

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
Eastern Division (Akron)

UNITED STATES OF AMERICA, *ex rel.*

KEVIN MANIERI, Relator,

Plaintiffs,

v.

AVANIR PHARMACEUTICALS, INC.,

and

DEEPAK RAHEJA,

Defendants.

5:15 CV 611

Civil No. \_\_\_\_\_

Judge JUDGE LIOI

MAG. JUDGE LIMBERT

FILED UNDER SEAL,  
pursuant to 31 U.S.C. § 3730(b)(2)

JURY TRIAL DEMANDED

COMPLAINT

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## **I. INTRODUCTION**

1. Relator Kevin Manieri, individually and on behalf of the United States of America, brings this action against Defendants Avanir Pharmaceuticals, Inc. and Dr. Deepak Raheja for violations of the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (“FCA”), and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (“AKS”).

2. Defendant Avanir is engaged in a drug kickback scheme with physicians around the United States, in which Avanir pays physicians speaking fees in exchange for the physicians’ promises to prescribe Nuedexta, a drug that Avanir sells as a treatment for pseudobulbar affect (PBA). PBA is a rare neurological condition that causes involuntary laughing and crying.

3. Defendant Dr. Raheja participated in this illegal kickback scheme by knowingly soliciting and accepting kickbacks from Avanir in return for prescribing Nuedexta to his patients.

## **II. JURISDICTION AND VENUE**

4. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a).

5. This Court has jurisdiction over Defendant Avanir pursuant to 31 U.S.C. § 3732(a) because Avanir does business in the Northern District of Ohio, including in Cuyahoga and Summit Counties, and knowingly offered inducements to Ohio physicians to induce those physicians residing in these counties to prescribe Nuedexta to patients residing in Ohio. These inducements took the form of paid speaking engagements at venues in the Northern District of Ohio. Avanir made these inducements through its Ohio-based sales employees for the purpose of establishing a network of prescribers of Nuedexta in Ohio. As a result, Avanir committed acts proscribed by 42 U.S.C. § 1320a-7b and 31 U.S.C. § 3729 in this judicial district.

6. This Court has personal jurisdiction over Defendant Dr. Raheja because he resides in Summit County, Ohio. He has his principal place of business in the Cleveland, Ohio area in Cuyahoga County and committed acts proscribed by 42 U.S.C. § 1320a-7b and 31 U.S.C. § 3729 in the Northern District of Ohio, Eastern Division (Akron).

7. Venue in the Northern District of Ohio, Eastern Division is proper pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claims herein occurred in this judicial district and this division.

8. Venue in the Northern District of Ohio, Eastern Division (Akron) is proper pursuant to 28 U.S.C. § 1391(b)(1) because Defendants Avanir and Dr. Raheja have extensive and deliberate contacts in this judicial district and division and because Dr. Raheja is a resident of Summit County.

9. None of the allegations set forth in this Complaint have been “publicly disclosed,” or are substantially the same as allegations that have been “publicly disclosed,” as that phrase is used in 31 U.S.C. § 3730(e)(4)(A).

### **III. PARTIES**

10. Relator Kevin Manieri is a Pennsylvania resident and U.S. citizen. Mr. Manieri was employed by Defendant Avanir as Sales Director—North from August 2014 to November 2014. As Sales Director—North, Mr. Manieri was responsible for overseeing all sales in the Northeast, Midwest, and California, including in Ohio.

11. Defendant Avanir Pharmaceuticals, Inc. is a biopharmaceutical company that markets and sells a single product, Nuedexta. Avanir’s net revenues from Nuedexta exceed \$25 million. Avanir is based in Aliso Viejo, California and has approximately 485 employees in the United States. Avanir is incorporated in Delaware.

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12. On January 13, 2015, Avanir was acquired by Otsuka Pharmaceuticals Co., Ltd. for \$3.5 billion. Avanir is now a wholly-owned subsidiary of Otsuka, but remains the same corporate entity with its headquarters in Aliso Viejo, California.

13. At all relevant times, Avanir's President and Chief Executive Officer (CEO) was Keith Katkin. The Chief Commercial Officer, Rohan Palekar, reports directly to the CEO. Mr. Palekar oversees the Sales, Marketing, and Business Development divisions, each of which is headed by a Vice President. The Vice President of Sales, Michael McFadden, reports directly to Mr. Palekar. Relator Manieri reported directly to Mr. McFadden.

14. Defendant Dr. Raheja is a neurologist whose practice is located at Grace Specialty Hospital, 2307 West 14<sup>th</sup> Street, Cleveland, Ohio. Dr. Raheja resides in Hudson, Ohio, in Summit County.

#### **IV. FACTUAL ALLEGATIONS**

##### **A. Nuedexta is FDA-Approved as a Treatment for Pseudobulbar Affect (PBA), a Rare Neurological Condition**

15. In October 2010, the U.S. Food and Drug Administration approved Nuedexta as a treatment for Pseudobulbar Affect, known as "PBA." Avanir began selling Nuedexta in January 2011.

16. PBA is a neurological condition that causes involuntary outbursts of laughing and/or crying. PBA can afflict people who suffer from more serious conditions, such as Alzheimer's, dementia, multiple sclerosis (MS), Lou Gehrig's disease (ALS), traumatic brain injury (TBI), and stroke. The severity and frequency of PBA symptoms vary widely among patients, such that only some patients exhibiting PBA symptoms benefit substantially from pharmacological treatment. Nuedexta is not effective for all patients with PBA symptoms. The

neurological standards for diagnosis of PBA as an illness have not been conclusively established by the medical community.

17. Doctors who observe PBA symptoms do not necessarily choose to treat PBA and frequently only treat the more serious underlying disease, which carries with it much greater health risks than PBA.

18. Avanir's marketing of Nuedexta targets Alzheimer's and dementia patients, who tend to be 65 years old and over and covered by Medicare. As a result, doctors who treat PBA with Nuedexta prescribe the drug predominantly to patients who are 65 years old and over.

19. Nuedexta can cause a number of side effects, including dizziness, diarrhea, hepatotoxicity, and certain cardiac effects. Nuedexta may cause "serotonin syndrome," with changes including altered mental status, restlessness, hyperthermia, shivering, and tremor.

20. To the best of Relator Manieri's knowledge, no independent studies have been conducted on the prevalence of PBA in the United States.

21. According to the American Academy of Neurology, PBA affects 20-50% of patients with ALS. Between 20,000 and 30,000 people in the United States have ALS, suggesting that somewhere between 4,000 and 15,000 people in the United States with ALS also have PBA.

22. The only published study on the prevalence of PBA in the U.S. is the PRISM study, released in 2013 and titled "PRISM: A Novel Research Tool to Assess the Prevalence of Pseudobulbar Affect Symptoms across Neurological Conditions" and authored by physicians Benjamin Rix Brooks, David Crumpacker, Jonathan Fellus, Daniel Kantor, and Randall E. Kaye. The article is available free online on the PLOS publication system, catalogued as August 2013 | Volume 8 | Issue 8 | e72232.

23. PRISM was funded and developed by Avanir. One of the study's five authors, Randall Kaye, is an Avanir employee. Another of the study's authors, Dr. Jonathan Fellus, received \$64,085.39 in payments from Avanir between August and December of 2013, including \$43,500 in speaking fees. Dr. Fellus's medical license was later revoked by the New Jersey Board of Medical Examiners for having a sexual relationship with a patient.

24. Funding for conducting the PRISM study on PBA patients and the efficacy of Nuedexta and editorial support for manuscript preparation of the published study were provided by Defendant Avanir Pharmaceuticals, Inc. Other potential conflicts of interest are as follows: Dr. Brooks has received funding and/or research grants from Avanir Pharmaceuticals, Inc.; Dr. Crumpacker has served on a scientific advisory board for and received speaking fees from Avanir Pharmaceuticals, Inc.; Dr. Fellus has received a research grant and consulting fees from, has served on the Speakers Bureau for, and is a stockholder of Avanir Pharmaceuticals, Inc.; Dr. Kantor has received speaking and consulting fees from Avanir Pharmaceuticals, Inc., including in 2013; and Dr. Kaye is an employee and stockholder of Avanir Pharmaceuticals, Inc.

25. The PRISM study used an overly broad definition of PBA, including within the 36.7% prevalence figure many participants who merely exhibited some of the symptoms commonly associated with PBA. The PRISM study's definition of PBA is not recognized by the American Academy of Neurology (AAN). AAN has not endorsed Avanir's estimate of the prevalence of PBA. Indeed, the PRISM study itself concluded that further research is needed to determine whether the definition of PBA it used actually confirms the presence of PBA. Accordingly, the number of participants in the PRISM study who were actually afflicted with PBA could be less than 1,941.

26. Clinical diagnosis of PBA is difficult, as physicians rarely observe the symptoms and must rely upon self-reporting of symptoms and their frequency and severity by patients or caregivers. Additionally, physicians trying to distinguish between PBA and other conditions must evaluate patients for other illnesses, often more serious and far more debilitating, which cause PBA-like symptoms, such as depression. The self-reporting interview process is time-consuming, particularly with elderly and disabled patients. Most busy physicians do not devote the time required for an in-depth review of patient symptoms necessary to make a definitive PBA diagnosis. While Avanir's sales and marketing promotes Nuedexta for all with PBA symptoms, a finding of PBA or PBA symptoms does not necessarily mean that pharmacological treatment with Nuedexta is appropriate. Many patients' PBA symptoms are not sufficiently severe to interfere with daily activities. Other patients' symptoms show little or no improvement with Nuedexta. Additionally, Nuedexta has potential side effects that can pose serious risks. Because Nuedexta may cause dizziness, the danger of falling is heightened, a serious consequence for the elderly and disabled.

27. Nuedexta is typically prescribed for 30 days at a time, so that a refill is required every month. The list price of the drug in 2014 was approximately \$625 for a 30-day prescription. Thus for a patient who takes the drug year-round, the annual cost (at list price) is about \$7,500. The cost of Nuedexta is ultimately reimbursed by Medicare, Medicaid, or another government payor.

28. Nuedexta is a combination of two generic drugs, quinidine and dextromethorphan, that cost about \$20 monthly in their generic form. Both drugs had been available for at least 60 years before Avanir started developing Nuedexta.

## **B. Avanir Encourages its Salesforce to Leverage Speaking Fees**

29. Avanir has a national sales operation to support Nuedexta sales. At the corporate level, Vice President of Sales Michael McFadden oversees sales for the entire United States.

30. Relator Manieri held the position of Sales Director—North and reported directly to Mr. McFadden. Mr. Manieri's counterpart in the southeastern states, Denise Prindiville, was Sales Director—South, and also reported directly to Mr. McFadden.

31. Avanir divided the North and South into regions, each headed by a Regional Business Manager. Eight Regional Business Managers reported directly to Mr. Manieri.

32. Each Regional Business Manager oversees 8 to 10 Sales Representatives, who are each responsible for generating Nuedexta prescriptions within a geographic subset of their respective regions.

33. Avanir Vice President of Sales McFadden oversees two Nuedexta sales groups: Specialty (where Relator Manieri worked) and Long-Term Care (LTC). The Specialty group markets Nuedexta to physicians' practices, while LTC markets Nuedexta primarily to nursing homes and long term care facilities.

34. Avanir's corporate leadership approves an annual speaker program budget, to be distributed in portions to each Sales Representative. Avanir approves these funds for Sales Representatives to use to pay Nuedexta prescribers to appear at speaking engagements.

35. Avanir Vice President of Sales McFadden approves the speaker program budgets for the North and South areas in the Specialty group and the national speaker program budget for LTC. Avanir's Chief Commercial Officer, Rohan Palekar, determines the overall speaker program budget for both sales forces.

36. Avanir allocates to each Sales Representative about \$15,000 annually for speaker programs. Although Regional Business Managers have discretion as to how to spend speaking funds, Vice President of Sales McFadden, as discussed below, intervened on at least two occasions to arrange for speaker programs for high-volume Nuedexta prescribers.

37. Avanir judges sales employees' performance based solely on the number of Nuedexta prescriptions written by physicians in their respective territories. In addition, Avanir ranks Sales Representatives in order of the number of prescriptions written in their territories, effectively pitting them against each other.

38. Avanir further encourages improper sales techniques by rewarding Sales Representatives based on the total number of prescriptions in their territories, rather than the number of new prescribers in their territories. Avanir measures prescription results solely based on the total number of prescriptions (which includes refills), which creates an incentive for sales employees to encourage existing physician prescribers to prescribe more Nuedextra for inappropriate and illegal reasons.

39. Avanir's intentional sales promotion policy enables and encourages Sales Representatives to meet their personal performance goals by maximizing the number of prescriptions written by a few high-volume prescribers.

40. The combination of Avanir's measure of performance with the low prevalence of diagnosed PBA necessarily leads to Sales Representatives rewarding high-volume prescribers with speaking fees to induce them to continue prescribing Nuedexta and to increase the number of their prescriptions.

41. The low prevalence of diagnosed PBA and the challenges involved in diagnosis make it difficult for an individual physician to consistently identify candidates for treatment with

Nuedexta. The only way for a physician to become a high-volume prescriber, then, is to prescribe the drug to patients who present questionable or borderline cases for treatment, but do not necessarily need or benefit from Nuedexta.

42. Avanir sales employees must give physicians an incentive to prescribe Nuedexta if they are to meet their performance goals, since sales employees are judged relative to the performance of their peers. The most effective incentive for physicians is a financial one.

43. Avanir's requirement that Sales Representatives draft "Money Maker" lists of the top 10 to 15 prescribers in their territories and concentrate their sales efforts on those "money makers" reinforces Avanir's sales and marketing policy of encouraging a small number of prescribers to write large numbers of Nuedexta prescriptions.

44. Because Regional Business Managers' performance depends on the prescriptions generated by the Sales Representatives they oversee, many Regional Business Managers instruct their employees to leverage speaking fees to induce physicians to prescribe Nuedexta. Most Regional Business Managers consider use of speaking fees as the only way to produce prescription results that are acceptable to management, as the low prevalence of diagnosed PBA often means that the only way to produce high-volume prescribers is to reward physicians who prescribe Nuedexta by paying them speaking fees.

45. As a result, most physicians who prescribe Nuedexta on a consistent basis do so because they expect to receive or have been promised future speaking fees from Avanir.

46. Avanir's business model is vividly illustrated by Avanir's relationship with Defendant Dr. Raheja.

**C. Avanir Has a *Quid Pro Quo* Relationship with Defendant Dr. Raheja, Who Writes Twice as Many Prescriptions as any Other Doctor in the Country**

47. Defendant Dr. Raheja is by far the most prolific prescriber of Nuedexta in the United States. In the six months ending September 19, 2014, Dr. Raheja wrote 1,287 prescriptions.

48. During this period, from March to September 2014, Dr. Raheja wrote an average of 50 prescriptions every week.

49. In the week of May 5, 2014 alone, Dr. Raheja wrote 68 prescriptions.

50. Dr. Raheja's total of 1,287 prescriptions is more than twice the number of prescriptions written by the physician with the second-highest number of prescriptions, Dr. Idan Sharon, who wrote 541 prescriptions in the same period.

51. In fact, Dr. Raheja wrote more prescriptions than the second- and third-ranked physicians in the United States combined (ranked by the total number of prescriptions written).

52. Consistent with Avanir's policy of rewarding high-prescribing physicians with lucrative speaking fees, Dr. Raheja is Avanir's highest-paid speaker in the United States.

53. In FY 2014, Avanir paid Dr. Raheja for 42 speaking programs. For these appearances, Avanir paid Dr. Raheja a total of \$56,250.

54. Relator Manieri learned during a September 29, 2014 conversation with Frank Mazzucco, Regional Business Manager for Ohio Valley, that Avanir paid Dr. Raheja speaking fees to induce him to prescribe Nuedexta.

55. During their September 29, 2014 conversation, Mr. Mazzucco told Relator Manieri that he needed additional speaker funds because he "need[ed] to have eight or nine speaking engagements guaranteed for Dr. Raheja."

56. When Relator Manieri asked Mr. Mazzucco why the speaker funds that had already been allocated to his region were not enough, Mr. Mazzucco replied, “He’s our biggest prescriber and he likes to speak,” referring to Dr. Raheja.

57. Relator Manieri responded that he was concerned that Mr. Mazzucco was offering Dr. Raheja speaking engagements to encourage Dr. Raheja to prescribe Nuedexta. Mr. Mazzucco replied, “Well yeah, that’s kind of what I’m doing.”

58. Relator Manieri told Mr. Mazzucco that he was not comfortable with his request for more speaker funds for Dr. Raheja and that Mr. Mazzucco should move forward with the existing funds that had been budgeted. Relator Manieri said he would reconsider the request if Mr. Mazzucco presented a compelling business reason why Avanir should budget additional funds for speaking programs.

59. That same day, Mr. Mazzucco forwarded Relator Manieri an email from his direct report, Sales Representative Bill Stackhouse, showing that Avanir paid Dr. Raheja a total of \$56,250 in FY 2014.

60. Mr. Stackhouse is responsible for Avanir’s Cleveland, Ohio territory, where Dr. Raheja’s practice is located. Dr. Raheja is Mr. Stackhouse’s most important physician on his sales call list.

61. Regional Sales Manager Mazzucco’s September 29, 2014 request to Relator Manieri for additional funds indicates that he needed the funds immediately, as Avanir allocated the FY 2015 speaker funds days later in early October 2014 (when the new fiscal year began).

62. Around this same time, in late September 2014, Dr. Raheja ramped up his prescription writing to help Mr. Stackhouse, the Sales Representative who arranges Dr. Raheja’s speaker programs, win a year-end sales bonus.

63. The bonus Mr. Stackhouse was vying for was the President's Club Trip, an all-expenses paid vacation that Avanir awards to Sales Representatives with the highest number of prescriptions written by physicians in their territories. Mr. Stackhouse was in the running for the bonus, but was competing with other top-producing Sales Representatives.

64. At Mr. Stackhouse's request, Dr. Raheja accelerated his prescription-writing in the final weeks of FY 2014, which ended September 30, 2014, to increase Mr. Stackhouse's total number of prescriptions for FY 2014. Mr. Stackhouse is credited with every Nuedexta prescription that Dr. Raheja writes.

65. Dr. Raheja accelerated his prescriptions by moving up his Nuedexta patients' regularly scheduled appointments so that he could refill Nuedexta prescriptions in September that he otherwise would have refilled in October 2014.

66. Accelerating patient visits necessarily meant that Dr. Raheja had fewer opportunities to prescribe the drug in October 2014; as a result, he wrote fewer prescriptions in October than in September. This was acceptable for both Mr. Stackhouse and Dr. Raheja, as their purpose was to give Stackhouse a final "bump" in FY 2014 sales production to increase his chances of winning the bonus. The bonus was not affected by his October 2014 sales results.

67. Dr. Raheja's prescription-writing surge in the final weeks of FY 2014 is such a common company sales practice that it is referred throughout Avanir as "closing business."

68. Relator Manieri heard other Regional Business Managers, as well as Vice President of Sales McFadden, discuss the need to "close business" in late September 2014. This indicates that other physicians were encouraged to employ Dr. Raheja's tactic in order to benefit the Avanir Sales Representatives calling upon them. The physicians had an incentive to trade

favors with Sales Representatives in this way, as the Sales Representatives have authority to schedule speaking engagements and authorize the lucrative payments made to Avanir speakers.

69. Accordingly, Dr. Raheja and other physicians participated in “closing business” with the expectation that Avanir would reward their efforts with future paid speaker programs.

70. Dr. Raheja also used his influence with Avanir’s management to try to win Mr. Stackhouse the year-end bonus. In early October 2014, Dr. Raheja called Vice President of Sales McFadden, who was responsible for deciding which sales employees would win the bonus. While the bonus was automatically awarded to employees who ranked in the top 10% nationally, Mr. McFadden had discretion to award the bonus to one “wild card” person outside the top 10%.

71. Because Mr. Stackhouse was not in the top 10% in Avanir’s Nuedexta sales results for FY 2014, when Dr. Raheja called Vice President of Sales McFadden, he urged Mr. McFadden to select Mr. Stackhouse as the “wild card” and award him the bonus.

72. The fact that Dr. Raheja went to such great lengths to benefit Mr. Stackhouse demonstrates that Dr. Raheja did so expecting something in return, namely, continued fees from paid speaker programs.

73. In addition to speaking fees, Avanir pays Dr. Raheja consulting fees for being a member of an Avanir advisory board. Avanir currently has no products on the market other than Nuedexta.

74. Under his consulting contract, Avanir pays Dr. Raheja a fixed sum for each board meeting he attends, plus reimbursement for travel expenses.

#### **D. Avanir’s Speaker Programs**

75. Dr. Raheja’s speaker programs usually take place in the Cleveland, Ohio area.

76. For each speaker program, Avanir Sales Representative Bill Stackhouse and Regional Business Manager Mazzucco organize the programs through a third-party speaker bureau. Up until recently, the speaker bureau Avanir retained was CRG. In the fall of 2014, Avanir switched to Healthstar.

77. Avanir's speaker programs typically take the form of a meeting in a restaurant. Avanir pays speakers a standard fee for each engagement. Avanir pays for the attendees' meals and reimburses the speaker for travel expenses. Attendance varies, but the attendance is generally small, often 5 to no more than 10 physicians. The responsible Avanir Sales Representative attends as well.

78. If the audience is mostly comprised of physicians affiliated with the same practice, Avanir may hold the speaker program in that practice's office.

79. When Avanir pays a physician to appear at a speaker program, Avanir requires the physician to read from a standard slide presentation that was prepared by Avanir's Compliance Department. The speaker programs focus on the prevalence of PBA, the PRISM study, and the use of Nuedexta as a treatment for patients with Alzheimer's and dementia. The physician's presentation is not supposed to go beyond the prepared slides, but Avanir allows speakers to talk about their own Nuedexta prescribing experiences with patients in response to participant questions.

80. Avanir encourages physicians to speak about a patient they diagnosed with PBA who had a positive experience with Nuedexta. Many Avanir Sales Representatives have commented that few physicians recognize when a patient has PBA.

81. Avanir's goal is for speakers to endorse diagnosing PBA and treating it by prescribing Nuedexta. From Avanir's point of view, the most effective speakers are those who promote diagnosis and treatment based upon a bare minimum of symptoms.

82. Avanir has approximately 150 physicians enrolled in its speaker bureau. Avanir does not enroll a physician in the speaker bureau unless the physician consistently prescribes Nuedexta.

83. As a result, many physicians prescribe Nuedexta to patients whom they would not otherwise prescribe the drug to because of the speaking fees they expect to receive. This financial motive is apparent in the case of Defendant Dr. Raheja.

**E. Avanir's Management Endorses the Use of Speaking Fees as Inducements**

84. Even before Relator Manieri learned of Avanir's *quid pro quo* relationship with Dr. Raheja, his boss, Vice President of Sales McFadden, was aware of the arrangement and tacitly approved it.

85. After Relator Manieri's September 29, 2014 conversation with Regional Business Manager Mazzucco, Mr. Manieri reported Mr. Mazzucco's request for additional speaker funds for Dr. Raheja to Mr. McFadden.

86. Relator Manieri told Mr. McFadden that he was concerned about the reason for Mr. Mazzucco's request for additional speaking funds and about Avanir's relationship with Dr. Raheja. Mr. McFadden responded, "Well, we just have to deal with people like that."

87. Mr. McFadden then told Relator Manieri about a New York doctor who demanded that Avanir arrange more speaker programs for him. After Avanir declined to do so, Mr. McFadden said, the doctor "stopped writing Nuedexta prescriptions in order to teach us a

lesson.” Mr. McFadden then said words to the effect of, “Avanir went back and provided him more speaking opportunities and now he’s writing prescriptions again.”

88. Avanir Vice President of Sales McFadden told Relator Manieri that the New York physician who demanded more speaker fees in return for writing prescriptions “is in a position where he can affect our goal nationally,” referring to Avanir’s national sales goal for Nuedexta sales.

89. After hearing about the additional speaker fees Avanir paid to the New York doctor who stopped writing Nuedexta prescriptions until his demand for more speaking engagements and fees was met, Relator Manieri asked Mr. McFadden if he was “comfortable with that.” Mr. McFadden replied, “It’s just something that we have to do.” Relator Manieri observed that Mr. McFadden was uncomfortable with Mr. Manieri raising this concern about the ethics and legality of Avanir’s response to physician demands for payments.

90. Avanir’s Chief Commercial Officer, Rohan Palekar, knew or should have known that a *quid pro quo* relationship exists between Dr. Raheja and Avanir.

91. Dr. Raheja and Mr. Palekar have met in person on more than one occasion to discuss Avanir’s business. Mr. Palekar reports directly to the CEO of Avanir, Keith Katkin.

92. Mr. Palekar has met in person with other physicians who are top prescribers of Nuedexta, including Dr. Zepure Kouyoumdjian, the sixteenth-highest ranking prescriber in the country, who Mr. Palekar met on November 7, 2014.

93. Dr. Raheja has met Relator Manieri and his counterpart, Denise Prindiville, the Sales Director for the South area. Relator Manieri and Ms. Prindiville had dinner with Dr. Raheja in Cleveland, Ohio, on October 30, 2014, where Ms. Prindiville introduced Relator Manieri as Dr. Raheja’s new Senior Sales Leadership contact.

94. Avanir Sales Director Prindiville approves of Avanir's use of speaking fees as inducements to physicians.

95. In late 2014, Avanir Sales Director Prindiville and Relator Manieri jointly interviewed Robert Crump, an applicant for an Ohio Sales Representative position. This interview took place in Dallas, Texas. At the time, Mr. Crump was a sales representative working for a different pharmaceutical company.

96. In the pre-employment interview with Mr. Crump, Relator Manieri asked him to describe a time when he developed a hard-to-reach physician into a great customer. Mr. Crump responded that he first invited the physician to join the company's speaker bureau. Then, once the physician was enrolled, Mr. Crump told the physician that Mr. Crump would not arrange any speaking engagements for him until he prescribed the company's drug to at least 100 patients.

97. After the interview, Relator Manieri told Ms. Prindiville that he was bothered by Mr. Crump's statement that he used his company's speaker bureau to generate business. Ms. Prindiville responded that she was not bothered by Mr. Crump's statement. Ms. Prindiville subsequently directed Human Resources to offer Mr. Crump the Sales Representative position, which he accepted. Ms. Prindiville made the final decision to hire Mr. Crump.

#### **F. Avanir Offers Speaking Fees as Inducements To Doctors around the Country**

98. Avanir has arrangements with doctors in New Jersey, New York, and California similar to its kickback arrangement with Dr. Raheja.

99. For example, Dr. Idan Sharon, a Brooklyn, New York-based neurologist, is the second-highest ranked prescriber of Nuedexta in the United States. Dr. Sharon is related to Odelia Harel, the Avanir Sales Representative responsible for sales in Brooklyn, New York. Ms. Harel has authority to arrange speaker programs for physicians in Brooklyn.

100. Avanir paid Dr. Sharon a total of \$20,322.72 over a four-month period in 2013. This amount includes \$18,000 in speaking fees and a \$500 “Consulting Fee,” indicating that Dr. Sharon, like Dr. Raheja, is a member of Avanir’s advisory board.

101. Dr. Jonathan Fellus, a neurologist based in New Jersey, was the seventeenth-highest ranked prescriber of Nuedexta in the United States. Dr. Fellus wrote 220 prescriptions in the six months ending on September 19, 2014. Dr. Fellus was one of the five authors of Avanir’s PRISM study, which was released in August 2013.

102. Avanir paid Dr. Fellus a total of \$64,085.39 between August and December of 2013. These payments included \$43,500 in speaking fees and \$6,125 in consulting fees. On September 25, 2013 alone—just before the end of fiscal year 2013—Avanir made 7 payments to Dr. Fellus for speaking fees, totaling \$9,000.

103. In June 2014, the New Jersey Board of Medical Examiners revoked Dr. Fellus’s medical license for having a sexual relationship with a woman he was treating for recurring seizures.

104. Avanir encourages Sales Representatives in upstate New York to leverage speaking fees to induce physicians to prescribe Nuedexta.

105. Albany, New York Sales Representative Karen Kaufman’s business plan for 2013 emphasizes the use of speaking fees in this way, as she lists one of her goals as: “Get my 3 speakers to write more consistently.”

106. Ms. Kaufman’s business plan also states that she plans to use the paid speaker programs to encourage Drs. Wymer and Grosso to write more Nuedexta prescriptions:

**Territory Goals:** (SMART - Specific, Measurable, Attainable, Realistic and Timely)

- Grow Nuedexta prescriptions with Wymer and Brehaut- additional 2 scripts a week by start of Q2
- Develop Wymer and Grosso as speakers

107. Avanir requires Sales Representatives to draft business plans for approval by their Regional Business Manager. Once approved, business plans are reviewed by the Area Sales Director (either Relator Manieri or Ms. Prindiville) and Vice President of Sales McFadden. Once a business plan is approved, that Sales Representative is bound to the plan's objectives and strategies.

108. Ms. Kaufman's 2014 business plan, which was approved by her Regional Business Manager, Matt Powers, contains further evidence that Avanir endorsed her tactic of offering speaker programs to physicians to induce the physicians to increase their Nuedexta prescriptions:

**High Access/High Decile:** (This is the list each of us created at our POA. Must be someone you can see at least 2x a month taken from 7-10s. You can include 6's if your number of 7-10s is relatively small)

- Brehaut 1p 6
- Wymer 9 N
- Gooch 9 N
- Kucherov 7 N

Does my call activity reflect what I committed to? It can improve on my high decile, high access doctors.

What is your plan to accelerate business among this group? Higher frequency, additional speaker opps, corp touches, updates on managed care

109. The excerpt above indicates that Ms. Kaufman only offers speaker programs to physicians who consistently prescribe Nuedexta, with the expectation that the physician will continue to prescribe at an equal or greater rate.

110. Sales Representative Kaufman's comments with respect to Dr. Buonnano illustrate Avanir's policy of rewarding only high-prescribing physicians with speaking fees. Ms. Kaufman states in her business plan: "Growing relationship. May consider as a speaker if vol[ume] continues to grow."

111. In Ms. Kaufman's August 26, 2013 evaluation, Regional Business Manager Matt Powers instructed her to "ask for more" from two doctors, Drs. Wymer and Gooch, who Mr. Powers referred to as "our Speakers."

112. In Ms. Kaufman's September 19, 2013 evaluation, Powers wrote: "For you to accomplish your goals--the ones you sent me, your speakers need to actively look for PBA and put pen to pad," referring to Drs. Wymer and Gooch. In her January 30, 2014 evaluation, Regional Business Manager Powers instructed her to "spend \$\$\$ [money] on lunches and programs" to encourage physicians to prescribe Nuedexta.

113. As a result, Ms. Kaufman arranged a speaker program on March 25, 2014, which Drs. Wymer and Gooch both attended. Nine people attended this program.

114. Ms. Kaufman arranged another speaker program on May 8, 2014, which nine people attended, including Dr. Gooch. Ms. Kaufman also arranged a speaker program on May 14, 2014, which seven people attended, including Dr. Wymer.

115. Avanir paid a total \$2,773.56 in speakers fees and expenses for these two small group presentations.

116. Regional Business Manager Powers's instruction to Ms. Kaufman, which she executed, shows that Avanir offers speaker programs as a thing of value in exchange for the physician-speakers' promise to prescribe Nuedexta.

117. Regional Business Manager Kevin Tiffany, who oversaw the entire Nuedexta California market, also encouraged his salesforce to use speaker programs as inducements. One of his top-performing Sales Representatives, Chris Lambrecht, offered speaker programs as either inducements or rewards to physicians who consistently prescribed Nuedexta. Mr. Lambrecht's business plan states that he sought to arrange a speaker program for Dr. Dramov simply because she requested it and not for any marketing or educational purpose. Mr. Lambrecht's business plan reveals that he was "working" to get Dr. Zepure Kouyoumdjian "trained as a speaker." Dr. Kouyoumdjian was the sixteenth-highest ranked prescriber of Nuedexta in the nation in 2014.

118. Avanir's sales methods, as demonstrated in the approved sales plan of Mr. Lambrecht, amount to *quid pro quo* arrangements between Avanir and Drs. Kouyoumdjian and Dramov.

119. Avanir's management encourages the use of *quid pro quo* arrangements by rewarding the sales behaviors practiced by Mr. Lambrecht.

120. At a sales leadership meeting in October 2014, Avanir's leadership commended Mr. Lambrecht's sales performance as an example of "best practices."

121. Regional Business Manager Kevin Tiffany, who approved Mr. Lambrecht's business plan, knew and approved of Mr. Lambrecht's use of speaker programs as inducements. Avanir has since promoted Mr. Tiffany to Sales Director—West.

122. Avanir's management encourages its salesforce to rank physicians by the number of Nuedexta prescriptions they write, which Avanir calls the "Money Maker List."

123. Avanir Sales Representative Reid Yoshimura, who reported directly to Regional Business Manager Kelly Martin, stated in his Money Maker List (contained in his business plan, which was approved by Ms. Martin) that he plans to "squeeze" his top-performing customer, Dr. Rajiv Kumar, to write more Nuedexta prescriptions.

124. The characterization of healthcare providers as "money makers" is encouraged by high-ranking Avanir officers, including Vice President of Sales McFadden, who prepared a PowerPoint presentation that contained an instruction that all Sales Representatives send their "money maker list[s]" to their Regional Business Manager.

125. In a September 25, 2014 email, Denise Prindiville, Sales Director—South, directed the Regional Business Managers under her direction to rank providers in "money maker" lists.

126. Regional Business Manager Matt Powers required his direct reports, including Nicole Guido and Karen Kaufman, to generate a "Money Maker List." Regional Business Manager Powers conveyed this instruction in an October 2, 2014 email and in Ms. Kaufman's 2013 business plan.

127. Avanir CEO Keith Katkin is aware of Avanir's use of "Money Maker Lists" and the reference to prescribers of Nuedexta as "money makers."

#### **G. Avanir Increased its Speaker Program Budget As Part of "Operation Barracuda"**

128. In late August 2014, Avanir began expanding its salesforce in anticipation of an aggressive marketing campaign that Avanir dubbed "Operation Barracuda:"

## Avanir Salesforce Size & Structure as of FY15



- ◆ 2 Salesforces: Specialty and Long Term Care
  
- ◆ Specialty
  - 2 Area Directors (North and South)
  - 17 Regions
  - 140 Specialty Neuroscience Area Managers

129. Operation Barracuda entailed a significant increase in the speaker funds allocated to each Sales Representative and an expansion of Avanir's Nuedexta salesforce.

130. Denise Prindiville, Sales Director—South, stated in a September 8, 2014 email that Operation Barracuda would increase the speaker funds for each Sales Representative to \$7,300 for the first half of the fiscal year, enough for about three speaker programs.

### **H. Avanir Fired Relator Manieri in Retaliation for Objecting to Avanir's *Quid Pro Quo* Relationship with Dr. Raheja**

131. At a meeting in Boston, Massachusetts on November 17, 2014, a Regional Business Manager in the New England region complained to Relator Manieri that some of his direct reports were underperforming.

132. Relator Manieri suggested to this Regional Business Manager that he consider terminating the underperforming employees. Relator Manieri's comment was overheard by a Sales Representative present at the meeting, who complained about Relator Manieri's suggestion. This complaint was passed on to Vice President of Sales McFadden.

133. A few days later, on November 21, 2014, Mr. McFadden reprimanded Relator Manieri during a phone call for the suggestion Mr. Manieri made at the November 17 meeting. Mr. McFadden criticized Mr. Manieri's management skills during this call. Mr. McFadden

never before criticized any aspect of Mr. Manieri's management skills, nor had Mr. Manieri received any negative performance evaluations or been subjected to any disciplinary actions.

134. Mr. McFadden ended the call by saying: "I have enough here to terminate you, but I'll give you an opportunity to resign." Relator Manieri defended his actions and urged Mr. McFadden not to terminate him, but Mr. McFadden ultimately said "the decision has been made." Mr. McFadden did not cite any reasons for the termination other than the suggestion Relator Manieri made to his direct report at the November 17 meeting.

135. Avanir terminated Mr. Manieri's employment on November 21, 2014.

**COUNT I**  
**Defendant Avanir Knowingly Caused to be Presented False or Fraudulent  
Claims for Payment in Violation of 31 U.S.C. § 3729(a)(1)(A)  
(Against Defendant Avanir)**

136. Relator Manieri realleges and incorporates the allegations set forth above as though fully alleged herein.

137. The False Claims Act imposes civil liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A).

138. The Anti-Kickback Statute deems a claim that results from an unlawful kickback to be a violation of 31 U.S.C. § 3729(a), providing that "a claim that includes items or services resulting from a violation of this section [42 U.S.C. § 1320a-7b] constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of Title 31." 42 U.S.C. § 1320a-7b(g).

139. Avanir knowingly caused false or fraudulent claims for payment to be presented to the United States for Nuedexta prescriptions to Medicare patients written in 2013 and 2014. These claims include, but are not limited to, prescriptions written by Defendant Dr. Raheja

(Cleveland, OH), Dr. Idan Sharon (Brooklyn, NY), Dr. James Wymer (Albany, NY), Dr. William Gooch (Kingston, NY), Dr. Zepure Kouyoumdjian (Morgan Hill, CA), and Dr. Borina Dramov (Salinas, CA) (collectively, the “Physicians”). The Physicians wrote these prescriptions knowing that the patients were enrolled in Medicare and knowing that payment for the drug would be made in whole or in part by the United States.

140. Under 42 U.S.C. § 1320a-7b(g), these claims were false or fraudulent because they included items or services resulting from a violation of 42 U.S.C. § 1320a-7b(b):

a. Dr. Raheja knowingly and willfully solicited or received speaking fees in return for prescribing Nuedexta to Medicare patients. Dr. Raheja wrote 1,287 prescriptions over the course of only six months; during this period, Dr. Raheja received \$56,250 in compensation from Avanir (not including fees Avanir paid Dr. Raheja pursuant to his consulting agreement). On September 29, 2014, Regional Business Manager Frank Mazzucco requested additional speaker funds specifically for Dr. Raheja and acknowledged that the speaking fees were meant as an inducement for Dr. Raheja to prescribe Nuedexta. At the time Mr. Mazzucco made this request, Dr. Raheja was ramping up his prescriptions to help Sales Representative Stackhouse win a year-end bonus, suggesting that Dr. Raheja and Mr. Stackhouse had an agreement that Dr. Raheja would ramp up his prescription writing in exchange for the promise of future speaking fees. That Dr. Raheja went to such great lengths to help Mr. Stackhouse win the bonus is itself evidence of a *quid pro quo*, as Dr. Raheja would not likely have done so unless he had been assured he would receive something in return.

b. Dr. Idan Sharon knowingly and willfully solicited or received speaking fees in return for prescribing Nuedexta to Medicare patients. Dr. Sharon wrote 541 prescriptions in only six months, more than any doctor in the country with the exception of Dr. Raheja; furthermore,

Dr. Sharon is related to the Avanir Sales Representative who had the authority to arrange speaking programs for Dr. Sharon.

c. Dr. Wymer knowingly and willfully solicited or received speaking fees in return for prescribing Nuedexta to Medicare patients. Dr. Wymer received speaking fees for at least two speaking programs in 2014. Dr. Wymer received these fees knowing that Avanir paid him these fees in return for his writing a certain number of prescriptions in a given week. This knowledge is demonstrated by Dr. Wymer's understanding with Sales Representative Karen Kaufman that she would arrange for paid speaking programs for Dr. Wymer only if Dr. Wymer wrote a certain number of Nuedexta prescriptions, as shown by Ms. Kaufman's business plans and Regional Business Manager Matt Powers's comments in Ms. Kaufman's performance evaluations.

d. Dr. Gooch knowingly and willfully solicited or received speaking fees in return for prescribing Nuedexta to Medicare patients. Dr. Gooch received speaking fees for at least three speaking programs in 2014. Dr. Gooch received these fees knowing that Avanir paid him these fees in return for his writing a certain number of prescriptions in a given week. This knowledge is demonstrated by Dr. Gooch's understanding with Sales Representative Karen Kaufman that she would arrange for paid speaking programs for Dr. Gooch only if Dr. Gooch wrote a certain number of Nuedexta prescriptions, as shown by Ms. Kaufman's business plans and Regional Business Manager Matt Powers's comments in Ms. Kaufman's performance evaluations.

e. Dr. Kouyoumdjian knowingly and willfully solicited or received speaking fees in return for prescribing Nuedexta to Medicare patients. Dr. Kouyoumdjian received speaking fees in return for writing a certain number of Nuedexta prescriptions, as shown by Sales

Representative Chris Lambrecht's business plan and the fact that Dr. Kouyoumdjian wrote 229 prescriptions in the six-month period ending September 12, 2014, placing her 16<sup>th</sup> in the United States in the number of Nuedexta prescriptions written.

f. Dr. Dramov knowingly and willfully solicited or received speaking fees in return for prescribing Nuedexta to Medicare patients. Chris Lambrecht's business plan indicates that he arranged a speaker program for Dr. Dramov simply because Dr. Dramov requested it, evidencing the existence of a *quid pro quo*.

141. Dr. Raheja presented claims for payment for Nuedexta prescriptions to Medicare patients that were false or fraudulent for the additional reason that they were not supported by medical necessity, since it is implausible that Dr. Raheja was seeing an average of 50 patients per week who actually exhibited symptoms of PBA, which affects less than one million Americans. As a result, Dr. Raheja knew that the vast majority of claims for Nuedexta prescriptions that he wrote to Medicare patients were not supported by medical necessity.

142. Avanir knew that the above-mentioned claims for payment that were presented to the United States for Nuedexta prescriptions written by the Physicians were false or fraudulent because Avanir knew that the prescriptions were written in return for speaker fees.

143. The knowledge of Sales Representatives Bill Stackhouse, Karen Kaufman and Chris Lambrecht; Regional Business Managers Frank Mazzucco, Kelly Martin, and Matt Powers; Sales Director Denise Prindiville; and Vice President of Sales Michael McFadden of the kickback scheme alleged herein is attributable to Defendant Avanir because each of these employees knew that Avanir paid speaking fees to the Physicians to induce the Physicians to prescribe Nuedexta and because each of these employees participated in Avanir's kickback scheme with intent to benefit Avanir.

**COUNT II**  
**Defendant Raheja Knowingly Presented or Caused to be Presented False or  
Fraudulent Claims for Payment in Violation of 31 U.S.C. § 3729(a)(1)(A)  
(Against Defendant Raheja)**

144. Relator Manieri realleges and incorporates the allegations set forth above as though fully alleged herein.

145. Dr. Raheja knowingly presented or caused to be presented false or fraudulent claims for payment for Nuedexta prescriptions to Medicare patients in 2013 and 2014. Dr. Raheja wrote these prescriptions knowing that payment for the drug would be made by the United States.

146. Under 42 U.S.C. § 1320a-7b(g), these claims were false or fraudulent because they included items or services resulting from a violation of 42 U.S.C. § 1320a-7b(b).

147. Specifically, Dr. Raheja knowingly and willfully solicited or received speaking fees in return for prescribing Nuedexta to Medicare patients. Dr. Raheja wrote 1,287 prescriptions over the course of six months; during this period, Dr. Raheja received \$56,250 in compensation from Avanir (not including consulting fees). On September 29, 2014, Regional Business Manager Frank Mazzucco requested additional speaker funds specifically for Dr. Raheja and acknowledged that the speaking fees were meant as an inducement for Dr. Raheja to prescribe Nuedexta. At the time Mazzucco made this request, Dr. Raheja was ramping up his prescriptions to help Sales Representative Stackhouse win a year-end bonus, suggesting that Dr. Raheja and Mr. Stackhouse had an agreement that Dr. Raheja would ramp up his prescription writing in exchange for the promise of future speaking fees. That Dr. Raheja went to such great lengths to help Mr. Stackhouse win the bonus is itself evidence of a *quid pro quo*, as Dr. Raheja would not likely have done so unless he had been assured he would receive something in return.

148. These claims were false or fraudulent for the additional reason that they were not supported by medical necessity, since it is implausible that Dr. Raheja was seeing an average of 50 patients per week who actually exhibited symptoms of PBA, which affects less than one million Americans. As a result, Dr. Raheja knew that the vast majority of claims for Nuedexta prescriptions that he wrote to Medicare patients were not supported by medical necessity.

**COUNT III**  
**Defendants Avanir and Raheja Knowingly Conspired to Present False  
or Fraudulent Claims in Violation of 31 U.S.C. § 3729(a)(1)(C)  
(Against Defendants Avanir and Raheja)**

149. Relator Manieri realleges and incorporates the allegations set forth above as though fully alleged herein.

150. Avanir and Dr. Raheja knowingly conspired to present false or fraudulent claims for payment to the United States.

151. Avanir and Dr. Raheja had an agreement that Avanir would give Dr. Raheja kickbacks in the form of speaker fees in exchange for Dr. Raheja writing Nuedexta prescriptions to Medicare patients. This scheme violated 42 U.S.C. § 1320a-7b(b), which provides for criminal penalties, and thus constituted an agreement to violate a federal criminal statute.

152. Avanir and Dr. Raheja knowingly and voluntarily participated in this kickback scheme, as shown by the pressure Dr. Raheja exerted on Avanir to offer him additional speaker fees and the acknowledgements by Regional Business Manager Frank Mazzucco and Vice President of Sales Michael McFadden that these speaker fees were intended to induce Dr. Raheja to prescribe Nuedexta.

153. Both Avanir and Dr. Raheja committed overt acts in furtherance of this conspiracy, including Avanir's payment of speaker fees to Dr. Raheja for the 42 speaking

programs he attended in FY 2014 and Dr. Raheja's acts of writing 1,287 Nuedexta prescriptions, the vast majority of which were for Medicare patients.

**COUNT IV**  
**Defendant Avanir Terminated Relator Manieri's Employment in  
Violation of the False Claims Act, 31 U.S.C. § 3730(h)  
(Against Defendant Avanir)**

154. Relator Manieri realleges and incorporates the allegations set forth above as though fully alleged herein.

155. Relator Manieri was an "employee" of Avanir as that term is used in 31 U.S.C. § 3730(h).

156. Relator Manieri engaged in protected activity under the False Claims Act when he objected to Avanir's illegal kickback scheme in conversations with Vice President of Sales Michael McFadden.

157. After Relator Manieri objected to Avanir's use of speaking fees as inducements in his conversation with Mr. McFadden, Mr. Manieri's relationship with Mr. McFadden quickly soured.

158. Mr. McFadden's criticism of Relator Manieri's management practices during their November 21, 2014 conversation was pretext for retaliation for Mr. Manieri's opposition to Avanir's illegal kickback scheme.

159. Avanir terminated Relator Manieri's employment in retaliation for his opposition to Avanir's kickback scheme, in violation of 31 U.S.C. § 3730(h).

160. Avanir's violation of 31 U.S.C. § 3730(h) has caused and will continue to cause Relator Manieri to sustain economic and other harm, including, but not limited to, the loss of employment opportunities, the loss of future earning power, back pay and front pay, and interest.

*CONFIDENTIAL AND UNDER SEAL*

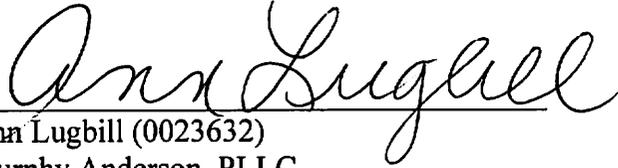
161. Avanim's violations of 31 U.S.C. § 3730(h) entitle Relator Manieri to reinstatement with the same seniority status that he would have had but for Avanim's unlawful retaliation, recovery of 2 times the amount of back pay, including interest on the back pay, and Mr. Manieri's special damages sustained as a result of the retaliation, including his litigation costs, expert witness fees, and attorney fees.

**PRAYER FOR RELIEF**

WHEREFORE, as to all claims brought by Relator Kevin Manieri on behalf of and in the name of the United States of America, Relator prays that judgment be entered against all Defendants as follows:

- (a) In favor of the United States and against Defendants for treble damages to the federal government from the submission of false or fraudulent claims, and the maximum civil penalties for each violation of the False Claims Act;
- (b) In favor of the United States and against Defendants for the maximum civil penalties for each violation of 42 U.S.C. § 1320a-7b(b), as provided for by 42 U.S.C. § 1320a-7a;
- (c) In favor of Relator Manieri for the maximum amount pursuant to 31 U.S.C. § 3730(d) to include reasonable expenses, attorney fees, and costs incurred by him;
- (d) In favor of Relator Manieri for the maximum relief allowed under 31 U.S.C. § 3730(h)(2), including 2 times the amount of back pay, interest on the back pay, and compensation for special damages sustained as a result of the retaliation, including litigation costs and reasonable attorneys' fees;
- (e) For all costs incurred as a result of maintaining this civil action; and
- (f) For such other and further relief as this Court deems just and proper.

Respectfully submitted,



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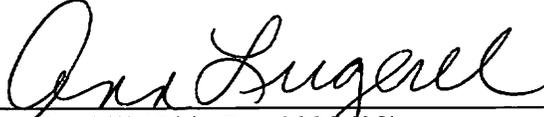
**REQUEST FOR TRIAL BY JURY**

Relator hereby demands a trial by jury.

  
Counsel for Relator

**CERTIFICATE OF SERVICE**

I hereby certify that on March 27, 2015, a true and correct copy of the foregoing was served upon the following and indicated below.



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