visited Apr. 20, 2022).

1 “Neudexta Enterprise”) were in furtherance of the enterprise and in violation of 18 U.S.C.
2 § 1962(d).

3 58. The Neudexta Enterprise participants include Avanir, the author-physicians
4 who Avanir paid to produce the PRISM study, and the physicians who received kickbacks
5 for prescribing Neudexta for off-label purposes. The Neudexta Enterprise is an
6 association-in-fact between the Enterprise participants.

7 59. The purpose of the Neudexta Enterprise was to conceal from the TPPs the
8 off-label marketing of Neudexta and the amount of information the assignors received
9 regarding claims for payment of Neudexta prescriptions so that the Neudexta Enterprise
10 participants could profit in some manner. The author-physicians of the PRISM study and
11 the physicians who prescribed Neudexta for off-label purposes, among others, profited
12 from the various kickbacks. Although Avanir was the leader of the Neudexta Enterprise,
13 each Neudexta Enterprise participant contributed to the purpose of concealing the off-
14 label marketing of Neudexta and financial incentives received as a result of writing
15 additional Neudexta prescriptions. Thus, each Neudexta Enterprise participant actively
16 contributed and advised the other Neudexta Enterprise participants as part of the overall
17 Enterprise.

18 60. As alleged in detail above, Avanir and the Neudexta Enterprise used
19 marketing and tactics, and Avanir and the co-conspirators executed these strategies to
20 increase the sales of Neudexta throughout the United States, all while deceiving the TPPs.

21 **CLASS REPRESENTATION ALLEGATIONS**

22 61. Plaintiff seeks to represent a Nationwide Class pursuant to Federal Rule of
23 Civil Procedure 23(a), 23(b)(2) and 23(b)(3) as defined below:

24 All third-party payers in the United States and its territories and
25 possessions that paid for Nuedexta from 2011 through the
26 present that was manufactured, distributed, or sold by
27 Defendant.

1 62. The Nationwide Class has a Subclass:

2 All third-party payers that paid for Nuedexta prescriptions
3 written by Dr. Deepak Raheja from 2011 through the present
4 that was manufactured, distributed, or sold by Defendant.

5 63. Plaintiff alleges additional sub-classes for all TPPs in each State, territory, or
6 possession—or combination(s) of States, territories, or possessions to the extent class
7 members from these jurisdictions can be grouped together for purposes of class
8 treatment—who, paid any amount of money out of pocket for Nuedexta that was
9 manufactured, distributed, or sold by Defendant (collectively, the “Subclasses”).

10 64. Collectively, the foregoing Nationwide Class and the Subclasses are referred
11 to as the “Class.”

12 65. Excluded from the Class are: (a) Defendant; (b) any parent, subsidiary, or
13 affiliate of Defendant; (c) any entity in which Defendant has or had a controlling interest,
14 or which the Defendant otherwise controls or controlled; and (d) any officer, director,
15 employee, legal representative, predecessor, successor, or assign of Defendant.

16 66. Plaintiff meets the prerequisites of Rule 23(a) to bring this action on behalf
17 of the Class.

18 67. **Numerosity:** Joinder of all members is impracticable. Upon information and
19 belief, the Class is comprised of hundreds TPPs, including commercial health plans,
20 Medicare Advantage Organizations (“MAO”), first tier entities, down-stream entities, or
21 their assignees throughout the United States of America and its territories, who paid for
22 Nuedexta during the class period.

23 68. **Existence and predominance of common questions of law and fact:**
24 Questions of law and fact are common to all members of the Class. Specifically, Avaniir’s
25 misconduct was directed at all Class Members and their affiliates. This is an action in
26 which Plaintiff and the Class Members assert claims alleging the same theory of recovery,
27

1 namely that they have the right to recover damages for Avanir's unlawful scheme to
2 increase Nuedexta prescriptions. Plaintiff and Class Members' claims arise from the same
3 practice or course of conduct: Avanir intentionally misled TPPs on the use of Nuedexta,
4 misled TPPs as to the prevalence of PBA, misled TPPs as to what PBA actually is, paid
5 physicians to increase their prescriptions of Nuedexta to patients regardless of whether the
6 patient actually suffered from PBA, and paid certain physicians to spread misinformation
7 on Nuedexta and PBA. Thus, all Class Members have common questions of fact and law,
8 i.e., whether Avanir illegally marketed Nuedexta and caused the Class Members to pay
9 for prescriptions of Nuedexta that physicians otherwise would never have written. Each
10 Class Member shares the same needed remedy: reimbursement. Plaintiff seeks to enforce
11 its own rights, as well as the rights of the Class Members.

12 69. **Typicality:** Plaintiff's claims are typical of the Class Members' claims, as
13 Avanir has damaged all in the same manner. Plaintiff's and the Class Members' claims
14 have the same essential characteristics, arise from the same course of conduct, share the
15 same legal theory, and are not subject to any unique defenses. As the class representative,
16 Plaintiff possesses the same interests and suffered the same injury as the other Class
17 Members, which demonstrates a legally sufficient nexus between Plaintiff's claims and
18 the Class Members' claims. Plaintiff's claims are typical of the Class Members' claims
19 because Avanir targeted TPPs in its illegal scheme to increase prescriptions of Nuedexta
20 and Plaintiff's assignors, like the Class Members, paid for an increased number of
21 prescriptions for a drug the FDA approved to treat a rare condition, PBA.

22 70. **Adequacy of Representation:** Plaintiff will fairly and adequately represent
23 and protect the interests of the Class. Plaintiff's interests in vindicating these claims are
24 shared with all Class Members, and there are no conflicts between the named Plaintiff and
25 the Class Members. Additionally, Plaintiff is represented by counsel who are competent
26 and experienced in class action litigation and have no conflicts.

27

1 71. The elements of Rule 23(b)(3) are met. Defendant has acted on grounds that
2 apply generally to Class Members so that preliminary and/or final injunctive relief and
3 corresponding declaratory relief is appropriate respecting the Class as a whole.

4 72. **Superiority:** A class action is superior to other available methods for the fair
5 and efficient adjudication of this litigation because it is the most manageable and efficient
6 way to resolve the individual claims of each Class Member. Specifically, a class action
7 will provide Class Members with what may be their only economically viable remedy.
8 Moreover, there are no known Class Members who are interested in individually
9 controlling the prosecution of separate actions. Additionally, a class action will
10 concentrate all litigation in one forum, which will conserve judicial and party resources
11 with no unusual manageability problems.

12 73. In the alternative, Plaintiff seeks to certify a national issues class under Rule
13 23(c)(4).

14 74. Rule 23(c)(4) provides that an action may be brought or maintained as a class
15 action with respect to particular issues when doing so would materially advance the
16 litigation as a whole.

17 75. In an effort to materially advance the litigation as a whole, pursuant to Rule
18 23(c)(4), Plaintiff brings this action on behalf of itself and the Class Members to resolve,
19 *inter alia*, several important issues, including: whether Avanir intentionally misled TPPs
20 on the use of Nuedexta, whether Avanir misled TPPs as to the prevalence of PBA, whether
21 Avanir misled TPPs as to what PBA actually is, whether Avanir paid certain physicians
22 to increase their prescriptions of Nuedexta to patients regardless of whether the patient
23 actually suffered from PBA, and whether Avanir paid certain physicians to spread
24 misinformation on Nuedexta and PBA, and whether Avanir illegally marketed Nuedexta
25 and caused the Class Members to pay for prescriptions of Nuedexta that physicians
26 otherwise would never have written.

TOLLING

1
2 76. Plaintiff’s assignors and the Class Members had no way of knowing about
3 Avanir’s illegal scheme to increase Nuedexta prescriptions.

4 77. Avanir and the physicians it paid refused to disclose the true nature of their
5 relationship regarding Nuedexta prescriptions.

6 78. Within the applicable statutes of limitation, Plaintiff’s assignors and the Class
7 Members could not have discovered, through exercise of reasonable diligence, that Avanir
8 was concealing the conduct complained of herein and misrepresenting its marketing
9 practices, the illegal kickbacks, and the prevalence of PBA.

10 79. Although Avanir and physicians reported payments on Medicare’s Open
11 Payment System, the true nature of the scheme went unreported, and Plaintiff’s assignors
12 and the Class Members had no way of knowing the true invidious nature of these
13 payments.

14 80. On September 24, 2019, a *qui tam* suit was unsealed. This suit, for the first
15 time, explained how payments to physicians were being used as quid pro quo to increase
16 Nuedexta sales to drive profits up to the detriment of Plaintiff’s assignors and the Class
17 Members.

18 81. On September 26, 2019, the DOJ filed a criminal Information that
19 demonstrated how Avanir was controlling the Nuedexta scheme.

20 82. On October 2, 2019, through a Deferred Prosecution Agreement with the
21 DOJ, Avanir, for the first time, admitted its role in the Nuedexta scheme. In this
22 Agreement, Avanir admitted that its sales and marketing management sought to conceal
23 communications from detection. In one exchange of messages, an Avanir executive
24 instructed another executive to “make sure to delete your text messages.” In that same
25 exchange of messages, one executive asked if text messages are discoverable if deleted.
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1 In a separate message exchange, one Avanir employee asked an Avanir executive to no
2 longer send emails regarding the scheme.

3 83. It was only in 2019 that the public (including Plaintiff’s assignors and the
4 Class Members) could have become aware of Avanir’s scheme to increase prescriptions
5 of Nuedexta. The unsealing of the *qui tam* complaint, along with the DOJ’s criminal
6 information against Avanir, was the first time that Avanir’s Nuedexta scheme was
7 revealed with first-hand accounts of how the scheme operated and how Avanir took steps
8 to conceal its actions.

9 84. Through this active concealment, and Avanir’s repeated insistence of lacking
10 any impropriety, Plaintiff’s assignors, the Class Members, and any reasonable person, had
11 no way of knowing the nature and prevalence of the Nuedexta scheme.

12 85. Further, all documents that would lead a reasonable person to suspect that the
13 Nuedexta scheme was ongoing, and is currently still ongoing, are in Avanir’s exclusive
14 custody and control.

15 86. Plaintiff’s assignors and the Class Members did not discover, and did not
16 know of facts, that would have led a reasonable person to suspect that Avanir was engaged
17 in an illegal scheme to increase Nuedexta prescriptions.

18 87. Accordingly, all applicable statutes of limitation have been tolled by
19 operation of the discovery rule with respect to all claims relating to Nuedexta.

20 **CAUSES OF ACTION**

21 **COUNT I**

22 **VIOLATION OF 18 U.S.C. § 1962(c)**

23 88. Plaintiff incorporates by reference paragraphs 1 to 87 as if fully stated herein.

24 89. Avanir is a “person” within the meaning of 18 U.S.C. § 1961(3). Avanir
25 conducted the affairs of the Nuedexta Enterprise through a pattern of racketeering activity
26 in violation of 18 U.S.C. § 1962(c).
27

1 90. The Nuedexta Enterprise is an association-in-fact within the meaning of 18
2 U.S.C. § 1961(4), consisting of Avanir, including its employees and agents, and the
3 prescribers which it paid to increase their prescription volume of Nuedexta and induce
4 other prescribers throughout the country to prescribe Nuedexta. All entities are persons
5 within the meaning of 18 U.S.C. § 1961(3) and acted to enable Avanir to fraudulently
6 market Nuedexta as a drug with more far-reaching potential than what was approved by
7 the FDA.

8 91. The Nuedexta Enterprise is an organization that functioned as an ongoing
9 organization and continuing unit. The Nuedexta Enterprise was created and used as a tool
10 to effectuate a pattern of racketeering activity. Each of these entities, including Avanir, is
11 a “person” distinct from the Nuedexta Enterprise.

12 92. Avanir, in concert with other participants in the Nuedexta Enterprise, created
13 and maintained systematic links for a common purpose, to aid in marketing Nuedexta as
14 an effective and safe alternative for treatment of conditions beyond PBA as well as
15 broadening the definition of PBA beyond its accepted use in the medical community.
16 Thus, the Nuedexta Enterprise improperly induced physicians to prescribe, and TPPs to
17 pay for, Nuedexta. Each of the enterprise participants received substantial revenue from
18 the fraudulent scheme to promote Nuedexta as safe and effective beyond its intended uses.
19 The paid physicians, among others, profited from speaking fees, consulting fees,
20 honoraria, and reimbursements. Such revenue was greater than it would have been if
21 Avanir had properly marketed Nuedexta. All enterprise participants were aware of
22 Avanir’s control over the activities of the Nuedexta Enterprise in promoting Nuedexta.
23 Furthermore, each portion of the enterprise benefited from the existence of the other parts.

24 93. The Nuedexta Enterprise engaged in and affected interstate commerce,
25 because, *inter alia*, it marketed, promoted, sold, or provided Nuedexta to thousands of
26 individuals and entities throughout the United States.

1 94. Avanir conducted and participated in the affairs of the Nuedexta Enterprise
2 through patterns of racketeering activity, including acts indictable under 18 U.S.C. §§
3 1341 (mail fraud); 1343 (wire fraud); and 1952 (use of interstate facilities to conduct
4 unlawful activity).

5 95. Avanir's fraudulent scheme consisted of, *inter alia*: (a) deliberately
6 misrepresenting what PBA was and the rarity of PBA in the general population; (b)
7 misrepresenting the effectiveness of Nuedexta for treatment of anything other than its
8 FDA-approved use so that Plaintiff's assignors unnecessarily paid for Nuedexta to treat
9 symptoms that were not scientifically proven to be safe and effective; and (c) actively
10 concealing and causing others to conceal, information about PBA.

11 96. Avanir's use of the mail and wires to perpetuate its fraud involved thousands
12 of communications, including, but not limited to:

13 (a) Communications with and among the Nuedexta Enterprise participants
14 that misrepresented the safety and risks of Nuedexta and information related
15 to PBA amongst themselves and others;

16 (b) Communications with Plaintiff's assignors and the Class Members
17 and/or their agents, inducing a lower placement of their respective drug
18 formularies for Nuedexta by misrepresenting Nuedexta and PBA;

19 (c) Communications with Plaintiff's assignors and the Class Members
20 and/or their agents, inducing payments for Nuedexta by misrepresenting
21 Nuedexta and PBA;

22 (d) Receiving the proceeds in the course of and resulting from Avanir's
23 improper scheme;

24 (e) Transmittal and receipt of monies from Plaintiff's assignors or their
25 agents; and
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1 (f) Transmittal and receipt of payments in exchange for, directly or
2 indirectly, activities in furtherance of the Nuedexta Enterprise.

3 97. At all times during the fraudulent scheme, Avanir and the Enterprise
4 participants had a legal and ethical obligation of candor to, and honest dealing with, public
5 and private TPPs, physicians, and the medical community. Further, as the manufacturer
6 of Nuedexta, it was unlawful for Avanir to promote Nuedexta for off-label use.

7 98. The conduct of the Nuedexta Enterprise described above constitutes
8 “racketeering activity” within the meaning of 18 U.S.C. § 1961(1). Avanir’s decisions and
9 activities in connection with the Nuedexta Enterprise to routinely conduct their
10 transactions in such a manner constitutes a “pattern of racketeering activity” within the
11 meaning of 18 U.S.C. § 1961(5).

12 99. Plaintiff’s assignors and the Class Members have been injured in their
13 property by reason of these violations in that Plaintiff’s assignors alone, paid over \$5.2
14 million for Nuedexta, which would not have paid had Avanir not engaged in this pattern
15 of racketeering activity.

16 100. The injuries to Plaintiff’s assignors and the Class Members were directly and
17 proximately caused by Avanir’s racketeering activity as Avanir knew health plans pay for
18 prescription drugs.

19 101. TPPs, including Plaintiff’s assignors and Class Members, directly relied on
20 the racketeering activities of Avanir and the Nuedexta Enterprise. This caused Plaintiff’s
21 assignors and the Class Members to place Nuedexta lower on their respective drug
22 formularies. Avanir also purposely kept the cost of Nuedexta low to ensure it remained in
23 a lower tier in Plaintiff’s assignors’ and the Class Members’ formularies, thereby evading
24 stricter scrutiny.

1 102. By virtue of these violations of 18 U.S.C. § 1962(c), Avanir is liable to
2 Plaintiff and the Class Members for three times the damages sustained, plus the costs of
3 this suit, including reasonable attorneys' fees.

4 103. By reason of the foregoing, and as a direct and proximate result of Avanir's
5 fraudulent misrepresentations, Plaintiff's assignors and the Class Members have suffered
6 damages. Plaintiff and the Class is entitled to compensatory damages, punitive damages,
7 costs and reasonable attorneys' fees.

8 **COUNT II**

9 **VIOLATION OF 18 U.S.C. § 1962(d)**

10 104. Plaintiff incorporates by reference paragraphs 1 to 87 as if fully stated herein.

11 105. Avanir and the Enterprise participants, as co-conspirators, violated 18
12 U.S.C. § 1962(d) by conspiring to violate section 1962(c). The object of the conspiracy
13 was to participate in the conduct of the affairs of the Nuedexta Enterprise through a pattern
14 of racketeering. Avanir conspired with prescribing physicians to promote Nuedexta by
15 expanding the meaning of PBA, marketing its off-label use, and inducing physicians to
16 prescribe Nuedexta without regard to a patient's actual diagnosis.

17 106. Avanir and the other co-conspirators engaged in numerous overt and
18 predicate fraudulent racketeering acts in furtherance of the conspiracy, including inducing
19 prescribers to increase their prescriptions of Nuedexta through a series of kickbacks.

20 107. Avanir was aware that its fraudulent acts were part of an overall pattern of
21 racketeering activity. Avanir knew that expanding the definition of PBA to physicians
22 would lead to increased prescriptions of Nuedexta.

23 108. As Avanir has already admitted, its sales executives intended for speaker fees
24 to be used to induce prescribers to increase prescriptions of Nuedexta.

25 109. In an exchange of messages, Avanir employees directly linked the increased
26 speaker program funding to increasing prescriptions. For instance, a regional business
27

1 manager said that one method of increasing prescriptions of Nuedexta was to have
2 educational programs for which a doctor would be paid.

3 110. Avanir ranked its employees by the number of prescriptions written in their
4 respective regions within a given year, which encouraged employees to compete against
5 each other for speaker program funding to give to physicians in exchange for higher
6 prescriptions.

7 111. In another exchange of messages between a physician and an Avanir
8 employee, the employee informed the prescriber that “[Avanir] ha[d] 20 programs
9 scheduled for Q1, compared to 6 last year in Q1” According to another Avanir
10 employee, that same physician “said he will rx 20 [Nuedexta prescriptions] from now until
11 the end of the month.”

12 112. Through the kickback scheme, Avanir paid this physician more than
13 \$330,000 in speaker fees and honoraria. As the highest prescriber of Nuedexta, this doctor
14 alone wrote thousands of prescriptions.

15 113. The nature of the co-conspirators’ acts, material misrepresentations, and
16 omissions in furtherance of the conspiracy gives rise to an inference that they not only
17 agreed to the objective of an 18 U.S.C. § 1962(d) violation by conspiring to violate 18
18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts
19 have been and are part of an overall pattern of racketeering activity.

20 114. As a direct and proximate result of Avanir’s and the Enterprise’s overt and
21 predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18
22 U.S.C. § 1962(c), Plaintiff’s assignors and the Class Members have been injured in their
23 property as set forth more fully above.

24 115. Avanir sought and engaged in the commission of overt acts, including the
25 following unlawful racketeering predicate acts:
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- 1 (a) Multiple instances of mail and wire fraud violations of 18 U.S.C. §§
- 2 1341 and 1342;
- 3 (b) Multiple instances of mail fraud violations of 18 U.S.C. §§ 1341 and
- 4 1346;
- 5 (c) Multiple instances of wire fraud violations of 18 U.S.C. §§ 1341 and
- 6 1346; and
- 7 (d) Multiple instances of unlawful activity in violation of 18 U.S.C. §
- 8 1952.

9 116. Plaintiff’s assignors and the Class Members have been injured because of
10 these violations. Plaintiff’s assignors alone paid more than \$5.1 million for Nuedexta
11 prescriptions during the time of the Nuedexta Enterprise. Plaintiff’s assignors would have
12 paid for fewer Nuedexta prescriptions had Avanir not conspired to violate 18 U.S.C. §
13 1962(c).

14 117. Avanir’s racketeering activity directly and proximately caused injury to
15 Plaintiff’s assignors and the Class Members.

16 **COUNT III**

17 **UNJUST ENRICHMENT**

18 118. Plaintiff incorporates by reference paragraphs 1 to 87 as if fully stated herein.

19 119. Avanir marketed Nuedexta as an effective treatment for PBA and for off-
20 label use.

21 120. By expanding the use of Nuedexta and who may suffer from PBA, Avanir
22 targeted TPPs, including Plaintiff’s assignors, to pay for prescriptions that otherwise
23 would never have been written.

24 121. Plaintiff’s assignors and the Class Members paid for Nuedexta during the
25 unlawful scheme. Plaintiff’s assignors alone paid, in total, \$5.2 million for Nuedexta.

1 122. Avanir has knowingly and intentionally benefitted, directly and indirectly,
2 from the illegal kickback scheme with doctors throughout the country.

3 123. Plaintiff's assignors and the Class Members have been damaged by paying
4 for prescriptions that they otherwise would not have paid for but for Avanir's aggressive,
5 illegal, and unfounded marketing campaign.

6 **COUNT IV**

7 **FRAUD**

8 124. Plaintiff incorporates by reference paragraphs 1 to 87 as if fully stated herein.

9 125. In its aggressive marketing push for Nuedexta, Avanir touted the PRISM
10 study but knowingly omitted to prescribers that the study focused on the prevalence of
11 PBA symptoms and not of the prevalence of PBA.

12 126. In its marketing campaign, Avanir marketed Nuedexta for a variety of
13 conditions unrelated to PBA and trained its sales representatives to aggressively promote
14 an expanded, inaccurate, and intentionally misleading definition of PBA.

15 127. In its marketing push, Avanir was illegally marketing off-label use of
16 Nuedexta.

17 128. As part of the scheme to increase prescriptions of Nuedexta, Avanir provided
18 illegal kickbacks to physicians so that the physicians would increase the number of
19 Nuedexta prescriptions they were writing, including for off-label use, and to spread
20 misinformation about Nuedexta and PBA.

21 129. In fact, Avanir has already admitted that one purpose of the Nuedexta scheme
22 was to provide remuneration for the prescribing of Nuedexta.

23 130. In communications between Avanir employees, an employee confirmed that
24 one of Nuedexta's highest prescribing doctors agreed to continue prescribing Nuedexta in
25 exchange for added speaker programs to be paid by the employee's commensurate fees.
26 One message in the exchange stated: "[Physician] is fired up and committed. [Physician]

1 said he will rx 20 per day from now until the end of the month[,]” to which another Avanir
2 employee responded, “[Physician]’s hungry so I’m accommodating an add’ prgm for weds
3 and I will sprinkle in a few others. . . .”

4 131. Moreover, Avanir’s sales executives intended for speaker fees to be used to
5 induce prescribers to increase prescriptions of Nuedexta.

6 132. To further perpetuate the fraud, Avanir knowingly represented false or
7 misleading information about Nuedexta to keep Nuedexta in a lower tier in Plaintiff’s and
8 Class Members’ formularies. Avanir did this to continue having Plaintiff’s assignors and
9 the Class Member pay for Nuedexta prescriptions and to avoid limitations that could
10 restrict sales growth.

11 133. Plaintiff’s assignors and the Class Members relied on Avanir’s false
12 representations, directly and indirectly, and ultimately paid for the influx of Nuedexta
13 prescriptions throughout the country.

14 134. In total, Plaintiff’s assignors alone paid over \$5.2 million for Nuedexta
15 prescriptions during the time of Avanir’s scheme, which led to criminal indictments
16 against doctors and former Avanir employees. Ultimately, a deferred prosecution
17 agreement was reached between Avanir and the DOJ.

18 **COUNT V**

19 **CONSPIRACY TO COMMIT FRAUD**

20 135. Plaintiff incorporates by reference paragraphs 1 to 87 as if fully stated herein.

21 136. Avanir unlawfully engaged in a kickback scheme with certain prescribers to
22 increase the volume of prescriptions for Nuedexta.

23 137. Avanir paid the prescribers to induce Plaintiff’s assignors and Class Members
24 to pay for Nuedexta prescriptions that Plaintiff’s assignors and Class Members would
25 never have otherwise paid.

1 138. Avanir induced the paid prescribers to prescribe Nuedexta for patients who
2 did not have PBA and for patients whom Nuedexta would be ineffective in treating.

3 139. Avanir and its paid prescribers also engaged in an effort to spread
4 misinformation and induce other prescribers to also increase their volume of prescriptions
5 for Nuedexta.

6 140. As a result of Avanir’s scheme, Plaintiff’s assignors and the Class Members
7 paid for Nuedexta throughout the term of Avanir’s scheme. Plaintiff’s assignors paid \$5.2
8 million in total for Nuedexta.

9
10 **PRAYER FOR RELIEF**

11 WHEREFORE, Plaintiff, individually and on behalf of the Class Members, pray for
12 the following relief:

- 13 A. An order that this action satisfies the prerequisites for maintenance of a class
14 action pursuant to Federal Rules of Civil Procedure 23(a), (b)(2), (b)(3)
15 and/or (c)(4), and certify the respective Classes;
- 16 B. An order designating Plaintiff as representative for the respective Classes and
17 Plaintiff’s undersigned counsel as Class Counsel for the respective Classes;
18 and
- 19 C. Judgement against defendant that:
 - 20 i. Awards compensatory damages;
 - 21 ii. Awards punitive damages;
 - 22 iii. Awards costs of litigation, including reasonable attorneys’ fees;
 - 23 iv. Awards such other relief as the Court deems appropriate.

24
25 **DEMAND FOR JURY TRIAL**

26 Plaintiff demands a trial by jury on all issues so triable.

1
2 Dated: May 20, 2022

Respectfully submitted,

3 By: /s/ Alex R. Straus

4 Alex R. Straus
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