

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

KEVIN MANIERI, <i>Plaintiff,</i> v. AVANIR PHARMACEUTICALS, INC., <i>Defendant.</i>))))))))))))	Civ. A. No. 5:15-cv-00611-SL JURY TRIAL DEMANDED
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**SECOND AMENDED CIVIL COMPLAINT FOR EQUITABLE AND MONETARY
RELIEF AND DEMAND FOR JURY TRIAL**

Plaintiff Kevin Manieri brings this lawsuit against Defendant Avanir Pharmaceuticals, Inc. for retaliating against him due to his complaints that Avanir was paying kickbacks to physicians to induce prescriptions of its drug Nuedexta. Specifically, Manieri alleges that Avanir unlawfully terminated in violation of the False Claims Act, 31 U.S.C. § 730(h) (“FCA”).

JURISDICTION AND VENUE

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

2. This Court has jurisdiction over Defendant Avanir pursuant to 31 U.S.C. § 3732(a) because Avanir does business in Ohio and knowingly offered inducements to Ohio physicians to induce those physicians to prescribe Nuedexta to patients residing in Ohio. These inducements took the form of paid speaking engagements at venues in Ohio. Avanir made these inducements through its Ohio-based sales employees for the purpose of establishing a network of

distributors 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.

3. Venue in this judicial district and 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.

4. Venue in this judicial district and division is also proper pursuant to 28 U.S.C. § 1391(b)(1) because Defendant Avanir has extensive and deliberate contacts in this judicial district and division.

PARTIES

5. Manieri is a citizen of the United States and is domiciled in Pennsylvania.

6. Defendant Avanir Pharmaceuticals, Inc. is a Delaware corporation, is headquartered in California, and conducts significant business in Ohio.

FACTUAL ALLEGATIONS

7. In or about October 2010, the U.S. Food and Drug Administration approved Nuedexta as a treatment for pseudobulbar affect (PBA), 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, Lou Gehrig's disease, traumatic brain injury, and stroke.

8. To the best of Manieri's knowledge, no independent studies have been conducted on the prevalence of PBA in the United States. Avanir conducted a study that found that of 5,290 participants who suffered from one of six underlying serious conditions, 36.7%, or 1,941 participants, may have PBA, but required further diagnostic assessment to determine whether they were candidates for treatment. The study used an overly broad definition of PBA, such that the 36.7% figure encompassed participants who merely exhibited some PBA symptoms. This definition

of PBA is not recognized by the American Academy of Neurology (AAN). The AAN has not endorsed Avanir's estimate of the prevalence of PBA.

9. Avanir began selling Nuedexta in or about January 2011.

10. Manieri joined Avanir in or about August 2014 as a sales director responsible for overseeing all sales in the Northeast, Midwest (including Ohio), and California.

11. All sales representatives are required to undergo extensive testing on products and practices, including simulations and role play exercises. Manieri was required only to attend training for familiarization given his experience and position but completed all the training and testing anyway to ensure he was knowledgeable of all Avanir's products and practices and show himself to be an exemplarily leader and manager. Manieri received multiple accolades from his direct supervisor, the vice president of sales Michael McFadden, the sales training department, his peer area director and several regional managers for completing this training.

12. Manieri reported to vice president of sales, Michael McFadden, who oversaw sales for the entire United States. McFadden's sales groups marketed Nuedexta to physicians, nursing homes, and long-term care facilities. According to an Avanir press release dated May 3, 2010, when McFadden joined Avanir in or about 2010, he had "20 years of pharmaceutical commercialization experience." Avanir also touted McFadden's recent leadership roles in sales and managed care at another pharmaceutical company. McFadden previously held commercial roles at Pharmacia and Eli Lilly and Company. During his career, McFadden was involved in marketing and "selling some of the pharmaceutical industry's most successful blockbuster prescription products."

13. Avanir website that states, "[w]e prohibit anyone working on our behalf from offering payments or other forms of rewards to health care professionals with the intention of inducing them to purchase, prescribe or recommend our products." Avanir's website also

includes information on anti-kickback statutes, the False Claims Act, and reporting violations. Avanir also states that management should be contacted for reporting potential or actual violations.

14. Avanir's corporate leadership approved an annual speaker program budget, which set aside money to pay Nuedexta prescribers to appear at speaking engagements. Generally, Avanir allocated \$15,000 annually to each sales representative, however occasionally, McFadden directed additional funds for certain doctors who prescribed a high volume of Nuedexta.

15. Avanir evaluated and ranked sales representatives based solely on the number of Nuedexta prescriptions written by physicians (rather than the number of new prescribers obtained). Thus, Avanir's sales policy encouraged sales representatives to meet their performance goals by maximizing the number of prescriptions written by a few high-volume prescribers.

16. Avanir also required its sales representatives to draft "money maker" lists that identified the top ten to fifteen prescribers in their territories and concentrate their sales efforts on those doctors; this reinforced Avanir's practice of encouraging a small number of prescribers to write large numbers of Nuedexta prescriptions. The characterization of healthcare providers as "money makers" was encouraged by high-ranking Avanir officers, including McFadden, who prepared a PowerPoint presentation that contained an instruction that all sales representatives send their money maker lists to their supervisors.

17. The regional business managers oversaw sales representatives and instructed them to leverage speaking fees to induce physicians to prescribe Nuedexta as they saw this as the most effective method to increase Nuedexta prescriptions given the low prevalence of PBA. As a

result, most physicians who prescribed Nuedexta on a consistent basis did so because they expected to receive (or were promised) future speaking fees from Avanir.

18. Avanir required sales representatives to draft business plans for approval by their regional business managers. Once approved, business plans were reviewed by the area sales director (either Manieri or another counterpart) and then McFadden. Once a business plan was approved, that sales representative was bound to the plan's objectives and strategies. At the direction of McFadden, these business plans frequently contained explicit objectives and offered speaker programs to physicians who consistently prescribed Nuedexta, with the expectation that the physician would continue to prescribe at an equal or greater rate. McFadden routinely reviewed and approved these business plans.

19. The Avanir's sales strategy caused doctors to prescribe PBA in high volumes to patients who presented borderline cases for treatment, but did not necessarily need Nuedexta.

20. Dr. Deepak Raheja, whose practice is in the Cleveland, Ohio metropolitan area, was by far the most prolific prescriber of Nuedexta in the United States. In the later part of 2014, Dr. Raheja wrote 1,287 prescriptions for Nuedexta. The doctor with the second highest number of prescriptions was Dr. Idan Sharon, who wrote 541 prescriptions in the same period. Avanir paid approximately \$56,260 to Dr. Raheja in 2014. Avanir also had other kickback arrangements with other physicians in other regions which were under McFadden's supervision.

21. In late August 2014, Avanir began expanding its salesforce in anticipation of an aggressive marketing campaign that Avanir dubbed "Operation Barracuda," which entailed a significant increase in the speaker funds of \$7,300 allocated to each Sales Representative and an expansion of Avanir's Nuedexta salesforce.

22. On or about September 29, 2019, regional business director Frank Mazzucco told Manieri that Avanir paid Dr. Raheja speaking fees to induce him to prescribe Nuedexta. Mazzucco further told Manieri that he needed additional speaker funds because he “need[ed] to have eight or nine speaking engagements guaranteed for Dr. Raheja.” When Manieri asked Mazzucco why the speaker funds that had already been allocated to his region were not enough, Mazzucco replied, “He’s our biggest prescriber and he likes to speak,” referring to Dr. Raheja. Manieri responded that he was concerned that Mazzucco was offering Dr. Raheja speaking engagements to encourage Dr. Raheja to prescribe Nuedexta. Mazzucco replied, “Well yeah, that’s kind of what I’m doing.”

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

24. That same day, Mazzucco forwarded Manieri an email from his direct report, sales representative Bill Stackhouse, showing that Avanir paid Dr. Raheja a total of approximately \$56,250 in FY 2014. Mazzucco wanted additional funds immediately to increase his sales volume to achieve a year-end sales bonus. Dr. Raheja’s surge in prescription-writing in the final weeks of FY 2014 was a common sales practice at Avanir, which it referred to as “closing business.”

25. While the bonus was automatically awarded to employees who ranked in the top 10% nationally, McFadden had discretion to award the bonus to one “wild card” person outside the top 10%.

26. In early October 2014, Dr. Raheja called McFadden, who was responsible for deciding which sales employees would win the bonus and urged him McFadden to select Stackhouse as the “wild card” and award him the bonus.

27. In addition to speaking fees, Avanir paid Dr. Raheja consulting fees for being a member of an Avanir advisory board. This board advised Avanir on marketing strategies, new studies, and medical developments that are relevant to Avanir’s business. At the time, Avanir had no products on the market other than Nuedexta. Under this consulting contract, Avanir paid Dr. Raheja a fixed sum for each board meeting he attended, plus reimbursement for travel expenses.

28. On or about October 10, 2014, McFadden and Manieri met for a regularly scheduled status call. Per McFadden’s standing request, prior to the call Manieri sent McFadden an agenda of about five items to discuss during the call. The call was scheduled for 60 minutes and usually lasted that amount of time.

29. During this call, McFadden asked Manieri about the speaker program budget allocation. Manieri disclosed to McFadden what occurred on the September 29, 2019 call with Mazzucco. Manieri reported to McFadden that he was concerned about the reason for Mazzucco’s request for additional speaking funds and also concerned about Avanir’s relationship with Dr. Raheja.

30. McFadden responded, “If he isn’t speaking, he isn’t writing.” and “there are people like this that we just have to deal with.” Manieri responded, “No we don’t” and “this is crossing the line.” In response, McFadden recounted a story about a doctor in New York for whom Avanir ceased speaker fees due to budget reasons. The doctor then decided to “teach them a lesson” and stopped writing prescriptions. Avanir ultimately had to continue paying the doctor

so he would start writing prescriptions again. McFadden ended the story telling Manieri: “These are the kind of people we need to deal with.” Manieri again told McFadden, “No we don’t” and that “this was crossing the line.”

31. After this exchange, McFadden stopped talking and there was silence on the line. At this point McFadden and Manieri had only been on the phone call for about 10 minutes of their 60-minute call and had only discussed approximately one of the five agenda items. McFadden abruptly ended the call. McFadden’s action was highly unusual. McFadden had never before abruptly ended a call in this manner.

32. McFadden knew or should have known that Manieri was referencing the kickback scheme during the October 10, 2014 (approximately) telephone call due to the nature of the industry’s focus on compliance, McFadden’s own extensive experience both in the pharmaceutical industry as well as in leadership positions, and Avanir’s own internal policies.

33. Throughout Manieri’s employment McFadden gave Manieri good feedback about his work. As just one example, in or about the middle of October 2014 McFadden complimented Manieri’s efforts with helping create the agenda for an upcoming, weeklong sales management meeting. McFadden presented Manieri with a \$250 special award for Manieri’s good performance in planning this meeting.

34. Avanir terminated Manieri’s employment on November 21, 2014 and provided him no reason for the termination. This occurred little over a month after Manieri reported his concerns and opposed Avanir’s kickback scheme to McFadden. At the time of Manieri’s termination, Avanir had not issued Manieri any documentation notifying him of poor performance, had not issued him any negative performance evaluations, and had not placed him on any performance improvement plans.

35. Following Manieri's termination, he filed a *qui tam* lawsuit against Avanir alleging violations of the False Claims Act. The government investigated and obtained a multi-million-dollar settlement against Avanir which included a Corporate Integrity Agreement that Avanir must abide by for five years. Several doctors, including Dr. Raheaja and Avanir former employees including Stackhouse, were criminally indicated for their conduct as it related to the kickback arrangement outlined above. This Department of Justice civil settlement and the criminal charges against Dr. Raheaja and others stemmed from Manieri's protected conduct.

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

36. Plaintiff Manieri realleges and incorporates the allegations set forth above as though fully alleged herein.

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

38. Manieri engaged in protected activity under the FCA when he reported and objected to Avanir's illegal kickback scheme to McFadden.

39. Manieri engaged in protected activity under the FCA when he attempted to stop a violation of the FCA by refusing to allocate more money to Stackhouse to provide a kickback to Dr. Raheaja

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

41. Avanir's reasons for terminating Manieri are pretext for illegal discrimination.

42. Avaniir's violation of 31 U.S.C. § 3730(h) has caused and will continue to cause 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.

43. Avaniir's violations of 31 U.S.C. § 3730(h) entitle Manieri to reinstatement with the same seniority status that he would have had but for Avaniir's unlawful retaliation, recovery of two times the amount of back pay, including interest on the back pay, and 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 Manieri prays that judgment be entered against Defendant as follows:

- (a) In favor of Plaintiff 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, expert witness fees, and reasonable attorneys' fees;
- (b) For all costs incurred as a result of maintaining this civil action; and
- (c) For such other and further relief as this Court deems just and proper.

Respectfully submitted,

/s/ Anita M. Chambers

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DEMAND FOR JURY TRIAL

Manieri demands a jury for all claims triable by a jury.

/s/ Anita M. Chambers

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