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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

INCHEN HUANG, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. ASSERTIO THERAPEUTICS, INC., ARTHUR JOSEPH HIGGINS, JAMES A. SCHOENECK, and AUGUST J. MORETTI, Defendants.	Case No. 3:17-cv-04830-JST **CLASS ACTION** **SECOND AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** Demand for Jury Trial Judge: Hon. Jon S. Tigar

Lead Plaintiffs Aurelio Scarpatetti, Manuele Scarpatetti, Duy Vu, and Mark Madrack, (collectively, the "Depomed Investor Group" or "Plaintiffs"), by and through their undersigned counsel, allege the following upon information and belief, except as to those allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs' information and belief is based upon, among other things, the investigation made by and through Plaintiffs' attorneys, which includes, without limitation: (a) review and analysis of regulatory filings made by Assertio Therapeutics, Inc., formerly known as Depomed, Inc. ("Depomed")[1] with the United States

[1] On August 14, 2018, Defendant Depomed, Inc., changed its name to Assertio Therapeutics, Inc. However, at all relevant times during the Class Period, Assrtio Therapeutics, Inc. operated under the

Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Depomed; (c) information retrieved from government websites; (d) interviews with former employees of Depomed; and (e) review of other publicly available information concerning Depomed.

Plaintiffs believe that substantial evidentiary support exists and will be uncovered by Plaintiffs for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE CLAIM

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired common shares of Depomed between July 29, 2015 and August 7, 2017, inclusive (the "Class Period"), and were damaged thereby (the "Class"). Plaintiffs allege that defendants Depomed, Arthur Joseph Higgins ("Higgins"), James A. Schoeneck ("Schoeneck"), and August J. Moretti ("Moretti") (collectively, "Defendants") violated the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §78a, *et seq.* Plaintiffs seek to recover compensable damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder.

2. Depomed was a specialty pharmaceutical company most widely known for its flagship opioid product, NUCYNTA. Under Defendants' direction, Depomed's sales team followed a company-wide campaign to market NUCYNTA for prohibited (or "off-label") uses during the Class Period. This off-label marketing scheme enabled Depomed to generate remarkable profits even as the rest of the opioid industry faltered in response to growing public resentment against opioid prescribing practices. Defendants hid from investors the secret to their success and, instead, claimed that it was the byproduct of hard work and smart business strategy. Depomed's winning streak, however, came to an end as government regulators began to examine Depomed more closely. News of investigations ultimately led to corporate admissions of wrongdoing and massive declines in the price of Depomed's stock. Defendants' illegal and deceptive conduct caused Plaintiffs and the other

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name Depomed, Inc. Therefore, Plaintiffs refer to Assertio Therapeutics, Inc., formerly known as Depomed, Inc. as "Depomed" throughout the Complaint.

Depomed investors who are Class members to suffer millions of dollars in damages. This action seeks to recover those losses for those Class members.

3. Throughout the Class Period, Defendants repeatedly promoted Depomed on the basis of its rising sales of NUCYNTA. Annual sales increased in the U.S. from $189.9 million in 2015 to approximately $281.3 million in 2016. This marked a 48% increase in sales of NUCYNTA in just one year, even as opioid sales throughout the rest of the industry were declining. Defendants attributed Depomed's success with NUCYNTA to the company's marketing strategy which they described frequently and in detail.

4. The marketing strategy causing the astronomical growth in sales, however, was illegal. In particular, Depomed promoted the use of opioids for all manners of pain management while downplaying the drug's addictive nature, often promoting the drug as a safer alternative to other opioids, despite this not being on the FDA-approved label. Evidence shows that when Depomed first purchased NUCYNTA in 2015 from its previous owner, Janssen Pharmaceuticals Inc., it implemented the same illegal and off-label marketing strategy used by Janssen. Former employees of Depomed also confirm that they were instructed to use a particular leaflet and various studies containing illicit marketing claims when trying to sell NUCYNTA to prescribing physicians. This leaflet compared NUCYNTA to other opioid drugs, namely Oxycodone CR, and claimed that it was "safer" and "more effective." This was prohibited by the FDA and was not part of the approved labeling materials for NUCYNTA. Depomed punished those employees who did not actively promote NUCYNTA in line with these claims, as evidenced by poor employee evaluation scores.

5. Depomed also orchestrated a kickback scheme whereby it would reward doctors who prescribed NUCYNTA. Specifically, Depomed offered ongoing speaker positions to pain management physicians whom it deemed "high writers" - physicians writing five or more prescriptions per month. This was the only requirement to become a speaker, thus academic pedigree and experience in the industry were of virtually no concern to Depomed. In total, Depomed made over $4.1 million in payments to physicians relating to speaker engagements alone in 2017, over $2.6 million in 2016, and over $3.2 million in 2015.

6. Additional evidence of Depomed's off-label marketing scheme comes from a number of government complaints against the company. More than 30 municipalities have sued Depomed for engaging in an intentional and deceptive marketing campaign to promote the use of NUCYNTA. In painstaking detail, the lawsuits allege that Depomed's marketing scheme persuaded doctors and patients that opioids can and should be used for chronic pain by: a) downplaying the serious risk of addiction; b) creating and promoting the concept of "pseudoaddiction" by advocating that signs of addiction should be treated with more opioids; c) exaggerating the effectiveness of screening tools to prevent addiction; d) claiming that opioid dependence and withdrawal are easily managed; e) denying the decreased effectiveness of opioids over long-term use and the corresponding need for increased dosages; and f) exaggerating the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction.

7. These marketing practices were illegal and exposed Depomed to extreme regulatory risk. These risks ultimately came to be realized and, in turn, resulted in massive losses for Depomed's investors. On March 28, 2017, former U.S. Senator Claire McCaskill, the then top-ranking Democrat on the Senate Homeland Security and Government Affairs Committee (the "Senate Committee"), announced that she was opening an investigation into the marketing and sales practices of the nation's top five manufacturers of prescription opioid products, including Depomed (the "Senate Investigation"). According to a statement by Senator McCaskill, "[the] investigation is about finding out whether the same practices that led to this [opioid] epidemic still continue today, and if decisions are being made that harm the public health."

8. In letters to the manufacturers, Senator McCaskill further stated that "[t]his epidemic is the direct result of a calculated sales and marketing strategy major opioid manufacturers have allegedly pursued over the past 20 years to expand their market share and increase dependency on powerful—and often deadly—painkillers . . .. To achieve this goal, manufactures have reportedly sought, among other techniques, ***to downplay the risk of addiction to their products and encourage physicians to prescribe opioids for all cases of pain and in high doses***."

9. In response to Senator McCaskill's statements, investors began to realize that Depomed's business and operations were substantially and materially more risky than previously

represented by the company. The investigation spurred serious concern and suspicion among Depomed investors and, as a result, investors began to sell their stock. As news of the investigation seeped into the market, Depomed's stock fell by nearly 16%, or a loss of $2.35 per share by March 31, 2017. Depomed's stock closed at $12.55 per share on March 31, 2017, compared to $14.90 per share on March 27, 2017, erasing more than $145.9 million in market capitalization.

10. Investors grew more suspicious on August 7, 2017, when Depomed confirmed in its Quarterly Report on Form 10-Q that it had received a request for information from the Senate Committee. Depomed further disclosed that it had received subpoenas related to its opioid sales and marketing from the Office of the Attorney General of Maryland and the U.S. Department of Justice. Reporting on its third fiscal quarter financial results in the same report on August 7, 2017, Depomed further revealed that its adjusted earnings amounted to just $5 million compared to $19.8 million for the same quarter the year before, and slashed its forecast for the full fiscal year 2017, predicting $10 million to $15 million, or 3.5%, less in revenue than previously reported and cutting its adjusted pretax operating profit projection by approximately 10%. Depomed was forced to admit that the increased regulatory oversight over the opioid markets and associated legal expenses effected its revenues and earnings projections.

11. Depomed's statements on August 7, 2017 further revealed to investors that Defendants had concealed serious risks associated with its business practices and, in particular, NUCYNTA. It was these risks that led to the Senate Investigation, the DOJ subpoena, and ultimately Depomed's decision to lower guidance, among other things.

12. Analysts and investors were taken aback in response to the news. For example, a Janney analyst report states that "After struggling for months to stem the negative prescription trends across its product portfolio, the revised guidance seems to be an admission the challenges facing its business are far greater to overcome than fixing the sales force realignment implemented by the prior CEO . . . but management seems to be conceding that headwinds against prescribing opioids are making a return to growth for NUCYNTA IR and ER uncertain at best."

13. In the wake of the August 7, 2017 disclosure, Depomed's stock plummeted more than 33%, or $3.08 per share on August 8, 2017, to close at $6.15 compared to the previous trading day's

closing of $9.23, erasing more than $194.3 million in market capitalization. Overall, Depomed's stock price has fallen over 80%, from a high of $33.28 per share shortly after the acquisition of NUCYNTA, to a low of $6.15 per share on August 8, 2017, after revealing ongoing investigations, a loss of $27.14 per share. Market capitalization fell more than $1.6 billion in just over two years.

14. Had Defendants been honest when discussing Depomed's marketing strategy, investors would have been able to assess the true level of risk inherent in their investments. Plaintiffs and the other Class members have lost millions of dollars as a result. Defendants should be held accountable for these losses.

JURISDICTION AND VENUE

15. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, Section 27 of the Exchange Act, 15 U.S.C. §78aa.

17. Venue is proper in this District pursuant to Section 27 of the Exchange Act, and 28 U.S.C. § 1391(b) because certain of the acts alleged herein, including the preparation and dissemination of material false and/or misleading information, occurred in this District.

18. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly and/or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

19. Plaintiffs Aurelio Scarpatetti, Manuele Scarpatetti, Duy Vu, and Mark Madrack purchased Depomed common stock at artificially inflated prices during the Class Period and were damaged upon the revelation of the Defendants' fraud. New certifications evidencing Plaintiffs' transactions are attached hereto as Exhibit B and are incorporated by reference.

20. Defendant Depomed was incorporated in the State of California on August 7, 1995 and its principal executive offices are located at 7999 Gateway Boulevard, Suite 300, Newark,

California 94560. At all relevant times, Depomed's common stock was traded on the NASDAQ under the ticker symbol "DEPO." On August 14, 2018, Defendant Depomed, Inc., changed its name to Assertio Therapeutics, Inc. Assertio's common stock is currently traded on the NASDAQ under the ticker symbol "ASRT."

21. Defendant Schoeneck served as a director of Depomed from December 2007 through March 28, 2017, and as its President and CEO from April 2011 until his resignation on March 28, 2017. From 2005 until he joined Depomed, Schoeneck was CEO of BrainCells, Inc. ("BrainCells"), a privately-held biopharmaceutical company. Prior to joining BrainCells, he served as CEO of ActivX BioSciences, Inc., a development stage biotechnology company. Schoeneck served as President and Chief Executive Officer of Prometheus Laboratories Inc. ("Prometheus") for three years. Prior to joining Prometheus, Schoeneck spent three years at Centocor, Inc. ("Centocor"), where he led the development of Centocor's commercial capabilities. His group launched Remicade®, which has become one of the world's largest pharmaceutical products. Earlier in his career, he spent 13 years at Rhone-Poulenc Rorer, Inc. (now Sanofi S.A.) serving in various sales and marketing positions of increasing responsibility. According to the 2016 Proxy, the Board considered "Mr. Schoeneck's experience and expertise within the following areas relevant to Depomed and its business in concluding that he should serve on the Board: Corporate Strategy; Corporate Management; Commercial Strategy; Pharmaceutical Product Launch; Strategic Transactions; and Corporate Leadership."

22. Defendant Higgins has served as a director and as President and Chief Executive Officer ("CEO") of Depomed since March 28, 2017. From 2010 until his appointment at Depomed, Higgins served as a Senior Advisor to Blackstone Healthcare Partners, the healthcare team of The Blackstone Group, where he focused on product-based healthcare acquisitions. Prior to 2010, Higgins held various high-ranking positions in several different pharmaceutical companies, including joining Bayer HealthCare AG in 2004, where he served as Chair of the Board Management of Bayer HealthCare AG, a developer and manufacturer of human and animal health care products, and Chairman of the Bayer HealthCare Executive Committee. From 2001 to 2004, Higgins served as Chairman, President and CEO of Enzon Pharmaceuticals. Prior to joining Enzon, Higgins spent

14 years at Abbott Laboratories. He also has served as a past Board member of the Pharmaceutical Research Manufacturers of America (PhRMA), of the Council of the International Federation of Pharmaceutical Manufacturers and Association (IFPMA), and President of the European Federation of Pharmaceutical Industries and Associations (EFPIA).

23. Defendant Moretti was Depomed's Senior Vice President and Chief Financial Officer until his departure on July 16, 2018. From 2004 to December 2011, Mr. Moretti served as Chief Financial Officer and Senior Vice President of Alexza Pharmaceuticals, Inc., a publicly-held pharmaceutical company. From 2001 to 2004, Mr. Moretti served as Chief Financial Officer of Alavita, Inc. (formerly Surromed, Inc.). Prior to Alavita, Mr. Moretti was a partner of Heller Ehrman LLP, an international law firm. Mr. Moretti holds a B.A. from Princeton University and a J.D. from Harvard Law School.

24. Defendants in paragraphs 21-23 are collectively referred to herein as the "Individual Defendants."

25. Each of the Individual Defendants:

(a) directly participated in the management of Depomed;

(b) was directly involved in the day-to-day operations of Depomed at the highest levels;

(c) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the materially false and misleading statements and information alleged herein;

(d) was directly or indirectly involved in the oversight or implementation of Depomed's internal controls;

(e) was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning Depomed; and/or

(f) approved or ratified these statements in violation of the federal securities laws.

26. Because of the Individual Defendants' positions within Depomed, they had access to undisclosed information about the opioid epidemic and Depomed's off-label marketing via access to

internal corporate documents (including Depomed's operating plans, budgets and forecasts and reports of actual operations and performance), conversations and connections with other corporate officers and employees, attendance at management and Board meetings and committees thereof and via reports and other information provided to them in connection therewith.

27. As officers and/or directors of a publicly-held company whose common stock was, and is, registered with the SEC pursuant to the federal securities laws of the United States, the Individual Defendants each had a duty to disseminate prompt, accurate and truthful information with respect to the opioid epidemic and Depomed's off-label marketing, including progress and issues concerning the development of the opioid epidemic, and Depomed's present and future business prospects, and to correct any previously-issued statements that had become materially misleading or untrue, so that the market price of Depomed's publicly-traded common stock would be based upon truthful and accurate information. The Individual Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

28. The Individual Defendants, because of their positions with Depomed, possessed the power and authority to control the contents of Depomed's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. Each Individual Defendant was provided with copies of Depomed's reports and press releases alleged herein to be materially misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information, each of these defendants knew, or recklessly disregarded, that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

29. Each of the Individual Defendants are liable as a participant in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Depomed common stock during the Class Period by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme deceived the investing public concerning Depomed's response to the opioid

crisis and promotion of off-label marking. This scheme caused Plaintiffs and the other Class members to purchase Depomed common stock at artificially inflated prices.

BACKGROUND

A. *Depomed's Background*

30. Depomed, a specialty pharmaceutical company, engages in the development, sale, and licensing of products for pain and other central nervous system conditions in the United States.

31. On April 2, 2015, Depomed acquired from Janssen Pharmaceuticals, Inc. and its affiliates the U.S. rights to the NUCYNTA franchise of pharmaceutical products for $1.05 billion in cash. The NUCYNTA franchise is an opioid that includes NUCYNTA ER (tapentadol) extended release tablets indicated for the management of pain, including neuropathic pain associated with diabetic peripheral neuropathy (DPN), severe enough to require daily, around-the-clock, long-term opioid treatment, NUCYNTA IR (tapentadol), an immediate release version of tapentadol, for management of moderate to severe acute pain in adults, and NUCYNTA (tapentadol) oral solution, an approved oral form of tapentadol that has not been commercialized.

32. NUCYNTA's annual sales increased in the U.S. from $189.9 million in 2015 to approximately $281.3 million in 2016, quickly becoming Depomed's best-selling product. This marked a 48% year-over-year growth in sales of NUCYNTA in just one year.

33. The marketing strategy causing the astronomical growth in sales, however, was fueled by Depomed's illegal practices in connection with its marketing of NUCYNTA for off-label and unsafe and unapproved uses. In particular, Depomed downplayed NUCYNTA's addictive nature, often promoting it as a safer alternative to opioids, despite this not being on the FDA label.

34. Further, Depomed promoted an increase in dosage while focusing on family physicians and internal medicine doctors who were less knowledgeable about the dangers of opioids.

35. Finally, in its company approved marketing materials, Depomed used a side by side study comparing withdrawal rates of NUCYNTA to Oxycodone CR. (Attached as "Exhibit C"). However, NUCYNTA's label specifically states that side by side comparison are not allowed.

36. In February 2017, Defendants Schoeneck increased its sales force for the specific purpose of targeting primary care physicians.

37. The FDA-approved labels for both NUCYNTA IR and NUCYNTA ER describe the tapentadol molecule as "a substance with a high potential for abuse similar to other opioids including fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, and oxymorphone." Nowhere on the FDA-approved label does it say or mention that NUCYNTA is safer, more tolerable, less abusive, or less addictive than other opioids. Despite this, NUCYNTA has a long history of its manufacturer (formerly Janssen, see supra) claiming these benefits in its sales pitches and marketing.

38. Nonetheless, Depomed directed its sales representatives to market NUCYNTA for unsafe and unapproved uses as a safer, less abusive, less addictive opioid that did not create the same euphoric feeling as other opioids, even though this was not on the FDA-approved label.

39. Depomed management knew that the FDA-approved label for NUCYNTA contained no information about it being safer, more tolerable, less addictive, or less abusive than alternative opioids, and knew, or recklessly disregarded, they could not market NUCYNTA this way.

40. On a June 23, 2015 investor call, Defendant August Moretti, Depomed's Senior Vice President and Chief Financial Officer, stated that "[a]lthough not in the label, there's a very low abuse profile and side effect rate."

41. Additionally, in a March 14, 2016 presentation at the ROTH Conference, then Director and Officer Schoeneck stated: "The addiction profile is thought to be better. I can't make a claim around that because we don't actually have that in the label." In February 2017, Schoeneck also told investors that Depomed was "initiating label enhancement studies, aimed at further differentiating NUCYNTA by highlighting its respiratory depression and abuse potential profile. These labeling studies will focus on the properties of the tapentadol molecule, and its uniqueness in the pain marketplace." The purpose of this was to "be able to get it hopefully into the label."

42. Depomed's marketing push was "Think Differently." Sales representatives were told by Depomed that NUCYNTA is a "safer opioid." They were told by Depomed to tell physicians about NUCYNTA and its value to patients in terms of, among other things, improved safety relative to other opioids on the market.

43. Depomed actively targeted primary care physicians with marketing presentations that described NUCYNTA as a safer, less addictive, less abusive opioid that did not contain the same

euphoric feeling as other opioids. Depomed did not have FDA-approval to market NUCYNTA in this manner, and also did not have any independent scientific evidence to support these claims.

44. Depomed represented that NUCYNTA was uniquely positioned to combat the negative public sentiment against opioids. Former President and CEO James Schoeneck described to investors that NUCYNTA had "different properties than the other opioids, particularly when it comes to the kind of activity that the CDC and others are most concerned about" and that there'll be relatively little impact on [Depomed] compared to where some other companies may fall in at."

45. Depomed knew, or recklessly ignored, that it could not promote NUCYNTA as a safer, less addictive, less abusive opioid that did not have the same euphoric feeling on patients because these properties were not on its FDA-approved label. Despite this knowledge, Depomed trained its sales representatives to use these marketing tactics to sell NUCYNTA, using the same sales team as Janssen had to promote NUCYNTA, knowing that Janssen was being sued for, among other things, improperly marketing NUCYNTA.

46. At all times, Depomed was not a company that was motivated by the idea that NUCYNTA was helping patients, but was driven by personal profit and fear of losing their jobs. This fear led Defendants to put Depomed gains over the public's safety, and although users of NUCYTNA paid a price in terms of serious health issues, investors also paid a price, albeit in a different way, when they saw the value of their investments in Depomed stock significantly shrink as the truth was revealed.

47. Schoeneck represented at a September 16, 2015 conference, that "it really is about value . . . We're not people that are here because we started this in our garage and we want to turn it over to our kids. It really is to find things . . . where we can create value; create the value; and eventually realize that value."

48. One main reason Depomed engaged in the off-label marketing campaign and concentrated on pushing NUCYNTA sales no matter the cost, was due to immense pressure from one of its largest shareholders, Starboard Value LP.

49. Starboard, an activist investor, consistently pressured Defendants to do whatever it took to increase results in the face of the headwinds.

50. On April 8, 2016, Starboard sent a letter to Depomed. In the letter, Starboard stated, "we are highly concerned regarding a number of actions that the Board has taken which indicate to us that meaningful change is needed to ensure the Company is acting in the best interest of all shareholders. Specifically, we have significant concerns regarding serious corporate governance deficiencies, questionable capital allocation decisions, and egregious actions taken by the Board to stymie strategic interest in acquiring Depomed. In combination, these concerns lead us to believe that management and the Board may be more interested in entrenching themselves than in delivering maximum value for all shareholders."

51. Starboard also sent letters to Depomed's shareholders on May 26, 2016, and July 26, 2016 expressing its desire to clean house and force its own agenda on Depomed.

52. Starboard's pressure on Defendants to maximize shareholder value led Schoeneck to fear that he would lose his job unless he was able to find a way to increase NUCYNTA sales. This fear eventually came to fruition. On March 29, 2017, after disappointing NUCYNTA sales and projections, Depomed announced that it had replaced Schoeneck with Higgins, and named two new directors to Depomed's board.

53. Ultimately, not even Starboard's intimidation tactics and influence could overcome the worsening opioid market. On December 4, 2017, due to the worsening headwinds within the opioid market, Depomed entered into a commercialization agreement with Collegium Pharmaceutical, Inc., for the NUCYNTA brand.

54. Additionally, Depomed changed its name to Assertio Therapeutics, Inc. on August 14, 2018 to further distance itself from the opioid market.

B. *The Opioid Epidemic*

55. The pain-relieving properties of opium have been recognized for millennia. So has the magnitude of its potential for abuse and addiction. Opioids, after all, include closely related illegal drugs like opium and heroin. During the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain—particularly on the battlefield—and were popularly used in a wide variety of commercial products ranging from pain elixirs to cough suppressants to beverages. By 1900, an

estimated 300,000 people were addicted to opioids in the United States, and many doctors prescribed opioids solely to avoid patients' withdrawal. Both the numbers of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive nature.

56. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970. The labels for scheduled opioid drugs carry black box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression," as a result of an excessive dose.

57. Most patients with more than a few weeks of opioid therapy will experience withdrawal symptoms if opioids are discontinued (commonly referred to as "dependence"). Once dependent, a patient experiences deeply unpleasant symptoms when his or her current dose of opioids loses effect and is not promptly replaced with a new dose. Among the symptoms reported in connection with opioid withdrawal are: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long opioids were used.

58. Dr. Andrew Kolodny, Chief Medical Officer for Phoenix House, a national addiction treatment program, has explained the effect of opioids as akin to "hijack[ing] the brain's reward system," which in turn convinces a user that "the drug is needed to stay alive." A patient's fear of the unpleasant effects of discontinuing opioids combined with the negative reinforcement during a period of actual withdrawal can drive a patient to seek further opioid treatment—even where ineffective or detrimental to quality of life—simply to avoid the deeply unpleasant effects of withdrawal.

59. When under the continuous influence of opioids over a period of time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same levels of pain reduction he or she has become accustomed to—up to and including doses that are considered to be "frighteningly high." At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. The FDA has acknowledged that available data suggest a relationship between increased doses and the risk of adverse effects.

60. Patients receiving high doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.

61. Further, "a potential side effect from chronic use [of opioids] can be abuse and addiction . . . . [i]n fact, correct use and abuse of these agents are not polar opposites—they are complex, inter-related phenomena." It is very difficult to tell whether a patient is physically dependent, psychologically dependent, or addicted. Drug-seeking behaviors, which are signs of addiction, will exist and emerge when opioids are suddenly not available, the dose is no longer effective, or tapering of a dose is undertaken too quickly.

62. Studies have shown that between 30% and 40% of long-term users of opioids experience problems with opioid use disorders.

63. Opioids vary by duration. Long-acting opioids, like NUCYNTA ER, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. While it was once thought that long-acting opioids would not be as susceptible to abuse and addiction as short-acting ones, this view has been discredited. All labels of Schedule II long-acting opioids, or which NUCYNTA ER is one, are required to state that the drug "exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death." The FDA has required extended release and long-acting opioids to adopt "Risk Evaluation Mitigation Strateg[ies]" on the basis that they present "a serious public health crisis of addiction, overdose, and death."

C. *Benefits Offered by Long-Term Opioid Use Are Unproven and Contradicted.*

64. Despite the fact that opioids now are routinely prescribed, there never has been evidence of their safety and efficacy for long-term use. Defendants always have been aware of these gaps in knowledge. While promoting opioids to treat chronic pain, Defendants have failed to disclose the lack of evidence to support their use long-term and have failed to disclose the contradictory evidence that chronic opioid therapy actually makes patients sicker.

65. Evidence exists to show that opioid drugs are not effective to treat chronic pain, and may worsen patients' health. A 2006 study-of-studies titled "*Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*" found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. Most notably, it stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids." Another review of evidence relating to the use of opioids for chronic pain, titled "*Are Opioids Effective in the Long-Term Treatment of Musculoskeletal Pain*?," found that up to 22.9% of patients in opioid trials dropped out before the study began because of the intolerable effects of opioids and that the evidence of pain relief over time was weak.

66. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.

67. As a pain specialist noted in an article titled, "*Are We Making Pain Patients Worse?*", "[O]pioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."

68. This is true both generally and for specific pain-related conditions. Studies of the use of opioids long-term for chronic lower back pain have been unable to demonstrate an improvement in patients' function. Instead, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not cause patients to return to work or physical activity. This is due partly to addiction and other side effects.

69. The lack of evidence for the efficacy of opioid use long-term has been well documented nationally in the context of workers' compensation claims, where some of the most detailed data exists. Claims involving workers who take opioids are almost four times as likely to reach costs of over $100,000 than claims without opioids, as these patients suffer greater side effects and are slower to return to work. Even adjusting for injury severity and self-reported pain score, receiving an opioid for more than seven days and receiving more than one opioid prescription

increased the risk that the patient would be on work disability one year later. A prescription for opioids as the first treatment for a workplace injury doubled the average length of the claim.

D. *Government Investigations and State of Emergency*

70. In response to the opioid epidemic, a number of states have filed lawsuits against opioid manufacturers. Between July 2016 and July 2017, at least 25 states, cities and counties have filed civil cases against manufacturers, distributors and large drugstore chains that make up the $13 billion-a-year opioid industry.

71. In May 2014, Santa Clara and Orange Counties in California filed a complaint in state court in Orange County, California against numerous pharmaceutical manufacturers, including Janssen, alleging claims related to opioid marketing practices, including false advertising, unfair competition, and public nuisance.

72. On August 26, 2015, the City of Chicago named Depomed as a defendant in a Second Amended Complaint (the "City of Chicago Complaint") filed in *City of Chicago v. Purdue Pharma L.P. et al.*, a federal case in the United States District Court, Northern District of Illinois (following removal from Cook County Circuit Court) against a number of pharmaceutical companies marketing and selling opioid pain medications. The original complaint in the action named as a defendant Janssen Pharma and its related companies. Janssen, at the time the original complaint was filed, marketed and sold NUCYNTA® and NUCYNTA® ER, the U.S. rights to which were sold to Depomed in a transaction that closed in April 2015. Depomed was dismissed without prejudice from the lawsuit on November 9, 2015, but the litigation is still on-going against the other defendants.

73. In addition to lawsuits, companies that manufacture opioids are also facing investigations by states' attorneys general and Congressional and Senate investigations. As discussed in more detail below, on March 28, 2017, Senator McCaskill announced that she was commencing the Senate Investigation into the marketing and sales practices of the nation's top five manufacturers of prescription opioid products, including Depomed. According to a statement by Senator McCaskill, "[the] investigation is about finding out whether the same practices that led to this [opioid] epidemic still continue today, and if decisions are being made that harm the public health." In letters to the manufacturers, Senator McCaskill further stated that "[t]his epidemic is the

direct result of a calculated sales and marketing strategy major opioid manufacturers have allegedly pursued over the past 20 years to expand their market share and increase dependency on powerful—and often deadly—painkillers…[t]o achieve this goal, manufactures have reportedly sought, among other techniques, to downplay the risk of addiction to their products and encourage physicians to prescribe opioids for all cases of pain and in high doses."

74. The opioid epidemic has become so severe that on October 26, 2017, President Donald Trump declared the opioid epidemic a national public health emergency.

E. *Guidelines and Regulations for Prescribing Opioids*

75. In an attempt to curb the opioid epidemic, on March 18, 2016, the CDC issued guidelines for prescribing opioids for chronic pain. The guideline provided recommendations for primary care clinicians prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. The guidelines address 1) when to initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use. CDC developed the guideline using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework, and recommendations were made on the basis of a systematic review of the scientific evidence while considering benefits and harms, values and preferences, and resource allocation. CDC obtained input from experts, stakeholders, the public, peer reviewers, and a federally chartered advisory committee.

76. The categorization of the recommendations was based on the assessment that a) No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤6 weeks in duration); b) Extensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury); and c) Extensive evidence suggests some benefits of nonpharmacologic and nonopioid pharmacologic treatments compared with long-term opioid therapy, with less harm.

77. The guidelines are as follows:

(1) ***Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain***. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to

outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate (recommendation category: A, evidence type: 3);

(2) Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety (recommendation category: A, evidence type: 4);

(3) Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy (recommendation category: A, evidence type: 3);

(4) When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids (recommendation category: A, evidence type: 4);

(5) When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day (recommendation category: A, evidence type: 3);

(6) Long-term opioid use often begins with treatment of acute pain. ***When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids.*** Three days or less will often be sufficient; more than seven days will rarely be needed (recommendation category: A, evidence type: 4);

(7) Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids (recommendation category: A, evidence type: 4);

(8) Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present (recommendation category: A, evidence type: 4);

(9) Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP)

> data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months (recommendation category: A, evidence type: 4); and
>
> (10) When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs (recommendation category: B, evidence type: 4).

78. The guidelines are intended to improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death.

F. *NUCYNTA's Label and History of Off-Label Marketing.*

79. On April 2, 2015, Depomed acquired from Janssen and its affiliates the U.S. rights to the NUCYNTA franchise of pharmaceutical products for $1.05 billion in cash. The NUCYNTA franchise is an opioid that includes NUCYNTA ER (tapentadol) extended release tablets indicated for the management of pain, including neuropathic pain associated with diabetic peripheral neuropathy (DPN), severe enough to require daily, around-the-clock, long-term opioid treatment, NUCYNTA IR (tapentadol), an immediate release version of tapentadol, for management of moderate to severe acute pain in adults, and NUCYNTA (tapentadol) oral solution, an approved oral form of tapentadol that has not been commercialized.

80. Tapentadol is a centrally-acting synthetic analgesic. Pre-clinical data demonstrate two mechanisms of action: mu-opioid receptor agonist activity and noradrenaline re-uptake inhibition. However, the exact mechanism of action is unknown. This differentiates tapentadol from other opioids that have a single mechanism of action, notwithstanding, the clinical relevance of this is unclear. https://www.nucynta.com/hcp/ir/mechanism-of-action/

81. The Controlled Substances Act ("CSA") places all substances which were in some manner regulated under existing Federal law into one of five schedules. This placement is based upon the substance's medical use, potential for abuse, and safety or dependence liability. Before placing a drug into schedule, the Drug Enforcement Agency (DEA) receives scientific and medical

evaluation from the Department of Health and Human Services (HHS). The DEA then evaluates all available data and makes a final decision whether to propose that a drug should be controlled and into which schedule it should be placed.

82. The DEA determined that NUCYNTA is a Schedule II controlled substance. Schedule II drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous.

83. As a Schedule II opioid, NUCYNTA exposes users to the risks of addiction, abuse, and misuse. NUCYNTA ER is at an even greater risk for overdose and death due to the larger amount of tapentadol present because extended-release products such as NUCYNTA ER deliver the opioid over an extended period of time.

84. Schedule II opioids, including NUCYNTA, are also subject to various federal laws and regulations governed by the FDA, which is responsible for protecting and promoting public health through the regulation and supervision of, among other things, prescription drugs. The FDCA gives authority to the FDA to oversee the safety of food, drugs, and cosmetics.

85. Under the FDCA, 21 U.S.C. §§301-97, and the Public Health Services Act ("PHSA"), 42 U.S.C. §262, et seq., drug manufacturers may not market or promote a drug for "off-label" use, or for a use the FDA has not approved. See 21 U.S.C. §331, §352; 42 U.S.C. §262(a)(1) and (b); 21 C.F.R. §601.12. A drug may not be marketed or sold in the United States unless the FDA has approved the drug as safe and effective for its intended use and intended indication. The intended indications for use of the drug are provided in the drug's label which the FDA reviews and approves. *See* 21 U.S.C. §355-1(d)(1) and (2). Violation of the FDCA and PHSA are punishable by criminal and civil penalties including substantial fines. 21 U.S.C. §333.

86. Proving that a specific use or dosage is safe and effective for large numbers of patients requires lengthy clinical trials and is very expensive. On the other hand, drug companies derive immediate and substantial profits from off-label prescriptions. As a result, drug companies have a substantial short-term financial incentive to break the law by marketing and promoting their drugs

for uses and dosages that are not proven to be medically safe and effective in treating large numbers of patients.

87. Drug companies that violate the FDCA prohibition against off-label marketing approval are also subject to criminal prosecution and, if convicted, face exclusion or "debarment" from federal healthcare programs. Such federal debarment would result in catastrophic damage to Depomed and its shareholders because Medicaid and Medicare would no longer cover the costs of any Depomed drug and most patients would therefore find an alternative drug sold by a competitor or would forego treatment altogether.

NUCYNTA IR's LABEL

88. The FDA-approved label for NUCYNTA IR warns users of the high level of addition and abuse of NUCYTA IR. For example, the following instructions appear on NUCYNTA IR's label:

a) NUCYNTA tablets expose users to risks of addiction, abuse, and misuse, which can lead to overdose and death. Assess patient's risk before prescribing and monitor regularly for these behaviors and conditions;

b) Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve NUCYNTA tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or opioid combination products):

- Have not been tolerated, or are not expected to be tolerated
- Have not provided adequate analgesia, or are not expected to provide adequate analgesia;

c) **Addiction, Abuse, and Misuse** NUCYNTA tablets exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing NUCYNTA tablets, and monitor all patients regularly for the development of these behaviors and conditions; and

d) NUCYNTA tablets contain tapentadol, a Schedule II controlled substance. As an opioid, NUCYNTA tablets exposes users to the risks of addiction, abuse, and misuse;

e) Although the risk of addiction in any individual is unknown, it can occur in patients appropriately prescribed NUCYNTA tablets. Addiction can occur at recommended dosages and if the drug is misused or abused.

89. NUCYNTA IR's label also indicates the proper dosage for users. In pertinent part, it states:

a) Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals;

b) Individualize dosing based on the severity of pain, patient response, prior analgesic experience, and risk factors for addiction, abuse, and misuse; and

c) Initiate treatment with NUCYNTA tablets at a dose of 50 mg, 75 mg, or 100 mg every 4 to 6 hours depending upon pain intensity. On the first day of dosing, the second dose may be administered as soon as one hour after the first dose, if adequate pain relief is not attained with the first dose. Subsequent dosing is 50 mg, 75 mg, or 100 mg every 4 to 6 hours and should be adjusted to maintain adequate analgesia with acceptable tolerability. Daily doses greater than 700 mg on the first day of therapy and 600 mg on subsequent days have not been studied and are, therefore, not recommended.

90. NUCYNTA IR's label also indicates that adverse events cannot be compared to other drugs. It states:

a) Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

91. NUCYNTA IR's label also includes an approved adverse event study comparing NUCYNTA to a placebo. The study shows:

Table 1 Adverse Reactions Reported by ≥1% of NUCYNTA-Treated Patients in Seven Phase 2/3 Placebo- and/or Oxycodone-Controlled, One Non-controlled, and One Phase 3 Oxycodone-Controlled Safety, Multiple-Dose Clinical Studies

System/Organ Class MedDRA Preferred Term	NUCYNTA 21 mg – 120 mg (n = 2178) %	Placebo (n = 619) %
Gastrointestinal disorders		
Nausea	30	13
Vomiting	18	4
Constipation	8	3
Dry mouth	4	<1
Dyspepsia	2	<1
General disorders and administration site conditions		
Fatigue	3	<1
Feeling hot	1	<1
Infections and infestations		
Nasopharyngitis	1	<1
Upper respiratory tract infection	1	<1
Urinary tract infection	1	<1
Metabolism and nutrition disorders		
Decreased appetite	2	0
Nervous system disorders		
Dizziness	24	8
Somnolence	15	3
Tremor	1	<1
Lethargy	1	<1
Psychiatric disorders		
Insomnia	2	<1
Confusional state	1	0
Abnormal dreams	1	<1
Anxiety	1	<1
Skin and subcutaneous tissue disorders		
Pruritus	5	1
Hyperhidrosis	3	<1
Pruritus generalized	3	<1
Rash	1	<1
Vascular disorders		
Hot flush	1	<1

92. Nowhere on the FDA-approved label does it say or mention, as Depomed has marketed NUCYNTA IR that it is safer, more tolerable, less abusive, or less addictive than other opioids.

NUCYNTA ER's LABEL

93. The FDA-approved label for NUCYNTA ER warns users of the high level of addition and abuse of NUCYTA ER. For example, the following instructions appear on NUCYNTA ER's label:

a) NUCYNTA ER exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk before prescribing, and monitor regularly for development of these behaviors or conditions;

b) Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve NUCYNTA ER for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain;

c) **Addiction, Abuse, and Misuse** NUCYNTA ER exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing NUCYNTA ER, and monitor all patients regularly for the development of these behaviors and conditions;

d) NUCYNTA ER contains tapentadol, a Schedule II controlled substance. As an opioid, NUCYNTA ER exposes users to the risks of addiction, abuse, and misuse. Because extended-release products such as NUCYNTA ER deliver the opioid over an extended period of time, there is a greater risk for overdose and death due to the larger amount of tapentadol present;

e) Although the risk of addiction in any individual is unknown, it can occur in patients appropriately prescribed NUCYNTA ER. Addiction can occur at recommended doses and if the drug is misused or abused;

f) NUCYNTA ER contains tapentadol, a substance with a high potential for abuse similar to other opioids including fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, and oxymorphone. NUCYNTA ER can be abused and is subject to misuse, addiction, and criminal diversion; and

g) The high drug content in extended-release formulations adds to the risk of adverse outcomes from abuse and misuse.

94. NUCYNTA ER's label also indicates the proper dosage for users. In pertinent part, it states:

h) Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals;

i) Initiate the dosing regimen for each patient individually, taking into account the patient's severity of pain, patient response, prior analgesic treatment experience, and risk factors for addiction, abuse, and misuse;

j) Discontinue all other tapentadol and tramadol products when beginning and while taking NUCYNTA ER;

k) Use of NUCYNTA ER as the First Opioid Analgesic (opioid-naïve patients) Initiate treatment with NUCYNTA ER with the 50 mg tablet orally twice daily (approximately every 12 hours); and

l) Use of NUCYNTA ER in Patients who are not Opioid Tolerant The starting dose for patients who are not opioid tolerant is NUCYNTA ER 50 mg orally twice daily (approximately every 12 hours). Use of higher starting doses in patients who are not opioid tolerant may cause fatal respiratory depression.

95. NUCYNTA ER's label also indicates that adverse events cannot be compared to other drugs. It states:

a) Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

96. NUCYNTA ER's label also includes an approved adverse event study comparing NUCYNTA ER to a placebo. The study shows:

Table 1 Adverse Drug Reactions Reported by ≥ 1% of NUCYNTA ER-Treated Patients and Greater than Placebo-Treated Patients in Pooled Parallel-Group Trials[1]

	NUCYNTA ER 50 to 250 mg BID[2] (n=980)	Placebo (n=993)
Nausea	21%	7%
Constipation	17%	7%
Dizziness	17%	6%
Headache	15%	13%
Somnolence	12%	4%
Fatigue	9%	4%
Vomiting	8%	3%
Dry mouth	7%	2%
Hyperhidrosis	5%	<1%
Pruritus	5%	2%
Insomnia	4%	2%
Dyspepsia	3%	2%
Lethargy	2%	<1%
Asthenia	2%	<1%
Anxiety	2%	1%
Decreased appetite	2%	<1%
Vertigo	2%	<1%
Hot flush	2%	<1%
Disturbance in attention	1%	<1%
Tremor	1%	<1%
Chills	1%	0%
Abnormal dreams	1%	<1%
Depression	1%	<1%
Vision blurred	1%	<1%
Erectile dysfunction	1%	<1%

[1] MedDRA preferred terms. The trials included forced titration during the first week of dosing.

[2] NUCYNTA ER dosed between 100 and 250 mg BID after a starting dose of 50 mg BID

Commonly-Observed Adverse Reactions in Clinical Studies with NUCYNTA ER in Patients with Neuropathic Pain Associated with Diabetic Peripheral Neuropathy

The types of adverse reactions seen in the studies of patients with painful diabetic peripheral neuropathy (DPN) were similar to what was seen in the low back pain and osteoarthritis trials. The safety data described in Table 2 below are based on two pooled, randomized withdrawal, double-blind, placebo-controlled, 12-week studies of NUCYNTA ER (dosed 100 to 250 mg BID) in patients with neuropathic pain associated with diabetic peripheral neuropathy. These trials included 1040 NUCYNTA ER-treated patients and 343 placebo-treated patients. The mean age was 60 years old; 40% were female and 60% were male; 76% were White, 12% were Black, and 12% were "Other". The most commonly reported ADRs (incidence ≥10% in NUCYNTA ER-treated subjects) were: nausea, constipation, vomiting, dizziness, somnolence, and headache.

Table 2 lists the common adverse reactions reported in 1% or more of NUCYNTA ER-treated patients and greater than placebo-treated patients with neuropathic pain associated with diabetic peripheral neuropathy in the two pooled studies.

97. An additional study on NUCYNTA ER's label shows :

Table 2: Adverse Drug Reactions Reported by ≥ 1% of NUCYNTA ER-Treated Patients and Greater than Placebo-Treated Patients in Pooled Trials (Studies DPN-1 and DPN-2)[1]

	NUCYNTA ER 50 to 250 mg BID[2] (n=1040)	Placebo[3] (n=343)
Nausea	27%	8%
Dizziness	18%	2%
Somnolence	14%	<1%
Constipation	13%	<1%
Vomiting	12%	3%
Headache	10%	5%
Fatigue	9%	<1%
Pruritus	8%	0%
Dry mouth	7%	<1%
Diarrhea	7%	5%
Decreased appetite	6%	<1%
Anxiety	5%	4%
Insomnia	4%	3%
Hyperhidrosis	3%	2%
Hot flush	3%	2%
Tremor[4]	3%	3%
Abnormal dreams	2%	0%
Lethargy	2%	0%
Asthenia	2%	<1%
Irritability	2%	1%
Dyspnea	1%	0%
Nervousness	1%	0%
Sedation	1%	0%
Vision blurred	1%	0%
Pruritus generalized	1%	0%
Vertigo	1%	<1%
Abdominal discomfort	1%	<1%
Hypotension	1%	<1%
Dyspepsia	1%	<1%
Hypoesthesia	1%	<1%
Depression	1%	<1%
Rash	1%	<1%
Chills[4]	1%	1%
Feeling cold[4]	1%	1%
Drug withdrawal syndrome	1%	<1%

[1] MedDRA preferred terms.

[2] NUCYNTA ER dosed between 100 and 250 mg BID after a starting dose of 50 mg BID. It includes ADR reported in the open-label titration period for all subjects and in the double-blind maintenance period for the subjects who were randomized to NUCYNTA ER.

[3] It includes ADR reported in the double-blind maintenance period for the subjects who were randomized to placebo after receiving NUCYNTA ER during the open-label titration period.

[4] Tremor was observed in 3.4% of NUCYNTA ER-treated subjects vs. 3.2% in placebo group, chills- in 1.3% vs.1.2% in placebo, and feeling cold- in 1.3% vs. 1.2% in placebo.

98. Nowhere on the FDA-approved label does it say or mention, as Depomed has marketed NUCYNTA ER that it is safer, more tolerable, less abusive, or less addictive than other opioids.

G. *NUCYNTA's Off-Label Marketing Under Depomed*

99. As discussed in further detail below, Defendants' statements and allegations of former employees show that Defendants engaged in off-label marketing throughout the Class Period.

100. Defendants' off-label marketing claims included:

NUCYNTA's LABEL:	**DEPOMED'S OFF-LABEL MARKTING:**
Labeling related to safety, and abuse: • NUCYNTA tablets expose users to risks of addiction, abuse, and misuse, which can lead to overdose and death. Assess patient's risk before prescribing and monitor regularly for these behaviors and conditions* • Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve NUCYNTA ER for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain • NUCYNTA ER contains tapentadol, a Schedule II controlled substance. As an opioid, NUCYNTA ER exposes users to the risks of addiction, abuse, and misuse.* Because extended-release products such as NUCYNTA ER deliver the opioid over an extended period of time, there is a greater risk for overdose and death due to the larger amount of tapentadol present; • Although the risk of addiction in any individual is unknown, it can occur in patients appropriately prescribed NUCYNTA tablets. Addiction can occur at recommended dosages and if the drug is misused or abused*	***Marketing related to safety, and abuse:*** • NUCYNTA has lower abuse than other opioids • NUCYNTA's dual mechanism of action makes NUCYNTA different than other opioids. • NUCYNTA has lower withdrawal symptoms compared to other opioids • NUCYNTA has less euphoria than other opioids

• NUCYNTA ER contains tapentadol, a substance with a high potential for abuse similar to other opioids including fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, and oxymorphone. NUCYNTA ER can be abused and is subject to misuse, addiction, and criminal diversion	
Labeling related to dosage: • Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals* • Individualize dosing based on the severity of pain, patient response, prior analgesic experience, and risk factors for addiction, abuse, and misuse • Initiate the dosing regimen for each patient individually, taking into account the patient's severity of pain, patient response, prior analgesic treatment experience, and risk factors for addiction, abuse, and misuse • Discontinue all other tapentadol and tramadol products when beginning and while taking NUCYNTA ER • Use of NUCYNTA ER as the First Opioid Analgesic (opioid-naïve patients) Initiate treatment with NUCYNTA ER with the 50 mg tablet orally twice daily (approximately every 12 hours) • Use of NUCYNTA ER in Patients who are not Opioid Tolerant The starting dose for patients who are not opioid tolerant is NUCYNTA ER 50 mg orally twice daily (approximately every 12 hours). Use of higher starting doses in patients who are not opioid tolerant may cause fatal respiratory depression	***Marketing related to dosage:*** • Increase average dosages of NUCYNTA • Increase starting dosages of NUCYNTA • Prescribe NUCYNTA ER and IR together
Labeling related to clinical trials: • Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice*	***Marketing related to clinical trials***: • Marketing materials of a side by side comparison of withdrawals rates of NUCYNTA ER compared to Oxycodone CR
* indicated on both NUCYNTA IR and ER labels	

101. As described in more detail below, these off-label marketing messages were a widespread campaign instigated by Depomed that were used to promote NUCYNTA as a more safe, less euphoric, and less abusive opioid.

Depomed Promoted NUCYNTA Off-Label by Promoting NUCYNTA as Safer, Less Euphoric, Less Abusive and More Tolerable than Other Opioids

102. Depomed promoted NUCYNTA off-label as a safer, less abusive, less euphoric and more tolerable opioid.

103. NUCYNTA's label indicates that "NUCYNTA ER contains tapentadol, a substance with a high potential for abuse similar to other opioids including fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, and oxymorphone. NUCYNTA ER can be abused and is subject to misuse, addiction, and criminal diversion."

104. Despite this, Depomed had a companywide policy to promote NUCYNTA as a different opioid that was less abusive, less euphoric, and generally safer than other opioids. In one specific instance during the Class Period, on June 21, 2016 at the JMP Securities Life Sciences Conference, Schoeneck stated the following about NUCYNTA: "you've got lower rates of abuse, lower rates of hospitalization;" "the street price of the drug is barely above the retail price of the drug . . . [s]o not particularly popular on the [s]treet either. And some of that has to do with the fact that if you look at just the drug in the two mechanisms of action, people don't tend to get -- they don't get the euphoria that they get with the classic opioids. You're not hitting the mu receptor nearly as hard because you're also hitting this other system. And with that you don't see the euphoria. And that's really what people want is they want that -- they like that good feeling and they want more of it. They start to tolerate to it, take higher and higher doses and that's where the category gets really dangerous."

105. Additionally, on a June 23, 2015 investor call, Defendant August Moretti, Depomed's Senior Vice President and Chief Financial Officer, stated that "[a]lthough not in the label, there's a very low abuse profile and side effect rate."

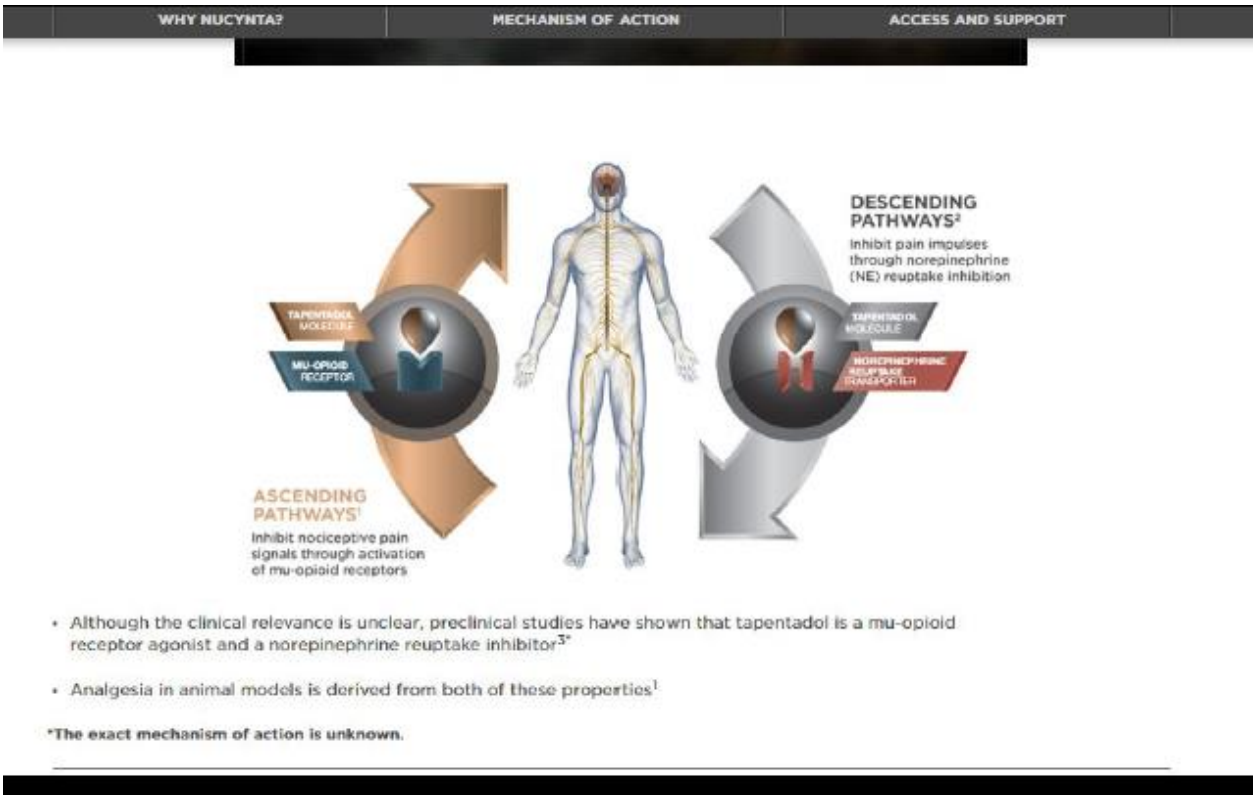
106. In a March 14, 2016 presentation at the ROTH Conference, Defendant Schoeneck stated: "The addiction profile is thought to be better. I can't make a claim around that because we

don't actually have that in the label." In February 2017, Schoeneck also told investors that Depomed was "initiating label enhancement studies, aimed at further differentiating NUCYNTA by highlighting its respiratory depression and abuse potential profile. These labeling studies will focus on the properties of the tapentadol molecule, and its uniqueness in the pain marketplace." The purpose of this was to "be able to get it hopefully into the label."

107. Defendants also represented that NUCYNTA was safer by indicating that NUCYNTA was a different opioid that did not have the same addictive properties as other opioids because NUCYNTA has "dual mechanisms of action" and is a "mu-opioid receptor agonist and a norepinephrine reuptake inhibitor."

108. On March 14, 2016, Defendant Moretti states: "As a dual mechanism of action, it does bind to the new opioid receptor, but at a binding strength that's 1/15th that of morphine. So as a result, the patient doesn't get the kind of euphoria that you get with other drugs in the category. The second mechanism of action, norepinephrine reuptake inhibition, synergizes with the new opioid agonist and provides effective pain relief without the euphoria to the patient. And as a result, you wind up with less likeability, less potential for abuse. And I think that the physicians feel that way about the drug; however, those claims are not in the label."

109. However, the "exact mechanism of action" of NUCYNTA is still unknown to this day, and the "clinical relevance is unclear" as to the benefits of having dual mechanisms of action. https://www.nucynta.com/hcp/ir/mechanism-of-action/.



110. Despite this, Defendants indicated that they had "repositioned the drug . . . by focusing on this dual mechanism of action . . . ." By focusing on the "dual mechanism" Defendants portrayed NUCYTA as a safer, less abusive, less euphoric opioid. However, this was not the case.

111. Additionally, on a website ran by Depomed that is designed to market NUCYNTA, Depomed promotes NUCYNTA ER as more tolerable because of fewer "discontinuation rates due to treatment-emergent adverse events" (see additional allegations below). Depomed goes on to set forth a number of treatment emergent adverse events and how they compare to one competitor, Oxycodone CR. The website also claims that NUCYNTA ER is safe because only 4.8% of NUCYNTA ER-treated patients experienced mild or moderate withdrawal. However, none of this appears on the FDA-approved label for NUCYNTA. Defendants encouraged their sales team to promote NUCYNTA off-label in the same manner.

112. Defendants pushed their sales to represent NUCYNTA off-label to physicians. Former employees of Depomed show that this was the Depomed's marketing practice of NUCYNTA.

113. FE1 worked as a former Specialty Sales Representative selling NUCYNTA at Depomed from October 2011 to March 2016. FE1 reported to David Sims, a former sales manager from Quintiles. According to FE1, Depomed appeared to change significantly in how it approached its sales practices and training following the acquisition of NUCYNTA. FE1 was trained on how to sell NUCYNTA by FE1's manager, David Sims, who formerly worked for Quintiles, the marketing firm used by Janssen. Sims trained FE1 by discussing the negative perception of opioids in general across the country, and by telling FE1 how to pushback against prescribers who cited concerns writing an opioid prescription

114. FE1 indicated that Depomed's marketing push was "Think Differently." FE1 stated that the manager was very vocal about NUCYNTA being a "safer opioid." FE1 indicated that Sims "would say that all the time" and that FE1 heard Sims call NUCYNTA a safer opioid to physicians. FE1 would listen to Sims preach to physicians about NUCYNTA and its value to patients in terms of, among other things, improved safety relative to other opioids on the market. According to FE1, Sims "would just tell the doctors it was much safer, and for them to prescribe it for their patients, and it was better for their patients." FE1 stated he[2] was aware Sims was speaking off-label about the drug and that it was not allowed by law.

115. FE1 was also paired with a former Quintiles sales representative who actively told physicians that NUCYNTA was a safer opioid.

116. Similarly FE2, a former Senior Specialty Representative at Depomed from June 2012 to July 2017, who was responsible for promoting NUCYNTA, and also for helping prepare other new employees to sell the drug, stated that Depomed convinced its sales force that NUCYNTA was different. "A lot of things changed because we brought on a huge group of people, and, for instance, where the Training Department would do the training on its own, now I was part of the trainers where I was training a full classroom of people on my own," FE2 said. "It was very different in the practices, in that regard. They had so many brought on." FE2 stated "We were being convinced it was a safer opioid" that was "the overall consensus that was being told to us." FE2 stated that when

[2] All FEs will be described and referred to in the masculine to help protect their identities.

the sales team complained about selling to neurologists, FE2's superiors would say that "this is a great opportunity to introduce them to the safer opioid." FE2 stated that the message that NUCYNTA was a safer opioid came from multiple people and "from different parts of the country."

117. FE3 was a Pain Sales Specialist at Depomed from November 2015 to August 2016 responsible for representing NUCYNTA. FE3 stated he was one of the dozens and dozens of new sales representatives that Depomed hired after acquiring NUCYNTA in early 2015. FE3 reported to his district manager Jessica Golino. FE3 was trained by Glenn Drummond who formerly represented Oxycontin for Purdue Pharma. FE3 said he had gone through sales training at several pharmaceutical companies prior to joining Depomed but that none of those was as intense as what he experienced with Drummond.

118. "There was always negativity associated with selling any opioid, but we believed in the molecule," FE3 said. "You weren't going to get the euphoric effect. That was discussed, that you would not see that." FE3 stated that, "I heard Jim Schoeneck talk a lot. The perception of opioids? You're selling a molecule that's not supposed to cause euphoria. You're kind of talking out both sides of your mouth. I'm selling a painkiller, but not the same as (the ones) on the street." FE3 stated, "You have to think about the molecule. Doctors didn't want to give something to patients that would give that high."

119. When asked about whether the sales representatives talked about the lower abuse of NUCYNTA to doctors, FE3 stated, "If they have specific questions about abuse, we did talk abuse. We did talk about it. Yeah, we did." When asked where FE3 heard NUCYNTA was safer and less euphoric, FE3 stated that they were told during sales training that NUCYNTA did not provide the same euphoria as other street-level opioids. "It was discussed in training. That's what made this molecule as successful as it was. There was less abuse potential. Addicts weren't going to be stealing it because they wouldn't get the buzz." FE3 added the caveat, "It was never on the marketing materials. I can't point fingers at the trainers. It was just a well-known fact you're not going to get the euphoria."

120. The fact that Depomed conspicuously omitted this training instruction from their printed training materials strongly suggests that Defendants knew or recklessly disregarded that the

instruction was inappropriate and improper, otherwise there would be no need to hide it in this manner. FE3 confirmed they were instructed that NUCYNTA presented less abuse potential because of its design. "Just the way it was manufactured," FE3 said. "If you tried to crush it, it was almost indestructible."

121. FE3 stated that the selling point on NUCYNTA was "because it was dual mechanism." FE3 stated that he did meet with physicians who wanted to talk about NUCYNTA's advantages. "They knew it was an opioid. They would ask a lot of questions about even writing an opioid," he said. "They wanted to talk about what was inside the pill. What was the deterrent in the pill."

122. FE4 was a former Specialty Pain Sales Representative at Depomed, Inc. from late 2011 to late November/early December 2016. In addition to selling NUCYNTA, FE4 was responsible in assisting with sales training related to the new employees hired to promote NUCYNTA. FE4 indicated that "there may have been some perception" that NUCYNTA was a safer painkiller. FE4 stated, "I was a guest trainer. I worked intimately with Glen [Drummond] on multiple things. He was very serious about training, there's no doubt in my mind. He could be very challenging, I wouldn't go so far as to say difficult, and he had expectations for people going through training. The agenda was rigorous. It was long hours. Glen was very, very good. He was professional, and he expressed that there was a 'gray area' when it comes to selling opioids."

123. FE4 confirmed that Depomed approached NUCYNTA by marketing the drug differently from other similar products. "Oh, absolutely," FE4 said. "The tagline was, Think Differently. That was the tagline for the marketing department. NUCYNTA is very different in its mechanism of action."

124. FE6 is a former Depomed Specialty Sales Representative who worked at Depomed from January 2012 – September 2015. FE6 was assigned a sales territory comprised of Rhode Island, Massachusetts, and Connecticut. FE6 seems to have variously reported to a District Manager named Jessica Golino, Dave Whitehead (although the witness was not reporting to Whitehead as of the time that Depomed acquired and began selling Nucynta), and John Hardiman. FE6 represented the entire portfolio of Depomed products. In descending order of priority and volume he was expected to sell

NUCYNTA, Gralise, and Zipsor. For instance, FE6 estimates that NUCYNTA represented 60% - 70% of his quota, Gralise perhaps 10% or 20% and Zipsor 10%. The quota was based on the number of prescriptions for these drugs written in his region, not a particular dollar goal, but he did not recall what his quotas had been.

125. As FE6 put it, there was a lot of looking "the other way" in regards to certain representations about NUCYNTA. He stated that there was a lot of insinuation and implication made to the sales representatives as to what they should say. For example, FE6 stated that during sales force meetings there would be breakout sessions of smaller, regional groups of sales personnel. FE6 explained that one ostensible purpose of the breakout sessions was to come up with ideas to increase sales. During such breakout sessions it was discussed that Oxycodone and NUCYNTA could each be used to treat neuropathy. However, FE6 stated that the difference was that NUCYNTA had "no street value," so "the way upper management spun it" was that the sales representatives could say that NUCYNTA "can't be abused because there was no street value" and also because patients were not coming to prescribers specifically asking for NUCYNTA, which was not the case with Oxycodone. FE6 stated that he felt this was not ethical and that he and other sales representatives always did "a double-take" when they were told this because, in fact, NUCYNTA is an opioid and just as addictive as Oxycodone, but they were supposed to ask the prescribers "when was the last time someone asked for NUCYNTA" and simply "let the doctors make the decision."

126. FE6 said that the representation about NUCYNTA not having any street value was made to him and other sales representations in the regional breakout sessions by Jessica Golino and John Hardiman. FE6 said that what was being suggested to say to the doctors in this regard was clearly wrong because it was not in the NUCYNTA package insert. FE6 said that as a sales representative it was critical to learn what was set forth in the package insert and to adhere to that information.

127. FE6 indicated that not only was this message conveyed "whenever we went to District breakout" sessions, but it was also strongly implied and reinforced by Golino when she went for ride-alongs with FE6 to visit prescribers. As he put it, Golino would suggest using "that verbiage" (that NUCYNTA did not have street value) following visits with the prescribers. FE6

stated that Golino was "big on schematics" in terms of suggesting that FE6 "choose this word" or that word in what he said during prescriber visits.

128. FE6 also stated that representing that NUCYNTA was less euphoric for users compared to other opioids was also part of the overall way that NUCYNTA was supposed to be represented. FE6 said that NUCYNTA was to be presented as giving "less of a high" and not being as addictive as Oxycodone because Oxycodone was both physically and mentally (emotionally) addictive, but that NUCYNTA supposedly did not cause emotional addiction. However, FE6 said that to his knowledge there was no real support for this assertion and even though "we were encouraged" to make these representations, he maintains that he never did because it was not supported by the "black box" label.

129. FE6 said that Hardeman and Golino definitely wanted the sales representatives, including himself, to be proactive in making these representations (that NUCYNTA gave "less of a high" and was not as addictive to Oxycodone) to prescribers, as opposed to only making these representations in response to questions posed by the prescribers. Although FE6 could not confirm if other sales representatives made these representations, he said that sales representatives were encouraged to talk to one another to learn what they were doing to be successful and what was necessary to obtain a satisfactory employee evaluation.

130. FE8 was a Pain Sales Specialist who worked at Depomed from beginning either the very last week of September 2015 or October 1, 2015 until the end of June 2017. As a Pain Sales Specialist, FE8 had represented NUCYNTA ER and IR, as well as Gralise, but not the other drugs in Depomed's portfolio. His territory had been comprised of part of Connecticut, as well as Rhode Island. He said the quotas were based on the number of prescriptions of the drugs he represented (as opposed to a monetary amount) and each drug had its own quota. He had reported to District Manager Jessica Golino, whose district had been all of the New England states (Rhode Island, Massachusetts, Vermont, Maine, and New Hampshire, as well as Westchester County, Connecticut). At some point in 2017, Golino began reporting to Ron Menezes.

131. FE8 explained that there were at least three major sales meetings a year: the first (at the beginning of the year) was the "POA" or "Plan of Action" meeting. This was followed in spring

or early summer with a National Sales meeting and then another meeting "in the last third of the year".

132. FE8 stated that at Depomed, there would be talk in meetings of sales personnel regarding the street value of pain medications, although this was supposed to be "for your information" only. He said he had been "smart enough" to know better than to make such representations, but he said that "others probably were not that smart", although he could not say "who did or who did not" engage in off-label practices.

133. FE8 went on to say that at periodic corporate sales training meetings he attended there would be informational discussions about "cross-titration" and the street value of opioids. As best FE8 could recall, one key individual who had made these ostensibly informational presentations had been Anna Copeland, although he was not positive. At another of these sales training meetings, he recalled that an individual who had not been in a sales training role had come to talk about NUCYNTA. As best FE8 could recall, this individual had been of Indian background and talked about the street value of Nucynta, but said it was "just for your information."

134. In regards to cross-titration, FE8 said this pertained to titrating a patient from one opioid to another (i.e., NUCYNTA). For instance, if a patient were using OxyContin, cross-titration entailed reducing the dosage of OxyContin while introducing a low dose of NUCYNTA and gradually replacing the OxyContin completely with NUCYNTA. The supposed benefit of going to NUCYNTA from OxyContin was that OxyContin had "a lot more abuse potential and withdrawal" risks compared to NUCYNTA. By cross-titrating, a patient could supposedly be taken off of OxyContin "without a lot of pain" and even "no withdrawal." However, according to FE8 cross-titration was *not* supported by the package insert for NUCYNTA and the only allowed method of switching a patient over to NUCYNTA from OxyContin was for the patient to first stop using OxyContin (or whatever opioid they were using) completely and then start the patient on NUCYNTA. But, again, FE8 indicated that Depomed indicated that the cross-titration information was said to be "just for information" purposes.

135. FE8 recalled hearing at one of the sales training meetings that while NUCYNTA could supposedly cause some euphoria, the MU part of the drug was supposed to counteract this.

136. FE9 worked at Depomed as a Senior Specialty Pharmaceutical Representative from July 2012 to September 2016. FE9 indicated that on October 28, 2016 he had written notes in his iPhone of "every unethical marketing practice" Depomed had engaged in because he had thought at the time he might need this information in the future. In the ensuing discussion, FE9 read from his iPhone and then explained what his notes meant.

137. FE9 made notes on his iPhone about Depomed's improper marketing. FE9 read from his iPhone that NUCYNTA had "less than 1% euphoria" and that this was to be told by the sales personnel to prescribers as applicable for all indications even though this was only supported by a study involving low back pain. FE9 said that there were not studies to support this low euphoria claim for other types of pain. As FE9 put it, "that's off-label."

138. The next note FE9 read was that NUCYNTA had "no street value" and that it was safe and "not really a Schedule II" drug. FE9 explained the context of this particular note. He said that Depomed had Regional Account Managers who "did managed care" and had in-depth knowledge about drug coverage. As a sales representative, FE9 would sometimes have a Regional Account Manager accompany him as "an expert to talk about coverage" and had done so during a lunch meeting with a potential prescriber. During this particular meeting, the Regional Account Manager – Kristen Knight – had told the prescriber that NUCYNTA had no street value and was not really a Schedule II drug. FE9 had asked her after the meeting where she had heard this and she told him she had heard it at a speaker program. Knight worked at Depomed for four years, first as a Senior Regional Account Manager beginning May 2015; and then as a Director of National Accounts beginning December 2016.

139. The following note that FE9 read pertained to low rates of withdrawal and euphoria with the implication being that NUCYNTA "shouldn't be Schedule II" FE9 indicated that sales representatives used this as a "wink-wink, nod-nod" implication that was based on the low withdrawal rates set forth in the lower back study. This was a comparison of data points that could be used to suggest that NUCYNTA was safe.

140. The next note FE9 read related to Depomed's off-label marketing of using NUCYNTA ER and IR together. FE9 stated that note read that NUCYNTA ER and NUCYNTA IR

could be used together because the only reason they could not be used together was because their joint use had not been studied. While elaborating, FE9 indicated that his District Manager Breakstone said that the sales representatives were to say that many doctors *were* using NUCYNTA ER and NUCYNTA IR together. FE9 said that Breakstone indicated that while there was not a study saying the two drugs could be used together there also was not any study that said they could not be used together. As FE9 put it, this was taking "the inverse to say it was OK" to use the two drugs together.

141. The next note FE9 read indicated that although Nucynta IR did not have a defined indication for Diabetic Peripheral Neuropathy, Nucynta IR was "the same molecule" as Nucynta ER which *did* have the DPN indication and therefore Nucynta IR could be used for DPN. He expanded on this to say that Depomed did not have any company materials indicating that Nucynta IR could be used to treat "flare ups and neuropathic pain" but that Depomed was nonetheless saying that both ER and IR could be used for this kind of pain. He said this was another "wink-wink, nod-nod" insinuation about acute, short-acting neuropathic pain, which he said is "the giant elephant" that Depomed apparently used when there were "guardrails" that ostensibly prevented such claims being made. FE9 explained that in essence, Nucynta ER and Nucynta IR had the same molecule and even though Nucynta IR had not been studied for the neuropathic pain indications, since Nucynta ER "had passed" (i.e., could be used for these indications), "so, why not IR?"

142. He next read a note that indicated reps were to use the low back study's claim of an overall very low rate of constipation for Nucynta ER and use the low constipation rate "regardless of the condition" for which Nucynta ER was being prescribed – i.e., not just for low back pain. But FE9 said that representations about drugs are "supposed to be held to the condition of the study" and that Depomed was seeking to "muddy waters" and make the low constipation rate claim no matter what the patient's condition was.

143. Depomed's public statements and website corroborate the former employees' representations that Depomed pushed NUCYNTA as a safer, less abusive, and less euphoric opioid.

144. Defendants' statements, website, and allegations from former employees show that the off-label marketing of NUCYNTA was not an isolated incident, rather, it was a widespread campaign put forward to maximize sales.

Depomed Promoted NUCYNTA Off-Label by Pushing Higher Dosages of NUCYNTA

145. NUCYNTA ER's label specifically states, under "Dosage and Administration" to a) "Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals;" b) "Initiate the dosing regimen for each patient individually, taking into account the patient's severity of pain, patient response, prior analgesic treatment experience, and risk factors for addiction, abuse, and misuse;" and c) "Initiate treatment with NUCYNTA ER with the 50 mg tablet orally twice daily (approximately every 12 hours)." Despite these clear instruction on NUCYNTA ER's label, based on Depomed's public statements, Depomed had a firm wide policy or practice to market and promote higher dosages of NUCYNTA regardless of the patient's severity of pain and other relevant factors, and to market a starting dose of 100 milligrams twice a day (instead of the 50 milligrams indicated by NUCYNTA's label).

146. Defendants admit that "proper dosing" was one of its "four pillars" to NUCYNTA's growth. Throughout the Class Period Defendants make reference to their marketing campaign. For example, on the July 29, 2015 earnings call, Schoeneck indicated that "The fourth opportunity for sales growth is proper dosing of NUCYNTA. This is another new observation we've had since we've taken over the brand. Here are the basic numbers. The average dose of NUCYNTA ER used by patients in the clinical trials for low back pain was approximately 400 milligrams per day. Yet when we look at the average doses in the marketplace, there are currently between 200 milligrams and 250 milligrams. We believe that education focused on proper titration can improve both the physician and patient experience with the product and we also feel it has the potential to increase sales by 50% or more as patients towards doses most often seen in the clinical trials."

147. Defendants also admit that they made these statements at speaker events and directly to physicians. For example, on the November 9, 2015 earnings call, Schoeneck states, "The average dose of NUCYNTA ER used by patients in the clinical trials for low back pain was approximately 400 milligrams per day, yet the average dose in the marketplace is between 200 and 250 milligrams.

We have been clarifying these points with physicians and believe that this message is resonating, as evidence by comments from speakers at Pain Week and in the field." Additionally, Moretti stated on November 18, 2015 at the Stifel Heathcare Conference, "So we -- ***through both the sales force, but most importantly in our peer-to-peer marketing and our speaker programs***, we have focused on the fact that increasing the dosing . . .".

148. Former employees also indicate that Depomed improperly promoted NUCYNTA off-label by pushing sales representatives to indicate to prescribing physicians that it was okay to prescribe NUCYNTA in higher dosages, and to start NUCYNTA ER at 100mg twice a day.

149. FE5 worked as a Sales Representative at Depomed from June 2014 – February 2018 in the Eugene, Oregon territory. FE5 was hired directly by Depomed and never worked for Quintiles. FE5 was responsible for selling the complete portfolio of Depomed products, with a quota of 90% NUCYNTA products. FE5 reported to his District Sales Manager Chris Cooper who had been responsible for Oregon, Washington, and possibly Idaho in a region referred to as Seattle-Cascades. Cooper reported to Jeff McCutcheon, who had been the regional sales director for the Western US. McCutcheon had reported first to National Sales Director Steve Greco and then to Ron Menezes. Both Greco and Menezes would have reported to whoever was CEO at the time – either Schoeneck or Arthur Higgins, depending on the time frame.

150. FE5 affirmed that Depomed engaged in off-label marketing. For example, FE5 stated that during a Depomed sales team meeting that he believed was in Dallas, Depomed told sales representatives to push NUCYNTA at higher starting doses than was approved on the label. FE5 stated that Janssen promoted prescribing NUCYNTA ER at 50 mg doses twice a day, but that the Depomed sales representatives were told by their Regional Directors that they should recommend that NUCYNTA ER be prescribed at 100mg doses twice a day. FE5 indicated that this was definitely "off-label" in regards to the recommended dosage.

151. FE5 remembered being told about recommending the increased dosage at a breakout session by his Regional Director (Chris Cooper) at the sales meeting and thinking at the time that this was "illegal."

152. FE5 explained that breakout meetings entailed each District Manager meeting with the sales reps who reported to that District Manager. He estimated there were around 15 breakout rooms available for the different districts. He thinks the other District Managers communicated to their teams the same message that Cooper had conveyed. As best FE5 could recall, this directive was issued around when NUCYNTA was launched by Depomed or just a little while after the launch. FE5 believes that whatever the District Managers conveyed about recommending an increase in the NUCYNTA ER dosage was based on a directive that had been conveyed to them from "upper management."

153. FE7 worked at Depomed, as a Senior Specialty Neuroscience/Pain Specialist from June 2014 – February 2018. FE7 stated that he had been assigned to four different territories over the course of his three and a half year tenure, to include separate stints focusing on pain practices and cancer practices, although he spent most of his time in San Antonio and Houston.

154. FE7 reported to Regional Manager Jaime Nassar who reported to Jeff McCutcheon who reported to Steve Greco. According to FE7 Greco was replaced by Ron Menezes who proceeded to hire Kevin Cotton to replace Nassar who ended up getting terminated. FE7's products included the NUCYNTA line.

155. FE7 confirmed FE5 statements. When asked about the sustainability of NUCYNTA sales without relying on off-label marketing, FE7 answered that "what [FE5] said" about increasing the recommended dosage of Nucynta ER from 50 mg twice daily to 100 mg twice daily "is true." FE7 said that recommending the dosage increase began in January 2017, but then said it had been happening before then as well.

156. Additionally, NUCYNTA ER's label states: "Discontinue all other tapentadol and tramadol products when beginning and while taking NUCYNTA ER." However, as indicated by FE9, Depomed told its sales team that that taking NUCYNTA IR and ER together was safe.

157. FE9 read a note related to Depomed's off-label marketing of using NUCYNTA ER and IR together. FE9 stated that the note read that NUCYNTA ER and NUCYNTA IR could be used together because the only reason they could not be used together was because their joint use had not been studied. While elaborating, FE9 indicated that his District Manager Breakstone said that the

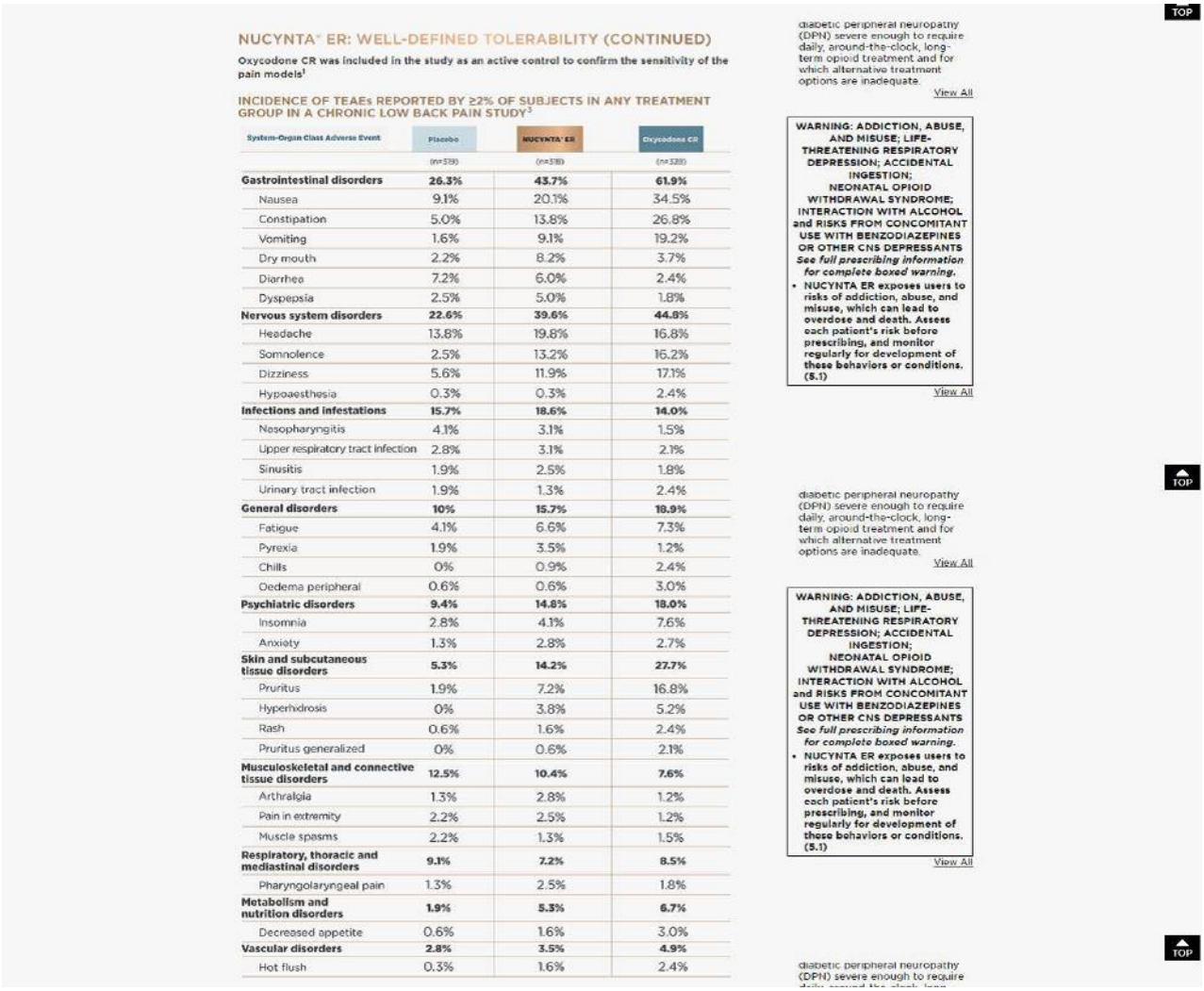
sales representatives were to say that many doctors *were* using NUCYNTA ER and NUCYNTA IR together. FE9 said that Breakstone indicated that while there was not a study saying the two drugs could be used together there also was not any study that said they could not be used together. As FE9 put it, this was taking "the inverse to say it was OK" to use the two drugs together.

158. Defendants' statements during the class period, combined with the former employees recollection, show that Depomed had a companywide policy to push dangerous and unapproved levels of NUCYNTA to the market.

Depomed Promoted NUCYNTA Off-Label by Using a Side By Side Comparison to a Competitor

159. NUCYNTA's labels indicated, "Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice."

160. Despite this clear instruction on NUCYNTA's label, that is exactly what Depomed did. Specifically, Depomed published on their website a study directly comparing rates of NUCYNTA ER to Oxycodone CR. The study is attached to the Complaint as Exhibit C, and incorporated by reference. A portion of the study is included below:



NUCYNTA® ER: WELL-DEFINED TOLERABILITY (CONTINUED)

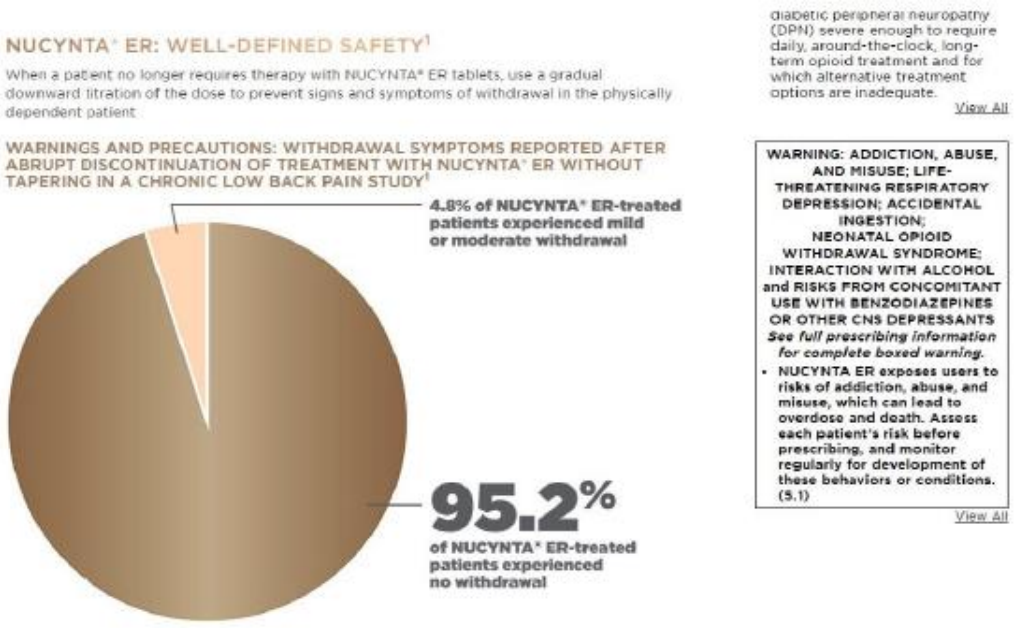
Oxycodone CR was included in the study as an active control to confirm the sensitivity of the pain models[1]

INCIDENCE OF TEAEs REPORTED BY ≥2% OF SUBJECTS IN ANY TREATMENT GROUP IN A CHRONIC LOW BACK PAIN STUDY[3]

System-Organ Class Adverse Event	Placebo (n=519)	NUCYNTA® ER (n=518)	Oxycodone CR (n=528)
Gastrointestinal disorders	**26.3%**	**43.7%**	**61.9%**
Nausea	9.1%	20.1%	34.5%
Constipation	5.0%	13.8%	26.8%
Vomiting	1.6%	9.1%	19.2%
Dry mouth	2.2%	8.2%	3.7%
Diarrhea	7.2%	6.0%	2.4%
Dyspepsia	2.5%	5.0%	1.8%
Nervous system disorders	**22.6%**	**39.6%**	**44.8%**
Headache	13.8%	19.8%	16.8%
Somnolence	2.5%	13.2%	16.2%
Dizziness	5.6%	11.9%	17.1%
Hypoaesthesia	0.3%	0.3%	2.4%
Infections and infestations	**15.7%**	**18.6%**	**14.0%**
Nasopharyngitis	4.1%	3.1%	1.5%
Upper respiratory tract infection	2.8%	3.1%	2.1%
Sinusitis	1.9%	2.5%	1.8%
Urinary tract infection	1.9%	1.3%	2.4%
General disorders	**10%**	**15.7%**	**18.9%**
Fatigue	4.1%	6.6%	7.3%
Pyrexia	1.9%	3.5%	1.2%
Chills	0%	0.9%	2.4%
Oedema peripheral	0.6%	0.6%	3.0%
Psychiatric disorders	**9.4%**	**14.8%**	**18.0%**
Insomnia	2.8%	4.1%	7.6%
Anxiety	1.3%	2.8%	2.7%
Skin and subcutaneous tissue disorders	**5.3%**	**14.2%**	**27.7%**
Pruritus	1.9%	7.2%	16.8%
Hyperhidrosis	0%	3.8%	5.2%
Rash	0.6%	1.6%	2.4%
Pruritus generalized	0%	0.6%	2.1%
Musculoskeletal and connective tissue disorders	**12.5%**	**10.4%**	**7.6%**
Arthralgia	1.3%	2.8%	1.2%
Pain in extremity	2.2%	2.5%	1.2%
Muscle spasms	2.2%	1.3%	1.5%
Respiratory, thoracic and mediastinal disorders	**9.1%**	**7.2%**	**8.5%**
Pharyngolaryngeal pain	1.3%	2.5%	1.8%
Metabolism and nutrition disorders	**1.9%**	**5.3%**	**6.7%**
Decreased appetite	0.6%	1.6%	3.0%
Vascular disorders	**2.8%**	**3.5%**	**4.9%**
Hot flush	0.3%	1.6%	2.4%

161. The off-label side by side study referenced above shows NUCYNTA ER (middle) being compared to a placebo (left) and Oxycodone CR (right). This study directly compares NUCYNTA ER to Oxycodone in violation of the label's instructions. As this study was not approved by the FDA for marketing purposes. The promotion of this study was off-label.

162. The study continued by showing a pie chart of NUCYNTA's "well-dined safety":



163. On March 23, 2016, Depomed admitted to using this study to promote NUCYNTA a safer and more tolerable. For example, at Depomed's Analyst and Investor Day held by Depomed, Depomed's Chief Commercial Officer stated: "And just some of the different messages; the uniqueness of the molecule, the fact that both the mu and the norepinephrine reuptake inhibitor, powerful efficacy that's coming across here ***with well-documented and a solid tolerability and safety profile***. ***And a very important thing that we've been able to communicate is that if the product is discontinued, 95% of these patients will not experience withdrawal, and that's a far better statistic than all other long-acting opioids have, and that infers a lot of good things about the product to physicians***."

164. In addition to publishing the study on the website, Depomed also gave the study to its sales representatives to distribute directly to physicians, and gave the study to its speakers to promote NUCYNTA off-label. These allegations are corroborated by former employees of Depomed.

165. When asked if the sales representatives were told to promote that NUCYNTA ER was safer, less addictive and less subject to abuse than other opioids, FE5 answered affirmatively. FE5 also said there was some data made available to sales representatives as part of their "marketing insert" for NUCYNTA ER.

166. FE5 recalled that there had been a study which represented that approximately 93% - 95% of patients who had used NUCYNTA ER did not experience any withdrawal. While this shows that NUCYNTA ER as being less prone to abuse by patients, FE5 said this was "really not the case." FE5 gave an example of an instance where he used this study and got "called out" by a doctor who had been selected as a speaker for Depomed. This doctor pointed out that the Oxycodone arm in the study that Depomed was citing showed that something like 91% of Oxycodone users did not suffer from withdrawal. FE5 stated that the doctor's point was that if Oxycodone was showing a relatively low rate of withdrawal for its users, this did not validate a low addictive risk for NUCYNTA ER given Oxycodone's well-known addictiveness. FE5 could not immediately recall the name of the study at issue, but noted that after a while this claim was removed from the marketing insert. The specific term for the marketing insert was "Comprehensive Visual Aid" or "CVA".

167. Plaintiffs in this action sent FE5 the study attached to the Complaint and featured above. FE5 confirmed that this was definitely the item to which he had been referring. He said it was "the exact piece" (and that whoever had obtained the item "nailed it") that the physician referenced in the original interviews had called out. More precisely, FE5 said the piece should be referred to as a "Comprehensive Visual Aid" or CVA, and was not a package insert. The CVA would have been approved by Depomed's corporate office for use by the sales reps.

168. FE5 indicated that when looking at the study that the efficacy of the NUCYNTA molecule was not meant to be comparative to Oxycodone, although it is still necessary to "measure efficacy against something other than a placebo." FE5 indicated that citing the study in the NUCYNTA package insert was a way to establish efficacy, but that the study result was "not comparative" between NUCYNTA and Oxycodone. FE5 believes that if a doctor had really studied the package insert they could have gleaned this distinction. However, he does not think this was the case with the "sales aid" which was the main information piece that "we gravitated to". As best FE5 could remember, the sales aid did not include this distinction even "in the fine print."

169. FE5 explained that a package insert is a more substantive "sales aid" than a pharmaceutical "slim jim" and is spiral-bound "8x14" "story book" about a given pharmaceutical product. FE5 explained that a package insert was inside the slim-jim (perhaps as a folded piece of

paper) and that every piece of marketing material had its own separate package insert to support it. In explaining what a "slim-jim" is (which was the term used internally at Depomed and also at numerous other pharmaceutical companies), FE5 said this was information about a given drug (e.g., NUCYNTA) that provided a "condensed version" of what was set forth in the Comprehensive Sales Aid used by the sales reps (and which was different from the CVA). To promote NUCYNTA ER, the sales representatives were supposed to follow what was in their "package insert" and "tell the story" of the drug: "here's the efficacy, side-effects" but according to FE5 this would not be the main emphasis when making presentations to prescribers. Instead, FE5 said that sales representatives would represent to the prescribers that "what we really show is here is 90% of patients having no withdrawal." FE5 said that physicians tend to "talk out of both sides of their mouth" when it comes to addictiveness of opioids because they would go ahead and prescribe bigger doses but might believe there was a lower risk in doing so because of the study.

170. In regards to the sustainability of NUCYNTA sales, FE7 said that the sales went "really downhill" when Greco was fired and replaced by Menezes. When asked if NUCYNTA sales had included off-label marketing, FE7 said, "yes, I can't lie." When asked for details regarding the nature of the off-label marketing of NUCYNTA, FE7 said that one of the main forms of off-label marketing was "that piece" (i.e., study) "that FE5 told you about" regarding NUCYNTA patients not experiencing withdrawals.

171. When asked about Depomed's study on NUCYNTA ER, FE8 indicated that he "vaguely remembers" this and that the study was "something about people stopping cold turkey" from opioid use and the percentage that experienced withdrawal symptoms. As he recalled, this claim came from a study in which people had been cut off "cold turkey". His recollection was that the percentage of users experiencing withdrawal was supposed to be lower with NUCYNTA than it had been with other opioids, like OxyContin.

172. FE8 indicated that he believed that this was "legally allowed" to be said, because it had been approved by Depomed's legal department, so he assumed it was permissible to say. FE8 indicated that during sales calls he would talk about the study and what the study said, but if he were

asked if the study meant something one way or another, his stock answer was that "the data is what it is" and that the questioner needed to draw his or her own conclusions.

173. FE8 would say whatever the withdrawal rate was per the study and if someone questioned him whether NUCYNTA was safer, he would answer that he could not speak to that. But he thinks that Depomed was trying to infer without actually saying it that NUCYNTA was safer because of the dual receptor. He said this went back to the "just for your information" types of presentations during the sales training meetings.

174. FE9 also read a note related to the study. FE9 stated that his last note pertained to NUCYNTA and according to FE9 was "a big one". As FE9 explained, there had been a "head to head trial" comparing Oxycodone and NUCYNTA ER. His note and recollection were not completely clear to him at this point, but as best he could recall, while the two drugs were being compared to one another, the study had not completely compared them "at every measure and point." FE9 indicated he was not totally sure at this point what exactly had been problematic about the study, but said that Oxycodone had been used as "an active control" but should not have been used to compare efficacy for pain relief.

175. In connection with the above comparison, Depomed also uses the following side by side graph to show the comparison between NUCYNTA and Oxycodone, and that NUCYNTA is safer than Oxycodone CR:

176. The fact that Depomed included on the label that they could not show adverse reactions side by side to a competitor, but gave its sales representatives marketing inserts doing this exact thing, shows that this was a companywide policy by Depomed to promote NUCYNTA off-label as safer, less abusive, and more tolerable than other opioids, specifically Oxycodone CR.

177. This study was Depomed's way to show physicians that NUCYNTA was safer and less abusive than other opioids, without directly stating so. Accordingly, Depomed promoted NUCYNTA off-label by using the above study as a market insert and on its website.

H. *Evidence that the Off-Label Promotion of NUCYNTA was a Widespread Marketing Campaign Pushed by Defendants and Not an Isolated Incidence*

178. Depomed promoted its branded opioids, including NUCYNTA, and NUCYNTA ER, through its sales representatives and a particularly active speakers program. Deceptive messages

regarding low addiction risk and low prevalence of withdrawal symptoms were a foundation of this marketing campaign. Depomed also conveyed other misrepresentations including that its opioids could safely be prescribed at higher doses and were safer than alternatives such as NSAIDs.

179. Depomed supplemented these efforts with its own unbranded website, as well as third-party publications and a Front Group website, to promote opioids for the treatment of chronic pain. These materials likewise made deceptive claims about addiction risk, safety at higher doses, and the safety of alternative treatments.

Depomed Pressured Sales Representatives to Promote NUCYNTA Off-Label

180. Depomed encouraged a culture where sales representatives were required to do anything possible to meet their quota. Engaging in off-label marketing was routinely encouraged and often required. To do this, representatives often targeted primary care physicians who were not as knowledgeable as pain specialists and encountered a more diverse group of patients, not all who were in chronic pain.

181. Depomed's sales force was compensated based on the number of NUCYNTA prescriptions written in each sales representative's territory. Depomed encouraged these sales representatives to maximize sales of NUCYNTA and meet their sales targets by relying on the false and misleading statements described above.

182. For example, Depomed's sales force was trained to trivialize addiction risk. During the very time Depomed was instructing its sales force to trivialize the risks of addiction and withdrawal associated with the use of NUCYNTA to treat chronic pain, it knew that significant numbers of patients using opioids to treat chronic pain experienced issues with addiction.

183. The compensation to Depomed's sales representatives for the deceptive messages they were promoting to increase sales of NUCYNTA and NUCYNTA ER, were directly tied to how many of these prescriptions were written by the doctors. These doctors were listed on the quarterly call plans they received from district managers, along with how many doctors or clinics in the assigned zip codes prescribed the drugs that they were being asked to sell. Family practices and internal medicine doctors made up a large percentage of the call plan targets for opioids, since, as

noted above, these generalists were less knowledgeable about opioids and more likely to fall victim to sales representatives' misrepresentations.

184. Depomed's sales representative were instructed to push the envelope when selling its prescription medications, such as NUCYNTA ER by stressing that NUCYNTA ER didn't hit receptors like other opioids so it was less addictive and had fewer withdrawal issues; to promote NUCYNTA and NUCYNTA ER as a safer alternative to nonsteroidal anti-inflammatory drugs; and, when discussing side effects related to NUCYNTA and NUCYNTA ER, to focus only on nausea, itchy skin, and vomiting. Depomed's sales representatives told physicians that they could prescribe higher doses of NUCYNTA ER because its mechanism works differently than other opioids; that Depomed's opioids can improve their patients' ability to function in their lives and enable them to get off workers' compensation or work pain-free; and, the physicians were provided various books, articles, and pamphlets as handouts by Depomed's sales representatives.

185. Depomed's sales representative were required to attend regional "Plan of Action" meetings several times a year, usually at a hotel or conference facility. These meetings would include presentations regarding the marketing of Depomed's drugs, including NUCYNTA and NUCYNTA ER. Based on the uniform character of Depomed's marketing, Depomed's sales representatives would have received the same sales training and made the same misrepresentations.

186. Depomed's sales representatives used a number of KOLs in support of its efforts to sell NUCYNTA and NUCYNTA ER. Based on the uniform and nationwide character of Depomed's marketing, these speakers were trained to deliver the misleading messages described above to prescribers.

187. Depomed's sales representatives promoted NYUCYNTA and NUCYNTA ER as safe and effective for the long-term treatment of chronic pain and told physicians that drugs like Tylenol kill the liver, thus, its medications were cleaner by comparison since they did not attack the organs.

188. Depomed's sales representatives were trained to tell prescribers that its medications such as NUCYNTA and NUCYNTA ER did not offer the same euphoric feeling as other opioids. It was common for Depomed's sales representatives to downplay the addictive nature of its medications such as NUCYNTA and NUCYNTA ER.

189. The misleading messages and materials Depomed provided to its sales force were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, irrespective of the risks, benefits, and alternatives.

190. This culture was corroborated and discussed in detail by Depomed's former employees as described below.

191. According to FE2, Depomed paid its sales force based on volume increases, meaning the more NUCYNTA that flooded the market, the higher the payouts. It would be volume, for sure," he said, referring to payment incentives. "We were being convinced it was safer opioids. It's funny – they were very cautious in how they chose their words because everybody was being sued for mixed marketing. You can't say to the doctor, 'It doesn't have street value.'" However, FE2 indicated that was "the overall consensus that was being told to us."

192. FE2 also said that Depomed constantly exerted pressure on its sales force to maintain and exceed sales expectations of NUCYNTA. "If we're not out there selling NUCYNTA, we're not going to have jobs." According to FE2, the pressure often came through subtle insinuations instead of direct mandates. "Just insinuation – if we want to keep this company going, NUCYNTA is our flagship." FE2 said management told employees, "What do you take it as? If you want your job, you keep selling."

193. FE3 indicated that it was clear to him that the company was pushing its sales force to move NUCYNTA. "We had quotas," he said. "Everybody had a quota. Everything was based on semesters. You would get new quotas, usually they were unobtainable working in Massachusetts. You tried your best. You were aiming to get so much of your quota so you could get your bonus."

194. Additionally, FE5 indicated that Depomed monitored the top prescribers of opioids and that he was assigned the top ten to fifteen prescribers of opioids in his region. In addition he indicated that he would also try and call on other physicians and prescribers besides those that he was assigned. FE5 said that the number of prescribers he called on varied quarter to quarter because Depomed would "reshuffle the deck" every quarter in regards to who he should call on and that at any given time he might be calling on ten to 25 of the top opioid prescribers. The prescribers also changed as FE5 successfully developed prescribers and therefore did not need to call on them.

195. FE5 stated that between 2015 through 2016, he and the other Depomed sales representatives "had definitely" been targeting primary care physicians. However, FE5 stated that once the new CDC guidelines were released, primary care physicians wrote fewer prescriptions, and instead referred their patients to pain clinics. FE5 stated that his quotas may have been around 100 NUCYNTA IR and ER prescriptions in a month, and that his NUCYNTA ER quota was probably 20-30 a week and 80-100 a month.

196. FE6 stated that he called on pain management practices, primary care physicians who were already prescribing a lot of opioids, nurse practitioners, and "anyone" in his region who was already prescribing opioids. When asked if primary care physicians were sufficiently knowledgeable about opioids, he said that in his experience in pharmaceutical sales, many primary care physicians are "so busy" that it's "go-go to the next patient" and they are "not totally educated."

197. FE6 indicated that for a lot of the products that Depomed sold the sales representatives were ostensibly "pushed to say" what the drugs were indicated for, but that when they were talking to doctors and if they were able to get an understanding of a particular patient the prescriber was treating, then they might make other representations. For instance, he said that Depomed's Gralise product was only indicated for post-neuralgia. However, Gralise competed against Lyrica (a competitor drug) which had more indications than Gralise. The Depomed sales representative would tell doctors that if they were to use Gralise they would see the same results as with Lyrica even though it had more indications than Gralise. And according to FE6 "with NUCYNTA it was the same thing" – i.e., that at Depomed it was "anything" to get prescribers "to put pen to pad."

198. FE6 indicated that as a sales representative, "you try to survive" and act ethically, but many times he wondered how Depomed could "get away with it." FE6 stated that many times as a sales representative, "you can't do anything" because reporting problematic conduct does not always result in companies taking appropriate actions. For example, FE6 said he had made a report about one of his Depomed managers, but Human Resources did nothing about it. He said that speaking up when a company engages in problematic conduct can result in getting "blackballed" in the pharmaceutical industry.

199. FE6 stated that "at the end of the day if you weren't saying" NUCYNTA was less addictive, the sales representative would not be directly written up for this omission, but instead, the employee's evaluation would say that the sales representatives sales were not where they needed to be and instead of receiving a rating of five (apparently the highest rating), the employee would receive a rating of 2.5 or 3.0.

200. FE6 stated that when Golino would accompany him in his visits to the prescribers and observe how he conducted himself, she might say to him if he had not made the representations about NUCYNTA being less addictive that his numbers needed to be higher. Occasionally, Golino would indicate that the prescriber had patients using Oxycodone and those patients "could be ours" and that FE6 could tell the prescriber that patients were not asking for NUCYNTA as they did for Oxycodone.

201. As a Pain Sales Specialist, FE8 had represented NUCYNTA ER and IR, as well as Gralise, but not the other drugs in Depomed's portfolio. His territory had been comprised of part of Connecticut, as well as Rhode Island. He said the quotas were based on the number of prescriptions of the drugs he represented (as opposed to a monetary amount) and each drug had its own quota.

202. FE8 said that Higgins "really had no ideas on how to get sales moving" and "no game plan" beyond telling employees to "just do it" (i.e., increase sales). Instead, FE8 indicated that the only way Higgins could motivate the sales force was through "fear and intimidation." FE8 recalled how at one meeting Higgins had enjoined the sales force that they needed to have "fortitude" but at the conclusion of the same talk said that if personnel did not meet their sales quotas many of them would be laid off. FE8 also stated that while Higgins may not explicitly threaten termination, it was "pretty implied" if one "read between the lines" of what Higgins said. FE8 stated that this threat had made it very unpleasant to work at the company. In the case of Menezes, FE8 said Menezes "didn't know what he was doing" and took actions that were very disruptive of the sales force. As FE8 pointed out, in 2016, prior to Menezes and Higgins coming on the scene, Depomed had been doing reasonably well, but Menezes made various changes to the sales force, including how promotions were awarded and how territories were assigned.

203. This cultivated culture by Depomed to use fear, bonuses, and intimidation to move NUCYNTA encouraged sales representatives to do anything to sell NUCYNTA, including engaging in off-label marketing.

Depomed Incentivized Speakers to Promote and Prescribe NUCYNTA Off-Label

204. Depomed did not stop at disseminating its misleading messages regarding chronic opioid therapy through its sales force. It also hired speakers to promote its drugs and trained them to make the very same misrepresentations made by its sales representatives.

205. Specifically, one of Depomed's "four pillars" to increase NUCYNTA sales was "significantly increased promotion." On September 16, 2015 at the Morgan Stanley Healthcare Conference, Schoeneck stated that "[w]e've already had speaker programs that have included even 1,000 people last week at a meeting called PAINWeek." Unbeknownst to investors, this included large payments to physicians to promote NUCYNTA off-label, and to induce them to write NUCYNTA prescriptions.

206. As a façade for this arrangement, Depomed conducted speaker programs that were actually vehicles for paying monies to physicians under the guise of honoraria. These financial benefits were offered with the understanding that, in exchange, the physicians would preferentially prescribe or indicate the use of NUCYNTA to treat their patients.

207. According to https://openpaymentsdata.cms.gov, Depomed made over $4.1 million in payments to physicians relating to speaker engagements alone in 2017, over $2.6 million in 2016, and over $3.2 million in 2015. The following chart shows the amount paid in "general expenses to physicians between 2015-2017:

	2017	2016	2015
Speaking, training, and education engagements that are not for continuing education.	$4,153,677.32	$2,695,125.00	$3,259,750.00
Food and beverage	$767,109.70	$770,253.90	$692,501.92
Travel and lodging	$562,089.99	$445,133.69	$536,567.07
Consulting	$67,900.00	$360,096.25	$231,703.75

Education	$3,436.60	$3,181.06	$14,639.92
Total:	$5,554,213.61	$4,276,289.90	$4,735,162.66

208. These payments were given to speakers as an incentive to promote NUCYNTA off-label and as an incentive to get physicians to write more NUCYNTA prescriptions.

209. Through Depomed's speaker programs, physician speakers were ostensibly paid to speak at ongoing speaking engagement events to educate other doctors and health care professionals about NUCYNTA. In practice, however, Depomed's speaker program exists to induce physicians to increase the quantity of NUCYNTA prescriptions they write.

210. Specifically, Depomed offered ongoing speaker positions to pain management physicians, whom it deemed "high writers" - physicians writing five or more prescriptions per month. These speaking arrangements usually consisted of dinners with colleagues.

211. The qualifications of the physicians hired as speakers by Depomed demonstrate that its speaker program was nothing more than a mechanism to facilitate kickbacks in return for writing NUCYNTA prescriptions. The criteria used to determine which physicians to offer speaker positions depended primarily upon the volume of NUCYNTA prescriptions written.

212. And, because Depomed's focus was on rewarding high writers and not on actually educating, Depomed did not screen speakers based on academic or clinical accomplishments.

213. Where a speaker's curriculum vitae ("CV") was relatively unspectacular, Depomed would simply not provide it to the speaker's "audience." In one example, a high writer/speaker's CV was never circulated before his speaking engagements because he attended Guadalajara Medical School, a school that was not prestigious enough.

214. FE6 explained that the physicians selected as speakers were supposed to be "KOL" [key opinion leaders] and influential amongst their peers. However, Hardiman, Golino, and another district manager – Steve Roman – told FE6 that a criterion for a physician who wanted to become a speaker was to tell them that they had to write prescriptions of Depomed products. FE6 was told to ask the physicians how they could expect to be speakers of NUCYNTA if they had not used the products. To the extent that FE6 told any physicians this, he was told to say that this was not coming

from him but was what his manager had said. For instance, FE6 would say something like, "I know you want to be a speaker, here's what you need to do."

215. FE6 estimated that speakers were paid approximately $1,000 - $1,500 depending on whether it was a dinner or lunch presentation. FE6 indicated that at first, there was no number of prescriptions that a prospective speaker needed to write, but in time FE6 would be asked by his managers, "why is your guy not writing?" FE6 explained that in order for a physician to be considered as a speaker, a "ballpark" estimate of what would be an acceptable number of prescriptions for the physician to write was perhaps 60 a week, whereas perhaps FE6's physician who wanted to be a speaker was only writing five a week. FE6 felt this requirement of a physician becoming eligible to be a paid speaker for Depomed based on writing prescriptions likely crossed an ethical line, but he emphasized that he was not the one making this a requirement – as he put it, his managers were "telling me to tell" the physicians they needed to write more if they wanted to become a speaker.

216. FE7 told a story in which two sales representatives set up a speaking engagement for Dr. Ellen Lin at a sushi restaurant. FE7 indicated that the attendees at the event were not pain doctors, but included a family practitioner and a neurologist who was a friend of Dr. Lin's. FE7 emphasized that the event had very little to do at all with Depomed products and that when Dr. Lin spoke she showed at most "maybe only a couple slides" related to Depomed, but the event was being paid for by Depomed's speaker program. Instead, the event was mostly to promote the association that Dr. Lin wanted to form and for which she would be the head. FE7 said that having Depomed pay for this event was "illegal" because the presentation should have been focusing on Depomed's drugs, not Dr. Lin's association. FE7 stated that his problem was that Dr. Lin was his top prescriber so he did not know how to handle the situation. FE7 stated that that even though Depomed had paid for the event, the event had served no legitimate educational function, but instead had been a way to keep Depomed in "Dr. Lin's good graces."

217. This shows that Depomed paid physicians to get in their good graces and to incentivize them to write NUCYNTA prescriptions.

218. The speakers above were also incentivized to promote NUCYNTA off-label. According to FE6, his speakers used the official slide-deck and package insert data provided by Depomed. As shown above, this study was not approved by the FDA, and therefore, its use in marketing was off-label.

219. Given Depomed's extremely high payments and incentives to physicians, in addition to its policy to only use speakers with a high percentage of NUCYNTA prescriptions, Depomed incentivized physicians to prescribe NUCYNTA off-label, as well as promote NUCYNTA off-label during speaker arrangements.

Fueling an Epidemic Study

220. Depomed's efforts were not limited to directly making misrepresentations through its sales force, speaker's bureau, and website. To avoid regulatory constraints and give its efforts and appearance of independence and objectivity, Depomed obscured its involvement in certain of its marketing activities by "collaborat[ing] with key patient advocacy organizations" to release misleading information about opioids.

221. On March 28, 2017, Senator McCaskill announced that she was commencing the Senate Investigation into the marketing and sales practices of the nation's top five manufacturers of prescription opioid products, including Depomed. According to a statement by Senator McCaskill, "[the] investigation is about finding out whether the same practices that led to this [opioid] epidemic still continue today, and if decisions are being made that harm the public health." In letters to the manufacturers, Senator McCaskill further stated that "[t]his epidemic is the direct result of a calculated sales and marketing strategy major opioid manufacturers have allegedly pursued over the past 20 years to expand their market share and increase dependency on powerful—and often deadly—painkillers . . . [t]o achieve this goal, manufactures have reportedly sought, among other techniques, to downplay the risk of addiction to their products and encourage physicians to prescribe opioids for all cases of pain and in high doses."

222. In response to Senator McCaskill's Senate investigation, on February 12, 2018, the Senate Homeland Security and Governmental Affairs Committee released a second minority staff report of the "Fueling an Epidemic" series titled, "Exposing the Financial Ties Between Opioid

Manufacturers and Third Party Advocacy Groups." This report discussed the relationship between Depomed and advocacy groups and professional societies operating in the area of opioid policy.

223. The report provides a comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies in the area of opioids policy. The study found that manufacturers of opioids, including Depomed, provided millions of dollars to groups that echoed and amplified messages favorable to increased opioid use. The groups also issued guidelines and policies minimizing the risk of opioid addition and promoting opioids for chronic pain, lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for over prescription and misbranding. Notably, a majority of these groups also strongly criticized the 2016 guidelines from the CDC that recommended limits on opioid prescriptions for chronic pain.

224. The report found that "[t]he fact that these same manufacturers provided millions of dollars to the groups described below suggests, at the very least, a direct link between corporate donations and the advancement of opioids friendly messaging. By aligning medical culture with industry goals in this way, many of the groups described in this report [including Depomed] may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic." Additionally, the report found that these groups that were paid by in part by Depomed, "amplified messages favorable to increased opioid use."

225. According to the study, between January 2012 and March 2017, the five opioid manufacturers featured in the report, including Depomed, contributed nearly $9 million to leading patient advocacy organizations and professional societies operating in the opioids policy area. Specifically, the companies provided at least $8,856,339.13 in funding to 14 outside groups working on chronic pain and other opioid-related issues between January 2012 and March 2017. Despite only owning NUCYNTA from 2015 – 2017, Depomed had the third highest payments of these five companies, totaling $1,071,116.95. As noted by the report, after Depomed acquired NUCYNTA, Depomed more than tripled its payments to the advocacy groups featured in this report in 2015 relative to 2014, and the payments total for 2016—$318,257.47—remained steady compared to the 2015 total. Depomed's payment of $350,000 in 2015 is almost three times the amount spent by

Janssen in 2014 for the promotion of NUCYNTA. Out of the over $1 million in payments made by Depomed, 69.9% of those payments came between 2015-2017, this was after Depomed's acquisition of NUCYNTA.

226. Additionally, Depomed attempted to hide many payments requested. For example, only after receiving additional correspondence did Depomed report five additional responsive payments—totaling $17,600 to the American Chronic Pain Association and $28,174.95 to the Academy of Integrative Pain Management. According to Depomed, these payments "were for advertising or promotional purposes," and the company initially considered them outside the scope of the March 28, 2017, requests.

227. Out of the almost $9 million in payments, the U.S. Pain Foundation received the largest amount of payments during the 2012–2017 period—almost $3 million. The Academy of Integrative Pain Management, formerly the American Academy of Pain Management, received $1,265,566.81 in donations—the second-highest total—followed closely by the American Academy of Pain Medicine with $1,199,409.95 in payments. The American Academy of Pain Medicine Foundation also received $304,605 in payments from Depomed alone during this period.

228. In addition, Dr. Charles Argoff, current president of the American Academy of Pain Medicine Foundation, received over $600,000 in payments from opioid manufacturers between 2013 and 2016, with Depomed paying him over $55,000 for NUCYNTA engagements for 2015-2016.[3]

229. In 2016, the current President of the American Academy of Pain Medicine, Dr. Steven Stanos, received over $30,000 in payments with over 28% of those payments coming directly from Depomed for NUCYNTA engagements.

230. National Pain Foundation chairman and founder Dr. Daniel Bennett also received compensation relating to NUCYNTA in 2016.

231. In addition, at least half of the members of the National Pain Foundation Clinical and Scientific Advisory Council have received general payments—totaling more than $7,900,000—from opioid manufacturers between 2013 and 2016. Manufacturer payments to all individuals affiliated

[3] https://projects.propublica.org/docdollars/doctors/pid/93628

with the National Pain Foundation total more than $8,000,000 since 2013—by far the largest total for the groups profiled in the report.

232. According to the HSGAC report, these doctors and companies that received payments directly from Depomed in connection with NUCYNTA, have amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain. Several groups have also lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for over prescription and misbranding.

233. On March 15, 2016, the CDC issued guidelines providing prescribing recommendations for "primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care."

234. In 2016 the immediate past president of the American Academy of Pain Medicine, Daniel Carr, criticized the prescribing guidelines, stating "that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence." Similarly, several advocacy groups criticized draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliations, and conflicts of interest of the individuals who participated in the construction of these guidelines." Dr. Richard Payne, a physician affiliated with the Center for Practical Bioethics, made a similar argument, criticizing the CDC guidelines as the product of "conflicts of interests in terms of biases [and] intellectual conflicts"—while himself maintaining "financial links to numerous drug companies."

235. The Washington Legal Foundation also strongly criticized the guidelines on procedural grounds, claiming CDC had developed its guidelines in an "overly secretive manner" and in violation of the Federal Advisory Committee Act, which called "into question the viability of the entire enterprise." The Washington Legal Foundation claimed, moreover, that "[s]tate governments and the medical community are unlikely to accept any guidelines tainted by charges that they were prepared in secret without meaningful stakeholder input."

236. When the CDC published its final opioid prescribing guidelines, Richard A. Samp, Washington Legal Foundation general counsel, reportedly believed the guidelines "were inherently biased, crafted by people who already had strong views about what opioid policy should look like."

237. The HSGAC report found that "the fact that these groups registered their opposition while receiving funding from the opioids industry raises the appearance—at the very least—of a direct link between corporate donations and the advancement of opioids-friendly messaging." Relatedly, in a March 2017 article published in JAMA Internal Medicine, researchers from Johns Hopkins University and Brandeis University examined industry payments to over 150 organizations that had submitted comments on the draft CDC guidelines. After coding guideline comments by supportiveness and reviewing financial disclosures, including annual reports, tax returns, and self-reported information, researchers found "opposition to the guidelines was significantly more common among organizations with funding from opioid manufacturers than those without funding from the life sciences industry."

238. Accordingly, a "major concern is that opposition to regulatory, payment, or clinical policies to reduce opioid use may originate from groups that stand to lose financially if opioids sales decline." In an extended version of their findings, the researchers are more explicit: "[O]pposition to more conservative opioid use may, at least in part, be financially motivated."

239. McCaskill's report also details a troubling lack of transparency surrounding the advocacy organizations. Due to their classification under the U.S. tax code, the groups profiled in the report have no obligation to disclose their donors publicly. As a result, each group maintains different levels of transparency regarding its financial connections to the pharmaceutical industry and has no obligation to publicly disclose their funding sources. These organizations have the ability to selectively disclose donors, donations, and other support - or no information at all. No organization profiled in McCaskill's report provides an online list linking donors, their specific donations, and the projects or events benefiting from each donation for each of the years between 2012 and 2017. McCaskill said, "The financial relationships between these groups and opioid manufacturers should be clear to the general public." "We passed a law ensuring the public had

information on payments to doctors by pharmaceutical companies, and I can't imagine why the same shouldn't be done in this space."

Depomed Hired Quintiles, the Same Sales Team that Previously Promoted NUCYNTA Off-Label

240. Additional evidence that Depomed engaged in a widespread off-label marketing campaign is the fact that Depomed hired Quintiles, the same marketing team that marketed NUCYNTA off-label for Janssen. NUCYNTA has a long history of its manufacturer claiming off-label benefits in their sales pitches and marketing. For example, Janssen promoted its branded opioids, including Duragesic, NUCYNTA, and NUCYNTA ER, through its sales representatives and a particularly active speakers program. Deceptive messages regarding low addiction risk and low prevalence of withdrawal symptoms were a foundation of this marketing campaign. Janssen also conveyed other misrepresentations, including that its opioids could safely be prescribed at higher doses and were safer than alternatives such as NSAIDs.

241. Janssen supplemented these efforts with its own unbranded website, as well as third-party publications and a Front Group website, to promote opioids for the treatment of chronic pain. These materials likewise made deceptive claims about addiction risk, safety at higher doses, and the safety of alternative treatments. They also claimed that opioid treatment would result in functional improvement, and further masked the risk of addiction by promoting the concept of pseudoaddiction.

242. Janssen sales representatives visited targeted physicians to deliver sales messages that were developed centrally and deployed identically across the country. These sales representatives were critical in transmitting Janssen's marketing strategies and talking points to individual prescribers. In 2011, at the peak of its effort to promote NUCYNTA ER, Janssen spent more than $90 million on detailing.

243. Janssen knew that there was no credible scientific evidence establishing that addiction rates were low among patients who used opioids to treat chronic pain. There is no evidence that NUCYNTA is any less addictive or prone to abuse than other opioids, or that the risk of addiction or abuse is low. Similarly, Janssen knew that there were severe symptoms associated with opioid withdrawal including, severe anxiety, nausea, vomiting, hallucinations, and delirium, but Janssen touted the ease with which patients could come off opioids.

244. These allegations were at the forefront of the City of Chicago Complaint. The City of Chicago Complaint was brought by Fiona A. Burke, Michael J. Dolesh and Mary Eileen Cuniff Wells of the Chicago Law Department in Chicago, Jason M. Bradford and Jeffrey D. Coleman of Jenner & Block in Chicago, Linda Singer and Joshua D. Glickman of Cohen, Milstein, Sellers & Toll PLLC in Washington, D.C., and Michael A. Scodro of the Illinois Attorney General's Office in Chicago. The City of Chicago Complaint states that "between 2009 and 2012, NUCYNTA and NUCYNTA ER sales representatives repeatedly promoted these drugs as less addictive than other opioids. For example, Janssen sales representatives described NUCYNTA as 'not an opioid' to one Midwestern internist at least twice in 2010. Similarly, a sales representative told a Midwestern physician that NUCYNTA was 'nonopioid yet opioid like' in 2011." Further, the City of Chicago interviewed a number of sales representatives from Quintiles that promoted NUCYNTA off-label.

245. Sales "Representative E," who worked in Janssen's Midwest Region (the Regional Manager had offices in Naperville, Illinois), was instructed to push the envelope when selling NUCYNTA ER and ***stress that NUCYNTA ER didn't hit receptors like other opioids so it was less addictive and had fewer withdrawal issues***. She also promoted NUCYNTA and NUCYNTA ER as a safer alternative to NSAIDs and, when discussing side effects related to NUCYNTA and NUCYNTA ER, she focused on nausea, itchy skin, and vomiting. ***She told physicians that they could prescribe higher doses of NUCYNTA ER because its mechanism works differently than other opioids.***

246. Sales "Representative G," whose territory included the suburbs northwest of Chicago, recalled selling NUCYNTA and NUCYNTA ER. She promoted NUCYNTA and NUCYNTA ER as safe and effective for the long-term treatment of chronic pain and told physicians that drugs like Tylenol kill the liver and that NUCYNTA and NUCYNTA ER were cleaner by comparison and did not attack the organs.

247. Sales "Representative H," who also worked in Janssen's Midwest Region, recalls selling NUCYNTA and NUCYNTA ER. ***She recalls being trained to say that NUCYNTA and NUCYNTA ER did not offer the same euphoric feeling as other opioids***. She also recalled referring prescribers to a YouTube video that asserted that NUCYNTA was more difficult to crush than other

pills, making it less likely to be abused or diverted. Representative H believed that it was common for Janssen sales representatives to downplay the addictive nature of NUCYNTA and NUCYNTA ER.

248. The City of Chicago also interviewed a number of Prescribers who were visited by Janssen sales representatives marketing NUCYNTA. "Prescriber C," as referred to in the City of Chicago Complaint, stated that Janssen, routinely omitted any discussion about addiction and overdose death and frequently overstated the benefits of opioids. These representatives taught that opioids would increase his patients' ability to function and increase their quality of life. Janssen's sales representatives also falsely stated that NUCYNTA was not being abused.

249. "Prescriber D" stated that representatives from Janssen said their drugs were '"steady state," which he interpreted to mean that they were less addictive.

250. "Prescriber B," an anesthesiologist, sees opioid drug company representatives on a regular basis, and he has seen representatives from Janssen. These representatives pushed the message that "steady-state" drugs have less potential for abuse. Further, he relies on the representations made by drug company representatives because he does not have the time to conduct his own research.

251. "Prescriber AA" indicated that she was visited by sales representatives from Janssen. She was detailed by this sales representative once a month for 6 months to a year. This sales representative marketed NUCYNTA to Prescriber AA, but not as an opioid. The City of Chicago Complaint states that, instead, Prescriber AA was told that NUCYNTA was an alternative to opioid therapy and ***that it worked on an alternate receptor***. This sales representative explained that NUCYNTA would be appropriate for chronic pain patients who were unable to continue opioid therapy due to excessive side effects. Further, the Janssen sales representative also told Prescriber AA that NUCYNTA didn't have a risk of addiction, unlike opioids, and that it would improve her patients' function

252. Many of the above statements are the same techniques used by Depomed, and the claims made by the prescribers that happened at Janssen are corroborated by the claims of the former employees cited herein. This shows that Depomed continued these off-label practices.

253. Depomed purchased NUCYNTA from Janssen in April 2015 despite Janssen's on-going litigation with the City of Chicago for the improper off-label marketing of NUCYNTA. On June 10, 2016, Depomed filed a Form 8-K/A stating that "Janssen has been named in a number of lawsuits alleging claims related to opioid marketing practices." Additionally, as stated by Schoeneck, Depomed had "significant insight" into NUCYNTA marketing prior to purchasing NUCYNTA in April 2015. Further, Defendants knew that the FDA-approved label for NUCYNTA contained no information about NUCYNTA being safer, more tolerable, less addictive, or less abusive than alternative opioids, and knew they could not market NUCYNTA this way.

254. On June 23, 2015, Moretti stated that "[a]lthough not in the label there's a very low abuse profile and side effect rate." Additionally, Schoeneck stated on March 14, 2016, "The addiction profile is thought to be better. I can't make a claim around that because we don't actually have that in the label." In February 2017, Schoeneck also announced that Depomed was "initiating label enhancement studies, aimed at further differentiating NUCYNTA by highlighting its respiratory depression and abuse potential profile. These labeling studies will focus on the properties of the tapentadol molecule, and its uniqueness in the pain marketplace." The purpose of this was to "be able to get it hopefully into the label." Further, Higgins on May 9, 2017 stated that Depomed was "looking to strengthen our label."

255. Despite knowing that Janssen was being sued for the off-label marketing of NUCYNTA and that it was illegal to promote NUCYNTA off-label, Defendants hired Quintiles, the same sales team Janssen used, to promote NUCYNTA at Depomed.

New Government Complaints Show that Depomed Engaged in Off-Label Marketing

256. At least thirty-eight opioid lawsuits have been filed against Depomed between March 2018 and December 2018. Many of these allegations show that Depomed engaged in off-label marketing and directly contributed to the opioid crisis.

257. These opioid lawsuits include:

a) *City of Rome, et al. v. Purdue Pharma L.P., et al.*, Case No. 4:18-cv-00052-MHC, filed March 2, 2018 in the U.S. District Court for the Northern District of Georgia,

transferred to the U.S. District Court for the Northern District of Ohio, Case No. 1:18-op-45282-DAP;

b) *State of Arkansas, et al. v. Purdue Pharma, L.P., et al.*, Case No. CV 2018-268, filed March 15, 2018 in the Circuit Court of Crittenden County, Arkansas;

c) *Family Practice Clinic of Booneville, Inc., et al. v. Purdue Pharma L.P., et al.*, Case No. 6:18-cv-00087-GFVT, filed March 21, 2018 in the U.S. District Court for the Eastern District of Kentucky, transferred to the U.S. District Court for the Northern District of Ohio, Case No. 1:18-op-45390-DAP;

d) *Medical Mutual of Ohio v. Purdue Pharma, L.P., et al.*, Case No. 1:18-op-45307-DAP, First Amended *Complaint* filed April 26, 2018 in the U.S. District Court for the Northern District of Ohio;

e) *Philadelphia Federation of Teachers Health and Welfare Fund v. Endo Pharmaceuticals, Inc., et al., Case* No. 180403891, filed April 26, 2018 in the Court of Common Pleas, Philadelphia County, Pennsylvania;

f) *Fiscal Court of Owen County, Kentucky v. Purdue Pharma L.P., et al.*, Case No. 1:18-op-45534-DAP, filed May 4, 2018 in the U.S. District Court for the Northern District of Ohio;

g) *Fiscal Court of Bourbon County, Kentucky v. Purdue Pharma L.P., et al.*, Case No. 1:18-op-45533-DAP, filed *May* 4, 2018 in the U.S. District Court for the Northern District of Ohio;

h) *Jay Brodsky v. Purdue Pharma L.P., et al.*, Case No. CV18-2788, filed May 7, 2018 in the U.S. District Court for the Eastern District of New York;

i) *County of Bexar v. Purdue Pharma L.P., et al.*, Case No. 2018-CI-08728, filed May 10, 2018 in the District Court of *Bexar* County, Texas, 224th Judicial District;

j) *Gwinnett County, Georgia v. Purdue Pharma L.P., et al.*, Case No. 1:18-cv- 02078-ELR, filed May 11, 2018 in the U.S. *District* Court for the Northern District of Georgia;

k) *Clark County v. Purdue Pharma, L.P., et al.*, Case No. A-17-765828-C, First Amended Complaint filed May 16, 2018 in the District Court, Clark County, Nevada;

l) *Iron Workers District Council of Philadelphia and Vicinity, Benefit Fund v. Abbott Laboratories, Inc., et al.*, Case No. *180502442*, filed May 23, 2018 in the Court of Common Pleas, Philadelphia County, Pennsylvania;

m) *County of San Patricio v. Purdue Pharma L.P., et al.*, Case No. S-18-5625CV-A, filed June 28, 2018 in the District Court *of* San Patricio County, Texas, 36th Judicial District;

n) *County of Nueces, et al. v. Purdue Pharma L.P., et al.*, Case No. 2018CCV-61176-4, filed July 3, 2018 in the Nueces Law Court of *Nueces* County, Texas;

o) *Village of Herkimer, New York v. Purdue Pharma, L.P., et al.*, Case No. 6:18-cv-00797-GLS-TWD, filed July 5, 2018 in the U.S. District Court for the Northern District of New York;

p) *Bon Secours Health System, Inc. Our Lady of Bellefonte Hospital, Inc., et al. v. Purdue Pharma L.P. et al.*, Case No. 1:18-op-45819-DAP, filed July 11, 2018 in the U.S. District Court for the Northern District of Ohio;

q) *Bon Secours Health System, Inc. Bon Secours-Richmond Community Hospital, Inc., et al. v. Purdue Pharma L.P., et al.*, Case No. 1:18-op-45820-DAP, filed July 12, 2018 in the U.S. District Court for the Northern District of Ohio;

r) *Bon Secours Health System, Inc. Bon Secours-St. Francis Xavier Hospital, Inc., et al. v. Purdue Pharma L.P., et al.*, Case No. 1:18-op-45821-DAP, filed July 12, 0218 in the U.S. District Court for the Northern District of Ohio;

s) *Bon Secours Health System, Inc. and Bon Secours Hospital Baltimore, Inc. v. Purdue Pharma L.P., et al.*, Case No. 1:18-op-45822-DAP, filed July 12, 2018 in the U.S. District Court for the Northern District of Ohio;

t) *City of Covington, Kentucky v. Purdue Pharma, L.P., et al.*, Case No. 2:18-cv- 00131-GFVT, filed July 24, 2018 in the U.S. District Court for the Eastern District of Kentucky;

u) *Jefferson County, et al. v. Purdue Pharma L.P., et al.*, Case No. 1822-CC10883, filed August 1, 2018 in the Missouri Circuit Court, Twenty-Second Judicial District;

v) *Tucson Medical Center v. Purdue Pharma L.P., et al.*, Case No. C20184213, filed August 22, 2018 in the Superior Court *of* the State of Arizona, Pima County;

w) *Davis County v. Purdue Pharma L.P., et al.*, Case No. 18070080, filed August 28, 2018 in the Second Judicial District *Court*, Davis County, State of Utah;

x) *City of Reno v. Purdue Pharma, L.P., et al.*, Case No. CV18-01895, filed September 18, 2018 in the Second Judicial *District* Court of the State of Nevada, Washoe County;

y) *Fiscal Court of Wolfe County, Kentucky v. Purdue Pharm L.P., et al.*, Case No. 1:18-op-46099-DAP, filed September 26, *2018* in the U.S. District Court for the Northern District of Ohio;

z) *Fiscal Court of Lee County, Kentucky v. Purdue Pharma L.P., et al.*, Case No. 1:18-op-46100-DAP, filed September 26, *2018* in the U.S. District Court for the Northern District of Ohio;

aa) *City of Syracuse, New York v. Purdue Pharma, L.P., et al.*, Case No. 5:18-cv-1184 (GTS/DEP), filed October 1, 2018 in the U.S. District Court for the Northern District of New York, transferred to the U.S. District Court for the Northern District of Ohio, Case No. 1:18-op-46169-DAP;

bb) *Terry Robertson v. Mallinckrodt PLC, et al.*, Case No. 1822-CC11422, filed October 15, 2018 in the Missouri Circuit Court, Twenty-Second Judicial District;

cc) *Western Pennsylvania Electrical Employees Insurance Trust Fund v. Endo Pharmaceuticals, Inc., et al.*, Case No. 181002038, filed October 16, 2018 in the Court of Common Pleas, Philadelphia County, Pennsylvania;

dd) *Iron County v. Purdue Pharma, L.P., et al.*, Case No. CV180500149, filed October 26, 2018 in the Fifth Judicial District Court, Iron County, Utah;

ee) *Carroll County v. Purdue Pharma, L.P, et al.*, Case No. 3:18-cv-00131-TCB, filed November 2, 2018 in the U.S. District Court for the Northern District of Georgia, transferred to the U.S. District Court for the Northern District of Ohio, 1:18-op-46269;

ff) *San Juan County v. Purdue Pharma L.P., et al.*, Case No. 180700011, filed November 6, 2018 in the Seventh Judicial *District* Court, San Juan County, Utah;

gg) *Grand County v. Purdue Pharma L.P., et al.*, Case No. 180700040, filed November 8, 2018 in the Seventh Judicial *District* Court, Grand County, Utah;

hh) *Millard County v. Purdue Pharma L.P., et al.*, Case No. 180700044, filed November 9, 2018 in the Fourth Judicial *District* Court, Millard County, Utah;

ii) *Sanpete County v. Purdue Pharma L.P., et al.*, Case No. 180600095, filed November 13, 2018 in the Sixth *Judicial* District Court, Sanpete County, Utah;

jj) *City of Utica, New York v. Purdue Pharma, et al.*, Case No. 6:18-cv-01394-BKS-ATB, filed November 30, 2018 in *the* U.S. District Court for the Northern District of New York;

kk) *Appalachian Regional Healthcare, Inc. v. Purdue Pharma, et al.*, Case No. 18-CI-00512, filed December 5, 2018 in the Circuit Court, Perry County, Kentucky; and

ll) *Nichole Poleski v. Mallinckrodt PLC, et al.*, Case No. 1822-CC11898, filed December 20, 2018 in the Missouri Circuit Court, Twenty-Second Judicial District.

258. The above lawsuits allege that Depomed engaged in an intentional and deceptive marketing campaign to promote the use of prescription opioids, including NUCYNTA, and that their conduct has resulted in a national epidemic of opioid overdose deaths and addictions.

259. These lawsuits also allege that Depomed engaged in a deceptive marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain by: a) downplaying the serious risk of addiction; b) creating and promoting the concept of "pseudoaddiction" by advocating that signs of addiction should be treated with more opioids; c)

exaggerating the effectiveness of screening tools to prevent addiction; d) claiming that opioid dependence and withdrawal are easily managed; e) denying the decreased effectiveness of opioids over long-term use and the corresponding need for increased dosages; and f) exaggerating the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction.

260. The lawsuits allege that Depomed made these materially false representations directly to doctors and patients through advertising campaigns and "detailers" (sales representatives who directly targeted doctors).

261. They further allege that Depomed marketed their products indirectly to avoid FDA scrutiny and regulation. They allege that Depomed did this through seemingly unbiased and independent third parties, including KOLs (seemingly independent doctors) and professional societies and patient advocacy groups ("Front Groups") funded in part by Depomed. They also allege that Depomed used "unbranded advertising" (promoting the general use of opioids without naming a specific drug) and manipulated published promotional materials about opioids in scientific literature to avoid FDA regulation and to give the false appearance that these were independent organizations outside of the Depomed's control.

262. These lawsuits corroborate statements made by former employees as detailed herein.

I. *Defendants Made Material Misrepresentations Related to Depomed's Off-label Marketing of NUCYNTA and Depomed's Sensitivity to the Opioid Headwinds*

263. During the Class Period, Defendants, including Depomed, Schoeneck, Moretti, and Higgins materially misrepresented NUCYNTA's susceptibility to the opioid headwinds, and Depomed's marketing and promotional practices relating to NUCYNTA's label.

Material Misrepresentations Related to the Opioid Headwinds

264. Depomed represented that NUCYNTA was uniquely positioned to combat the negative public sentiment against opioids. For example, on a May 5, 2016 earnings call, Defendant Schoeneck described to investors that NUCYNTA had "different properties than the other opioids, particularly when it comes to the kind of activity that the CDC and others are most concerned about" and that "there'll be relatively little impact on [Depomed] compared to where some other companies may fall in at."

265. Additionally, on Depomed's August 3, 2016 earnings call, Schoeneck, stated: "During the first full year after our relaunch, we delivered $274 million of total NUCYNTA net sales, an increase of 59% over the final year of sales under the previous owner. NUCYNTA ER prescriptions continued to accelerate in June, up 26% over the prior year and achieving all-time high prescription volume and market share. And this is against a backdrop of challenging opioid market conditions that see declining prescriptions for the overall market and other leading brands. We are also encouraged by the positive NUCYNTA IR trends, with May and June showing a 2% prescription volume increase year-over-year, reversing the 10% decline seen before our re-launch. ***We believe that our flagship franchise is well-positioned for continued growth.***"

266. These statements were materially false. In reality, the opioid headwinds were heavily affecting NUCYNTA prescriptions because NUCYNTA was a Schedule II opioid subject to the same laws and regulations as other opioids. Physicians, and especially primary care physicians were hesitant to prescribe NUCYNTA due to its Schedule II status as a highly addictive and abused opioid. As discussed by Depomed's former employees, as alleged herein, Depomed was just as susceptible to the headwinds as other opioid products.

267. FE1 stated that he and other sales representatives were aware that Depomed's sales of NUCYNTA were not meeting company expectations as early as January 2016 – just seven months after the product launched. FE1 said the company convened its sales force for a national POA (plan of action) conference at the Hilton Anaheim in Anaheim, California that commenced on January 24, 2016. Both her bosses, David Sims and a sales representative named Jamie Dunham were at that meeting. According to FE1, also in attendance was then-CEO James Schoeneck and Steve Greco, Depomed's then-vice president of sales.

268. FE1 indicated that he "heard them [Schoeneck and Greco] speak." FE1 didn't "think NUCYNTA was doing as well as they hoped at that time." FE1's recollection was "they weren't doing as well as Depomed had hoped, and I'm almost certain, and that was addressed at the POA."

269. FE1 indicated that general knowledge of the downturn in sales among employees "was a given." FE1 stated that at the meeting they "did a lot of role-playing for NUCYNTA to tighten up our message, so we could move numbers and get scripts."

270. FE1 said he believes hearing some officials specifically outline why NUCYNTA wasn't selling as well as hoped. He believes one of the reasons he heard the official outlining for concern at the national meeting was "because [NUCYNTA] had greater potential."

271. FE1 also said he believed another point discussed was the amount of money Depomed spent to acquire NUCYNTA. Asked whether there concern that the company might not recoup its investment, FE1 said: "Yes."

272. FE2 stated that less than a year after Depomed bought NUCYNTA, FE2 and other sales representatives began to worry – in part, because of the growing national discourse on opioids, and in part, because of how focused Depomed's survival became on NUCYNTA'S success.

273. Accordingly to FE2, "the sales people knew the ship was sinking." "I'd say six to eight months after we bought it [NUYCYNTA]. All you had to do was open up a paper and realize the opioid market was in trouble. [Yet] we're sitting here, saying, 'The business is great!'"

274. FE2 stated that "we were all thinking that the company was going down owning an opioid. You weren't going to recoup your money. That's why I got out."

275. According to FE2, Depomed paid its sales force based on volume increases, meaning the more NUCYNTA that flooded the market, the higher the payouts. It would be volume, for sure," he said, referring to payment incentives. "We were being convinced it was safer opioids. It's funny – they were very cautious in how they chose their words because everybody was being sued for mixed marketing. You can't say to the doctor, 'It doesn't have street value.'" However, FE2 indicated that was "the overall consensus that was being told to us."

276. FE2 also said that Depomed constantly exerted pressure on its sales force to maintain and exceed sales expectations of NUCYNTA. "If we're not out there selling NUCYNTA, we're not going to have jobs." According to FE2, the pressure often came through subtle insinuations instead of direct mandates. "Just insinuation – if we want to keep this company going, NUCYNTA is our flagship." FE2 said management told employees, "What do you take it as? If you want your job, you keep selling."

277. Despite a growing negative perception of opioids, FE2 said during his time promoting NUCYNTA, his sales goals were never adjusted, or lowered, based on a reflection of a downturn in

demand. "No, no, no, no!" he said. "We were still constantly being told that it's the flagship, and you've got to keep the business going."

278. FE2 also talked about the change in management from Schoeneck to Higgins. FE2 stated that Depomed doubled-down on the pressure exerted on its sales force once Schoeneck was forced to resign in March 2017.

279. FE2 described what occurred when CEO Arthur Higgins was named as Schoeneck's replacement. "He was more, 'You better get your asses out there pushing this drug, or the company's not going to be around.'"

280. FE2 recalled a corporate retreat, the President's Trip, in April 2017 where the top 10-to-15 percent of the entire sales force was gifted a trip to the Grand Caymans. Higgins was introduced as the new CEO during that event. FE2 stated, "[Higgins], pretty much the first night we met him, was – he pretty much came up there, this is the top 10 percent, 15 percent of your sales team, [Higgins said,] 'If you're not out there working harder and selling more medication then this company is going to go under, and I'm pretty much here to fix what the other people screwed up.'"

281. FE2 stated that the downturn in prescriptions of NUCYNTA was noticeable to him and other employees. "Obviously enough that they got rid of Jim [Schoeneck] and brought someone else in, and brought someone in to be the hatchet man," he said.

282. FE2 said he based the sales drop, and the company's knee-jerk reaction to it, on "the perception of opioids, and just what's going on with the market, and the fact that we owed so much money for this opioid, and we weren't going to recoup our money."

283. FE3 said when he started with Depomed, he was well aware of the growing national concern with opioid medications. According to FE3 however, at no time did Depomed seem concerned about the industry or the possibly negative perception of such drugs as NUCYNTA.

284. FE3 stated, "Everybody said we were doing really good, but I didn't think we were. We weren't getting a lot of scripts from orthopedics. I know a lot of the orthopedics were burnt the first go-round with Janssen."

285. FE3 stated that despite the negative headwinds, Depomed seemed confident in its opioid product NUCYNTA, in particular, because the company was promoting NUCYNTA

internally as an opioid that didn't present the same kind of reaction as street level opioids. Despite the company's messaging, FE3 said it was evident, at least to him, that NUCYNTA was not being embraced the way the company touted. "NUCYNTA was not a gangbuster. I just remember being very disappointed," he said. "I worked so hard to get it going again, and it was not taking off. Then we lost coverage."

286. FE4 stated the company was being driven by a downturn in sales of NUCYNTA around the time that Schoeneck was ousted. "There was definitely a sense of urgency," he said. "There was absolutely a sense of urgency with NUCYNTA, the whole portfolio, to right the ship. I don't know the ship was listing that much. It was just a difficult time in the market, (the) opioid crisis. I say that with air quotes. I don't think Depomed or Starboard were prepared for the challenges that would come with the opioid market."

287. Despite the growing negative headwind nationally toward opioid products, FE4 stated that there was surprisingly little discussion about the overall 'epidemic,' or its ramifications, internally. FE4 said he wasn't terribly surprised most people kept quiet – after all, NUCYNTA was not considered the same as other medications in the opioid market.

288. FE4 said that the sales downturn, coupled with the national discourse on opioids, never became a 'talking point' internally. "Not proactively," he said. "Candidly, when you would have some side-conversations with people in the executive team, I would bring it up, or others would bring it up, and they would minimize the concern. It was never anything discussed proactively at any level."

289. When asked to whom he spoke on the executive team about the issues, FE4 said: "It would vary from regional managers to Ron Menezes, Scott Shively, to people in marketing, people in training. Augie [August Moretti] was always quiet. He was there if he had to raise his hand and say 'here,' but in terms of being accessible to the sales team, it was not very often. Jim [Schoeneck] was approachable. You could go up to him and discuss things. He was very positive about the opportunity."

290. FE5 stated that the decline in NUCYNTA ER prescriptions coincided with a change in CDC guidelines for so-called "morphine dosage equivalents". Essentially, the new CDC

guidelines "squashed" the dosage rate for morphine equivalents so low as to be at an "almost non-therapeutic" level. At that point, the emphasis went from NUCYNTA ER to NUCYNTA IR, which he called "a crazy move" because Depomed was now trying to compete against Oxycodone, but this was not where the "market is at" in regards to opioids, nor could NUCYNTA IR compete effectively against Oxycodone (or Vicodin).

291. FE5 knew about the drop-off in prescriptions because graphs were distributed to the sales reps showing the prescription activity in their territories and which would show "where I was losing or gaining" in terms of prescriptions. FE5 only received such graphs for his territory, but he would talk to the other reps in the District. As he explained, the District was comprised of ten reps, "so we talked" and "the general belief" was that the new CDC guidelines for morphine equivalent dosages was responsible for the decline in opioid prescribing activity. Oregon and Washington were "hit hard" by the new regulations. As he put it, "Doctors were moving away" from opioids because they did not want to prescribe non-therapeutic doses (per the new guidelines), but also did not want to jeopardize their patients' lives. This was at least the case amongst primary care physicians.

292. FE8 also talked about the opioid headwinds. FE8 cited increasing regulatory hurdles for opioid prescribing that he anticipated would make it difficult for him to achieve his quotas. FE8 said that a lot of doctors were losing their licenses and were fearful of legal retaliation for prescribing opioids. The regulatory changes for opioids had begun in Vermont, followed by Rhode Island and Connecticut. Overall, the pharmaceutical pain market was in "double-digit freefall" even as Higgins increased the sales quotas by 10%.

293. FE8 said the changing regulatory environment was clearly having a negative impact on NUCYNTA prescriptions because the overall market for opioids had a double digit recline in sales percentages going into 2017. But even as the opioid market had clearly retracted, Depomed increased the quotas for the sales reps by 10% over what they had achieved in 2016, which FE8 said was simply "crazy". Furthermore, FE8 said that even if the opioid market had not been declining, the quotas for 2017 were still too high and not attainable. FE8 noted that if the market had been growing and/or stable then the 10% quota increases were "maybe obtainable". But in a declining market, with the media proclaiming an opioid crisis, and the associated scrutiny of opioid

prescribing, to include doctors being arrested, then Depomed senior management were "out of their minds" to increase the quotas. The "long-term sustainability was not there". And in his opinion, Depomed senior management should have held a stockholder meeting in which they acknowledged these realities (e.g., market decline, regulatory hurdles and so forth) and then adjust and reduce the company's forecast. In his opinion, Depomed would have been in a better position if they had done this.

294. FE8 had thought to himself that he was doing OK with his sales, but he had wondered for how much longer he could do so. For instance, Rhode Island had imposed some of the strictest opioid regulations in the country on the heels of Vermont doing so, so Rhode Island had become very limited as an opioid market. FE8 said that Rhode Island was only allowing for a five-day prescription of Percocet following surgery whereas before surgeons had been prescribing upwards of one to two months of whatever their favorite pain product happened to be. In FE8's view, increasing the quotas in 2017 was "sheer desperation" on the part of Depomed management because Starboard Value wanted profits for the company, but they were "in over their heads" (including trying to bring a new drug to market).

295. FE8 stated that Depomed's management were not reacting to the opioid market, which was shrinking because of increased regulations. According to FE8, the management "didn't want to hear" that certain state regulations were making it very tough to prescribe opioids, even though these market shifts were well understood at the local level. FE8 also explained that there were "people like me" who voiced their opinions up the reporting chain about these matters. However, FE8 said that the response at Depomed was "crickets" (i.e., nothing). FE8 said that most companies will try to come up with a solution when there are negative matters raised by personnel, but this was not the case at Depomed.

296. FE10 was employed from September 2011 to February 2017 by Depomed as a Specialty Sales Representative, based in the company's Evansville, Indiana office. Around the June 2015 launch of NUCYNTA, FE10 began reporting to Depomed District Sales Manager David Sims, who had been hired by Depomed because he previously worked with NUCYNTA as a contract sales representative when it was owned by Janssen.

297. FE10 said it was clear almost immediately following NUCYNTA's launch in June 2015 that the drug was not performing and selling as well as Depomed officials had hoped. FE10 stated, "NUCYNTA had already been on the market by J&J. It was doing decently, but not great."

298. Asked how soon after the launch Depomed realized NUCYNTA was not doing as well as promised, FE10 said: "Pretty much right off the bat." Asked whether that indication come from his own experience, from other sales reps or from the corporate home office, FE10 said the lagging sales indicators were "coming from corporate."

299. FE10 explained that with any sales campaign, once a company realizes that its sales force is not hitting established quotas then it knows its sales quota projections are not reflective of market demand. With NUCYNTA, he said, it was clear early on that Depomed's sales goals were unrealistic. Depomed responded by adjusting its goals. "After they realized that reps were not going to be making any bonus money, they retooled the incentive compensation formula so we would be able to make some money on selling NUCYNTA," FE10 said.

300. According to FE10, the fact that Depomed had to go back and revise its quota goals so soon after the launch was a clear indicator that the drug was not selling as expected. "The sales numbers and the realization that, yeah, they had to redo everybody's sales goals," he said.

301. FE10 did recall hearing Schoeneck and/or Greco address the issue. FE10 stated "That was no surprise for Jim or Steve to say, 'We're not hitting our goals. We need to do better.' It would have been at the national meetings. That was pretty much the only time you heard Jim or Steve."

302. FE10 recalled hearing about NUCYNTA's lagging sales during at least one national sales meeting stating, "We were told at national meetings we needed to do better because we weren't hitting goals." FE10 stated that the lagging sales performance was a weekly topic on the district sales calls. FE10 stated that "Weekly district calls, we would talk about goals and how far we were from them." Accordingly to FE10, every month during his tenure, sales representatives would receive evidence that the company's actuals were far removed from its projections. FE10 stated that "Every time we got new sales figures, every month, we could see individually how far we were from goals."

303. FE10 said Depomed did not make any adjustments to its marketing and/or sales strategy for NUCYNTA, even as the national perception of opioids became more negative. FE10 stated that "It did make our jobs harder because state legislators would change the laws and make it harder for family practitioners and family physicians to write opioids."

304. The statements made by Defendants were shown to be false on November 7, 2016, and August 7, 2016 when Depomed significantly decreased guidance due to the opioid headwinds. As stated by Higgins on August 7, 2016, NUCYNTA "is clearly not immune to these developments." This revealed to the market that as a Schedule II opioid, NUCYNTA was just as susceptible to the opioid headwinds as its competitors.

Misrepresentations related to Defendants' widespread Off-label Marketing Campaign

305. While instructing Depomed's sales team to promote NUCYNTA off-label, Defendants made material misrepresentations to investors regarding Depomed's marketing strategy. Throughout the Class Period Depomed described its marketing strategy. Defendants routinely told investors of its "four pillars" to increase NUCYNTA prescription growth. For example, on Depomed's July 29, 2015 earnings call, Schoeneck stated: "There are four key elements to our NUCYNTA plan: one, significantly increased promotion, two, totally revamped product positioning and messaging, three, pricing and access strategies to maximize the brand and this is new, four, proper dosing. Each has an impact on our sales ramp and the ultimate peak sales potential for NUCYNTA." Schoeneck continued stating in pertinent part: "First, promotion. The key component of our strategy is the strength of our sales and marketing force"; "Our medical and marketing activities have ramped up as well"; "The fourth opportunity for sales growth is proper dosing of NUCYNTA"; and "We've changed the NUCYNTA message to focus on the product's dual mechanisms of action and different patient types."

306. Additionally, on Depomed's November 9, 2015 earnings call, Schoeneck stated: "There are four pillars that we have identified as the keys to NUCYNTA's growth: promotion, positioning, patient access and proper dosing." These statements continued through the Class Period and described how NUCYNTA increased its promotion through speaker programs, were concentrated on increasing dosage, and pushed NUCYNTA's dual mechanism of action.

307. For example, on Depomed's August 3, 2016 earnings call, Schoeneck stated: "we have focused on the growth of NUCYNTA IR with four pillars; promotion, positioning, patient access and proper dosing."

308. The above statements were materially false and misleading because Depomed's "four key elements" to its "NUCYNTA plan" were materially false. In reality, Depomed's NUCYNTA plan actually included a widespread off-label marketing scheme by Defendants. As explained above, Depomed's "significantly increased promotion" of NUCYNTA actually included promoting Depomed off-label as a safer, less abusive opioid. Defendants did this in part by a) distributing a study comparing NUCYNTA directly to Oxycodone CR, and b) training Depomed's sales representatives to affirmatively represent that NUCYNTA was less euphoric, less abusive, and generally a safer opioid alternative.

309. Similarly, Depomed's representation that it "totally revamped product positioning and messaging," was materially false and misleading because it was actually just continuing Janssen's illegal off-label marketing.

310. Further, Depomed misled investors by indicating that physicians were improperly dosing patients at lower levels. However, in reality, physicians were actually complying with the FDA approved label. Defendants' push for "proper dosing" was actually just a widespread scheme to increase NUCYNTA sales by promoting off-label dosage levels.

311. Finally, Defendants statements that NUCYNTA's focus would be on its dual mechanism of action, despite the fact that it has no clinical relevance, shows that Depomed promoted NUCYNTA in a way to mislead physicians and investors alike. By focusing on the "dual mechanism" Defendants portrayed NUCYTA as a safer, less abusive, less euphoric opioid. However, this was not the case. Accordingly, these statements throughout the Class Period were materially false and misleading.

312. Additionally, the above statements omitted material information to make the statements not misleading. Although the statements provided investors with a description of Depomed's alleged marketing strategy, the description omitted material information concerning Defendants' off-label marketing strategy. In particular, absent from Defendants' above statements

was the fact that Depomed was promoting NUCYNTA to primary care physicians as a safer, less addictive, less abusive opioid that did not contain the same euphoric feeling as other opioids. Depomed did not have FDA-approval to market NUCYNTA in this manner. Depomed's off-label marketing strategy allowed Defendants to continue promoting Depomed as a positive investment, one that had beaten (and would continue to beat) the generally declining opioid market. Indeed, Defendants raised their product revenue estimates based, in part, on their strong marketing strategy.

313. Depomed's off-label marketing strategy allowed Defendants to continue promoting Depomed as a positive investment, one that had beaten (and would continue to beat) the generally declining opioid market. Indeed, Defendants raised their product revenue estimates based, in part, on their strong marketing strategy.

314. Additionally, Depomed's SG&A expenses in its earnings calls and financials, as detailed below, were materially false and misleading because throughout the Class Period Depomed failed to inform investors that a substantial portion of its SG&A was going to speakers to promote NUCYNTA off-label.

315. Depomed's publically disseminated risk warnings in its SEC filings, as detailed below, were also materially false. Although Defendants stated that "We may incur significant liability if it is determined that we are promoting or have in the past promoted the 'off-label' use of drugs" in Depomed's "risk factors" section, it did so in a materially misleading manner. Depomed had already been engaging in off-label marketing. Accordingly, Depomed's quarterly report should have described the risks associate with off-label marketing as having already materialized, and thus the potential exposure arising therefrom as a far more likely event. By discussing off-label marketing as something that "might" occur when in fact it "already" occurred, Defendants materially misled investors.

316. These risks ultimately came to bear and, through no fault of their own, Depomed's investors suffered significant losses.

SUBSTANTIVE ALLEGATIONS

A. Defendants' Material Misrepresentations Concerning the Marketing of NUCYNTA, and the Effect of the Opioid Crisis on Depomed

317. Public sentiment towards opioid prescription and use deteriorated dramatically over the course of the Class Period. Companies in the opioid industry uniformly reported reduced sales due to worsening market conditions, except Depomed. Depomed, for a while, against all indications, was able to report increased sales and business development. Unbeknownst to investors, Depomed's operations were far less positive than represented. The headwinds within the opioid industry had been affecting, and would continue to affect, Depomed on a severe level. To the extent Depomed achieved positive earnings relative to its peers, it did so by engaging in an illicit off-label marketing scheme in which Depomed targeted primary care physicians in an effort to increase prescriptions and dosage.

318. Defendants' statements concealed these facts from investors. Instead of disclosing the true nature of Depomed's industry obstacles, Defendants created the materially false impression that business was carrying on as usual (if not improving). The extent to which Depomed was engaging in off-label marketing in order to counter the negative effects of the opioid crisis was material to investors. Had investors known the truth about Depomed's operations, they would have been able to evaluate the exposure Depomed faced from engaging in illicit sales tactics and, in turn, consider these risks when deciding whether to invest in Depomed stock.

319. Investors did not begin to doubt the veracity of Defendants' statements until November 7, 2016, when Defendants lowered Depomed's top-line revenue estimate from $505 million to $465 million in part because of the worsening opioid market. Investors developed additional questions concerning Defendants' statements as Defendants began to admit that Depomed's business prospects were not as bright as initially represented. The Senate Investigation and the investigation by U.S. Department of Justice solidified investor concerns and, with each new revelation, Depomed's stock price declined further and further.

July 29, 2015 – Earnings Call

320. On July 29, 2015, Depomed held an earnings call to discuss Depomed's second-quarter fiscal year 2015 financial results. Schoeneck and Moretti attended the call and stated the following:

> **Jim Schoeneck** - Depomed, Inc. - President & CEO
> Continuity was a key to our second quarter success as well as we hired Quintiles, the same contract sales organization that had marketed NUCYNTA previously to continue selling on our behalf while we completed the recruitment for positions in our expanded sales force leading up to our re-launch of NUCYNTA in June. As impressive as NUCYNTA's second quarter numbers are, we believe we've just scratched the surface with this innovative product and that we have the potential to reach peak sales higher than we initially anticipated. ***Our new NUCYNTA positioning and expanded commercial re-launch efforts are now well underway***.
>
> * * *
>
> Augie will provide specific product sales results for the second quarter and you may also find this information in today's press release and on Depomed's quarterly report on Form 10-Q that will be filed later this week. In addition to pointing to a superb second quarter, these product sales and prescription results speak broadly to an important component of our continuing growth story. We have demonstrated repeatedly that we can acquire, integrate and grow products marked by sales growth, prescription growth, market share growth. We expect that trend to continue and with it, a period of accelerated growth for our company extending well into the future.
>
> I'd now like to spend a few minutes on each of these growth opportunities. First and foremost, we believe NUCYNTA has blockbuster potential and can achieve greater peak sales than we originally anticipated. ***There are four key elements to our NUCYNTA plan: one, significantly increased promotion, two, totally revamped product positioning and messaging, three, pricing and access strategies to maximize the brand and this is new, four, proper dosing.*** Each has an impact on our sales ramp and the ultimate peak sales potential for NUCYNTA.
>
> Now let me give you some more info on each one. ***First, promotion. The key component of our strategy is the strength of our sales and marketing force.*** We officially re-launched NUCYNTA in June with a significantly expanded sales force of 275 highly experienced and specialized pain and neurology reps. This sales force is over three times larger than the prior sales force and allows us to rapidly and effectively engage to more than 25,000 target prescribers as we raise the profile of NUCYNTA. Our sales force is fully deployed and energized targeting eight to 10 prescriber calls per day.
>
> And here's one new observations since our re-launch. There seems to be a group of physicians that have either prescribed NUCYNTA in the past or prescribe more NUCYNTA than they have recently. This latent demand may turn out to be an additional driver of NUCYNTA as Depomed re-engages these physicians.

> ***Our medical and marketing activities have ramped up as well***. During the month of July, over 300 medical support and speaker programs are being executed, including a national webcast that is expected to draw healthcare professionals from nearly every state. It's important to note that while we began distributing NUCYNTA at the beginning of April, our re-launch took place in mid June so the benefits from our commercial re-launch strategy should become evident later this year.
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> * * *
>
> ***The fourth opportunity for sales growth is proper dosing of NUCYNTA***. This is another new observation we've had since we've taken over the brand. Here are the basic numbers. The average dose of NUCYNTA ER used by patients in the clinical trials for low back pain was approximately 400 milligrams per day. Yet when we look at the average doses in the marketplace, there are currently between 200 milligrams and 250 milligrams. We believe that education focused on proper titration can improve both the physician and patient experience with the product and we also feel it has the potential to increase sales by 50% or more as patients towards doses most often seen in the clinical trials.
>
> (emphasis added)

321. The above statements were materially false and misleading because Depomed's "four key elements" to its "NUCYNTA plan" were materially false. In reality, Depomed's NUCYNTA plan actually included a widespread off-label marketing scheme by Defendants. As explained above, Depomed's "significantly increased promotion" of NUCYNTA actually included promoting Depomed off-label as a safer, less abusive opioid. Defendants did this in part by a) distributing a study comparing NUCYNTA directly to Oxycodone CR, and b) training Depomed's sales representatives to affirmatively represent that NUCYNTA was less euphoric, less abusive, and generally a safer opioid alternative. Similarly, Depomed's representation that it "totally revamped product positioning and messaging," was materially false and misleading because it was actually just continuing Janssen's illegal off-label marketing. Further, Depomed misled investors by indicating that physicians were improperly dosing patients at lower levels. However, in reality, physicians were actually complying with the FDA approved label. Defendants' push for "proper dosing" was actually just a widespread scheme to increase NUCYNTA sales by promoting off-label dosage levels. Accordingly, the above statements were materially false and misleading.

322. Additionally, the above statements omitted material information to make the statements not misleading. Although the statements provided investors with a description of

Depomed's alleged marketing strategy, the description omitted material information concerning Defendants' off-label marketing strategy. In particular, absent from Defendants' above statements was the fact that Depomed was promoting NUCYNTA to primary care physicians as a safer, less addictive, less abusive opioid that did not contain the same euphoric feeling as other opioids. Depomed did not have FDA-approval to market NUCYNTA in this manner. Depomed's off-label marketing strategy allowed Defendants to continue promoting Depomed as a positive investment, one that had beaten (and would continue to beat) the generally declining opioid market. Indeed, Defendants raised their product revenue estimates based, in part, on their strong marketing strategy.

323. Moretti also made materially misleading statements on the earnings call related to Depomed's financials. Moretti stated:

> **August Moretti** - Depomed, Inc. - CFO & SVP
> Now let's look at our expense levels. ***Selling, general and administrative expenses were $57.4 million for the second quarter of 2015. The increase in SG&A expense in second quarter 2015 were primarily due to additional headcount in our sales and marketing organizations in connection with the NUCYNTA acquisition and relaunch and related headcount increases necessary to support the larger sales organization.*** We added 110 sales representatives to our sales force in connection with the NUCYNTA acquisition and re-launch.
>
> * * *
>
> In light of our strong Q2 results, we are updating our guidance for 2015. Guidance for the year is based on actual results for the first six months of the year and our current budget for the second half of the year. Our budget is based on a large number of assumptions and there are significant uncertainties in estimating future product revenues. This is particularly true for our largest revenue products, NUCYNTA and NUCYNTA ER. For a more complete discussion of the relevant risks relating to our guidance, I will direct you to the Risk Factors section of our quarterly report on Form 10-Q that we expect to file later this week.
>
> With that said, aggregate net product revenues for our six products for 2015 are expected to be $320 million to $340 million. This is an increase of $10 million on the bottom of the range and $5 million on the top. We expect total revenues to be approximately the same as we're not anticipating any milestone revenue in 2015.
>
> * * *
>
> ***SG&A expense for the remainder of the year reflect the costs associated with our increased sales force, the additional headcount increase necessary to support the sales force and the marketing expense for both NUCYNTA and NUCYNTA ER.*** In addition, they reflect the expenses of the NUCYNTA and the litigation that we

> have assumed in connection with the acquisition. Research and development expenses include pediatric studies for NUCYNTA, Cambia and Zipsor.
>
> (emphasis added).

324. The above statements (identified in bold) were materially misleading because Depomed was actually using SG&A to improperly promote NUCYNTA off-label by paying third parties and physicians to promote opioids and speak about NUCYNTA off-label as a safer, less euphoric, and less abusive opioid alternative.

325. Defendants' statements on July 29, 2015 prompted an immediate rise in the price of Depomed stock. From a closing price of $31.87 on July 29, 2015, Depomed's stock climbed to $32.25 the following day on July 30, 2015, on unusually heavy volume. The truth about Depomed's illegal off-label marketing practice would have alerted investors to Depomed's widespread off-label scheme and altered the total mix of information available to investors. Defendants failed to disclose this information and, in doing so, allowed the statements they made to be materially misleading.

Second Quarter 2015 Form 10-Q

326. On August 3, 2015, Depomed filed a Form 10-Q for the second quarter ending June 30, 2015 ("Second Quarter 2015 Form 10-Q"). The Second Quarter 2015 Form 10-Q was certified and signed by Schoeneck and Moretti.

> ***We may incur significant liability if it is determined that we are promoting or have in the past promoted the "off-label" use of drugs.***
>
> Companies may not promote drugs for "off-label" use—that is, uses that are not described in the product's labeling and that differ from those approved by the FDA. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across some medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDCA and FDA regulations restrict communications on the subject of off-label uses of drug products by pharmaceutical companies. The Office of Inspector General of the Department of Health and Human Services (OIG), the FDA, and the Department of Justice (DOJ) all actively enforce laws and regulations prohibiting promotion of off-label use and the promotion of products for which marketing clearance has not been obtained. If the OIG or the FDA takes the position that we are or may be out of compliance with the requirements and restrictions described above, and we are investigated for or found to have improperly promoted off-label use, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. In addition, management's attention could be diverted from our business operations and our reputation could be damaged.

Second Quarter 2015 Form 10-Q at 52 (emphasis added).

327. Defendants included the above statement in its quarterly report within a section titled "RISK FACTORS." Although the above statement discussed the risk of "incur[ring] significant liability" in connection with off-label marketing, it did so in a misleading manner. Depomed, by this point in time, had already been deliberately engaging in off-label marketing. Accordingly, Depomed's quarterly report should have described the risks associate with off-label marketing as having already materialized, and thus the potential exposure arising therefrom as a far more likely event. By discussing off-label marketing as something that "might" occur when in fact it "already" occurred, Defendants materially misled investors.

September 16, 2015 – Morgan Stanley Healthcare

328. On September 16, 2015, Depomed presented at the Morgan Stanley Heathcare Conference. Defendants Schoeneck and Moretti participated on behalf of Depomed. At the conference Schoeneck made materially false and misleading statements relating to NUCYNTA. Schoeneck stated:

> We really are thrilled to have NUCYNTA now as part of our product portfolio and in our bag. This is NUCYNTA and NUCYNTA ER, so a short-acting and a long-acting version of this. This is a product that's in the Schedule II opioid class. In fact, it's the only new chemical entity into that class in the last 30 years. With that, ***what we're particularly excited about, about the chemical itself, is the two mechanisms of action***. So it works differently, and really is a next-generation molecule.
>
> * * *
>
> ***We have also repositioned the drug, and we've done that by focusing on this dual mechanism of action and really different patient types***: patient types that have not only classical pain that you might use an opioid for, but also with neuropathic or radiating pain, where we believe this molecule is particularly good for those that have that mixed type of pain. We've also made an adjustment on the pricing and brought it into parity with the market leader in the class, OxyContin. And look to continue the coverage -- and I'm sure Dave always asks questions about Managed Care, so I'm sure that will be in there, so I'll leave that.
>
> (emphasis added).

329. These statements were materially false and misleading because Schoeneck represented that because of NUCYNTA's "two mechanisms of action" that NUCYNTA was "a next-

generation molecule." In reality, the "exact mechanism of action [of NUCYNTA] is unknown." By praises NUCYNTA's "dual mechanism of action" while not knowing the exact mechanism, Depomed misled investors as to NUCYNTA's application. Accordingly, Schoeneck had no basis to make the above statements.

330. Additionally, the above statement was materially false and misleading because Depomed actually repositioned NUCYNTA by engaging in a widespread off-label marketing scheme to promote NUCYNTA off-label in order to increase sales.

331. Schoeneck also misrepresented at the conference NUCYNTA's promotion of NUCYTA. Schoeneck stated:

> But I think the important thing is, now that we've brought it into the bag and bought it from J&J, what is it that we think we can do differently? And some of you in the room will have heard this from us, but I think it's important just to move through it again quickly, and that is, one, ***we have taken the promotion up on the drug dramatically.*** We have taken the sales rep coverage up on it by over threefold from what J&J has been doing for the last three years. We've added full medical support back to the product. ***We've already had speaker programs that have included even 1,000 people last week at a meeting called PAINWeek, which is one of the two largest pain management meetings of the year.***
>
> * * *
>
> And then the final thing that we've seen, and actually seen it since we've made the acquisition, ***is the dosing level of the drug,*** where in the clinical studies, the dosing was around an average of 400 milligrams a day of the product. The current dosing in the marketplace is around 200 or 250 milligrams of the product. ***And this was actually a big focus of a lot of the talks that we heard last week*** at PAINWeek: that people may not have been titrating this drug up to the levels that have been seen in the clinical trials, which will help both the patients get better efficacy; but also, because the pricing in this category is linear -- literally, a 200 milligram tablet is approximately twice the amount of 100 milligram, so it also is another way that we should see boosting in revenue.
>
> (emphasis added).

332. The above statements were materially false and misleading because Depomed's "promotion" of NUCYNTA actually included a widespread off-label marketing scheme by Defendants. As explained above, Depomed's "promotion" of NUCYNTA actually included promoting Depomed off-label as a safer, less abusive opioid. Defendants did this in part by a) distributing a study comparing NUCYNTA directly to Oxycodone CR, and b) training Depomed's

sales representatives to affirmatively represent that NUCYNTA was less euphoric, less abusive, and generally a safer opioid alternative.

333. Further, Depomed misled investors by indicating that physicians were improperly dosing patients at lower levels. However, in reality, physicians were actually complying with the FDA approved label. Defendants' push for "proper dosing" was actually just a widespread scheme to increase NUCYNTA sales by promoting off-label dosage levels. Accordingly, the above statements were materially false and misleading.

334. The above statements were also misleading because Depomed failed to inform investors that Depomed was actually engaging the speakers to engage in a widespread off-label marketing scheme to increase NUCNTA prescriptions. In reality, Depomed was paying speakers to promote NUCYNTA off-label.

November 9, 2015 – Earnings Call

335. On November 9, 2015, Depomed held an earnings call to discuss Depomed's third-quarter fiscal year 2015 financial results. Schoeneck and Moretti participated on the call and stated the following:

> **Jim Schoeneck** - Depomed, Inc. - President & CEO
> In line with this strong performance, today we announced we are raising guidance for our 2015 product sales to a range of $336 million to $348 million, which is more than triple our 2014 product sales, and raising our non-GAAP adjusted earnings to $58 million to $66 million, an increase of almost 40% over our prior guidance. Augie will provide a comprehensive look of our revised guidance in his remarks.
>
> Our relaunch of NUCYNTA is off to an exceptional start with growth accelerating ahead of our initial expectations. The third quarter was the first full quarter of NUCYNTA promotion by our expanded sales force, along with resumption of full marketing and medical support. Third-quarter net sales for NUCYNTA were $65 million, an increase of 15% compared to $57 million for the second-quarter 2015. ***We believe that our commercial strategy is already having a significant impact on unit demand and will serve as the platform for continued growth for many years***. Total NUCYNTA ER prescriptions for the quarter were 80,000, up 8% compared to second-quarter 2015.
>
> * * *
>
> ***There are four pillars that we have identified as the keys to NUCYNTA's growth: promotion, positioning, patient access and proper dosing***. Let's take a closer look at the four pillars of our NUCYNTA growth strategy and our early observations in the market.

First, promotion. As you all know, we tripled the size of the NUCYNTA sales force effort, now promoting NUCYNTA with 277 sales reps. This experienced group is delivering about 10,000 sales calls per week, focusing on high prescribers in our product categories. Their hard work is already moving NUCYNTA scripts and market share. ***About four weeks ago we held sales meetings across the country, and I was able to meet with many of our people. They are focused and motivated.*** We are seeing new physician prescribers of NUCYNTA each week and we are seeing increased prescriptions from existing prescribers. ***I also believe that these meetings prepared our sales force to be even more effective in the fourth quarter as we continue the NUCYNTA relaunch.***

We also significantly ramped up our marketing and medical programs. By the end of the year we will execute over 850 speaker programs reaching thousands of potential prescribers. This market thrust converged for the first time at the Pain Week conference in September. Pain Week is the second largest pain conference in the US and represented a truly watershed moment for Depomed. Well over 1,000 potential prescribers of Depomed products attended our sponsored sessions, including a NUCYNTA symposium that had the largest attendance in the history of the conference. The audience was enthused, fully engaged and asked great questions. We believe that Depomed left a very favorable impression among those in attendance that will help support future growth.

The second pillar of NUCYNTA growth is product positioning. ***We've changed the NUCYNTA message to focus on the product's dual mechanisms of action and different patient types.*** This includes those patients with classic pain for whom an opioid may be prescribed and also with neuropathic or nerve pain where NUCYNTA ER is the only opioid with an FDA-approved indication. We're also focusing on certain types of patients, targeting the chronic lower back pain population, which numbers about 30 million in the US, and those patients with painful diabetic neuropathy, or DPN. Many of these patients report symptoms of both types of pain, nociceptive and neuropathic. The messages are being well received by physicians, and we believe that this change is already beginning to contribute to our growth.

* * *

The final pillar of NUCYNTA growth is proper dosing. Specifically, we believe that effective prescriber education focused on proper titration and optimal dosing can improve both the physician and patient experience. The average dose of NUCYNTA ER used by patients in the clinical trials for low back pain was approximately 400 milligrams per day, yet the average dose in the marketplace is between 200 and 250 milligrams. We have been clarifying these points with physicians and believe that this message is resonating, as evidence by comments from speakers at Pain Week and in the field.

(emphasis added).

336. The above statements were materially false and misleading because Depomed's "four pillars" to "NUCYNTA's growth" were materially false. In reality, Depomed's NUCYNTA plan actually included a widespread off-label marketing scheme by Defendants. As explained above, Depomed's "significantly increased promotion" of NUCYNTA actually included promoting Depomed off-label as a safer, less abusive opioid. Defendants did this in part by a) distributing a study comparing NUCYNTA directly to Oxycodone CR, and b) training Depomed's sales representatives to affirmatively represent that NUCYNTA was less euphoric, less abusive, and generally a safer opioid alternative. Similarly, Depomed's "product positioning and messaging," was actually just continuing Janssen's illegal off-label marketing, and promoting NUCYNTA's dual mechanism of action as less abusive. Further, Depomed misled investors by indicating that physicians were improperly dosing patients at lower levels. However, in reality, physicians were actually complying with the FDA approved label. Defendants' push for "proper dosing" was actually just a widespread scheme to increase NUCYNTA sales by promoting off-label dosage levels. Accordingly, the above statements were materially false and misleading.

337. Additionally, the above statements omitted material information to make the statements not misleading. Although the statements provided investors with a description of Depomed's alleged marketing strategy, the description omitted material information concerning Defendants' off-label marketing strategy. Depomed had been targeting (and would continue to target) primary care physicians by representing that NUCYNTA was a safer, less addictive, less abusive opioid that did not contain the same euphoric feeling as other opioids. Depomed did not have FDA-approval to market NUCYNTA in this manner and lacked credible, scientific support to make these claims. But for Depomed's off-label marketing scheme, the company would have been subject to the same negative headwinds that had been affecting the opioid industry in general.

338. At the same earnings call, Moretti also made materially misleading statements related to Depomed's financials. Moretti stated:

> **August Moretti** - Depomed, Inc. - SVP & CFO
> Now to our guidance. In light of our strong Q3 results, we're updating our guidance for 2015. Guidance for the year is based on actual results for the first nine months of the year and our current budget for the remainder of the year. Our budget is based

> on a large number of assumptions and there are significant uncertainties in estimating future product revenues. This is particularly true for our largest revenue products, NUCYNTA and NUCYNTA ER. For a more complete discussion of the relevant risks relating to our guidance, I direct you to the Risk Factor section of our quarterly report on Form 10-Q that we will file with the SEC today.
>
> With that said, aggregate net product revenues for our six products for 2015 are expected to be $336 million to $348 million. This is an increase from our previous guidance of a range of $320 million to $340 million. We expect total revenues to be approximately the same, as we're not anticipating any milestone revenue in 2014. COGS for NUCYNTA and NUCYNTA ER will be approximately 25% for the remainder of 2015, reflecting the manufacturing costs and the royalties on net sales over to Grunenthal. COGS on our other products are expected to be approximately 10% of net sales. Operating expenses exclusive of amortization are expected to be $200 million to $210 million, an increase from our previous guidance of $195 million to $210 million.
>
> ***SG&A expense for the remainder of the year reflects the costs associated with our increased sales force, the additional headcount increases necessary to support the increased sales force, and the marketing expense for both NUCYNTA and NUCYNTA ER***. In addition, they reflect the expenses of the NUCYNTA and a litigation that we've assumed in connection with the acquisition and the expenses that we will incur in connection with the Horizon matter. Research and development expenses include pediatric studies for NUCYNTA, Cambia and Zipsor.

339. The above statements were materially misleading because Depomed was actually using SG&A to improperly promote NUCYNTA off-label by paying third parties and physicians to promote opioids and speak about NUCYNTA off-label as a safer, less euphoric, and less abusive opioid alternative.

Third Quarter 2015 Form 10-Q

340. On November 9, 2015, Depomed filed a Form 10-Q for the third quarter ending September 30, 2015 ("Third Quarter Form 10-Q"). The Third Quarter Form 10-Q was certified and signed by Schoeneck and Moretti. It stated in pertinent part:

> ***We may incur significant liability if it is determined that we are promoting or have in the past promoted the "off-label" use of drugs.***
>
> Companies may not promote drugs for "off-label" use—that is, uses that are not described in the product's labeling and that differ from those approved by the FDA. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across some medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDCA and FDA regulations restrict communications on the subject of off-label uses of

> drug products by pharmaceutical companies. The Office of Inspector General of the Department of Health and Human Services (OIG), the FDA, and the Department of Justice (DOJ) all actively enforce laws and regulations prohibiting promotion of off-label use and the promotion of products for which marketing clearance has not been obtained. If the OIG or the FDA takes the position that we are or may be out of compliance with the requirements and restrictions described above, and we are investigated for or found to have improperly promoted off-label use, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. In addition, management's attention could be diverted from our business operations and our reputation could be damaged.

Third Quarter Form 10-Q at 54 (emphasis added).

341. Defendants included the above statement in the Third Quarter 2015 Form 10-Q within a section titled "RISK FACTORS." Defendants' description of the risks relating to off-label marketing were materially misleading. Depomed, by this point in time, had already deliberately engaged in off-label marketing and, as such, had already significantly increased the company's exposure to significant liability. By discussing off-label marketing as something that "might" occur when in fact it "already" occurred, Defendants materially misled investors.

November 18, 2015 – Stifel Heathcare Conference

342. On November 18, 2015, Depomed presented at the Stifel Heathcare Conference. Defendant Moretti participated on behalf of Depomed. At the conference Moretti made materially false and misleading statements relating to NUCYNTA. Moretti stated:

> ***Our strategy to grow sales of NUCYNTA really have four elements to it, promotion, positioning, pricing and access, and proper dosing***, and I will take a minute to go through each of those.
>
> ***In terms of promotion, we've significantly increased the promotion on the NUCYNTA franchise***. When we bought it from J&J, J&J was promoting the product with a contract sales force of approximately 85 people. Today, our sales force of 277 reps is promoting NUCYNTA, along with GRALISE, Cambia, and Zipsor.
>
> * * *
>
> And a fourth element of the relaunch of ***NUCYNTA had to do with proper dosing***. This is something that came to our attention. When we looked at the clinical work that was done to secure approval of NUCYNTA, the maintenance dose -- as you can see from this slide, the maintenance dose in the clinical trials was approximately 400 milligrams a day. When we look at the markets today, the average dosing for patients is somewhere between 200 and 250 milligrams per day.
>
> So we -- through both the sales force, ***but most importantly in our peer-to-peer marketing and our speaker programs, we have focused on the fact that increasing***

> ***the dosing -- proper titration up to a higher dose will probably improve the patient and physician experience with NUCYNTA***. I think that this is a opportunity for us in the sense that higher dosing -- in the Schedule II world, doses -- the dosing is priced linearly, so that higher doses have higher sales prices. And so if we are successful over time in increasing the average dose, that's an opportunity for us in terms of increasing net sales.

(emphasis added).

343. The above statements were materially false and misleading because Depomed's "promotion" of NUCYNTA actually included a widespread off-label marketing scheme by Defendants. As explained above, Depomed's "promotion" of NUCYNTA actually included promoting Depomed off-label as a safer, less abusive opioid. Defendants did this in part by a) distributing a study comparing NUCYNTA directly to Oxycodone CR, and b) training Depomed's sales representatives to affirmatively represent that NUCYNTA was less euphoric, less abusive, and generally a safer opioid alternative.

344. Further, Depomed misled investors by indicating that physicians were improperly dosing patients at lower levels. However, in reality, physicians were actually complying with the FDA approved label. Defendants' push for "proper dosing" was actually just a widespread scheme to increase NUCYNTA sales by promoting off-label dosage levels. Accordingly, the above statements were materially false and misleading.

February 22, 2016 – Earnings Call

345. On February 22, 2016, Depomed held an earnings to discuss Depomed's fourth-quarter fiscal year 2015 financial results. Schoeneck and Moretti participated on the call. Schoeneck made the following misrepresentations on the call:

> **Jim Schoeneck** - Depomed, Inc. - President and CEO
> I'm pleased to report that the NUCYNTA relaunch is exceeding our expectations. ***Fourth-quarter net sales for NUCYNTA were $68 million***, up 55% over the approximately $44 million generated by Janssen in the fourth quarter of 2014. Fourth-quarter total NUCYNTA ER prescriptions reached an all-time high of about 87,000 and, during December, achieved an all-time weekly and monthly high, surpassing the October 2012 records established by Janssen.
>
> ***The cornerstone to our NUCYNTA growth strategy is the implementation of our four pillars of growth; promotion, positioning, patient access and proper dosing***. We are already seeing the initial signs of success on the promotion front as the

> expanded reach of our sales force is gaining traction with high prescribers and influential thought leaders in the pain space.
>
> This is evidenced by the increasing number of new prescribers, as well as increased prescriptions from existing prescribers. In addition, more physicians are prescribing both brands, both immediate release and long-acting NUCYNTA.
>
> In less than seven months, our sales and marketing team ***executed over 900 speaker programs educating over 10,000 healthcare professionals***. ***Our sales force continues to target approximately 10,000 sales calls per week and is rolling out new marketing materials aimed at highlighting NUCYNTA's dual mechanism of action***.
>
> Last month our 300-person-strong sales team gathered for our national sales meeting. They are committed, energized and unwavering in their desire to grow the portfolio. Their 2015 efforts translated into success with the recent all-time prescription highs. They also recognize that there is plenty of room for growth.
>
> The ***meeting gave us an opportunity to strengthen their successful play book with an enhanced set of tools, including new digital and printed marketing materials needed to help take them to the next level***. We are also rolling out new customized managed care resources tailored for each position.
>
> Finally, we have added 24 additional voices to our NUCYNTA sales effort. Starting in February, our Lazanda sales team is now also selling NUCYNTA and NUCYNTA ER.
>
> * * *
>
> ***Proper dosing makes up the final pillar of our NUCYNTA strategy***. Our goal is to achieve a more favorable patient and physician experience by optimizing titration and dosage. The disconnect between the average dose of approximately 400 mg per day of NUCYNTA ER used by patients in the clinical trials for low back pain, versus the average dose in the marketplace of between 200 and 250 mg, presents us with a key messaging opportunity.

346. The above statements were materially false and misleading because Depomed's "four key elements" to its "NUCYNTA plan" were materially false. In reality, Depomed's NUCYNTA plan actually included a widespread off-label marketing scheme by Defendants. As explained above, Depomed's "significantly increased promotion" and "marketing" of NUCYNTA actually included promoting Depomed off-label as a safer, less abusive opioid. Defendants did this in part by a) distributing a study comparing NUCYNTA directly to Oxycodone CR, and b) training Depomed's sales representatives to affirmatively represent that NUCYNTA was less euphoric, less abusive, and generally a safer opioid alternative. Similarly, Depomed's "marketing materials" included an off-

label study comparing NUCYNTA directly to Oxycodone CR. Further, Depomed misled investors by indicating that physicians were improperly dosing patients at lower levels. However, in reality, physicians were actually complying with the FDA approved label. Defendants' push for "proper dosing" was actually just a widespread scheme to increase NUCYNTA sales by promoting off-label dosage levels. Accordingly, the above statements were materially false and misleading.

347. Depomed also misled investors by failing to tell investors that a material portion of Depomed's revenue was directly attributable to Depomed's illegal off-label marketing practice. Many of these sales were incentivized by Depomed's speaker program. Accordingly, Depomed's revenue was materially false and misleading.

348. Additionally, the above statements omitted material information to make the statements not misleading. Although the statements provided investors with a description of Depomed's alleged marketing strategy, the description omitted material information concerning Defendants' off-label marketing strategy. In particular, absent from Defendants' above statements was the fact that Depomed was promoting NUCYNTA to primary care physicians as a safer, less addictive, less abusive opioid that did not contain the same euphoric feeling as other opioids. Defendants did this in part by a) distributing a study comparing NUCYNTA directly to Oxycodone CR, and b) training Depomed's sales representatives to affirmatively represent that NUCYNTA was less euphoric, less abusive, and generally a safer opioid alternative. Depomed did not have FDA-approval to market NUCYNTA in this manner. Depomed's off-label marketing strategy allowed Defendants to continue promoting Depomed as a positive investment, one that had beaten (and would continue to beat) the generally declining opioid market.

349. On the same earnings call, Moretti also made materially misleading statements related to Depomed's financials. Moretti stated:

> **August Moretti** - Depomed, Inc. - CFO & SVP
> For the fourth quarter, ***NUCYNTA sales were $68 million***, an increase of 5% from the previous quarter. Prescriptions for the NUCYNTA franchise for the quarter were over 219,000. ER prescriptions were up 9% over Q3 and, as Jim mentioned, we have reversed the decline in IR prescriptions. The Q4 results further solidify NUCYNTA as Depomed's largest product franchise. That said, the rest of our products also delivered strong performances in the fourth quarter.
> * * *

> Now let's look at expense levels. GAAP ***selling, general and administrative expenses were $58.3 million for the fourth quarter of 2015***. These expenses include $8.2 million associated with the Company's evaluation, consideration and defense of the unsolicited proposal from Horizon. Excluding stock-based compensation, contingent consideration and the one-time expenses associated with Horizon, ***non-GAAP SG&A expenses were $45.6 million for the fourth quarter of 2015***.

350. The above statements (identified in bold) were materially misleading because Depomed was actually using SG&A to improperly promote NUCYNTA off-label by paying third parties and physicians to promote opioids and speak about NUCYNTA off-label as a safer, less euphoric, and less abusive opioid alternative. Depomed also misled investors by failing to tell investors that a material portion of Depomed's sales were directly attributable to Depomed's illegal off-label marketing practice. Many of these sales were incentivized by Depomed's speaker program. Accordingly, Depomed's revenue was materially false and misleading.

2015 Form 10-K

351. On February 26, 2016, Depomed filed its Annual Report for 2015 on Form 10-K with the SEC, announcing Depomed's financial and operating results for the quarter and year ended December 31, 2015 (the "2015 Form 10-K"). Schoeneck and Moretti signed and certified the 2015 Form 10-K. In the 2015 Form 10-K, Depomed stated, in relevant part:

> **MARKETING AND SALES**
>
> We have developed capabilities in various aspects relating to the commercialization of our marketed products, including sales, marketing, manufacturing, quality assurance, wholesale distribution, managed market contracting, government price reporting, medical affairs, compliance, and regulatory. Members of our commercial organization are also engaged in the commercial and marketing assessments of other potential product candidates.
>
> Our sales organization includes approximately 300 full-time sales representatives. ***Our sales force primarily calls on pain specialists, neurologists and primary care physicians throughout most of the United States***. Our marketing organization is comprised of professionals who have developed a variety of marketing techniques and programs to promote our products, including promotional materials, speaker programs, industry publications, advertising and other media.

2015 Form 10-K at 11 (emphasis added).

352. The above statements (identified in bold) were materially misleading. Defendants described Depomed's recent marketing achievements as successes, but at the same time did not disclose that these supposed successes were obtained in part through an illicit off-label marketing campaign. Depomed was actively targeting primary care physicians with marketing presentations that described NUCYNTA as a safer, less addictive, less abusive opioid that did not contain the same euphoric feeling as other opioids. Depomed did not have FDA-approval to market NUCYNTA in this manner. Depomed also did not have any independent scientific evidence to support these claims. Defendants opted to discuss Depomed's marketing program while, at the same time, omitting that the company's marketing strategy relied in part on off-label promotion. Defendants' omission in this regard was materially misleading.

353. The 2015 Form 10-K also included the same "risk warning" that appeared in Depomed's quarterly reports discussed above. In pertinent part, the 2015 Form 10-K stated:

> ***We may incur significant liability if it is determined that we are promoting or have in the past promoted the "off-label" use of drugs.***
>
> Companies may not promote drugs for "off-label" use—that is, uses that are not described in the product's labeling and that differ from those approved by the FDA. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across some medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDCA and FDA regulations restrict communications on the subject of off-label uses of drug products by pharmaceutical companies. The Office of Inspector General of the Department of Health and Human Services (OIG), the FDA, and the Department of Justice (DOJ) all actively enforce laws and regulations prohibiting promotion of off-label use and the promotion of products for which marketing clearance has not been obtained. If the OIG or the FDA takes the position that we are or may be out of compliance with the requirements and restrictions described above, and we are investigated for or found to have improperly promoted off-label use, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. In addition, management's attention could be diverted from our business operations and our reputation could be damaged.
>
> (emphasis added).

354. Defendants included the above statement in its quarterly report within a section titled "RISK FACTORS." Defendants' description of the risks relating to off-label marketing were materially misleading. Depomed, by this point in time, had already deliberately engaged in off-label

marketing and, as such, had already significantly increased the company's exposure to significant liability. By discussing off-label marketing as something that "might" occur when in fact it "already" occurred, Defendants materially misled investors. Defendants conduct in this regard concealed from investors the true risks they faced as a result of investing in Depomed.

March 14, 2016 – ROTH Conference

355. On March 14, 2016, Depomed presented at the Roth Conferences. Defendants Schoeneck and Moretti presented for Depomed. In response to a question, Schoeneck discussed the marketing of NUCYNTA. Schoeneck stated:

> **Scott Henry** - ROTH Capital Partners - Analyst
> Okay, that is helpful. Are there any questions in the audience? Let's continue just a little bit more on NUCYNTA. There's been a lot of talk against opioids.
>
> I don't want to distract your CMO, but I think the perception is that perhaps yours may be a little less addictive. Do you think some of that macro trend could favor NUCYNTA? And is that, can that be part of the marketing message in growing that product?
>
> **Jim Schoeneck** - Depomed, Inc. - President and CEO
> I think it's certainly part of the medical rationale on the product. I think the marketing messaging getting into the label in terms of the differentiation, much tougher standard with the agents, with the FDA to do that.
>
> But if you look at tapentadol with the two mechanisms of action, with the norepinephrine mechanism in addition to the mu mechanism, you do are getting of lower level of hits against the mu receptor and with that we see lower levels on respiratory depression.
>
> The addiction profile is thought to be better. ***I can't make a claim around that because we don't actually have that in the label***. We are doing some things to be able to flesh out some of the different categories of abuse protection, if you want to call it that, with the FDA. But still in some discussions.
>
> We have to have a unique piece there. With the drugs that have abuse-deterrent technologies, they actually compare those to an abused version of the same drug. ***And the FDA really doesn't have a provision when you have got a drug that's not abused to start with like the immediate-release version of tapentadol -- of NUCYNTA with the long-acting version that has some additional properties on it that would protect it***.
>
> ***So we really don't have a provision for it.*** So we have got to actually talk to them about what can we do on an epidemiologic basis or what can we do with a known abused comparator drug since we can't use our own? It's a bit outside of their

> normal paradigm, so that means you get to sit down with the agency and try and figure it out.

(emphasis added).

356. The above statements were materially misleading. While Schoeneck told investors that he could not make a claim about NUCYNTA being less addictive because it is not on the label, that is exactly what Schoeneck and Depomed were pushing their sales force to do. Additionally, Schoeneck actually stated that NUCYNTA was "not abused to start." This was false. NUCYNTA is a Schedule II opioid that was and is abused. By representing that NUCYNTA was less abusive was materially false and misleading.

March 23, 2016 – Analyst and Investor Day

357. On March 23, 2016, Depomed held its first Analyst and Investor Day. Defendants Schoeneck and Moretti along with Scott Shively, Depomed's Chief Commercial Officer presented for Depomed. Shively stated:

> And then as I mentioned, ***the optimal dose was not often achieved***, and in fact, well below what the dose was reached in the pivotal clinical studies have suggested. So a communication opportunity there. And so, taking that information and once we acquired the product, ***our high level launch strategy is focused on offsetting those things and in many cases doing them differently***. So we ramped up our sales force very quickly, initially the 277 reps versus the 77 or so that Janssen had, and subsequently, have added about 24 more to kickoff this year supporting product and made it our number one priority by far.
>
> Major repositioning work here and evolving a whole different marketing campaign and it's not so easy to reposition something that's been in the market already for several years. But we really hit the mark on that, and I will show you some data that suggests that we're spot on with what we're doing there. We actually were very successful in how we converted the Johnson & Johnson contract with payers and actually enhanced our position a bit more terms of market access especially in the commercial side of things. And then really working on through training of our sales force and educating the physicians how to really titrate the product effectively to reach the optimal dose because optimal dose goes hand in hand with efficacy and also managing tolerability.
>
> Those are the four fundamental pieces that we really worked hard to do at launch and have been doing so since. ***And it kind of boils down at a very high level to a four-prong strategy around promotion and putting the right effort with the right physicians and customers, positioning, revamping the messaging, looking at pricing and access differently***. And so I ***think we have hit the mark on the pricing piece and really working through the access piece as well and in the proper***

> ***dosing***. Those four things together will lead us to say that we really do believe this is a potential blockbuster with a billion dollar opportunity for the products.

(emphasis added).

358. The above statements were materially false and misleading because Depomed's "promotion" of NUCYNTA actually included a widespread off-label marketing scheme by Defendants. As explained above, Depomed's "promotion" of NUCYNTA actually included promoting Depomed off-label as a safer, less abusive opioid. Defendants did this in part by a) distributing a study comparing NUCYNTA directly to Oxycodone CR, and b) training Depomed's sales representatives to affirmatively represent that NUCYNTA was less euphoric, less abusive, and generally a safer opioid alternative.

359. Further, Depomed misled investors by indicating that physicians were improperly dosing patients at lower levels. However, in reality, physicians were actually complying with the FDA approved label. Defendants' push for "proper dosing" was actually just a widespread scheme to increase NUCYNTA sales by promoting off-label dosage levels. Accordingly, the above statements were materially false and misleading.

360. Shively continued:

> And when you factor all that in, it gives us a much more comprehensive and precise view of what the highest target position it should be and this is really paying off big dividends. It's much more sophisticated than what had been done in the past in terms of targeting. And then we amped up every aspect of promotion including just the number of details, so over 300,000 details since launch, that's a pretty good size number. ***We have had two separate speaker training meetings just in the first six months post-launch and over 900 speaker programs held in six months. That's a lot, that's a lot to squeeze in the timeframe and they're very effective.***
>
> We've had 10 ad boards, for example, significant presence at all the big pain meetings, most recently AAPM. Pain week was kind of our kickoff congress back in September. And then kind of rekindle things again this year, so we have what we call in our business POA meetings, or plan of action meetings. These are national sales force meetings where we get the whole gang together, roll out new strategies and new materials. We did this in mid-January and really fired things up again. So lot of excitement in our sales team already and this has been amplified at even more focus. We're rolling out some new innovative approaches as of January. So it's looking pretty good for this year as well.
>
> What about the positioning? You know, what's the secret sauce behind this? And ***just to give you a flavor of what we did differently, really focusing on the dual***

mechanism of action of this product, the very unique nature of the molecule itself, but how that relates to the clinical advantages for the physician and the patients. And because of this dual mechanism, the product is ideal for patients who have both nociceptive and neuropathic pain. And in fact, we're the only product with an indication for neuropathic indication for neuropathic pain area, diabetic peripheral neuropathy in the whole opioid category.

And so, ***this is the way it comes to life in our promotional campaign***. Two sources of pain, once source of relief. The image here is one that, and hopefully you're getting this, kind of strength and power. So that kind of goes at this efficacy misperception that I talked about where some doctors were feeling that the product is not as strong as other products.

And then just the way the image is dealing with both nociceptive pain, or muscle pain if you will, as well as neuropathic pain, and these images have been coming through and [including] that meeting to docs as we've rolled the campaign out. ***And just some of the different messages***; the uniqueness of the molecule, the fact that both the mu and the norepinephrine reuptake inhibitor, ***powerful efficacy that's coming across here with well-documented and a solid tolerability and safety profile***. ***And a very important thing that we've been able to communicate is that if the product is discontinued, 95% of these patients will not experience withdrawal, and that's a far better statistic than all other long-acting opioids have, and that infers a lot of good things about the product to physicians.***

So, playing on what Joe Pergolizzi had said, we're actually using some of this mechanistic stuff in our commercial campaign and really worked hard to train our sales force to be able to deliver this and articulate it very clearly.

But ***it talks about the dual mechanism and how this is advantageous*** and how the product works mechanistically at both the mu receptor as well as the norepinephrine reuptake inhibitor. And so, going from that into what the clinical meaning and relevance of all that, so I wanted to just take a second and share with you a real brief video which kind of brings this to life which we have been playing at various settings.

I hope that brings it to life a little bit. And so an important part of our commercial campaign is understanding the mechanism and why this is a unique molecule. And as Joe said, this is the first new molecule in the opioid field for 25 years; the rest are quite old, been around a long, long time. And all the other molecules are quite similar in terms of the way they work and the way they bind to the mu receptors.

So it's not enough to talk about mechanism. ***The important thing with your customers, with physicians is how is it relevant clinically? And so, we bring this to life through patient profiles. That's how our sales force is trained and that's what they tend to focus the conversation with doctors***.

(emphasis added).

361. The above statement was materially false and misleading. Defendants' represented that NUCYNTA was safer and more tolerable because of its dual mechanism of action. However, in reality, the "clinical relevance is unclear" as to the benefits of having dual mechanisms of action. Despite this, Depomed pushed this message on its speakers, sales force, analysts, and investors.

362. In response to an analyst question about marketing NUCYNTA as abuse deterrent, Shively again pointed to the study of NUCYNTA compared to Oxycodone CR.

> **Dave Risinger** - Morgan Stanley - Analyst
> Just one more. So with respect to NUCYNTA and its abuse deterrent properties, could you just talk about how you can get that message out more, what you're able to do and then whether there are any conversation you can have with the FDA about that? Thank you.
>
> **Scott Shively** - Depomed, Inc. - Chief Commercial Officer
> Thank you. Sure. So I'll turn the second half to Srini probably but the first part, ***that's one other thing at pre-launch we're a little bit concerned about because we don't have claims in our labels for ADF technology***.
>
> What we found to our surprise and our delight was there was sort of this ambient knowledge of the fact the molecule doesn't really have street value**. It really isn't abuse[d]**. So pain docs, they know which products abusers turn deterrent to and it's not the case for this product.
>
> It has not been initiative for us. ***What's been very impacting for us is the withdrawal data that I talked about which we can promote that 95% of the patients who come off the product did not experience withdrawal and that enables docs to kind of, if you will connect the dots there, that's about as far as we can take up from a commercial perspective but that has been very effective for us***.
>
> (emphasis added).

363. The above statement was materially false and misleading. While Depomed informed analyst and investors that they could use the fact that they "can promote that 95% of the patients who come off the product did not experience withdrawal," Shively failed to inform investors that they were using this study to also compare it to the withdrawal rate of Oxycodone CR. This side by side comparison that can be seen in the study was off-label. Further, this statement shows that Depomed pushed NUCYNTA off-label as less abusive.

May 5, 2016 – Earnings Call

364. On May 5, 2016, Depomed held an Earnings Call to discuss Depomed's first-quarter fiscal year 2016 financial results. Schoeneck and Moretti participated on the call and stated the following:

> **Jim Schoeneck** - Depomed, Inc. - President & CEO
> We continue to be pleased with the Nucynta re-launch. ***The first quarter saw net sales of our Nucynta franchise of $69.4 million***. In March, Nucynta ER prescriptions reached an all-time high of over 28,767, surpassing our previous record set last December and posted a 22.6% year-over-year increase in prescription volume. The prescription trends continued to accelerate. The most recent data for the week ending April 22 shows a prescription increase of 27.9% as compared to the same week last year.
>
> While our re-launch strategy is primarily focused on Nucynta ER, it is important to note that Nucynta IR has also shown favorable prescription trends. Immediately prior to our re-launch, Nucynta IR prescription volume was down 9% year-over-year. Since then, we have changed this trend with Nucynta IR prescriptions coming in above the prior-year levels for four of the past five months. Going forward, we believe that Nucynta IR prescriptions will grow as we target the appropriate specialists.
>
> ***We are continuing to see progress implementing our four pillars of Nucynta growth; promotion, positioning, patient access and proper dosing***.
>
> On the promotion front, we are focused on growing Nucynta ER with pain specialists as well as our physician's assistant and nurse practitioners. These two groups write almost 75% of the prescriptions for Nucynta ER and the brand is growing faster in these specialties than the rest.
>
> In fact, prior to our re-launch, Nucynta ER prescriptions from pain specialists were only growing 1% year-over-year. In March 2016, pain specialist preps were up 25% over the same month last year and our market share of the long-acting opioid prescriptions is now almost 3%.
>
> ***Since one of the effects of the increased scrutiny on opioid prescribing maybe further concentration in the pain specialists' office, we believe that we are well positioned to continue to accelerate growth.***
>
> * * *
>
> You certainly have seen more drops than that in OxyContin and to a lesser degree OPANA, but we're still seeing the growth and still seeing acceleration of the growth. And ***I think once physician realize that Nucynta ER has different properties than the other opioids, particularly when it comes to the kind of activity that the CDC and others are most concerned about***.
>
> And then I think the other part of it is, because of it is starting to concentrate more in the pain specialist office, and that's where we have our greatest impact and our greatest market share. So, ***I think these things actually could play in our favor as***

we continue to see the acceleration. We're experiencing something very different than some of our peers.

(emphasis added).

365. The above statements were materially misleading. The above statements were materially false and misleading because Depomed's "four pillars" to "NUCYNTA's growth" were materially false. In reality, Depomed's NUCYNTA plan actually included a widespread off-label marketing scheme by Defendants. As explained above, Depomed's "promotion" of NUCYNTA actually included promoting Depomed off-label as a safer, less abusive opioid. Defendants did this in part by a) distributing a study comparing NUCYNTA directly to Oxycodone CR, and b) training Depomed's sales representatives to affirmatively represent that NUCYNTA was less euphoric, less abusive, and generally a safer opioid alternative. Similarly, Depomed's "product positioning and messaging," was Depomed pushing NUCYNTA as less addictive due to the dual mechanism of action. Further, Depomed misled investors by indicating that physicians were improperly dosing patients at lower levels. However, in reality, physicians were actually complying with the FDA approved label. Defendants' push for "proper dosing" was actually just a widespread scheme to increase NUCYNTA sales by promoting off-label dosage levels. Notably, Schoeneck did not talk about the "proper dosage" pillar in his talk.

366. Schoeneck also indicated that Depomed was "well positioned to continue to accelerate growth" in light of the "increased scrutiny on opioid prescribing". This was false, in reality, Depomed was just as susceptible to the opioid scrutiny as other Schedule II drugs.

367. Absent from Schoeneck's discussion about Depomed's marketing was any mention of the fact that Depomed was engaging in an ongoing illicit, off-label marketing campaign. Depomed was actively targeting primary care physicians, among others, with presentations that portrayed NUCYNTA as a safer, less addictive, less abusive opioid that did not contain the same euphoric feeling as other opioids. Unbeknownst to investors, it was this off-label marketing campaign that enabled Depomed to avoid the negative business and market trends that were affecting its competitors within the opioid industry. Indeed, Defendants represented that NUCYNTA was uniquely positioned to combat the negative public sentiment against opioids. Schoeneck described NUCYNTA as having "***different properties than the other opioids, particularly when it comes to***

the kind of activity that the CDC and others are most concerned about" and that "***there'll be relatively little impact on [Depomed] compared to where some other companies may fall in at.***" In reality, Depomed faced the same negative headwinds as its peers and was only avoiding the repercussions due to an ongoing illegal and improper off-label marketing campaign. Investors deserved to know the truth in this regard, as they would have considered the significant risks associated with off-label marketing when deciding to invest in Depomed.

368. On the same call, Moretti also made materially misleading statements related to Depomed's financials. Moretti stated:

> **August Moretti** - Depomed, Inc. - SVP & CFO
> Now let's look at expense levels. ***Non-GAAP SG&A expense was $48.7 million in Q1 2016 compared to $33.4 million in the prior year***. These amounts exclude stock-based compensation as well as the costs associated with the Horizon takeover attempt.
>
> ***The increase in non-GAAP SG&A expense over the prior year is a result of Nucynta marketing and sales expenses*** and costs associated with the Nucynta ANDA litigation. For the first quarter of 2016, fees associated with the Nucynta ANDA litigation were approximately $5 million and we expect ANDA related expenses of approximately $1.5 million in Q2.
>
> The increase in non-GAAP SG&A expense in Q1 2016 relative to Q4 2015 is largely due to the Nucynta ANDA litigation. We have previously guided non-GAAP SG&A expense to be in the range of $180 million and $195 million. We currently believe we are trending towards the upper half of our range.
>
> * * *
>
> With that said, total revenues for our six products for 2016 are expected to be in the range of $490 million to $520 million. ***SG&A expenses for the remainder of the year reflects the cost associated with marketing expenses for both Nucynta and Nucynta ER***, as well as cost associated with the Nucynta litigation that we have assumed in connection with the acquisition. ***Non-GAAP SG&A expenses are expected to be in the range of $185 million to $195 million***.
> (emphasis added).

369. The above statements were materially misleading because Depomed was actually using SG&A to improperly promote NUCYNTA off-label by paying third parties and physicians to promote opioids and speak about NUCYNTA off-label as a safer, less euphoric, and less abusive opioid alternative. Accordingly, the statements above failed to disclose to investors that a material amount of these expenses were for illegal marketing that would subject Depomed to extensive litigation.

First Quarter 2016 Form 10-Q

370. On May 6, 2016, Depomed filed a Form 10-Q for the first quarter ending March 31, 2016. The First Quarter 2016 Form 10-Q was certified and signed by Schoeneck and Moretti

> ***We may incur significant liability if it is determined that we are promoting or have in the past promoted the "off-label" use of drugs.***
>
> Companies may not promote drugs for "off-label" use—that is, uses that are not described in the product's labeling and that differ from those approved by the FDA. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across some medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDCA and FDA regulations restrict communications on the subject of off-label uses of drug products by pharmaceutical companies. The Office of Inspector General of the Department of Health and Human Services (OIG), the FDA, and the Department of Justice (DOJ) all actively enforce laws and regulations prohibiting promotion of off-label use and the promotion of products for which marketing clearance has not been obtained. If the OIG or the FDA takes the position that we are or may be out of compliance with the requirements and restrictions described above, and we are investigated for or found to have improperly promoted off-label use, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. In addition, management's attention could be diverted from our business operations and our reputation could be damaged.

First Quarter 2016 Form 10-Q at 42 (emphasis added).

371. Defendants included the above statement in its quarterly report within a section titled "RISK FACTORS." Defendants' description of the risks relating to off-label marketing were materially misleading. Depomed, by this point in time, had already deliberately engaged in off-label marketing and, as such, had already significantly increased the company's exposure to significant liability. By discussing off-label marketing as something that "might" occur when in fact it "already" occurred, Defendants materially misled investors. Defendants conduct in this regard concealed from investors the true risks they faced as a result of investing in Depomed.

May 10, 2016 – Bank of America Merrill Lynch Health Care Conference

372. On May 10, 2016, Depomed presented at the Bank of America Merrill Lynch Health Care Conference. Defendant Moretti presented for Depomed. Moretti discussed the four pillars, and again discussed "proper dosage." Moretti stated:

> Finally, ***proper dosing is an element of our repositioning of the dru***g. When you look at the clinical trial data of the clinical trials that support the approval of

> NUCYNTA, you will see that the maintenance doses of the patients in those trials was approximately 400 milligrams a day. Today in the marketplace, the average milligram dosage is more like 258 to 260.
>
> ***We have been making a point in our promotion to physicians to remind them that the clinical trials that demonstrated the strong efficacy of the NUCYNTA franchise were at much higher daily doses, and we think that this can be an element of the growth strategy***. We don't think that the daily dose is ever going to get up to 350 milligrams a day. But we think we can make progress on this and that we can generate additional growth to the franchise by picking the average daily dose -- moving it from where it is today, certainly up to 275 or something in that neighborhood.

373. The above statements were materially misleading. The above statements were materially false and misleading because Depomed's "four pillars" to "NUCYNTA's growth" were materially false. In reality, Depomed's NUCYNTA plan actually included a widespread off-label marketing scheme by Defendants. As explained above, Depomed's "promotion" of NUCYNTA actually included promoting Depomed off-label as a safer, less abusive opioid. Defendants did this in part by a) distributing a study comparing NUCYNTA directly to Oxycodone CR, and b) training Depomed's sales representatives to affirmatively represent that NUCYNTA was less euphoric, less abusive, and generally a safer opioid alternative. Similarly, Depomed's "product positioning and messaging," was Depomed pushing NUCYNTA as less addictive due to the dual mechanism of action. Further, Depomed misled investors by indicating that physicians were improperly dosing patients at lower levels. However, in reality, physicians were actually complying with the FDA approved label. Defendants' push for "proper dosing" was actually just a widespread scheme to increase NUCYNTA sales by promoting off-label dosage levels. Notably, Schoeneck did not talk about the "proper dosage" pillar in his talk.

May 23, 2016 – UBS Global Healthcare Conference

374. On May 23, 2016, Depomed presented at the UBS Global Healthcare Conference. Defendants Schoeneck and Moretti presented for Depomed. Defendant Schoeneck stated:

> **Ami Fadia** - UBS - Analyst
> Let's talk about a big picture question. We had CDC come out with some guidelines around the prescription of opioids and you have several products focused on the pain space. How do you see that impacting? Do you think that is going to reduce the prescription volume or even the average dosage of prescriptions in the space and how does that impact some of the Depomed products?

* * *

> **Jim Schoeneck**
> One of the things people have looked at the Oxy scripts being down 18% to 20% year-over-year but much of that is being picked up by the long-acting generic that is available now on a limited basis. So right now I think it is a flat market is the way I would think about it. ***I think for us there is actually an interesting advantage***. What it is doing and probably the biggest effect of it is ***primary care doctors are getting more reticent to prescribe long-acting opioids and that is pushing patients to the pain specialist office***. And in fact I used the word earlier with somebody in the hallway that they are actually being overrun. I mean the number of patients that are coming out of primary care to pain specialists is a very heavy volume.
>
> For us that is good because our market share in the pain office is about three times what it is the primary care office. So we have almost a 3% market share in pain, we are at 0.86% in primary care. So that is actually a help to us in that office and actually three quarters of our prescriptions for NUCYNTA ER come from either pain specialists or the nurse practitioners and PAs that work with them.

375. The above statements omitted material information to make the statements not misleading. Defendants informed investors that they have an advantage over other opioids. However, Defendants omitted material information concerning Defendants' off-label marketing strategy. In particular, absent from Defendants' above statements was the fact that Depomed was promoting NUCYNTA to primary care physicians as a safer, less addictive, less abusive opioid that did not contain the same euphoric feeling as other opioids. Depomed did not have FDA-approval to market NUCYNTA in this manner. Depomed's off-label marketing strategy allowed Defendants to continue promoting Depomed as a positive investment, one that had beaten (and would continue to beat) the generally declining opioid market.

June 21, 2016 – JMP Securities Life Sciences Conference

376. On June 21, 2016, Depomed presented at the JMP Securities Life Sciences Conferences. Defendants Schoeneck and Moretti presented for Depomed. Defendants discussed how they determined the four pillars prior to even acquiring NUCYNTA, and again discussed "proper dosage." Defendant Schoeneck stated:

> **Jason Butler** - JMP Securities - Analyst
> So, then just turning back to the strategy. You had some key focus points for the re-launch in terms of, well, not just increasing the magnitude of detail effort but the specific message around it. Can you talk to us about how that's resonated with physicians? And are you continuing to find physicians that are -- new physicians that are coming back -- or coming to the product or physicians that are coming back to the product?

* * *

Jim Schoeneck - Depomed, Inc. - President & CEO
In terms of what we focused on, there were really four things that we looked at changing and we did all this in terms of the market research prior to putting in the final bid for the drug and buying it from J&J. One of it was the promotion that I've already mentioned.

* * *

And then the fourth aspect was on what we refer to as proper dosing. And what we saw was that physicians were dosing the drug at lower doses than you saw in the clinical trials. By a substantive amount, they were prescribing for the long-acting version of NUCYNTA about 250 milligrams a day and the trials were around 400, so that is the other piece.

That piece really hasn't taken off yet. I think some of what's happened there is with the recent CDC guidelines and some of the other push on watching opioid prescribing, we haven't seen an uptick in the dose. And I think that maybe some of it, just some of the public rhetoric that's out there and physician audience specific rhetoric.

(emphasis added).

377. The above statement was materially false and misleading. Depomed misled investors by indicating that physicians were improperly dosing patients at lower levels. However, in reality, physicians were actually complying with the FDA approved label. Defendants' push for "proper dosing" was actually just a widespread scheme to increase NUCYNTA sales by promoting off-label dosage levels.

378. Also on the call, in response to a question from an analyst, Schoeneck spoke about Depomed's susceptibility to the opioid headwinds and how NUCYNTA's dual mechanism of action contributes to the safety profile of NUCYNTA. The exchange stated in pertinent part:

Jason Butler - JMP Securities - Analyst

That's a great (inaudible). So there has been a lot of negative media coverage around opioids in general, different types of opioids, different types of abuse. ***Are you seeing that impact physicians' prescribing habits*** both with NUCYNTA and other drugs in the opioid class?

Jim Schoeneck - Depomed, Inc. - President & CEO

So if you look at the overall class of opioids, certainly overall prescribing is down for opioids. It's down about 3% on the short acting opioids. It's down about 1% on the long-acting. ***And yet at the same time, the scripts for NUCYNTA ER are accelerating. So I think that gives you some of the answer right there***.

> I think some physicians look at this drug and see it as one from the data that you don't see as much of the issues that they are looking for – or looking out for, ***which is you've got lower rates of abuse, lower rates of hospitalization and these are out of some of the database that the FDA uses, [RADAR] is an inflection. You see lower incidences of it***.
>
> And the street price of the drug is barely above the retail price of the drug, where something like OxyContin is about $1 a milligram, we're at about $0.06 a milligram. ***So not particularly popular on the Street either***. And ***some of that has to do with the fact that if you look at just the drug in the two mechanisms of action, people don't tend to get -- they don't get the euphoria that they get with the classic opioids***.
>
> ***You're not hitting the mu receptor nearly as hard because you're also hitting this other system. And with that you don't see the euphoria***. And that's really what people want is they want that -- they like that good feeling and they want more of it. They start to tolerate to it, take higher and higher doses and that's where the category gets really dangerous.
>
> (emphasis added).

379. The above statements were materially false and misleading. First, Schoeneck indicated that the increased prescriptions of NUCYNTA show that NUCYNTA was not subject to the opioid headwinds. This was materially false. In reality, NUCYNTA was not as far along as Defendants were hoping and the CDC guidelines were highly affecting sales. Further, Schoeneck continues to discuss why NUCYNTA was not subject to the headwinds – because of "lower rates of abuse", low "street" value, and less euphoria due to the dual mechanism of action. In reality, NUCYNTA was just as subjected to the headwinds as any other opioid. Further, there was no evidence that NUCYNTA was less euphoric due to the dual mechanism of action. In fact, there was absolutely no evidence of "clinical relevance" as to the benefits of having dual mechanisms of action.

July 12, 2016 – Cantor Fitzgerald Healthcare Conference

380. On July 12, 2016, Depomed presented at the Cantor Fitzgerald Healthcare Conferences. Defendant Schoeneck presented for Depomed. Schoeneck again discussed how NUCYNTA was less euphoric and less abusive. Schoeneck stated:

> Significantly, it's the only new chemical entity that has been introduced into the schedule 2 opioid space in the last 30 years. Everything else has been a reformulation of some existing molecule. So I think when we hear some of the comments around abuse-deterrent formulations, those are taking drugs that already

> have issues -- things like oxycodone -- and they put it into a formulation that is either a chemical or physical barrier around that to try and keep people from abusing it. And that can be to try and keep them from chewing it to get a sooner high, a quicker high; to try and extract the medication, either snort it or shoot it.
>
> ***What we have with tapentadol is a molecule that doesn't give people the buzz that they get from the other ones, but it gives the people the relief. And some of that is because it has a dual mechanism of action. It works in two different ways: in addition to getting the mu opioid receptor, it hits a second receptor***.

(emphasis added).

381. The above statements were materially false and misleading. Schoeneck pushed NUCYNTA as a safer, less euphoric opioid due to NUCYNTA's dual mechanism of action. In reality, there was no evidence that NUCYNTA was less euphoric due to the dual mechanism of action. In fact, there was absolutely no evidence of "clinical relevance" as to the benefits of having dual mechanisms of action. Accordingly, this statement was materially false and misleading.

382. Schoeneck also discussed dosage. Schoeneck stated:

> The last piece was on the titration of the drug ***and how do you get to the right doses***. What we heard from physicians was oftentimes on NUCYNTA, they gave one dose at the 50-milligram entry dose. If it didn't work, they titrated up one more time, and then they were kind of done. On most opioids, there can be a second, third, or even fourth titration step.
>
> ***And so we have worked with doctors to look at this.*** Currently, to give you just a comparison, the average dose in the clinical studies, the Phase 3 studies, is approximately 400 milligrams of drug. What we see in the marketplace is just under 260 milligrams. So we think that this is an opportunity to both get a better patient response -- in addition to that, to get a better position feedback loop in terms of the drug.

383. This statement was misleading, Depomed misled investors by indicating that physicians were improperly dosing patients at lower levels. However, in reality, physicians were actually complying with the FDA approved label. Defendants' push for "proper dosing" was actually just a widespread scheme to increase NUCYNTA sales by promoting off-label dosage levels.

August 3, 2016 – Press Release & Earnings Call

384. On August 3, 2016, Depomed issued a press release titled "Depomed Reports Second Quarter 2016 Financial Results." The press release was also filed with the SEC on the same day. The Press Release stated in pertinent part:

> NEWARK, CA. August 3, 2016 - Depomed, Inc. (Nasdaq: DEPO) today reported financial results and highlighted operational achievements for the quarter ended June 30, 2016.
>
> "The second quarter marked the 1-year anniversary of the mid-June relaunch of our flagship NUCYNTA franchise," said Jim Schoeneck, President and CEO of Depomed. "***During the first full year after our relaunch, we delivered $274 million of total NUCYNTA net sales, an increase of 59% over the final year of sales under the previous owner. NUCYNTA ER prescriptions continued to accelerate in June, up 26% over the prior year and achieving all-time high prescription volume and market share. And this is against a backdrop of challenging opioid market conditions that see declining prescriptions for the overall market and other leading brands. We are also encouraged by the positive NUCYNTA IR trends, with May and June showing a 2% prescription volume increase year-over-year, reversing the 10% decline seen before our re-launch.*** We believe that our flagship franchise is well-positioned for continued growth. The rest of our portfolio also performed well, delivering $45 million in combined revenues, with record quarterly revenues from both Gralise and Lazanda. Going forward we remain focused on growing our highly-differentiated portfolio and delivering value to all the groups we serve."
>
> (emphasis added).

385. The above statement was materially misleading. Defendants applauded Depomed's marketing efforts while, at the same time, omitting any mention of the fact that their marketing involved off-label tactics. Moreover, while Defendants claimed to have successfully avoided the "challenging opioid market conditions" that had negatively impacted their competitors, they did not attribute their supposed success to Depomed's illicit off-label marketing scheme.

386. Depomed also held an earnings call on August 3, 2016, to discuss Depomed's second-quarter fiscal year 2016 financial results. Schoeneck and Moretti were on the call. Schoeneck stated the following:

> **Jim Schoeneck** - Depomed, Inc. - President & CEO
> ***I believe that the growth of both NUCYNTA ER and IR is particularly impressive, especially given the backdrop of the opioid market. The overall market for opioids is down 4% with leading brands declining more rapidly.*** We fully support the appropriate prescribing of opioids and we believe that tapentadol, the molecule in NUCYNTA, may be uniquely positioned to help pain patients and their physicians while also addressing concerns raised by community leaders and the media. As we mentioned before, ***we have focused on the growth of NUCYNTA IR with four pillars; promotion, positioning, patient access and proper dosing***.
>
> Let's look at what we've accomplished in the past year since our relaunch of NUCYNTA. On the promotion front we continue to perform well with pain

> specialists plus the nurse practitioners and PAs that work with them. Our market share with pain specialists now exceeds 3% of the long-acting opioid market and is almost that high with NPs and PAs. These groups together write about 75% of the NUCYNTA ER prescriptions. This is even more important when you consider that many primary care physicians are slowing their use of long-acting opioids and referring more and more patients to pain specialists where we are much more likely to capture the scripts for NUCYNTA ER.
>
> * * *
>
> As I mentioned earlier, we fully support the appropriate prescribing of opioids including using the lowest effective dose for each patient. ***Even with these market headwinds that have affected both the overall market prescriptions and the dosing levels, we saw NUCYNTA ER and NUCYNTA prescriptions and sales trends continuing to accelerate***. We believe that the unique value proposition offered by NUCYNTA will continued to fuel growth for years to come.
>
> (emphasis added).

387. The above statement was materially misleading. Defendants, on one hand, portrayed Depomed as having successfully avoided the negative ramifications associated with the worsening opioid market while, on the other hand, omitting to tell investors that they were able to do this in part because they were engaging in off-label marketing. Defendants' statements prevented investors from obtaining the information they needed to accurately evaluate the risks associated with investing in Depomed. Had investors known the truth about Depomed's marketing conduct and how the company was able to outpace the market, they would have considered this information before investing in Depomed.

Second Quarter 2016 Form 10-Q

388. On August 3, 2016, Depomed filed a Form 10-Q for the second quarter ending June 30, 2016 ("Second Quarter 2016 Form 10-Q"). The Second Quarter 2016 Form 10-Q was certified and signed by Schoeneck and Moretti

> ***We may incur significant liability if it is determined that we are promoting or have in the past promoted the "off-label" use of drugs.***
>
> Companies may not promote drugs for "off-label" use—that is, uses that are not described in the product's labeling and that differ from those approved by the FDA. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across some medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDCA and FDA regulations restrict communications on the subject of off-label uses of drug products by pharmaceutical companies. The Office of Inspector General of

> the Department of Health and Human Services (OIG), the FDA, and the Department of Justice (DOJ) all actively enforce laws and regulations prohibiting promotion of off-label use and the promotion of products for which marketing clearance has not been obtained. If the OIG or the FDA takes the position that we are or may be out of compliance with the requirements and restrictions described above, and we are investigated for or found to have improperly promoted off-label use, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. In addition, management's attention could be diverted from our business operations and our reputation could be damaged.

Second Quarter 2016 Form 10-Q at 46 (emphasis added).

389. Defendants included the above statement in its quarterly report within a section titled "RISK FACTORS." Defendants' description of the risks relating to off-label marketing were materially misleading. Depomed, by this point in time, had already deliberately engaged in off-label marketing and, as such, had already significantly increased the company's exposure to significant liability. Defendants portrayed the risk of exposure from off-label marketing as a mere potentiality when, in fact, Depomed was actively engaging in off-label marketing. Defendants conduct in this regard concealed from investors the true risks they faced as a result of investing in Depomed.

September 12, 2016 – Morgan Stanley Global Healthcare Conference

390. On September 12, 2016, Depomed presented at the Cantor Fitzgerald Healthcare Conferences. Defendant Schoeneck presented for Depomed. Schoeneck again discussed how NUCYNTA was less euphoric and less abusive. Schoeneck stated:

> **Unidentified Participant**
> Very interesting. So, is that one of the things that is actually putting pressure on the number of total opioids prescribed in the country? I guess it's sort of a -- an incremental effect of the general scrutiny of opioid prescribing that is resulting in what you have just described.
>
> **Jim Schoeneck** - Depomed, Inc. - President and CEO
> ***I think it's the CDC guidelines; it's the press that has been out around opioids***. And, again, the sense that I have and reinforced last week is that it's a number of the primary care physicians that are going, I am not going to do this for long-acting anymore. They really can't say that they are going to totally step out of the short-acting opioid market. That would mean that anybody with a bone break or anything minor like -- relatively minor like that, they would still prescribe the short-acting opioids. But the longer-acting opioids, yes.
>
> ***And interestingly, we are seeing that concentration in the market may actually play pretty well to us.*** We've got about 72% of the scripts for NUCYNTA are

> actually in either the pain specialist's hand or with the nurse practitioners and PAs that work with them. The overall long-acting market is about 55%. So the concentration and focus of the market actually helps us in terms of efficiency of sale, but also is where we are strongest. And both the pain physicians and the nurse practitioners and PAs are still growing in terms of their long-acting opioid writing versus the rest of the market that is contracting.

391. The above statements were materially false and misleading. Schoeneck indicated that the CDC guidelines would "play pretty well to us" because it was forcing patients to go to pain specialist. In reality, NUCYNTA was not as far along as Defendants were hoping and the CDC guidelines were highly affecting sales. Accordingly, this was materially false and misleading.

B. The Truth Begins to Emerge as the Risks Concerning Depomed's Marketing Practices Begin to Materialize

November 7, 2016 – Press Release & Earnings Call

392. On November 7, 2016, Depomed issued a press release titled "Depomed Reports Second Quarter 2016 Financial Results." The press release was also filed with the SEC on the same day. The Press Release stated in pertinent part:

> NEWARK, CA., November 7, 2016 — Depomed, Inc. (Nasdaq:DEPO) today reported financial results and highlighted operational achievements for the quarter ended September 30, 2016.
>
> "Although our third quarter revenues increased by 5% over the previous year's quarter, they did not meet our expectations, as several factors, including a disconnect between prescription demand and wholesaler shipments, influenced net sales of the NUCYNTA franchise and Gralise. Prescriptions for NUCYNTA ER grew 4% over the second quarter, while shipments to wholesalers were down 1%. Prescriptions for NUCYNTA and Gralise were equal to the second quarter, however, shipments were down 6% and 12%, respectively," said Jim Schoeneck, President and CEO of Depomed. "In addition, we made adjustments to our reserve accounts, including managed care and PBM rebate submissions from prior quarters, which impacted our product net sales."
>
> Continued Mr. Schoeneck, "For the rest of 2016 and beyond, we are fully committed to continuing the successful relaunch of our Nucynta franchise and building prescription demand for our products. For the third quarter, NUCYNTA ER reached all time high monthly market share and total prescriptions, with year-over-year prescription growth of approximately 20%. In addition, the rest of our portfolio achieved revenues of $45 million, an increase of 13% year-over-year. Finally, Depomed's recent NUCYNTA ANDA patent litigation win marked a major milestone for the company, giving us more than 9 years to continue to grow the NUCYNTA franchise, with exclusivity established until December 2025."

Business and Financial Highlights

- Third quarter 2016 revenues were $111 million, compared to $105 million for third quarter of 2015, an increase of 5%
- Quarterly net loss of ($12.9) million or ($0.21) per share
- Quarterly non-GAAP adjusted earnings of $20.9 million, or $0.28 per share
- Quarterly non-GAAP adjusted EBITDA of $35.4 million
- Favorable District Court ruling in the company's patent litigation against all three filers of Abbreviated New Drug Applications (ANDAs) of the NUCYNTA franchise with expected market exclusivity until December 2025
- Settlement agreement reached with Starboard Value LP including the addition of three independent directors, James P. Fogarty, Robert G. Savage and James L. Tyree, to Depomed's Board of Directors
- Introduction of a new aspartame-free formulation of CAMBIA® (diclofenac potassium for oral solution)

NUCYNTA Franchise Highlights

- Third quarter 2016 net sales of $65 million
- Net sales of $396 million since acquisition on April 2, 2015
- NUCYNTA ER reached record all-time monthly high prescription volume of over 30,000 reached in August, an increase of 20.4% over August 20151
- NUCYNTA ER reached record all-time monthly high market share of 6.85% of branded long acting opioids and 1.99% of total long acting opioids in September1

* * *

Updated 2016 Financial Outlook

Depomed is updating its 2016 financial guidance as follows:

	Updated Guidance	**Prior Guidance**
Total Revenue	$455 to $465 million	$480 to $505 million
GAAP SG&A Expense	$204 to $208 million	Previously not given
GAAP R&D Expense	$33 to $36 million	Previously not given
Non-GAAP SG&A Expense	$183 to $187 million	$185 to $190 million
Non-GAAP R&D Expense	$32 to $35 million	$28 to $35 million
GAAP Net Loss	$43 to $49 million	Previously not given
Non-GAAP Adjusted Earnings	$79 to $85 million	$95 to $105 million
Non-GAAP Adjusted EBITDA	$152 to $160 million	$175 to $190 million

393. On November 7, 2016, Depomed also held an earnings call to discuss Depomed's third-quarter fiscal year 2016 financial results. Schoeneck and Moretti were on the call and stated the following:

Jim Schoeneck - Depomed, Inc. - President and CEO

First, let me say that our quarterly results fell well short of our expectations. During the quarter, several factors influenced the net sales of NUCYNTA and Gralise. The shortfall is in three areas: ***a disconnect in the quarter between prescription, demand, and shipments***; changes in product reserve accounts linked to rebate submissions for prior periods and additional units falling under existing contracts; and ***prescription demand growth for our key products that did not meet our forecast***. I will address these areas, then Augie will speak to the financial implications in greater detail.

* * *

With that as background, let me now turn to the results from the quarter. Depomed posted third-quarter revenue of $111 million, an increase of 5% compared to $105 million for the third quarter last year. We had GAAP quarterly net loss of $13 million or $0.21 a share.

Our third-quarter non-GAAP adjusted earnings were $21 million or $0.28 a share, and our non-GAAP adjusted EBITDA was $35 million. Augie will review our GAAP to non-GAAP methodology later in the call.

In the third quarter, the NUCYNTA franchise generated net sales of $65 million and has produced $396 million of revenue since its acquisition in April of 2015. During the third quarter, NUCYNTA ER achieved approximately 20% year-over-year prescription volume growth as well as all-time record highs for both total and branded prescription market share.

In August, the brand reached an all-time monthly high of over 30,000 prescriptions, surpassing the previous monthly record set in June. Third-party data shows that we are increasing unique or new prescribers of NUCYNTA, with new prescribers up 10% for the first three quarters of 2016 versus the same period last year.

We continue to see NUCYNTA IR prescription showing signs of growth, with August up 5% versus the prior year and September up 1%. You'll recall that the brand was declining 10% per year prior to our relaunch. Unique or new prescribers for IR are increasing 4% for the first nine months of 2016 versus the same period last year. We also see an increase in dual prescribers, meaning those that prescribe both NUCYNTA ER and IR.

All these are positive signs for the future, especially when you consider that the overall opioid market is down, with the long-acting market showing a 4% year-over-year decline and the short-acting opioid market down 6%. We believe that NUCYNTA offers differentiated properties that favorably position it despite these market pressures.

* * *

August Moretti - Depomed, Inc. - SVP and CFO
Moving on to guidance, we are revising our 2016 financial guidance in light of our performance to date. Guidance for the year is based on actual results for the first nine months of the year and our current budget and expectations for the remainder of the year.

Our budget is based on a large number of assumptions, and there are significant uncertainties in estimating future product revenues. This is particularly true for our largest-revenue products, NUCYNTA and NUCYNTA ER. For a more complete discussion of the relevant risks related to our guidance, I'll direct you to the risk factors section of our quarterly report on Form 10-Q that we expect to file either later today or first thing tomorrow.

With that said, total revenues for our six products for 2016 are expected to be in the range of $455 million to $465 million. This is a reduction from our previous guidance of $480 million to $505 million. We are also reducing our non-GAAP SG&A expense guidance -- non-GAAP SG&A expenses, that is, GAAP expense minus stock compensation; purchase accounting; contingent consideration adjustments; and nonrecurring costs – are expected to be in the range of $183 million to $187 million, a reduction from our previous guidance of $185 million to $190 million. We are also providing GAAP SG&A expense of $204 million to $208 million.

* * *

Ken Trbovich - Janney Montgomery Scott - Analyst
I guess I'm trying to rationalize some of the commentary around the changing guidance, and I just want to make sure I fully understand it. If I understand that commentary, there was sort of three buckets.

First bucket was the change in the wholesaler inventories, which -- if we look at that as being a couple of days, we're talking about 83% of sales somewhere in the single digits, $3 million to $5 million, maybe. And if I understand the adjustments on the rebates, the number that was given was $2.3 million. So if we aggregate those, we are still well less than half of what I'm looking at as the shortfall in the quarter. And certainly maybe the expectations and the impacts going forward, those would be nonrecurring. So then it begs the question of whether or not the difference is entirely a result of the change in prescription demand and your expectations around that.

I guess the reason for the question is that if I look at the guidance and the change in guidance, on the one hand it would suggest that there might not be much of a change in the fourth quarter in terms of the implications. On the other hand, we could see another $20 million change on the other end of -- on the guided range. So I'm trying to better understand how much of this is recurring versus nonrecurring.

Jim Schoeneck - Depomed, Inc. - President and CEO
I think we have -- as -- you've got a good handle, Ken. And Augie and Jack can comment more on the numbers per se.

But I think in terms of the one-time items that are there, in terms of the prescription demand piece, certainly the prescription demand -- while we are setting records on NUCYNTA IR, and while we have made a turn on NUCYNTA, we still in our plan had it moving farther than it has to date.

And that is one that I will be digging into significantly over the next few weeks here on what we can do to make sure that that is accelerating as we would expect.

> ***I think a piece of that is certainly the opioid market***. When we came into this last year, the opioid market was -- long-acting market was growing about 1% a year. Now it's declining 4%. It looks like it's stabilized at about that 4% year-over-year decline, at least for the last three months. We will see where it continues for the rest of the year.
>
> I mentioned on our last call as well that ***we had some downtick in the milligrams per script***. That has continued as well. It hasn't gone down much farther, but it has continued at that lower level. And that puts us in additional 4% or 5% of revenue loss, since this is basically a linear pricing. So as we have continued to see some of those things and not seen changes in those, it certainly does affect both the script numbers going forward and some of the realization per script, in addition to what some of Augie and Jack had mentioned in terms of the gross-to-net change.
>
> (emphasis added).

394. The above statements signaled to investors that Depomed was susceptible to the negative market conditions affecting the opioid industry in general. In the press release and during the earnings call, Defendants disclosed that Depomed was lowering its estimate with respect to revenue and that this decision was in part due to the conditions in "the opioid market" generally. Depomed's disclosures on November 7, 2016 signaled to investors that Defendants' previous statements were misleading, and that perhaps risks existed with regard to Depomed's business that had not been properly disclosed. In response to Depomed's disclosures, the price of Depomed stock declined from $22.89 per share to $19.01 per share on November 8, 2016.

395. At the same time, Defendants also continued to mislead the public with respect to Depomed's marketing practices and ability to avoid the effects of negative sentiment towards the opioid industry. The above statements (identified in bold) misled investors by attributing their relative success to the company's marketing efforts, but omitted to disclose that these marketing efforts included illicit, off-label marketing presentations. Depomed encouraged its sales team to promote NUCYNTA as a safer, less addictive, less abusive opioid that did not contain the same euphoric feeling as other opioids, even though Depomed did not have FDA approval to market NUCYNTA in this regard.

Third Quarter 2016 Form 10-Q

396. On November 7, 2016, Depomed filed a Form 10-Q for the third quarter ending September 30, 2016 ("Third Quarter 2016 Form 10-Q"). The Third Quarter 2016 Form 10-Q was certified and signed by Schoeneck and Moretti

> ***We may incur significant liability if it is determined that we are promoting or have in the past promoted the "off-label" use of drugs.***
>
> Companies may not promote drugs for "off-label" use—that is, uses that are not described in the product's labeling and that differ from those approved by the FDA. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across some medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDCA and FDA regulations restrict communications on the subject of off-label uses of drug products by pharmaceutical companies. The Office of Inspector General of the Department of Health and Human Services (OIG), the FDA, and the Department of Justice (DOJ) all actively enforce laws and regulations prohibiting promotion of off-label use and the promotion of products for which marketing clearance has not been obtained. If the OIG or the FDA takes the position that we are or may be out of compliance with the requirements and restrictions described above, and we are investigated for or found to have improperly promoted off-label use, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. In addition, management's attention could be diverted from our business operations and our reputation could be damaged.

Third Quarter 2016 Form 10-Q at 47-48 (emphasis added).

397. Defendants included the above statement in its quarterly report within a section titled "RISK FACTORS." Defendants' description of the risks relating to off-label marketing were materially misleading. Depomed, by this point in time, had already deliberately engaged in off-label marketing and, as such, had already significantly increased the company's exposure to significant liability. By discussing off-label marketing as something that "might" occur when in fact it "already" occurred, Defendants materially misled investors. Defendants conduct in this regard concealed from investors the true risks they faced as a result of investing in Depomed.

December 11, 2016 – Analyst Report

398. On December 11, 2016, PiperJaffray, a well-respected firm that followed Depomed, issued an analyst report titled "Depomed Inc. (DEPO) Downgrading to Underweight; Trajectory of Underlying Business a Real Concern." The report stated in pertinent part:

CONCLUSION

> We are downgrading Depomed to an Underweight from Neutral and lowering our PT to $14 from $17 based on a closer look at prescription (Rx) trends for the commercial portfolio that heightens our concern that management will not be able to drive significant growth from the business in 2017+. Further, ***it has become clear to us that management, based in part on its own commentary, does not really have a new strategy in place to wring significant further volume growth out of Nucynta ER in the face of more challenging market dynamics***. As such, we believe that further multiple contraction is warranted (i.e., current 2017 P/E of 19x our revised estimate in the context of visibility on a long-term EPS CAGR (2017+) in the high-single digits at best).

(emphasis added).

399. This report signaled to investors that Depomed was misleading investors as to the effect of the opioid market on Depomed. As a result of this partial revelation, Depomed's stock significantly sank from a close of $20.20 on December 9, 2016, the previous trading day, to a low of $17.74 per share of common stock on December 12, 2016. This resulted in a decrease of $2.46 per share, or 12% on unusually heavy volume.

February 21, 2017 – Press Release & Earnings Call

400. On February 21, 2017, Depomed issued a press release announcing its fourth quarter and full year 2016 financial results. The press release was also filed with the SEC, and states in relevant part:

> NEWARK, CA., February 21, 2017 — Depomed, Inc. (Nasdaq:DEPO) today reported financial results and highlighted operational achievements for the quarter and twelve months ended December 31, 2016 and provided 2017 guidance.
>
> "In 2016, we achieved key milestones strengthening our portfolio and de-leveraging our balance sheet. We ended the year with record annual and quarterly revenue and EBITDA. In addition, we posted all-time net sales highs for every one of our brands," said Jim Schoeneck, President and Chief Executive Officer of Depomed. "Our full-year net revenue reached $456 million, representing a 33% increase over 2015, with quarterly revenue of $124 million, an 11% increase year over year. In addition, we have been successful in growing EBITDA from $7 million in 2014 to $111 million in 2015 and $156 million in 2016. This, along with the early pay down of $100 million of our debt, significantly improves our credit profile and positions us well to refinance. We also built future value into the business as legal victories provided us with 9 more years to grow our flagship NUCYNTA franchise and allowed us to advance our patent infringement case against Purdue."
>
> Continued Mr. Schoeneck, "With the clarity on NUCYNTA's exclusivity until December 2025 and the insights gained since its relaunch, ***in February we began***

implementing a multi-faceted growth initiative to increase the appropriate use of NUCYNTA Extended Release and Immediate Release and to drive growth across the portfolio. We continue to focus on opportunities to further differentiate our product portfolio, all with the goal of delivering value to our shareholders and to those we serve."

Business and Financial Highlights

- Record full year net product sales for 2016 were $455 million, an increase of 33% compared to $342 million for full year 2015
- Full year GAAP net loss of ($89) million or ($1.45) per share, which includes a non-cash tax reserve adjustment of ($43) million
- Full year non-GAAP adjusted earnings of $86 million, or $1.15 per share. We are modifying our method of calculating non-GAAP income taxes for non-GAAP adjusted earnings and non-GAAP adjusted earnings per share to align with the guidance under the Non-GAAP Financial Measures Compliance and Disclosure Interpretations issued by the SEC on May 17, 2016. The amounts above reflect the Company's prior methodology of calculating its non-GAAP income taxes for comparability to prior periods and to the Company's prior guidance for 2016. Please see the non-GAAP tax discussion below for further discussion of the new methodology.
- Full year non-GAAP adjusted EBITDA of $156 million
- Fourth quarter 2016 net product sales were a record $124 million, compared to $111 million for fourth quarter of 2015, an increase of 11%
- NUCYNTA franchise reported fourth quarter record net sales of $75 million
- Fourth quarter ending cash and marketable securities was $177 million, cash generated during the quarter was $40 million
- Quarterly GAAP net loss of ($44) million or ($0.72) per share, which includes a non-cash tax reserve adjustment of ($43) million
- Quarterly non-GAAP adjusted earnings of $37 million, or $0.48 per share under the Company's prior method of calculating its non-GAAP income tax expense.
- Quarterly non-GAAP adjusted EBITDA of $51 million
- U.S. District Court rules in favor of two key NUCYNTA patents, providing market exclusivity until December 2025
- U.S. Court of Appeals upheld patents asserted against Purdue Pharma
- Early payment of $100 million of secured debt in April 2016

NUCYNTA® Franchise Highlights

- Full year 2016 record net sales of $281 million
- Fourth quarter 2016 record net sales of $75 million
- Net sales of $471 million since acquisition on April 2, 2015
- NUCYNTA ER® reached record all-time quarterly prescription volume of over 90,000 in fourth quarter(1)
- NUCYNTA ER 2016 total prescriptions of over 344,000, an increase of 19% over 2015(1)

- NUCYNTA ER reached record all-time quarterly market share of 2.08% of total long acting opioids in December(1)
- NUCYNTA reached record all-time quarterly market share of 0.29% in fourth quarter(1)

Marking a continued commitment to unlock value from its portfolio, in February, the company launched the first of a series of initiatives aimed at driving NUCYNTA growth in 2017 which include:

- Salesforce Deployment: ***adds 75 reps to Pain sales force for a total of 257, an increase of 41%;*** Neuro and Oncology sales forces reduced by 70 positions to offset increase; ***new physician targeting emphasizes reimbursement coverage along with prescription volume***
- ***Primary Care Physician Expansion: new salesforce deployment targets more coverage of high decile primary care prescribers***
- NUCYNTA ER Diabetic Peripheral Neuropathy (DPN) Indication: highlights indication in category unique to NUCYNTA ER
- NUCYNTA Immediate Release Promotion: introduces a focused, stand-alone promotional campaign for the first time since relaunch
- NUCYNTA Label Expansion Studies: initiating studies aimed at strengthening NUCYNTA's respiratory depression and abuse profiles

(emphasis added).

401. On February 21, 2017, Depomed also held an earnings call to discuss Depomed's fourth-quarter and fiscal year 2016 financial results. Schoeneck and Moretti were on the call and Schoeneck stated the following:

Jim Schoeneck - Depomed, Inc. - President, CEO
2016 was a year of growth, challenges, and building value. In 2016 we set a full year record with net revenue of $456 million, up 33% over the prior year. In fact, each of our products achieved the highest revenue in their history in 2016, led by our NUCYNTA franchise. Our progress over the past three years has been dramatic, with net product revenue increasing from $114 million in 2014, to $342 million in 2015, and $455 million last year. Our cash flow and bottom line performance has been even more impressive, growing EBITDA from $7 million in 2014, to $111 million in 2015, and $156 million in 2016. ***And all of this was accomplished against three substantive headwinds, changes in the opioid market, continuing pricing pressure from payors, and the challenges of growing a business and a team with regular headline distractions***.

* * *

Now I'll turn back to our commercial and financial performance for last year. ***Starting with NUCYNTA ER, in 2016 we achieved all-time record prescription volumes for the brand, and grew prescriptions 19% over the prior year. And that was against a challenging and changing backdrop in the opioid market.*** In 2015, the long-acting opioid market was stable compared to the prior year. After the release of the new CDC opioid guidelines in early 2016, the market moved steadily

> downward, with the long-acting opioid prescription market ending the year down 5% compared to 2015. We saw daily dosing levels drop as well. Both of these market trends were different than we had anticipated at the beginning of 2016. ***Even with these headwinds, we still saw significant growth in NUCYNTA ER.***

(emphasis added).

402. The above statements were materially misleading. Defendants, on one hand, portrayed Depomed as having successfully avoided the negative ramifications associated with the worsening opioid market while, on the other hand, omitting to tell investors that they were able to do this in part because they were engaging in off-label marketing. Defendants' statements prevented investors from obtaining the information they needed to accurately evaluate the risks associated with investing in Depomed. Had investors known the truth about Depomed's marketing conduct and how the company was able to outpace the market, they would have considered this information before investing in Depomed.

2017 Form 10-K

403. On February 24, 2017, Depomed filed an Annual Report on Form 10-K with the SEC, announcing Depomed's financial and operating results for the quarter and year ended December 31, 2016 (the "2016 Form 10-K"). Schoeneck and Moretti signed and certified the 2016 Form 10-K. In the 2016 Form 10-K, Depomed stated, in relevant part:

> **MARKETING AND SALES**
>
> We have developed capabilities in various aspects relating to the commercialization of our marketed products, including sales, marketing, manufacturing, quality assurance, wholesale distribution, managed market contracting, government price reporting, medical affairs, compliance, and regulatory. Members of our commercial organization are also engaged in the commercial and marketing assessments of other potential product candidates.
>
> Our sales organization includes approximately 300 full time sales representatives. ***Our sales force primarily calls on pain specialists, neurologists and primary care physicians throughout most of the United States.*** Our marketing organization is comprised of professionals who have developed a variety of marketing techniques and programs to promote our products, including promotional materials, speaker programs, industry publications, advertising and other media.

2016 Form 10-K at 8 (emphasis added).

404. The above statements were materially misleading. Defendants described Depomed's recent marketing achievements as successes, but at the same time did not disclose that these supposed successes were obtained in part through an illicit off-label marketing campaign. Depomed was actively targeting primary care physicians with marketing presentations that described NUCYNTA as a safer, less addictive, less abusive opioid that did not contain the same euphoric feeling as other opioids. Depomed did not have FDA-approval to market NUCYNTA in this manner. Depomed also did not have any independent scientific evidence to support these claims. Defendants opted to discuss Depomed's marketing program while, at the same time, omitting that the company's marketing strategy relied in part on off-label promotion. Defendants' omission in this regard was materially misleading.

405. The 2016 Form 10-K also included the same "risk warning" that appeared in Depomed's quarterly reports discussed above. In pertinent part, the 2016 10-K stated:

> ***We may incur significant liability if it is determined that we are promoting or have in the past promoted the "off-label" use of drugs.***
>
> Companies may not promote drugs for "off-label" use—that is, uses that are not described in the product's labeling and that differ from those approved by the FDA. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across some medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDCA and FDA regulations restrict communications on the subject of off-label uses of drug products by pharmaceutical companies. The Office of Inspector General of the Department of Health and Human Services (OIG), the FDA, and the Department of Justice (DOJ) all actively enforce laws and regulations prohibiting promotion of off-label use and the promotion of products for which marketing clearance has not been obtained. Such liabilities would harm our business, financial condition and results of operations as well as divert management's attention from our business operations and damage our reputation.

2016 Form 10-K at 17-18.

406. Defendants included the above statement in its year-end report within a section titled "RISK FACTORS." Defendants' description of the risks relating to off-label marketing were materially misleading. Depomed, by this point in time, had already deliberately engaged in off-label marketing and, as such, had already significantly increased the company's exposure to significant liability. By discussing off-label marketing as something that "might" occur when in fact it "already"

occurred, Defendants materially misled investors. Defendants conduct in this regard concealed from investors the true risks they faced as a result of investing in Depomed.

March 13, 2017 – ROTH Conference

407. On March 13, 2017, Depomed presented at the Roth Conferences. Defendant Moretti presented for Depomed. Moretti stated:

> **August Moretti** - Depomed, Inc. - SVP and CFO
> Right. With all the appropriate caveats, my long-term view is that this is the best molecule in the category. As a dual mechanism of action, it does bind to the new opioid receptor, but at a binding strength that's 1/15th that of morphine. So as a result, ***the patient doesn't get the kind of euphoria that you get with other drugs in the category***.
>
> The second mechanism of action, norepinephrine reuptake inhibition, synergizes with the new opioid agonist and provides effective pain relief ***without the euphoria to the patient***. And as a result, ***you wind up with less likeability, less potential for abuse.*** And I think that the physicians feel that way about the drug; however, those claims are not in the label.
>
> And in terms of some of the -- you see the abuse-deterrent formulations that people are getting approved today. Typically, those claims in the label have to do with particular types of abuse. Opana has a hearing this week. And historically, what they tried -- they tried to get abuse-deterrent labeling indicating that the new formulation of Opana was less subject to abuse by intranasal inhalation, and they didn't succeed with that. But if you look at the labeling, it's that kind of limited abuse-deterrent labeling that people are getting less subject to abuse by inhalation, or less subject to abuse by injection, based on formulations.
>
> And the FDA is very clear to say, all of this is important in the public health approach to opioids. But the number-one way that people abuse opioids is they take too many of them. And nobody has technology that prevents someone from simply taking too many pills. So it's an interesting area. It's an area that the FDA would like to be able to come up with better solutions for. But I think the briefing documents for Opana are very interesting in terms of the FDA's views on the data sources, and how it is that they can get comfortable that a particular drug is, in fact, less abused or less abusable than other drugs.
>
> Our view is that our abuse deterrents comes from the molecule itself, ***in that the molecule provides less euphoria; and, as a result, is less abusable***. It's equal pain relief but ***less threat of abuse and addiction***. But that's different from a physical barrier, or what have you -- a [hardened] pill that might support an abuse-deterrent claim for a particular route of administration.
>
> (emphasis added).

408. The above statements were materially false and misleading. Defendants' represented that NUCYNTA was safer, less abusive, and less euphoric than other opioids due to its dual mechanism of action. However, in reality, the "clinical relevance is unclear" as to the benefits of having dual mechanisms of action. Despite this, Depomed pushed this message on its speakers, sales force, analysts, and investors.

March 21, 2017 – Oppenheimer Healthcare Conference

409. On March 21, 2017, Depomed presented at the Oppenheimer Healthcare Conference. Defendant Moretti presented for Depomed. Moretti stated:

> So it's interesting. When I look back on what our thesis was when we bought the NUCYNTA franchise, at that time the long-acting and short-acting opioid markets were stable. They were demonstrating unit growth of about 1% to 2% per year.
>
> And that macroenvironment has changed since we acquired NUCYNTA. Both the long-acting and short-acting opioid markets are declining year over year. Looking at January numbers the long-acting opioid market is down about 6% and the short-acting opioid market down about 5%.
>
> So that's a change in the macroenvironment. ***We believe that that's the principal focal point or inflection point for that change is really the CDC guidelines that were issued in May of 2016 focusing on opioid prescription for general practitioners. And those guidelines have reinforced the mantra of start low and go slow and that's had an impact.***
>
> There was one additional thesis in our purchasing NUCYNTA which was that when we looked at the daily, the average daily dosage for NUCYNTA, we believed that we could gradually increase the dosage. All of the clinical work for approval of NUCYNTA ER was done at maintenance doses of400 milligrams a day and when we took over the product the average patient dose, daily dosage was in the sort of 270 range. We thought that we would get a mild tailwind, something on the order of 3% or 4% per year from the ability to gradually increase the daily dose.
>
> ***In the event instead of a tailwind we have had a headwind and, again, I think because of the reinforcement of the start low, go slow mantra in the CDC guidelines the average daily dosage has actually come down since we bought the product. So it's now down around I think the last data I saw about 257 milligrams a day.***
>
> ***So I think the opioid market has presented us some headwinds***. I think ultimately for us we believe that NUCYNTA is a unique molecule and that ultimately we have got the best molecule in the class.
>
> (emphasis added).

410. The above statements signaled to investors that Depomed was susceptible to the negative market conditions affecting the opioid industry in general. Specifically, this disclosed for the first time that the CDC was actually presenting significant headwinds to Depomed, and not as they previously stated an additional opportunity. In response to Depomed's disclosures, the price of Depomed stock declined from $15.75 per share at open on March 21, 2017 to $14.95 per share at close on March 22, 2017.

March 28, 2017 – Letter from McCaskill

411. On March 28, 2017, U.S. Senator Claire McCaskill, the top-ranking Democrat on the Senate Homeland Security and Government Affairs Committee, announced that she was opening an investigation into the marketing and sales practices of the nation's top five manufacturers of prescription opioid products, including Depomed (the "Senate Investigation"). The press release stated the following, in relevant part:

> **BREAKING: Opioid Manufacturers are Subject of New McCaskill-Led, Wide-Ranging Investigation**
>
> **Tuesday, March 28, 2017**
>
> **WASHINGTON** – Opioid manufacturers will be the subject of a new, wide-ranging investigation being launched by U.S. Senator Claire McCaskill, the top-ranking Democrat on the Senate Homeland Security and Governmental Affairs Committee. McCaskill is requesting information from the manufacturers of the nation's top five prescription opioid products by 2015 sales, including sales and marketing materials, internal addiction studies, details on compliance with government settlements and donations to third party advocacy groups.
>
> The investigation will explore whether pharmaceutical manufacturers—at the head of the opioids pipeline—have contributed to opioid overutilization and overprescription as overdose deaths in the last fifteen years have approached nearly 200,000. According to the Centers for Disease Control and Prevention, deaths from opioids, including prescription opioids and heroin, reached over 30,000 in 2015 alone, and sales of prescription opioids have quadrupled since 1999.
>
> "I hear it everywhere I go—drug overdose deaths, the vast majority of them related to prescription opioids or heroin, are single-handedly destroying families and communities across Missouri and the country, and I refuse to just stand by and watch—we have an obligation to everyone devastated by this epidemic to find answers," McCaskill said. "All of this didn't happen overnight—it happened one prescription and marketing program at a time. The vast majority of the employees, executives, sales representatives, scientists, and doctors involved with this industry

are good people and responsible actors, but some are not. This investigation is about finding out whether the same practices that led to this epidemic still continue today, and if decisions are being made that harm the public health."

In letters to the heads of Purdue, Janssen/Johnson & Johnson, Insys, Mylan, and Depomed, McCaskill requested:

- Documents showing any internal estimates of the risk of misuse, abuse, addiction, overdose, diversion or death arising from the use of any opioid product or any estimates of these risks produced by third-party contractors or vendors.
- Any reports generated within the last five years summarizing or concerning compliance audits of sales and marketing policies.
- Marketing and business plans, including plans for direct-to-consumer and physician marketing, developed during the last five years.
- Quotas for sales representatives dedicated to opioid products concerning the recruitment of physicians for speakers programs during the last five years.
- Contributions to a variety of third party advocacy organizations.
- Any reports issued to government agencies during the last five years in accordance with corporate integrity agreements or other settlement agreements.

"This epidemic is the direct result of a calculated sales and marketing strategy major opioid manufacturers have allegedly pursued over the past 20 years to expand their market share and increase dependency on powerful—and often deadly—painkillers," McCaskill wrote. "To achieve this goal, manufactures have reportedly sought, among other techniques, to downplay the risk of addiction to their products and encourage physicians to prescribe opioids for all cases of pain and in high doses."

412. In connection with this announcement Senator McCaskill sent a letter to Schoeneck on March 28, 2017. The letter stated in pertinent part:

I am writing to request information from Depomed, as the manufacturer of one of the top five opioid products by 2015 sales, related to the sales, marketing, and educational strategies it has employed to promote opioid use. In the United States today, too many opioids are prescribed, too many are abused, and too many are purchased by the federal government. Medicare Part D spending on commonly abused opioids has increased 165% between 2006 and 2015, reaching a cost of $4. l billion, and almost 30% of Part D recipients received at least one commonly abused opioid in 2015. Financial waste is just one measure of the cost of our national opioid epidemic; in 2015, more than 15,000 Americans died from overdoses involving prescription opioids, and opioid-related hospitalizations and emergency room visits in Missouri, for example, doubled between 2005 and 2014.

This epidemic is the direct result of a calculated sales and marketing strategy major opioid manufacturers have allegedly pursued over the past 20 years to expand their market share and increase dependency on powerful-and often deadly-painkillers.

> To achieve this goal, manufactures have reportedly sought to downplay the risk of addiction to their products and encourage physicians to prescribe opioids for all cases of pain and in high doses. . . . An October 2016 complaint filed by the City of Chicago against Janssen, among other parties, similarly alleges that the company employed "'[d]eceptive messages regarding low addiction risk and low prevalence of withdrawal symptoms" as a "foundation of [its] marketing campaign." At the same time, certain manufacturers allegedly premised their sales and marketing approach on the addictive qualities of opioids. Alec Burlakoff, former sales vice president for lnsys, which manufactures a fentanyl spray-Subsys that is 100 times more powerful than morphine, reportedly stated, for example: "If you can keep [patients] on [Subsys] for four months, they're hooked. Then they'll be on it for a year, maybe longer.''
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> * * *
>
> Other manufacturers have simply targeted physicians with abnormally high opioid prescribing histories.
>
> * * *
>
> Opioid manufacturers have also apparently attempted to influence prescribing behavior through the creation of continuing medical education (CME) to promote opioids for pain management. In a study by Georgetown University, Dr. Adriane Fugh-Berman found that industry-sponsored CME failed to mention opioid death altogether, compared to 26 mentions of the risk of death in non-industry sponsored presentations. Physicians viewing industry-created CME later noted their impression that opioids were underprescribed for chronic pain, and less frequently mentioned risks of addiction than their peers viewing non-industry CME. This practice appears to be widespread across the opioid manufacturing industry. The City of Chicago has alleged in a recent complaint, for example, that major opioid manufacturers, including Purdue and ***Janssen, have "sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating ... deceptive and biased messages***," including presentations that "***focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects***."
>
> * * *
>
> ***Manufacturers have also allegedly provided funding to advocacy groups like the American Geriatrics Society (AGS) and the American Academy of Pain Medicine (AAPM) to develop materials supportive of opioid use; Janssen***, for example, allegedly partnered with AGS and AAPM to create a guide stating that "[rn]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain."
>
> (emphasis added).

March 29, 2017 – Form 8-K

413. On March 29, 2017, Depomed filed a Form 8-K with the SEC titled "Depomed Announces Cooperation Agreement with Starboard Value LP Including CEO and Board Changes" and concurrently filed a Form 8-K with the SEC attaching the press release. The press release stated in relevant part:

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Resignation of James Schoeneck as Chief Executive Officer

On March 28, 2017, the Company announced the resignation of James Schoeneck as President and Chief Executive Officer of the Company and as a Director on the Board. The Company and Mr. Schoeneck entered into a Waiver and Release Agreement (the "Waiver and Release Agreement") in connection with Mr. Schoeneck's resignation. Mr. Schoeneck's resignation is not due to a disagreement with the Company on any matter relating to the Company's operations, policies or practices.

Under the terms of the Waiver and Release Agreement, the Company has agreed to pay Mr. Schoeneck (i) $825,000, which is equal to 12 months of his current base salary, payable in equal installments in accordance with the Company's ordinary payroll practices, (ii) the full cost of the health insurance benefits provided to Mr. Schoeneck, his spouse and dependents, as applicable, pursuant to the terms of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") or other applicable law through the earlier of (a) the end of the 12 month period following the date of the Waiver and Release Agreement or (b) the date on which Mr. Schoeneck is no longer eligible for such COBRA or other benefits under applicable law and (iii) up to six months of documented, bona fide, outplacement services not to exceed $5,000 per month. Pursuant to the Waiver and Release Agreement Mr. Schoeneck has agreed to forfeit all of his outstanding stock options (whether vested or unvested) and unvested restricted stock units granted to him under the Company's equity compensation plans (as in effect from time to time). The Waiver and Release Agreement also includes a standard a non-disparagement covenant, confidentiality covenant, as well as a release of claims.

* * *

Resignation of Samuel Saks and David Zenoff from the Board

On March 28, 2017, each of Dr. Samuel Saks, M.D and Mr. David Zenoff, D.B.A. resigned as directors on the Board, effective immediately. Neither Dr. Saks's nor Mr. Zenoff's resignation is due to a disagreement with the Company on any matter relating to the Company's operations, policies or practices.

414. A number of news outlets reported the Senate Investigation, including USA Today, the Washington Post, and The Hill. As the market received word of the Senate Investigation, investors began to further question Depomed's marketing practices and, in turn, the veracity of Defendants' previous statements. Depomed's stock price declined in response to news about the Senate Investigation. Beginning on March 28, 2017, the price of Depomed's stock declined from its

closing price of $14.90 per share on March 27, 2017, to $14.23 per share on March 28, 2017, to $13.79 on March 29, 2017.

415. Further, despite the fact that investors and analysts generally regarded Depomed's move to replace the CEO and several directors as a positive development, Depomed's stock priced continued to decline due to news about the Senate Investigation. Depomed's stock price declined from $12.82 on March 30, 2017 to $12.55 on March 31, 2017.

416. On March 28, 2017, RBC noted that despite positive legal news related to NUCYNTA, they has also seen "steady downward revision as well as continued opioid related headline risk. We saw more of the latter this week, as Senator McCaskill has launched an investigation into five opioid manufacturers including DEPO around marketing tactics."

417. As reported by Janney, on March 29, 2017, this was directly due to the McCaskill letter and reduced guidance. Janney stated: "The Bad - DEPO is named in a political charged probe by a U.S. Senator into the marketing practices of leading marketers of opioids. The Ugly - DEPO pre-released negative 1Q17 guidance ($95-100 mln, which is at least $6 mln below our estimate and at least $15 mln below FactSet consensus) and will revise '17 guidance the week of May 8, 2017."

418. Notwithstanding, Depomed's share price continued to decline due to news about the Senate Investigation.

May 9, 2017 – Press Release & Earnings Call

419. On May 9, 2017, Depomed issued a press release titled "Depomed Announces Second Quarter 2017 Financial Results" and concurrently filed a Form 8-K with the SEC attaching the press release. The press release stated in relevant part:

> NEWARK, California, May 9, 2017 - Depomed, Inc. (Nasdaq: DEPO) today reported financial results for the quarter ended March 31, 2017 and outlined a set of strategic initiatives aimed at positioning the Company for future growth.
>
> "I am excited to have joined Depomed and am confident in our future," said Arthur Higgins, President and Chief Executive Officer of Depomed. "We are currently facing a number of challenges in our business and they are reflected in our first quarter performance which fell well short of expectations. During my first month on the job, I have worked across the Company to diagnose our recent performance. The key drivers of our first quarter shortfall include: significant declines in the

opioid market and a highly disruptive salesforce realignment which was implemented in February."

Mr. Higgins continued: "Despite these challenges, Depomed has a valuable set of differentiated assets and, as a team, we are working rapidly to address the issues within our control. ***We are in the process of implementing a number of actions that are compatible with market realities and the promotional needs of our products***. These initiatives should have an impact in the coming quarters as we stabilize the business and look to exit the year well positioned to drive sustainable long-term growth and shareholder value."

Business and Financial Highlights

- First quarter 2017 GAAP revenues were $90 million, impacted by a one-time $4.7 million Managed Care rebate charge. Non-GAAP revenues were $95 million excluding the charge
- First quarter ending cash and marketable securities was $195 million, an increase of $17 million during the quarter
- Quarterly GAAP net loss of ($27) million or ($0.43) per share
- Quarterly non-GAAP adjusted earnings of $4 million, or $0.07 per share
- Quarterly non-GAAP adjusted EBITDA of $25 million
- Early repayment of $100 million of secured debt in April 2017
- U.S. District Court upheld 5 of the 6 disputed claim terms of U.S. Patents in Depomed's patent infringement case against Purdue Pharma
- Appointment of Sharon D. Larkin, Senior Vice President of Human Resources and Administration

* * *

Strategic Initiatives Aimed at Driving Sustainable Portfolio Growth

The Company today is announcing a series of initiatives aimed at driving growth and increasing efficiencies in the business.

Improved Salesforce Alignment: the Company has implemented the following adjustments to its recent salesforce realignment. Importantly, the overall headcount of the salesforce will not be impacted.

> Pain Team: the Pain salesforce, which was recently increased from 190 to 258, will remain at 258 and continue to carry NUCYNTA ER and NUCYNTA IR as their primary focus. Gralise has been reassigned to the Neurology team where it will receive proper focus. ***Call plan targets will be optimized to ensure Pain Specialists are sufficiently covered given their increasing importance in this market.***
>
> Neurology Team: the Company will be re-investing in the Neurology franchise and salesforce. The Neurology salesforce numbering 40 will be increased to 60, reflecting allocation of Oncology headcount as outlined below. This group will carry Gralise and Cambia, which are promotionally sensitive products.

> Elimination of Oncology Salesforce***:*** due to the significant deterioration within the Fentanyl market, the Company will stop promoting Lazanda through its field force. The 20 Oncology headcount will be allocated to the Neurology salesforce to enhance the support of Gralise and Cambia.

Streamlining of Corporate Functions: today the Company is implementing a series of cost saving initiatives including an approximately 30 person reduction in force at the Company's headquarters, representing 20% of the home office staff. As a result, the Company intends to take a one-time charge of approximately $5 million in the second quarter of 2017.

Cebranopadol: in light of the changing opioid landscape, the Company is exploring ways to improve cebranopadol's differentiated profile and potential modifications to the development program prior to its entry into Phase 3 trials, which is now anticipated to begin in late 2018.

2017 Financial Outlook

Depomed is issuing new 2017 financial guidance:

	2017 Guidance
Total Revenue (GAAP)	$405-$425 million
Total Revenue (Non-GAAP)	$410-$430 million
Non-GAAP Adjusted EBITDA	$120-$130 million
Total Non-GAAP SG&A Expense	$187-$197 million
Total Non-GAAP R&D Expense	$22-$29 million

This new revenue guidance includes an expectation that wholesaler inventories will be reduced during the year resulting in a reduction of revenue of approximately $7 to $8 million.

The Company is not providing GAAP net loss or GAAP expense guidance as the Company is not able to estimate its non-recurring expenses for 2017.

(emphasis added).

420. Also on May 9, 2017 Depomed held an earnings call to discuss Depomed's first-quarter fiscal year 2017 financial results. Higgins and Moretti were on the call and stated the following:

> **Arthur Joseph Higgins** - Depomed, Inc. - CEO, President and Director
> As you will have noted, the company's first quarter results fell well short of our expectations. While I've only been in the role for a little over a month, I am pleased to report that as a team, we've been able to quickly diagnose the issues behind this disappointing performance and more importantly, are acting decisively to address these issues. Our initiatives will have an impact in the coming quarters as we

stabilize the business and look to exit the year well positioned to drive sustainable long-term growth and shareholder value.

Let me start with the reasons behind our recent performance, which are primarily two-fold: first, challenging and changing market conditions, especially in the pain market; and secondly, a highly disruptive sales force realignment that was implemented in early February, which negatively impacted our sales force execution across all of our products.

First, the market. ***As you're aware, in March 2016, the CDC announced guidelines for primary care physician prescribing of opioids***. ***It is clear to us, though that these guidelines have resulted in a more significant decline in the opioid market than we projected, both in terms of fewer prescriptions and lower daily doses***. Specifically, these pressures have resulted in year-over-year decreases of 9% in the long-acting opioid market and 8% in the short-acting market. Furthermore, in both of these markets, primary care physicians are the fastest-declining prescriber base, with their long-acting prescriptions down 14% year-over-year and their short-acting down 10% year-over-year.

It is important, however, to note that despite these significant market headwinds, we were able to grow NUCYNTA ER 1,200 basis points above the market and NUCYNTA IR 400 basis points. This is an illustration of how these products are valued in the market**.** Of course, we're not projecting that market conditions will improve in the short term. We remain confident that, over time, the pendulum will shift back to more appropriate focus on the vast majority of patients that are using opioid responsibly and rely on them for effective pain control. With differentiated products in NUCYNTA ER and IR, each with lengthy periods of exclusivity, as a company, we are uniquely positioned to benefit from this ultimate recovery.

Secondly, our sales force realignment. As you recall from the company's last earnings call, we implemented a new strategy to alter the configuration and detail in priorities in our pain, neurology and oncology field forces. This change was designed to primarily increase the support and growth of NUCYNTA IR in primary care, and we expect to have a spillover effect onto NUCYNTA ER. It was also assumed we could expand our pain sales force from 182 representatives to 258 by decreasing the field resources behind our non-NUCYNTA portfolio by approximately half, and that we could do this without impacting sales in these products. It has become readily apparent that the decision to significantly expand our reach with NUCYNTA IR into primary care physicians in the face of their increasing reluctance to prescribe opioids was misguided. We also found that the shifting of resources and focus away from our non-NUCYNTA portfolio was negatively impacting their performance to a significantly higher degree than we had expected.

Furthermore, the sales force alignment was highly disruptive, impacting every sales force, every sales representative and every product. As a result, 55% of our prescribing doctors where reassigned to a different sales representative during the first quarter. This severe disruption led us to not achieve the same level of historical performance across our product range.

Based on our first quarter results and a frank, comprehensive internal assessment, we have learned some hard but valuable lessons and are moving decisively to take corrective action. We are implementing the following initiatives that are in line with an evolving marketplace and aimed at optimizing the promotion of our products.

Let me review these initiatives in detail.

For the pain sales force that we increased from 182 to 258, we can adequately cover pain specialists. We will expand most selectively into the primary care physician's base, with an emphasis still on NUCYNTA ER. We are in the process of modifying our co-plan targets. These adjustments will result in an even deeper reach and frequency to the pain specialists. We are now seeing more and more patients refer to them by primary care physicians. At the same time, we will be much more selective in our coverage of the primary care audience, focusing on those decision that act as de facto pain specialists within their communities.

* * *

August J. Moretti - Depomed, Inc. - CFO and SVP

As Arthur just outlined, the first quarter was disappointing. Total GAAP revenues for the quarter ended March 31, 2017 were $90 million. GAAP product revenues reflect a onetime charge of $4.7 million for a dispute with the PBM over rebates relating to NUCYNTA ER, NUCYNTA and Gralise. Excluding this onetime item, non-GAAP revenues were $95 million.

* * *

Now turning to updated 2017 guidance. Guidance for the year is based on our Q1 results and our current budget. Our budget is based on a large number of assumptions, and there are significant uncertainties in estimating future product revenues and operating expenses. For a more complete discussion of the relevant risks relating to our guidance, I'll direct you to the Risk Factors section of our Annual Report on Form 10-K that we filed in February and the Risk Factors section of our quarterly report on Form 10-Q that we expect to file either later today or first thing tomorrow.

With that said, total 2017 GAAP revenues are expected to be $405 million to $425 million, and non-GAAP revenues are expected to be $410 million to $430 million.

We expect total product revenues to be approximately the same, as we are not anticipating any milestone revenue or any significant royalty revenue in 2017.

We expect that the NUCYNTA franchise will represent approximately 64% to 66% of total net sales for the year.

* * *

Unidentified Analyst

This is actually [Brendan] on for Ken. So I was hoping to speak a little bit more about this pendulum of the opioid market. And the first question would be, do you see an opportunity to be more proactive around that? And perhaps, highlighting the differences in NUCYNTA because it's not a traditional opioid. Are there any plans to perhaps change your labeling around or add further data around respiratory data or the market equivalency?

> **Arthur Joseph Higgins** - Depomed, Inc. - CEO, President and Director
> Yes, look, I think, in every dimension, we want to be seen as leaders in this pain opioid space. So you are going to see us be more proactive. I think management in previous calls has mentioned that we are looking to strengthen our label. Again, that data is probably not going to be available until 2019. Again, very consistent with my view of stabilize this year, finish the year strong, grow in 2018 and break out in 2019. In addition, you will see us, [Brendan], take a more active voice in trying to shape opinion in this space. As leaders, I think we've got start to get behind initiatives that focus on responsible prescribing of opioids. And one of the challenges our field force is having, that's such a lot of negative press surrounding opioids, and we need to do our best to make people aware that the vast majority, and I mean, the vast majority of patients on opioids use them responsibly. And if you're going to choose an opioid, choose an opioid like tapentadol which has characteristics that, I believe, make it a drug of choice when you have concerns about opioid use.
>
> (emphasis added)

421. The statements in the press release and earnings call revealed to investors that Defendants' previous statements were misleading. While Defendants previously represented that Depomed had been able to largely avoid the negative impact of the worsening opioid market, that was not so. Indeed, Higgins admitted that Depomed's marketing efforts with regard to primary care physicians was "misguided" given the "increasing reluctance to prescribe opioids." However, despite making certain admissions concerning Depomed's susceptibility to overall negative market sentiments, Defendants continued to mislead investors. Defendants' statements during the earnings call (identified in bold) represented that Depomed's marketing practices had proven successful in spite of worsening market conditions, while at the same time omitting that these marketing practices involved off-label promoting that was exposing Depomed to significant liability risks.

422. These statements also revealed that Defendants off-label scheme was not working. For example, Defendants stated, "the CDC announced guidelines for primary care physician prescribing of opioids. It is clear to us, though that these guidelines have resulted in a more significant decline in the opioid market than we projected, both in terms of fewer prescriptions and lower daily doses." This revealed to the market that the physicians were no longer complying with Depomed's off-label campaign to promote higher dosages. The stock price declined from a close of $10.96 on May 9, 2017 to $9.55 at open on May 10, 2017, a decline of approximately 12.8%.

First Quarter 2017 Form 10-Q

423. On May 10, 2017, after hours Depomed filed a Form 10-Q with the SEC announcing Depomed's financial and operating results for the first fiscal quarter ended March 30, 2017 ("First Quarter 2017 Form 10-Q") which was signed and certified under the Sarbanes Oxley Act of 2002 by Higgins and Moretti. The First Quarter 2017 Form 10-Q stated in relevant part:

> ***We may incur significant liability if it is determined that we are promoting or have in the past promoted the "off-label" use of drugs.***
>
> Companies may not promote drugs for "off-label" use—that is, uses that are not described in the product's labeling and that differ from those approved by the FDA. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across some medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDCA and FDA regulations restrict communications on the subject of off-label uses of drug products by pharmaceutical companies. The Office of Inspector General of the Department of Health and Human Services (OIG), the FDA, and the Department of Justice (DOJ) all actively enforce laws and regulations prohibiting promotion of off-label use and the promotion of products for which marketing clearance has not been obtained. Such liabilities would harm our business, financial condition and results of operations as well as divert management's attention from our business operations and damage our reputation.

First Quarter 2017 Form 10-Q at 51 (emphasis added).

424. Defendants included the above statement in its quarterly report within a section titled "RISK FACTORS." Defendants' description of the risks relating to off-label marketing were materially misleading. Depomed, by this point in time, had already deliberately engaged in off-label marketing and, as such, had already significantly increased the company's exposure to significant liability. By discussing off-label marketing as something that "might" occur when in fact it "already" occurred, Defendants materially misled investors. Defendants conduct in this regard concealed from investors the true risks they faced as a result of investing in Depomed.

July 13, 2017 – Press Release

425. On July 13, 2017, Depomed issued a press release titled "Depomed Announces Intent to Effect a Debt Refinancing" and concurrently filed a Form 8-K with the SEC attaching the press release. The press release included preliminary results for the second quarter and reaffirmed guidance. The press release stated in relevant part:

Preliminary Second Quarter 2017 Financial Results

In connection with the proposed debt refinancing, Depomed today announced selected preliminary financial results for the quarter ended June 30, 2017 and reconfirmed its full year guidance.

The Company currently expects net sales to be in the range of approximately $98 million to $103 million for the quarter ended June 30, 2017. The Company also expects non-GAAP Adjusted EBITDA for the second quarter to be in the range of approximately $23 million to $28 million. Cash and investments as of June 30, 2017 were approximately $117 million. Depomed currently expects to report its full second quarter 2017 financial results in early August.

"Our second quarter performance marked an improvement over our first quarter and was consistent with our expectations," said Arthur Higgins, President and CEO of Depomed. "***We believe that in light of the quarter's performance we are on track to achieve our previously stated financial guidance for the full year***. Refinancing our debt is an important 2017 goal and we expect that we will be able to refinance on significantly more favorable terms given our solid net sales and EBITDA. Our intent is to close the refinancing during the quarter."

(emphasis added)

426. The above statements were materially false. By July 13, 2017, the second quarter had already ended, meaning that Defendants knew how much revenue they needed to generate in order to meet their previously stated financial guidance. In just three weeks, Defendants would materially lower this guidance to $395 million to $410 million from $405 million to $425 million, in part due to worsening market sentiment in the opioid industry. Defendants, however, already knew that Depomed had been negatively affected by worsening market conditions and that their previously-stated guidance was all but impossible. Defendants affirmed the guidance on July 13, 2017 in order to obtain refinancing terms, which Depomed identified as an "important 2017 goal."

427. By affirming this guidance, Defendants provided investors with a false impression of Depomed's operations and finances and further concealed the true effects of the worsening market conditions in the opioid industry. Investors relied upon Defendants' statements to their detriment.

August 7, 2017 – Press Release & Earnings Call

428. On August 7, 2017, Depomed issued a press release titled "Depomed Announces Second Quarter 2017 Financial Results" and concurrently filed a Form 8-K with the SEC attaching the press release. The press release stated in relevant part:

NEWARK, California, August 7, 2017 - Depomed, Inc. (Nasdaq: DEPO) today reported financial results for the quarter ended June 30, 2017 and provided an update to the business.

"Our second quarter product revenue was broadly in line with our expectations," said Arthur Higgins, President and CEO of Depomed. "***We continue to operate in an environment that is challenging and rapidly evolving. The increasing public focus on opioids as well as opioid manufacturers, including by government agencies and other industry stakeholders, will continue to disrupt the opioid markets***. ***While our flagship NUCYNTA franchise continues to outperform the long and short-acting markets, it is clearly not immune to these developments***. Despite these challenges we continue to see opportunities to develop a leadership position in the treatment of pain by working with all stakeholders to encourage the appropriate prescribing and use of opioids. As a company, we remain committed to serving the pain management needs of patients and their physicians."

Business and Financial Highlights

- Second quarter 2017 revenues were $100 million, broadly in line with our estimates
- Second quarter ending cash and marketable securities was $117 million, an increase of $26 million during the quarter after prepayment of $100 million of secured debt and an associated $4 million prepayment fee
- Quarterly GAAP net loss of ($27) million or ($0.43) per share
- Quarterly non-GAAP adjusted earnings of $5 million, or $0.08 per share
- Quarterly non-GAAP adjusted EBITDA of $28 million
- Instituted corporate governance updates to further align shareholder interests and corporate governance best practices
- Increasing Neurology salesforce effective September

* * *

Updated 2017 Financial Outlook

The Company is updating its 2017 financial guidance as a result of recent developments, including (a) ***increased pressure on short-acting and long-acting opioid markets by federal and state governments, managed care and other stakeholders***, (b) July shipment and prescription demand trends, (c) ***increased legal expenses associated with responding to recent government inquiries and subpoenas directed to opioid manufacturers*** and (d) expenses associated with the increase in the neurology salesforce:

	Updated Guidance	Prior Guidance
Total Revenue (GAAP)	$395 to $410 million	$405-$425 million
Total Revenue (Non-GAAP)	$400 to $415 million	$410-$430 million
Non-GAAP SG&A Expense	$195 to $201 million	$187-$197 million
Non-GAAP R&D Expense	$18 to $23 million	$22-$29 million
Non-GAAP Adjusted EBITDA	$107 to $117 million	$120-$130 million

(emphasis added).

429. Despite reaffirming guidance less than one month prior, Depomed revised guidance by 10 million on the low end and 15 million on the high end, over 3.5% less.

430. The same day, Depomed held a conference call with analysts concerning Depomed's second quarter fiscal results. During the call, Defendants Higgins and Moretti each spoke about the opioid crisis' effect on Depomed. In relevant part, Higgins and Moretti stated:

> **Arthur Joseph Higgins - Depomed, Inc. - CEO, President & Director**
>
> ***It is clear we are operating in a challenging and volatile environment***. You only have to turn on the television or read the newspaper to understand that opioid addiction and the resulting overdoses and deaths are a national crisis. Recently, ***the new FDA Commissioner, Scott Gottlieb, called the opioid epidemic the biggest crisis facing the FDA***. Janet Yellen, Chairman of the Federal Reserve, called the opioid epidemic a threat to the U.S. labor force.
>
> And the Commission on Combating Drug Addiction and Opioid Abuse, led by Governor Chris Christie, urged the President Trump last week to declare it a national emergency. Also last week, the FDA announced plans to expand the existing long-acting REMS program to include immediate-release, short-acting opioids.
>
> We are also seeing governmental stakeholders question the role of drugmakers, wholesalers and prescribers in the space. To that end, ***on July 28, we received a subpoena from the Department of Justice regarding our commercialization practices for our NUCYNTA products*** and Lazanda. Similar inquiries have been made to other pharmaceutical companies in the opioid space, and we, as a company, look forward to cooperating with this request.
>
> * * *
>
> ***Not surprisingly and we feel, justifiably, this environment has significantly impacted the overall opioid market.*** In the second quarter, the long-acting and short-acting market showed a year-over-year decline of approximately 11% and 7%, respectively. Against this background, we were able to continue to grow our market share of our NUCYNTA franchise and deliver company-wide revenue of $100.4 million, which was broadly in line with our expectations. However, in the past several weeks, we have experienced some softness versus our forecast in weekly prescriptions and ex-factory shipments of both IR -- NUCYNTA IR and ER. This may reflect the events that we just outlined and does coincide with recent feedback from our pain sales force that ***the primary care segment is becoming more conservative in their rating of opioids and that pain specialists are facing tougher roadblocks in getting prescriptions through the reimbursement system***.
>
> I had thought that given the expansion of our pain sales force earlier this year, we would see a clear separation of our performance versus the market by the year-end.

And while I am not giving up on that goal, I think it's more realistic that this will not be fully apparent until sometime in 2018.

For the reasons I just described, and ***coupled with the associated costs required to respond to incoming legal inquiries*** as well as our very positive recent decision to accelerate our neurology field force build-out, we feel it's prudent to be more conservative with our full year outlook. Augie will give you more specifics on our financials for the quarter and revised guidance shortly.

* * *

Two of the more important moves we'll make in the coming quarters are: firstly, we are reducing the number of calls on targets -- or our call targets in our pain sales force by approximately 20%. ***The vast majority of that target reduction comes from primary care physicians, and it's becoming clear they will play a reduced role in pain management***. This move will allow our sales force to increase frequency and focus and resources to the pain specialists, who are playing an ever-increasing role in the treatment of these patients. To illustrate that point, pain specialists and their physicians, assistants and nurses currently account for approximately 70% of our NUCYNTA franchise. By focusing on the pain specialists, we will protect our base business, and by increasing our frequency and resources to the pain specialists, we will be in a position to efficiently grow the business over time.

* * *

August J. Moretti - Depomed, Inc. - CFO & Senior VP

I want to discuss government inquiries for a moment. Recently, Depomed and other pharmaceutical companies received subpoenas ***relating to opioid sales and marketing practices from the Office of the Attorney General of Maryland and, as you heard from Arthur, the United States Department of Justice***. We are currently cooperating with the state of Maryland and the DOJ in their respective investigations. In addition, Depomed and other pharmaceutical companies earlier received a request for information from Senator McCaskill, the ranking minority member of the United States Senate Committee on Homeland Security and Governmental Affairs, ***relating to the company's promotion of opioid products***. The company has voluntarily furnished information responsive to such requests. As a result of the activity required to respond to these requests, we will be incurring legal expenses in support of our responses, which are reflected in our updated guidance.

So turning now to guidance. We're updating our 2017 financial guidance as a result of recent developments, including an increased pressure on short-acting and long-acting opioid markets by federal and state governments, managed care and other stakeholders; July shipment and prescription demand trends; increased legal expenses associated with responding to recent government inquiries and subpoenas; and expenses associated with the increase in the neurology sales force that Arthur mentioned.

* * *

With that said, total revenues for our 6 products for 2017 are expected to be in the range of $395 million to $410 million. This is a reduction from our previous guidance of $405 million to $425 million. Non-GAAP SG&A expenses, that is GAAP minus stock compensation, purchase accounting contingent consideration adjustments and nonrecurring costs, are expected to be in the range of $195 million to $201 million.

> This is an increase from our previous guidance of $187 million to $197 million and reflects the costs associated with responding to the government inquiries and the increase in the neurology sales force. Non-GAAP R&D expenses are expected to be $18 million to $23 million. This is a decrease from our previous guidance of $22 million to $29 million. Non-GAAP adjusted EBITDA is expected to be in the range of $107 million to $117 million.
>
> (emphasis added).

431. Further, in response to an analyst's question about the opioid market, Higgins stated the following:

> **Ashley Ryu** - RBC Capital Markets, LLC, Research Division - Senior Associate
> This is Ashley Ryu on for Randall. I just want to start with NUCYNTA. So in light of the continued pressures in the opioid space, how much visibility do you feel that you have? It sounds like the market has worsened relative to your initial expectations last quarter. And how do you feel comfortable that this updated outlook kind of captures the right level?
>
> **Arthur Joseph Higgins** - Depomed, Inc. - CEO, President & Director
> Ashley, I think that's a very good question. And I think, again, in my opening remarks, we said we wanted to be more conservative and cautious. This is a highly volatile environment. It's moving rapidly, and we're doing our best to stay on top of it. So what we have presented today is our best outlook based on the information we have available. We believe it's right, but I caveat that by saying this is a very challenging and volatile marketplace.

432. This information further revealed to the market the impact of the opioid crisis on Depomed. Despite Depomed's illegal and improper promotion of NUCYNTA, Depomed was not immune to the opioid epidemic. Further, as a result of Depomed's illegal and improper off-label promotion and marketing of NUCYNTA, Depomed was under investigation from the Office of the Attorney General of Maryland and the United States Department of Justice. Defendants' marketing practices had, all along, subjected Depomed to extreme liability risks. These investigations (along with the Senate Investigation) represented the materialization of these risks. But for Defendants' material misrepresentations and omissions, investors would have been able to appreciate the risks associated with Depomed's marketing practices and considered them when deciding to invest in Depomed.

Second Quarter 2017 Form 10-Q

433. On August 7, 2017, after hours Depomed filed a Form 10-Q with the SEC announcing Depomed's financial and operating results for the second fiscal quarter ended June 30, 2017

("Second Quarter 2017 Form 10-Q") which was signed and certified under the Sarbanes Oxley Act of 2002 by Higgins and Moretti. The Second Quarter 2017 Form 10-Q included never before seen warnings and disclosures. The Second Quarter 2017 Form 10-Q stated in relevant part:

> ***Opioid-Related Request and Subpoenas***
>
> The Company and a number of other pharmaceutical companies recently received a request for information from the ranking minority member of the United States Senate Committee on Homeland Security and Governmental Affairs related to the promotion of opioids. The Company has voluntarily furnished information responsive to such request.
>
> The Company and a number of other pharmaceutical companies recently received subpoenas related to opioid sales and marketing from the Office of the Attorney General of Maryland and the United States Department of Justice. The Company is currently cooperating with the State of Maryland and the Department of Justice in their respective investigations.

Second Quarter 2017 Form 10-Q at 23, 44.

> While we expect NUCYNTA franchise product sales to increase in the second half of 2017 over first half of 2017, ***prescriptions in the opioid market have declined in recent quarters as a result of, among other things, regulatory actions, government investigations and heightened public attention on opioid abuse, and we expect prescriptions in the opioid market to continue to decline at least in the short term***.

Second Quarter 2017 Form 10-Q at 32 (emphasis added).

> ***Changes in laws and regulations applicable to and investigations of, the pharmaceutical industry, including the opioid market, may adversely affect our business, financial condition and results of operations.***
>
> The manufacture, marketing, sale, promotion and distribution of our products are subject to comprehensive government regulation. Changes in laws and regulations applicable to the pharmaceutical industry could potentially affect our business. For instance, federal, state and local governments have recently given increased attention to the public health issue of opioid abuse. The Centers for Disease Control (CDC) recently issued national, non-binding guidelines on the prescribing of opioids, providing recommended considerations for primary care providers when prescribing opioids, including specific considerations and cautionary information about opioid dosage increases and morphine milligram equivalents (MME). Certain third-party payers are, or are considering, adopting these CDC guidelines. In July 2017, the Pharmaceutical Care Management Association, a trade association representing pharmacy benefit managers, wrote a letter to the commissioner of FDA in which it expressed support for, among other things, the CDC guidelines and a seven-day limit on the supply of opioids for acute pain. In addition, states, including the Commonwealth of Massachusetts and the States of

New York, Ohio and New Jersey, have either recently enacted or have pending legislation or regulations designed to among other things, limit the duration and quantity of initial prescriptions of immediate release form of opiates and mandate the use by prescribers of prescription drug databases. Also, at the state and local level, a number of states and major cities have brought separate lawsuits against various pharmaceutical companies marketing and selling opioid pain medications, alleging misleading or otherwise improper promotion of opioid drugs to physicians and consumers. In addition, the attorneys general from several states have announced the launch of a joint investigation into the marketing and sales practices of drug companies that market opioid pain medications. These and other similar initiatives and actions, whether taken by governmental authorities or other industry stakeholders, may result in the reduced prescribing and use of opioids, including NUCYNTA and NUCYNTA ER, which could adversely affect our business, financial condition and results of operations.

At the federal level, the White House Office of National Drug Control Policy continues to coordinate efforts between the FDA, the U.S. Drug Enforcement Agency (DEA) and other agencies to address this issue. The DEA continues to increase its efforts to hold manufacturers, distributors, prescribers and pharmacies accountable through various enforcement actions as well as the implementation of compliance practices for controlled substances. In addition, many state legislatures are considering various bills intended to reduce opioid abuse, for example by establishing prescription drug monitoring programs and mandating prescriber education. Further, the FDA is requiring "black-box" warnings on immediate release opioids highlighting the risk of misuse, abuse, addiction, overdose and death. In addition, during the 2016 presidential campaign, President Trump called for the DEA to restrict the amount of opioids that can be manufactured in the U.S. In March 2017, President Trump announced the creation of a commission to make recommendations to the president regarding new laws and policies to combat opioid addiction and abuse. In August 2017, the commission issued a preliminary report calling on President Trump to officially declare the crisis of opioid abuse a national emergency. These and other changes, and potential changes in laws, regulations and industry practices including those that have the effect of reducing the overall market for opioids or reducing the prescribing of opioids, could adversely affect our business, financial condition and results of operations.

Heightened attention on the problems associated with the abuse of opioids could adversely affect our business, financial condition and results of operations.

In recent years, there has been increased public attention on the problem of opioid abuse. The ability of drug abusers to discover previously unknown ways to abuse and misuse opioid products; public inquiries and investigations into prescription drug abuse; litigation and heightened regulatory activity regarding the sales, marketing, distribution or storage of opioid products, among other things, could cause additional unfavorable publicity regarding the use and misuse of opioids, which could have a material adverse effect on our products and our reputation. Such negative publicity could reduce the potential size of the market for our products and product candidate and decrease the revenues we are able to generate from their sale. Additionally, such increased scrutiny of opioids generally, whether focused on our

products or otherwise, could have the effect of negatively impacting our relationships with healthcare providers and other members of the healthcare community, reducing the overall market for opioids or reducing the prescribing and use of our products.

Governmental investigations and inquiries as well as regulatory actions with respect to the commercialization and use of opioids could adversely affect our business, financial condition and results of operations.

As a result of the greater public awareness of the problem of opioid abuse, there has been increased scrutiny of, and investigation into, the commercial practices of opioid manufacturers generally by federal, state and local regulatory and governmental agencies. For example, we were named as a defendant in a case brought by the City of Chicago against a number of pharmaceutical companies marketing and selling opioid based pain medications, alleging misleading or otherwise improper promotion of opioid drugs to physicians and consumers. This case against the Company was dismissed. We recently received a letter from Senator Claire McCaskill, the Ranking Member on the United States Senate Committee on Homeland Security and Governmental Affairs, requesting certain information from the Company regarding its commercialization of opioid products. We have voluntarily furnished information responsive to Sen. McCaskill's requests. We recently received an Administrative Subpoena from the Office of the Attorney General of Maryland seeking documents and information regarding the sales and marketing of opioid products. We are currently cooperating with the State of Maryland in its investigation. We recently received a subpoena from the United States Department of Justice (DOJ) seeking documents and information regarding the sales and marketing of opioid products. We are currently cooperating with the DOJ in its investigation.

These and other governmental investigations or inquiries in which we may become involved may result in claims being brought against the Company by governmental agencies or private parties. It is not possible at this time to predict the outcome of any governmental investigations or inquiries of the Company or any lawsuits or regulatory responses that may result from such investigations or inquiries or otherwise. However, the initiation of any investigation, inquiry or lawsuit relating to the Company, or any assertion, claim or finding of wrongdoing by the Company, could:

- adversely affect our business, financial condition and results of operations;
- result in reputational harm and reduced market acceptance and demand for our products;
- harm our ability to market our products;
- cause us to incur significant costs and expenses; and
- cause our senior management to be distracted from execution of our business strategy.

> Furthermore, governmental regulators could take measures that could have a negative effect on the Company's business. For example, Endo Pharmaceuticals, Inc. recently voluntarily withdrew, at the FDA's request, OPANA® ER from the market due to the FDA's view that the risks associated with the use of the product outweighed the potential benefits. Any negative regulatory request or action taken by a regulatory agency, including the FDA, with respect to NUCYNTA or NUCYNTA ER would adversely affect our business, results of operations and financial condition.

Second Quarter 2017 Form 10-Q at 48-49.

> ***Pharmaceutical marketing is subject to substantial regulation in the U.S. and any failure by us or our collaborative partners to comply with applicable statutes or regulations could adversely affect our business.***
>
> All marketing activities associated with NUCYNTA ER, NUCYNTA, Gralise, CAMBIA, Zipsor and Lazanda, as well as marketing activities related to any other products that we may acquire, or for which we obtain regulatory approval, will be subject to numerous federal and state laws governing the marketing and promotion of pharmaceutical products. The FDA regulates post-approval promotional labeling and advertising to ensure that they conform to statutory and regulatory requirements. In addition to FDA restrictions, the marketing of prescription drugs is subject to laws and regulations prohibiting fraud and abuse under government healthcare programs. For example, the federal healthcare program anti-kickback statute prohibits giving things of value to induce the prescribing or purchase of products that are reimbursed by federal healthcare programs, such as Medicare and Medicaid. In addition, federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government. Under this law, in recent years, the federal government has brought claims against drug manufacturers alleging that certain marketing activities caused false claims for prescription drugs to be submitted to federal programs. Many states have similar statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, and, in some states, such statutes or regulations apply regardless of the payer. If we, or our collaborative partners, fail to comply with applicable FDA regulations or other laws or regulations relating to the marketing of our products, we could be subject to criminal prosecution, civil penalties, seizure of products, injunctions and exclusion of our products from reimbursement under government programs, as well as other regulatory actions against our product candidates, our collaborative partners or us.
>
> ***We may incur significant liability if it is determined that we are promoting or have in the past promoted the "off-label" use of drugs.***
>
> Companies may not promote drugs for "off-label" use—that is, uses that are not described in the product's labeling and that differ from those approved by the FDA. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across some medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDCA and FDA regulations restrict communications on the subject of off-label uses of

> drug products by pharmaceutical companies. The Office of Inspector General of the Department of Health and Human Services (OIG), the FDA, and the Department of Justice (DOJ) all actively enforce laws and regulations prohibiting promotion of off-label use and the promotion of products for which marketing clearance has not been obtained. Such liabilities would harm our business, financial condition and results of operations as well as divert management's attention from our business operations and damage our reputation.

Second Quarter 2017 Form 10-Q at 51.

434. The Second Quarter 2017 Form 10-Q further confirmed to investors that Depomed was susceptible to the worsening market conditions in the opioid industry. Moreover, it confirmed that Depomed's marketing practices were not as successful or legitimate as Defendants had previously represented. In connection with Depomed's illegal and improper off-label promotion and marketing of NUCYNTA, Depomed was under investigation from the Office of the Attorney General of Maryland and the United States Department of Justice. For the first time, Depomed's quarterly report included disclosures that detailed the risks it faced in connection with worsening market conditions as well as its efforts to avoid the negative effects from the market conditions, *i.e.*, Depomed's off-label marketing.

435. PiperJaffray issued an analyst report on August 7, 2017 titled "Another Downwards Guidance Revision; Hard to Envision Multiple Recovery." The PiperJaffray report stated in pertinent part that Depomed "cut its 2017 revenue and EBITDA guidance ranges once again, driven in part by continued headwinds facing the NUCYNTA franchise and also higher spend." It continued "Management conceded that the opioid crisis has clearly had an impact on the NUCYNTA franchise even though the products have hardly been among the worst offenders when it comes to diversion, misuse and abuse."

436. Janney issued an analyst report on August 8, 2017 titled "Another disappointment, downgrading DEPO to Neutral, lowering FV to $8." The Janney report stated in pertinent part:

> Just weeks ago, DEPO pre-released 2Q17 results (in-line with our estimates) and reaffirmed its full year guidance. The quarter came in generally as expected, but DEPO surprised by lowering its full-year guidance for revenues by $10-$15mln and raising its expense guidance (low-end raised by $4 mln). After struggling for months to stem the negative prescription trends across its product portfolio, ***the revised guidance seems to be an admission the challenges facing its business are far greater to overcome than fixing the sales force realignment implemented by the prior CEO***. The new CEO's hope for demonstrating separation for negative

> industry trends for opioids by year-end has been replaced by the possibility it happens sometime next year. On lower estimates, we downgrade to NEUTRAL and lower our fair value estimate from $18 to $8.

(emphasis added).

437. Depomed's August 7, 2017 disclosures, including the press release, earnings call, and quarterly report, prompted a stark response from investors. In response to the news, Depomed's share price declined from $9.23 per share of common stock to $6.15 share per share of common stock on August 8, 2017, a decline of $3.09, or 33.42%.

C. Post Class Period Events

438. Due to the worsening headwinds within the opioid market, Depomed ultimately sold Lazanda to Slán Medicinal Holdings on November 7, 2017, and entered into a commercialization agreement with Collegium Pharmaceutical, Inc., for the NUCYNTA brand on December 4, 2017. Investors and analysts alike were generally relieved that Depomed was abandoning the opioid drugs. Depomed's stock price increased following these announcements.

439. In response to Senator McCaskill's Senate investigation, on February 12, 2018, the Senate Homeland Security and Governmental Affairs Committee released a second minority staff report of the "Fueling an Epidemic" series titled, "Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups." This report discussed the relationship between Depomed and advocacy groups and professional societies operating in the area of opioid policy.

440. The report provides a comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies in the area of opioids policy. The study found that manufacturers of opioid, including Depomed, provided millions of dollars to groups that echoed and amplified messages favorable to increased opioid use. The groups also issued guidelines and policies minimizing the risk of opioid addition and promoting opioids for chronic pain, lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for over prescription and misbranding. Notably, a majority of these groups also strongly criticized the 2016 guidelines from the CDC that recommended limits on opioid prescriptions for chronic pain.

441. The report found that "[t]he fact that these same manufacturers provided millions of dollars to the groups described below suggests, at the very least, a direct link between corporate donations and the advancement of opioids friendly messaging. By aligning medical culture with industry goals in this way, many of the groups described in this report [including Depomed] may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic." Additionally, the report found that these groups that were paid by in part by Depomed, "amplified messages favorable to increased opioid use."

442. Additionally, between March 2018 and December 2018 alone, at least thirty-eight opioid lawsuits have been filed against Depomed. The lawsuits allege from extensive investigations that Depomed engaged in an intentional and deceptive marketing campaign to promote the use of prescription opioids, including NUCYNTA, and that their conduct has resulted in a national epidemic of opioid overdose deaths and addictions.

443. These lawsuits also allege that Depomed engaged in a deceptive marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain by: a) downplaying the serious risk of addiction; b) creating and promoting the concept of "pseudoaddiction" by advocating that signs of addiction should be treated with more opioids; c) exaggerating the effectiveness of screening tools to prevent addiction; d) claiming that opioid dependence and withdrawal are easily managed; e) denying the decreased effectiveness of opioids over long-term use and the corresponding need for increased dosages; and f) exaggerating the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction.

444. The lawsuits allege that Depomed made these false representations directly to doctors and patients through advertising campaigns and "detailers" (sales representatives who directly targeted doctors).

445. They further allege that Depomed marketed their products indirectly to avoid FDA scrutiny and regulation. They did this through seemingly unbiased and independent third parties, including KOLs (seemingly independent doctors) and professional societies and patient advocacy groups ("Front Groups") funded in part by Depomed. They also allege that Depomed used "unbranded advertising" (promoting the general use of opioids without naming a specific drug) and

manipulated published promotional materials about opioids in scientific literature to avoid FDA regulation and to give the false appearance that these were independent organizations outside of the Depomed's control.

D. Scienter Allegations

446. As alleged herein, Defendants acted with fraudulent intent and/or deliberate recklessness when making the above misrepresentations and material omissions. As explained in detail below, Defendants knew that they could not promote NUCYNTA off-label, but nonetheless engaged in a widespread campaign to promote NUCYNTA off-label by a) promoting NUCYNTA as a safer, less addictive, less abusive opioid that did not have the same euphoric feeling on patients; b) promoting dosages inconsistent with NUCYNTA's label; and c) marketing a side-by-side comparison of NUCYNTA to Oxycodone CR. Despite this knowledge, Defendants trained their sales representatives to use off-label marketing tactics and material to sell NUCYNTA. Defendants also knew about the allegations against Janssen in the City of Chicago Complaint related to the illegal and improper marketing of NUCYNTA. However, Defendants used the same sales team as Janssen to promote NUCYNTA, knowing that Janssen was being sued for, among other things, improperly marketing NUCYNTA. Defendants had done significant research into NUCYNTA before acquiring the drug from Janssen, closely monitored the opioid market, and were intimately familiar with Depomed's sales team training and strategy. Defendants also had motive to defraud investors and incentivized both its speakers and sales representatives to promote NUCYNTA off-label. This companywide culture at minimum caused Defendants to be deliberately reckless in making the false and misleading statements. Accordingly, Defendants acted with scienter when they portrayed Depomed as having successfully avoided the negative ramifications associated with the worsening opioid market while, on the other hand, omitting to tell investors that they were able to do this in part because they were engaging in off-label marketing.

447. The critical nature of NUCYNTA and the scrutiny surrounding off-label marketing of Schedule II drugs strongly supports the conclusion that, at the very least, Depomed acted with scienter under the corporate scienter doctrine.

Defendants Knew or Recklessly Disregarded that NUCYNTA Was Being Affected by the Opioid Headwinds but Misled Investors Regardless

448. At all relevant times, opioids were under intense scrutiny due to their addictive and dangerous nature. Defendants were well aware of this fact, but indicated that sales of NUCYNTA would not be affected by the opioid headwinds because NUCYNTA was a "different" opioid that was less abusive, and less euphoric. According to Defendants, it was these properties that would cause physicians to migrate towards NUCYNTA while turning away from other opioids. In reality, the reason NUCYNTA was doing so well in the face of the headwinds was due to its off-label marketing campaign. This would eventually catch up to Depomed and lead to a huge lowering of its forecast.

449. The FDA explicitly indicated that NUCYNTA is a Schedule II opioid. Further, there is no evidence that NUCYNTA is less addictive than other opioids. Therefore, regardless of any perceived benefits of NUCYNTA, NUCYNTA would always be impacted by the same regulations, and government crackdowns and investigations as were its competitors.

450. Throughout the Class Period, Defendants knew or recklessly disregarded that NUCYNTA was being affected by the government crackdown on opioids. Despite this fact, Defendants misled investors that NUCYNTA sales were not affected by the headwinds.

451. In an attempt to curb the opioid epidemic, on March 18, 2016, the CDC issued guidelines for prescribing opioids for chronic pain. The guideline provided recommendations for primary care clinicians prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. These guidelines directly affected NUCYNTA as NUCYNTA was used primarily for chronic lower back pain.

452. The CDC guidelines explicitly state that opioids like NUCYNTA should not be used if possible. According to the CDC, nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.

453. Additionally, the CDC states that when the use of opioids are needed, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting opioids. It also states that when opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.

454. The above regulations that primary care physicians were supposed to follow as of March 2016, were in direct contrast to NUCYNTA's marketing campaign. Depomed's "four pillars" to increase growth surrounded on increases the dosages of NUCYNTA ER to patients. The fact that the CDC was directly aimed at opioids like NUCYNTA show that Defendants knew, or were deliberately reckless, that NUCYNTA was being affected by government regulations, *i.e.* the opioid headwinds throughout the class period.

455. Additionally, statements made by Depomed's former employees show that NUCYNTA was being affected by the headwinds, and that Defendants knew or were deliberately reckless in not knowing that they were misleading investors.

456. FE1 stated that he and other sales representatives were aware that Depomed's sales of NUCYNTA were not meeting company expectations as early as January 2016 – just seven months after the product launched. FE1 said the company convened its sales force for a national POA (plan of action) conference at the Hilton Anaheim in Anaheim, California that commenced on January 24, 2016. Both her bosses, David Sims and a sales representative named Jamie Dunham were at that meeting. According to FE1, also in attendance was then-CEO James Schoeneck and Steve Greco, Depomed's then-vice president of sales.

457. FE1 indicated that general knowledge of the downturn in sales among employees "was a given." FE1 stated that at the meeting they "did a lot of role-playing for NUCYNTA to tighten up our message, so we could move numbers and get scripts."

458. FE2 stated that less than a year after Depomed bought NUCYNTA, FE2 and other sales representatives began to worry – in part, because of the growing national discourse on opioids, and in part, because of how focused Depomed's survival became on NUCYNTA's success.

459. Accordingly to FE2, "the sales people knew the ship was sinking." "I'd say six to eight months after we bought it [NUYCYNTA]. All you had to do was open up a paper and realize the opioid market was in trouble. [Yet] we're sitting here, saying, 'The business is great!'"

460. FE2 also said that Depomed constantly exerted pressure on its sales force to maintain and exceed sales expectations of NUCYNTA. "If we're not out there selling NUCYNTA, we're not going to have jobs." According to FE2, the pressure often came through subtle insinuations instead of direct mandates. "Just insinuation – if we want to keep this company going, NUCYNTA is our flagship." FE2 said management told employees, "What do you take it as? If you want your job, you keep selling."

461. Despite a growing negative perception of opioids, FE2 said during his time promoting NUCYNTA, his sales goals were never adjusted, or lowered, based on a reflection of a downturn in demand. "No, no, no, no!" he said. "We were still constantly being told that it's the flagship, and you've got to keep the business going."

462. FE2 stated that the downturn in prescriptions of NUCYNTA was noticeable to him and other employees. "Obviously enough that they got rid of Jim and brought someone else in, and brought someone in to be the hatchet man," he said.

463. FE2 said he based the sales drop, and the company's knee-jerk reaction to it, on "the perception of opioids, and just what's going on with the market, and the fact that we owed so much money for this opioid, and we weren't going to recoup our money."

464. FE3 said when he started with Depomed, he was well aware of the growing national concern with opioid medications. According to FE3 however, at no time did Depomed seem concerned about the industry or the possibly negative perception of such drugs as NUCYNTA.

465. FE3 stated, "Everybody said we were doing really good, but I didn't think we were. We weren't getting a lot of scripts from orthopedics. I know a lot of the orthopedics were burnt the first go-round with Janssen."

466. FE3 stated that despite the negative headwinds, Depomed seemed confident in its opioid product NUCYNTA, in particular, because the company was promoting NUCYNTA internally as an opioid that didn't present the same kind of reaction as street level opioids. Despite the company's messaging, FE3 said it was evident, at least to him, that NUCYNTA was not being embraced the way the company touted. "NUCYNTA was not a gangbuster. I just remember being very disappointed," he said. "I worked so hard to get it going again, and it was not taking off. Then we lost coverage."

467. FE4 stated the company was being driven by a downturn in sales of NUCYNTA around the time that Schoeneck was ousted. "There was definitely a sense of urgency," he said. "There was absolutely a sense of urgency with NUCYNTA, the whole portfolio, to right the ship. I don't know the ship was listing that much. It was just a difficult time in the market, (the) opioid crisis. I say that with air quotes. I don't think Depomed or Starboard were prepared for the challenges that would come with the opioid market."

468. Despite the growing negative headwind nationally toward opioid products, FE4 stated that there was surprisingly little discussion about the overall 'epidemic,' or its ramifications, internally. FE4 said he wasn't terribly surprised most people kept quiet – after all, NUCYNTA was not considered the same as other medications in the opioid market.

469. FE4 said that the sales downturn, coupled with the national discourse on opioids, never became a 'talking point' internally. "Not proactively," he said. "Candidly, when you would have some side-conversations with people in the executive team, I would bring it up, or others would bring it up, and they would minimize the concern. It was never anything discussed proactively at any level."

470. When asked to whom he spoke on the executive team about the issues, FE4 said: "It would vary from regional managers to Ron Menezes, Scott Shively, to people in marketing, people in training. Augie [August Moretti] was always quiet. He was there if he had to raise his hand and say 'here,' but in terms of being accessible to the sales team, it was not very often. Jim [Schoeneck] was approachable. You could go up to him and discuss things. He was very positive about the opportunity."

471. FE5 stated that the decline in NUCYNTA ER prescriptions coincided with a change in CDC guidelines for so-called "morphine dosage equivalents". Essentially, the new CDC guidelines "squashed" the dosage rate for morphine equivalents so low as to be at an "almost non-therapeutic" level. At that point, the emphasis went from NUCYNTA ER to NUCYNTA IR, which he called "a crazy move" because Depomed was now trying to compete against Oxycodone, but this was not where the "market is at" in regards to opioids, nor could NUCYNTA IR compete effectively against Oxycodone (or Vicodin).

472. FE5 knew about the drop-off in prescriptions because graphs were distributed to the sales representatives showing the prescription activity in their territories and which would show "where I was losing or gaining" in terms of prescriptions. FE5 only received such graphs for his territory, but he would talk to the other reps in the District. As he explained, the District was comprised of ten representatives, "so we talked" and "the general belief" was that the new CDC guidelines for morphine equivalent dosages was responsible for the decline in opioid prescribing activity. Oregon and Washington were "hit hard" by the new regulations. As he put it, "Doctors were moving away" from opioids because they did not want to prescribe non-therapeutic doses (per the new guidelines), but also did not want to jeopardize their patients' lives. This was at least the case amongst primary care physicians.

473. FE8 also talked about the opioid headwinds. FE8 cited increasing regulatory hurdles for opioid prescribing that he anticipated would make it difficult for him to achieve his quotas. FE8 said that a lot of doctors were losing their licenses and were fearful of legal retaliation for prescribing opioids. The regulatory changes for opioids had begun in Vermont, followed by Rhode Island and Connecticut. Overall, the pharmaceutical pain market was in "double-digit freefall" even as Higgins increased the sales quotas by 10%.

474. FE8 said the changing regulatory environment was clearly having a negative impact on NUCYNTA prescriptions because the overall market for opioids had a double digit recline in sales percentages going into 2017. But even as the opioid market had clearly retracted, Depomed increased the quotas for the sales reps by 10% over what they had achieved in 2016, which FE8 said was simply "crazy". Furthermore, FE8 said that even if the opioid market had not been declining,

the quotas for 2017 were still too high and not attainable. FE8 noted that if the market had been growing and/or stable then the 10% quota increases were "maybe obtainable". But in a declining market, with the media proclaiming an opioid crisis, and the associated scrutiny of opioid prescribing, to include doctors being arrested, then Depomed senior management were "out of their minds" to increase the quotas. The "long-term sustainability was not there". And in his opinion, Depomed senior management should have held a stockholder meeting in which they acknowledged these realities (e.g., market decline, regulatory hurdles and so forth) and then adjust and reduce the company's forecast. In his opinion, Depomed would have been in a better position if they had done this.

475. FE8 had thought to himself that he was doing OK with his sales, but he had wondered for how much longer he could do so. For instance, Rhode Island had imposed some of the strictest opioid regulations in the country on the heels of Vermont doing so, so Rhode Island had become very limited as an opioid market. FE8 said that Rhode Island was only allowing for a five-day prescription of Percocet following surgery whereas before surgeons had been prescribing upwards of one to two months of whatever their favorite pain product happened to be. In FE8's view, increasing the quotas in 2017 was "sheer desperation" on the part of Depomed management because Starboard Value wanted profits for the company, but they were "in over their heads" (including trying to bring a new drug to market).

476. FE8 stated that Depomed's management were not reacting to the opioid market, which was shrinking because of increased regulations. According to FE8, the management "didn't want to hear" that certain state regulations were making it very tough to prescribe opioids, even though these market shifts were well understood at the local level. FE8 also explained that there were "people like me" who voiced their opinions up the reporting chain about these matters. However, FE8 said that the response at Depomed was "crickets" (i.e., nothing). FE8 said that most companies will try to come up with a solution when there are negative matters raised by personnel, but this was not the case at Depomed.

477. FE10 said it was clear almost immediately following NUCYNTA'S launch in June 2015 that the drug was not performing and selling as well as Depomed officials had hoped. "NUCYNTA had already been on the market by J&J. It was doing decently, but not great."

478. Asked how soon after the launch Depomed realized NUCYNTA was not doing as well as promised, FE10 said: "Pretty much right off the bat." Asked whether that indication come from his own experience, from other sales reps or from the corporate home office, FE10 said the lagging sales indicators were "coming from corporate."

479. FE10 explained that with any sales campaign, once a company realizes that its sales force is not hitting established quotas then it knows its sales quota projections are not reflective of market demand. With NUCYNTA, he said, it was clear early on that Depomed's sales goals were unrealistic. Depomed responded by adjusting its goals. "After they realized that reps were not going to be making any bonus money, they retooled the incentive compensation formula so we would be able to make some money on selling NUCYNTA," FE10 said.

480. According to FE10, the fact that Depomed had to go back and revise its quota goals so soon after the launch was a clear indicator that the drug was not selling as expected. "The sales numbers and the realization that, yeah, they had to redo everybody's sales goals," he said.

481. FE10 did recall hearing both Schoeneck and/or Greco address the issue. FE10 stated "That was no surprise for Jim or Steve to say, 'We're not hitting our goals. We need to do better.' It would have been at the national meetings. That was pretty much the only time you heard Jim or Steve."

482. FE10 recalled hearing about NUCYNTA'S lagging sales during at least one national sales meeting stating, "We were told at national meetings we needed to do better because we weren't hitting goals." FE10 stated that the lagging sales performance was a weekly topic on the district sales calls. FE10 stated that "Weekly district calls, we would talk about goals and how far we were from them." Accordingly to FE10, every month during his tenure, sales representatives would receive evidence that the company's actuals were far removed from its projections. FE10 stated that "Every time we got new sales figures, every month, we could see individually how far we were from goals."

483. FE10 said Depomed did not make any adjustments to its marketing and/or sales strategy for NUCYNTA, even as the national perception of opioids became more negative. FE10 stated that "It did make our jobs harder because state legislators would change the laws and make it harder for family practitioners and family physicians to write opioids."

484. Defendants did not disclose NUCYNTA's susceptibility to the opioid headwinds until November 7, 2016, and August 7, 2016 when Depomed significantly decreased guidance due to the opioid headwinds. As stated by Higgins on August 7, 2016, NUCYNTA "is clearly not immune to these developments." This revealed to the market that as a Schedule II opioid, NUCYNTA was just as susceptible to the opioid headwinds as its competitors.

485. The above allegations show that Defendants knew, or were deliberately reckless in not knowing, that their representations to investors that Depomed was not subject to the opioid headwinds were misleading.

Defendants Knew or Recklessly Disregarded that NUCYNTA Was Being Promoted Off-Label and that its Statements were Materially False and Misleading due to Depomed's Widespread Off-Label Marketing Campaign

Depomed Trained and Pressured its Sales Representatives to Promote NUCYNTA Off-label

486. Defendants encouraged and promoted a companywide culture of selling NUCYNTA by marketing NUCYNTA off-label and by any means necessary. For example, Depomed had at least three national sales meetings per year. At these events, Depomed provided the sales representatives with information and marketing materials that were "off-label." For example, Defendants told its sales representatives that NUCYNTA had a lower street value than other opioids, that it was less euphoric due to NUCYNTA's dual mechanism of action, and that it was less addictive compared to its competitors. Defendants also told its sales representatives to promote increased starting dosages of NUCYNTA, and distributed a side-by-side comparison of NUCYNTA to Oxycodone CR.

487. Depomed encouraged a culture where sales representatives were required to do anything possible to meet their quota. Engaging in off-label marketing was routinely encouraged and often required. To do this, representatives often targeted primary care physicians who were not

as knowledgeable as pain specialists and encountered a more diverse group of patients, not all who were in chronic pain.

488. Depomed's sales force was compensated based on the number of NUCYNTA prescriptions written in each sales representative's territory. Depomed encouraged these sales representatives to maximize sales of NUCYNTA and meet their sales targets by relying on the false and misleading statements described above.

489. For example, Depomed's sales force was trained to trivialize addiction risk. During the very time Depomed was instructing its sales force to trivialize the risks of addiction and withdrawal associated with the use of NUCYNTA to treat chronic pain, it knew that significant numbers of patients using opioids to treat chronic pain experienced issues with addiction.

490. The compensation to Depomed's sales representatives for the deceptive messages they were promoting to increase sales of NUCYNTA and NUCYNTA ER, were directly tied to how many of these prescriptions were written by the doctors. These doctors were listed on the quarterly call plans they received from district managers, along with how many doctors or clinics in the assigned zip codes prescribed the drugs that they were being asked to sell. Family practices and internal medicine doctors made up a large percentage of the call plan targets for opioids, since, as noted above, these generalists were less knowledgeable about opioids and more likely to fall victim to sales representatives' misrepresentations.

491. Depomed's sales representative were instructed to push the envelope when selling its prescription medications, such as NUCYNTA ER by stressing that NUCYNTA ER didn't hit receptors like other opioids so it was less addictive and had fewer withdrawal issues; to promote NUCYNTA and NUCYNTA ER as a safer alternative to nonsteroidal anti-inflammatory drugs; and, when discussing side effects related to NUCYNTA and NUCYNTA ER, to focus only on nausea, itchy skin, and vomiting. Depomed's sales representatives told physicians that they could prescribe higher doses of NUCYNTA ER because its mechanism works differently than other opioids; that Depomed's opioids can improve their patients' ability to function in their lives and enable them to get off workers' compensation or work pain-free; and, the physicians were provided various books, articles, and pamphlets as handouts by Depomed's sales representatives.

492. Depomed's sales representative were required to attend regional "Plan of Action" meetings several times a year, usually at a hotel or conference facility. These meetings would include presentations regarding the marketing of Depomed's drugs, including NUCYNTA and NUCYNTA ER. Based on the uniform character of Depomed's marketing, Depomed's sales representatives would have received the same sales training and made the same misrepresentations.

493. Depomed's sales representatives used a number of KOLs in support of its efforts to sell NUCYNTA and NUCYNTA ER. Based on the uniform and nationwide character of Depomed's marketing, these speakers were trained to deliver the misleading messages described above to prescribers.

494. Depomed's sales representatives promoted NYUCYNTA and NUCYNTA ER as safe and effective for the long-term treatment of chronic pain and told physicians that drugs like Tylenol kill the liver, thus, its medications were cleaner by comparison since they did not attack the organs.

495. Depomed's sales representatives were trained to tell prescribers that its medications such as NUCYNTA and NUCYNTA ER did not offer the same euphoric feeling as other opioids. It was common for Depomed's sales representatives to downplay the addictive nature of its medications such as NUCYNTA and NUCYNTA ER.

496. The materially misleading messages and materials Depomed provided to its sales force were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, irrespective of the risks, benefits, and alternatives.

497. This culture was corroborated and discussed in detail by former employees as described below.

498. According to FE2, Depomed paid its sales force based on volume increases, meaning the more NUCYNTA that flooded the market, the higher the payouts. It would be volume, for sure," he said, referring to payment incentives. "We were being convinced it was safer opioids. It's funny – they were very cautious in how they chose their words because everybody was being sued for mixed marketing. You can't say to the doctor, 'It doesn't have street value.'" However, FE2 indicated that was "the overall consensus that was being told to us."

499. FE2 also said that Depomed constantly exerted pressure on its sales force to maintain and exceed sales expectations of NUCYNTA. "If we're not out there selling NUCYNTA, we're not going to have jobs." According to FE2, the pressure often came through subtle insinuations instead of direct mandates. "Just insinuation – if we want to keep this company going, NUCYNTA is our flagship." FE2 said management told employees, "What do you take it as? If you want your job, you keep selling."

500. FE3 indicated that it was clear to him that the company was pushing its sales force to move NUCYNTA. "We had quotas," he said. "Everybody had a quota. Everything was based on semesters. You would get new quotas, usually they were unobtainable working in Massachusetts. You tried your best. You were aiming to get so much of your quota so you could get your bonus."

501. Additionally, FE5 indicated that Depomed monitored the top prescribers of opioids and that he was assigned the top ten to fifteen prescribers of opioids in his region. In addition he indicated that he would also try and call on other physicians and prescribers besides those that he was assigned. FE5 said that the number of prescribers he called on varied quarter to quarter because Depomed would "reshuffle the deck" every quarter in regards to who he should call on and that at any given time he might be calling on ten to 25 of the top opioid prescribers. The prescribers also changed as FE5 successfully developed prescribers and therefore did not need to call on them.

502. FE5 stated that between 2015 through 2016, he and the other Depomed sales representatives "had definitely" been targeting primary care physicians. However, FE5 stated that once the new CDC guidelines were released, primary care physicians wrote fewer prescriptions, and instead referred their patients to pain clinics. FE5 stated that his quotas may have been around 100 NUCYNTA IR and ER prescriptions in a month, and that his NUCYNTA ER quota was probably 20-30 a week and 80-100 a month.

503. FE6 stated that he called on pain management practices, primary care physicians who were already prescribing a lot of opioids, nurse practitioners, and "anyone" in his region who was already prescribing opioids. When asked if primary care physicians were sufficiently knowledgeable about opioids, he said that in his experience in pharmaceutical sales, many primary care physicians are "so busy" that it's "go-go to the next patient" and they are "not totally educated."

504. FE6 indicated that for a lot of the products that Depomed sold the sales representatives were ostensibly "pushed to say" what the drugs were indicated for, but that when they were talking to doctors and if they were able to get an understanding of a particular patient the prescriber was treating, then they might make other representations. For instance, he said that Depomed's Gralise product was only indicated for post-neuralgia. However, Gralise competed against Lyrica (a competitor drug) which had more indications than Gralise. The Depomed sales representative would tell doctors that if they were to use Gralise they would see the same results as with Lyrica even though it had more indications than Gralise. And according to FE6 "with NUCYNTA it was the same thing" – i.e., that at Depomed it was "anything" to get prescribers "to put pen to pad."

505. FE6 indicated that as a sales representative, "you try to survive" and act ethically, but many times he wondered how Depomed could "get away with it." FE6 stated that many times as a sales representative, "you can't do anything" because reporting problematic conduct does not always result in companies taking appropriate actions. For example, FE6 said he had made a report about one of his Depomed managers, but Human Resources did nothing about it. He said that speaking up when a company engages in problematic conduct can result in getting "blackballed" in the pharmaceutical industry.

506. FE6 stated that "at the end of the day if you weren't saying" NUCYNTA was less addictive, the sales representative would not be directly written up for this omission, but instead, the employee's evaluation would say that the sales representatives sales were not where they needed to be and instead of receiving a rating of five (apparently the highest rating), the employee would receive a rating of 2.5 or 3.0.

507. FE6 stated that when Golino would accompany him in his visits to the prescribers and observe how he conducted himself, she might say to him if he had not made the representations about NUCYNTA being less addictive that his numbers needed to be higher. Occasionally, Golino would indicate that the prescriber had patients using Oxycodone and those patients "could be ours" and that FE6 could tell the prescriber that patients were not asking for NUCYNTA as they did for Oxycodone.

508. As a Pain Sales Specialist, FE8 had represented NUCYNTA ER and IR, as well as Gralise, but not the other drugs in Depomed's portfolio. His territory had been comprised of part of Connecticut, as well as Rhode Island. He said the quotas were based on the number of prescriptions of the drugs he represented (as opposed to a monetary amount) and each drug had its own quota.

509. FE8 said that Higgins "really had no ideas on how to get sales moving" and "no game plan" beyond telling employees to "just do it" (i.e., increase sales). Instead, FE8 indicated that the only way Higgins could motivate the sales force was through "fear and intimidation." FE8 recalled how at one meeting Higgins had enjoined the sales force that they needed to have "fortitude" but at the conclusion of the same talk said that if personnel did not meet their sales quotas many of them would be laid off. FE8 also stated that while Higgins may not explicitly threaten termination, it was "pretty implied" if one "read between the lines" of what Higgins said. FE8 stated that this threat had made it very unpleasant to work at the company. In the case of Menezes, FE8 said Menezes "didn't know what he was doing" and took actions that were very disruptive of the sales force. As FE8 pointed out, in 2016, prior to Menezes and Higgins coming on the scene, Depomed had been doing reasonably well, but Menezes made various changes to the sales force, including how promotions were awarded and how territories were assigned.

510. This cultivated culture by Depomed to use fear, bonuses, and intimidation to move NUCYNTA encouraged sales representatives to do anything to sell NUCYNTA, including engaging in off-label marketing.

511. Further evidence that Defendants knew of the off-label marketing is the fact that on November 7, 2016, Schoeneck stated that with Scott Shivley's resignation "the sales, marketing, and managed care functions previously reporting to Scott will now report directly to me . . . ." With Shively's resignation, Schoeneck became further involved with sales and marketing. Depomed's off-label marketing practices were front and center, and Schoeneck perpetuated the illicit marketing scheme.

512. These allegations show that Defendants knew that NUCYNTA was being promoted off-label, and that they were misleading investors with their public statements.

Depomed Incentivized Speakers to Promote and Prescribe NUCYNTA Off-Label

513. Depomed did not stop at disseminating its misleading messages regarding chronic opioid therapy through its sales force. It also hired speakers to promote its drugs and trained them to make the very same misrepresentations made by its sales representatives. These speaker programs could reach thousands of physicians at just one meeting. According to Schoeneck's statements on September 16, 2015, "We've already had speaker programs that have included even 1,000 people last week at a meeting called PAINWeek, which is one of the two largest pain management meetings of the year."

514. As a façade for this arrangement, Depomed conducted speaker programs that were actually vehicles for paying monies to physicians under the guise of honoraria. These financial benefits were offered with the understanding that, in exchange, the physicians would preferentially prescribe or indicate the use of NUCYNTA to treat their patients.

515. According to https://openpaymentsdata.cms.gov, Depomed made over $4.1 million in payments to physicians relating to speaker engagements alone in 2017, over $2.6 million in 2016, and over $3.2 million in 2015. The following chart shows the amount paid in "general expenses to physicians between 2015-2017:

	2017	2016	2015
Speaking, training, and education engagements that are not for continuing education.	$4,153,677.32	$2,695,125.00	$3,259,750.00
Food and beverage	$767,109.70	$770,253.90	$692,501.92
Travel and lodging	$562,089.99	$445,133.69	$536,567.07
Consulting	$67,900.00	$360,096.25	$231,703.75
Education	$3,436.60	$3,181.06	$14,639.92
Total:	$5,554,213.61	$4,276,289.90	$4,735,162.66

516. These payments were given to speakers as an incentive to promote NUCYNTA off-label and as an incentive to get physicians to write more NUCYNTA prescriptions.

517. Through Depomed's speaker programs, physician speakers were ostensibly paid to speak at ongoing speaking engagement events to educate other doctors and health care professionals about NUCYNTA. In practice, however, Depomed's speaker program exists to induce physicians to increase the quantity of NUCYNTA prescriptions they write.

518. Specifically, Depomed offered ongoing speaker positions to pain management physicians, whom it deemed "high writers" - physicians writing five or more prescriptions per month. These speaking arrangements usually consisted of dinners with colleagues.

519. The qualifications of the physicians hired as speakers by Depomed demonstrate that its speaker program was nothing more than a mechanism to facilitate kickbacks in return for writing NUCYNTA prescriptions. The criteria used to determine which physicians to offer speaker positions depended primarily upon the volume of NUCYNTA prescriptions written.

520. And, because Depomed's focus was on rewarding high writers and not on actually educating, Depomed did not screen speakers based on academic or clinical accomplishments.

521. Where a speaker's curriculum vitae ("CV") was relatively unspectacular, Depomed would simply not provide it to the speaker's "audience." In one example, a high writer/speaker's CV was never circulated before his speaking engagements because he attended Guadalajara Medical School, a school that was not prestigious enough.

522. FE6 explained that the physicians selected as speakers were supposed to be "KOL" [key opinion leaders] and influential amongst their peers. However, Hardiman, Golino, and another district manager – Steve Roman – told FE6 that a criterion for a physician who wanted to become a speaker was to tell them that they had to write prescriptions of Depomed products. FE6 was told to ask the physicians how they could expect to be speakers of NUCYNTA if they had not used the products. To the extent that FE6 told any physicians this, he was told to say that this was not coming from him but was what his manager had said. For instance, FE6 would say something like, "I know you want to be a speaker, here's what you need to do."

523. FE6 estimated that speakers were paid approximately $1,000 - $1,500 depending on whether it was a dinner or lunch presentation. FE6 indicated that at first, there was no number of prescriptions that a prospective speaker needed to write, but in time FE6 would be asked by his

managers, "why is your guy not writing?" FE6 explained that in order for a physician to be considered as a speaker, a "ballpark" estimate of what would be an acceptable number of prescriptions for the physician to write was perhaps 60 a week, whereas perhaps FE6's physician who wanted to be a speaker was only writing five a week. FE6 felt this requirement of a physician becoming eligible to be a paid speaker for Depomed based on writing prescriptions likely crossed an ethical line, but he emphasized that he was not the one making this a requirement – as he put it, his managers were "telling me to tell" the physicians they needed to write more if they wanted to become a speaker.

524. FE7 told a story in which two sales representatives set up a speaking engagement for Dr. Ellen Lin at a sushi restaurant. FE7 indicated that the attendees at the event were not pain doctors, but included a family practitioner and a neurologist who was a friend of Dr. Lin's. FE7 emphasized that the event had very little to do at all with Depomed products and that when Dr. Lin spoke she showed at most "maybe only a couple slides" related to Depomed, but the event was being paid for by Depomed's speaker program. Instead, the event was mostly to promote the association that Dr. Lin wanted to form and for which she would be the head. FE7 said that having Depomed pay for this event was "illegal" because the presentation should have been focusing on Depomed's drugs, not Dr. Lin's association. FE7 stated that his problem was that Dr. Lin was his top prescriber so he did not know how to handle the situation. FE7 stated that that even though Depomed had paid for the event, the event had served no legitimate educational function, but instead had been a way to keep Depomed in "Dr. Lin's good graces."

525. The speakers above promoted NUCYNTA off-label. According to FE6, his speakers used the official slide-deck and package insert data provided by Depomed. As shown above, this study was not approved by the FDA, and therefore, its use in marketing was off-label.

526. Given Depomed's extremely high payments and incentives to physicians, in addition to its policy to only use speakers with a high percentage of NUCYNTA prescriptions, Depomed incentivized physicians to prescribe NUCYNTA off-label, as well as promote NUCYNTA off-label during speaker arrangements.

527. This practice shows that Defendants knew they were making false and misleading statements to investors but did so regardless.

Depomed Used Third Parties to Promote Opioids

528. Depomed's efforts were not limited to directly making misrepresentations through its sales force, speaker's bureau, and website. To avoid regulatory constraints and give its efforts and appearance of independence and objectivity, Depomed obscured its involvement in certain of its marketing activities by "collaborat[ing] with key patient advocacy organizations" to release misleading information about opioids.

529. In response to Senator McCaskill's Senate investigation, on February 12, 2018, the Senate Homeland Security and Governmental Affairs Committee released a second minority staff report of the "Fueling an Epidemic" series titled, "Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups." This report discussed the relationship between Depomed and advocacy groups and professional societies operating in the area of opioid policy.

530. The report provides a comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies in the area of opioids policy. The study found that manufacturers of opioid, including Depomed, provided millions of dollars to groups that echoed and amplified messages favorable to increased opioid use. The groups also issued guidelines and policies minimizing the risk of opioid addition and promoting opioids for chronic pain, lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for over prescription and misbranding. Notably, a majority of these groups also strongly criticized the 2016 guidelines from the CDC that recommended limits on opioid prescriptions for chronic pain.

531. The report found that "[t]he fact that these same manufacturers provided millions of dollars to the groups described below suggests, at the very least, a direct link between corporate donations and the advancement of opioids friendly messaging. By aligning medical culture with industry goals in this way, many of the groups described in this report [including Depomed] may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic."

Additionally, the report found that these groups that were paid by in part by Depomed, "amplified messages favorable to increased opioid use."

532. According to the study, between January 2012 and March 2017, the five opioid manufacturers featured in the report, including Depomed, contributed nearly $9 million to leading patient advocacy organizations and professional societies operating in the opioids policy area. Specifically, the companies provided at least $8,856,339.13 in funding to 14 outside groups working on chronic pain and other opioid-related issues between January 2012 and March 2017. Despite only owning NUCYNTA from 2015 – 2017, Depomed had the third highest payments of these five companies, totaling $1,071,116.95. As noted by the report, after Depomed acquired NUCYNTA, Depomed more than tripled payments to the advocacy groups featured in this report in 2015 relative to 2014, and the payments total for 2016—$318,257.47—remained steady compared to the 2015 total. Depomed's payment of $350,000 in 2015 is almost three times the amount spent by Janssen in 2014 for the promotion of NUCYNTA. Out of the over $1 million in payments made by Depomed, 69.9% of those payments came between 2015-2017, this was after Depomed's acquisition of NUCYNTA.

533. Additionally, Depomed attempted to hide many payments requested. For example, only after receiving additional correspondence did Depomed report five additional responsive payments—totaling $17,600 to the American Chronic Pain Association and $28,174.95 to the Academy of Integrative Pain Management. According to Depomed, these payments "were for advertising or promotional purposes," and the company initially considered them outside the scope of the March 28, 2017, requests.

534. Out of the almost $9 million in payments, the U.S. Pain Foundation received the largest amount of payments during the 2012–2017 period—almost $3 million—which includes $2,500,000 in payments from Insys. The Academy of Integrative Pain Management, formerly the American Academy of Pain Management, received $1,265,566.81 in donations—the second-highest total—followed closely by the American Academy of Pain Medicine with $1,199,409.95 in payments. The American Academy of Pain Medicine Foundation also received $304,605 in payments from Depomed alone during this period.

535. In addition, Dr. Charles Argoff, current president of the American Academy of Pain Medicine Foundation, received over $600,000 in payments from opioid manufacturers between 2013 and 2016, with Depomed paying him over $55,000 for NUCYNTA engagements alone for 2015-2016.[4]

536. In 2016 alone, the current President of the American Academy of Pain Medicine, Dr. Steven Stanos, received over $30,000 in payments with over 28% of those payments coming directly from Depomed for NUCYNTA engagements.

537. National Pain Foundation chairman and founder Dr. Daniel Bennett also received compensation relating to NUCYNTA in 2016.

538. In addition, at least half of the members of the National Pain Foundation Clinical and Scientific Advisory Council have received general payments—totaling more than $7,900,000—from opioid manufacturers between 2013 and 2016. Manufacturer payments to all individuals affiliated with the National Pain Foundation total more than $8,000,000 since 2013—by far the largest total for the groups profiled in the report.

539. According to the HSGAC report, these doctors and companies that received payments directly from Depomed in connection with NUCYNTA, have amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain. Several groups have also lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for over prescription and misbranding.

540. On March 15, 2016, the CDC issued guidelines providing prescribing recommendations for "primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care."

541. In 2016 the immediate past president of the American Academy of Pain Medicine, Daniel Carr, criticized the prescribing guidelines, stating "that the CDC guideline makes

[4] https://projects.propublica.org/docdollars/doctors/pid/93628

disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence." Similarly, several advocacy groups criticized draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliations, and conflicts of interest of the individuals who participated in the construction of these guidelines." Dr. Richard Payne, a physician affiliated with the Center for Practical Bioethics, made a similar argument, criticizing the CDC guidelines as the product of "conflicts of interests in terms of biases [and] intellectual conflicts"—while himself maintaining "financial links to numerous drug companies."

542. The Washington Legal Foundation also strongly criticized the guidelines on procedural grounds, claiming CDC had developed its guidelines in an "overly secretive manner" and in violation of the Federal Advisory Committee Act, which called "into question the viability of the entire enterprise." The Washington Legal Foundation claimed, moreover, that "[s]tate governments and the medical community are unlikely to accept any guidelines tainted by charges that they were prepared in secret without meaningful stakeholder input."

543. When the CDC published its final opioid prescribing guidelines, Richard A. Samp, Washington Legal Foundation general counsel, reportedly believed the guidelines "were inherently biased, crafted by people who already had strong views about what opioid policy should look like."

544. The HSGAC report found that "the fact that these groups registered their opposition while receiving funding from the opioids industry raises the appearance—at the very least—of a direct link between corporate donations and the advancement of opioids-friendly messaging." Relatedly, in a March 2017 article published in JAMA Internal Medicine, researchers from Johns Hopkins University and Brandeis University examined industry payments to over 150 organizations that had submitted comments on the draft CDC guidelines. After coding guideline comments by supportiveness and reviewing financial disclosures, including annual reports, tax returns, and self-reported information, researchers found "opposition to the guidelines was significantly more common among organizations with funding from opioid manufacturers than those without funding from the life sciences industry."

545. Accordingly, a "major concern is that opposition to regulatory, payment, or clinical policies to reduce opioid use may originate from groups that stand to lose financially if opioids sales decline." In an extended version of their findings, the researchers are more explicit: "[O]pposition to more conservative opioid use may, at least in part, be financially motivated."

546. Depomed's use of third parties to promote opioids is additional evidence that Defendants had a widespread campaign to promote NUCYNTA off-label. Defendants' payments to third parties is further evidence that Defendants knew they were promoting NUCYNTA off-label but misrepresented Depomed's marketing practice and financials.

Additional Government Complaints against Depomed

547. At least thirty-eight opioid lawsuits have been filed against Depomed (and other manufacturers and distributors) between March 2018 and December 2018 alone. Many of these allegations show that Depomed engaged in off-label marketing and directly contributed to the opioid crisis.

548. The FDA-approved labels for both NUCYNTA IR and NUCYNTA ER describe the tapentadol molecule as "a substance with a high potential for abuse similar to other opioids including fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, and oxymorphone." Nowhere on the FDA-approved label does it say or mention that NUCYNTA is safer, more tolerable, less abusive, or less addictive than other opioids. Despite this, NUCYNTA has a long history of its manufacturer claiming these off-label benefits in their sales pitches and marketing.

549. The lawsuits allege that Depomed engaged in an intentional and deceptive marketing campaign to promote the use of prescription opioids, including NUCYNTA, and that their conduct has resulted in a national epidemic of opioid overdose deaths and addictions.

550. These lawsuits also allege that Depomed engaged in a deceptive marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain by: a) downplaying the serious risk of addiction; b) creating and promoting the concept of "pseudoaddiction" by advocating that signs of addiction should be treated with more opioids; c) exaggerating the effectiveness of screening tools to prevent addiction; d) claiming that opioid dependence and withdrawal are easily managed; e) denying the decreased effectiveness of opioids

over long-term use and the corresponding need for increased dosages; and f) exaggerating the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction.

551. The lawsuits allege that Depomed made these false representations directly to doctors and patients through advertising campaigns and "detailers" (sales representatives who directly targeted doctors).

552. They further allege that Depomed marketed their products indirectly to avoid FDA scrutiny and regulation. They did this through seemingly unbiased and independent third parties, including KOLs (seemingly independent doctors) and professional societies and patient advocacy groups ("Front Groups") funded in part by Depomed. They also allege that Depomed used "unbranded advertising" (promoting the general use of opioids without naming a specific drug) and manipulated published promotional materials about opioids in scientific literature to avoid FDA regulation and to give the false appearance that these were independent organizations outside of the Depomed's control.

553. This further adds to the inference of scienter. These complaints show that Depomed engaged in a widespread off-label marketing campaign. As a result of this campaign, Defendants above statements were knowingly false and misleading.

Former Employees Confirm that this was a Widespread Off-label Marketing Campaign

554. Former employees confirm that Defendants not only knew about the off-label marketing, but in fact promoted an off-label marketing campaign. This is evident based upon information obtained from former employees of Depomed, detailed below.

555. FE1 worked as a former Specialty Sales Representative selling NUCYNTA at Depomed from October 2011 to March 2016. FE1 reported to David Sims, a former sales manager from Quintiles. According to FE1, Depomed appeared to change significantly in how it approached its sales practices and training following the acquisition of NUCYNTA. FE1 was trained on how to sell NUCYNTA by FE1's manager, David Sims, who formerly worked for Quintiles, the marketing firm used by Janssen. Sims trained FE1 by discussing the negative perception of opioids in general across the country, and by telling FE1 how to pushback against prescribers who cited concerns writing an opioid prescription

556. FE1 indicated that Depomed's marketing push was "Think Differently." FE1 stated that the manager was very vocal about NUCYNTA being a "safer opioid." FE1 indicated that the Sims "would say that all the time" and that FE1 heard Sims call NUCYNTA a safer opioid to physicians. FE1 would listen to Sims preach to physicians about NUCYNTA and its value to patients in terms of, among other things, improved safety relative to other opioids on the market. According to FE1, Sims "would just tell the doctors it was much safer, and for them to prescribe it for their patients, and it was better for their patients." FE1 stated he was aware Sims was speaking off-label about the drug and that it was not allowed by law.

557. FE1 was also paired with a former Quintiles sales representative who actively told physicians that NUCYNTA was a safer opioid.

558. Similarly FE2, a former Senior Specialty Representative at Depomed from June 2012 to July 2017, who was responsible for promoting NUCYNTA, and also for helping prepare other new employees to sell the drug, stated that Depomed convinced its sales force that NUCYNTA was different. "A lot of things changed because we brought on a huge group of people, and, for instance, where the Training Department would do the training on its own, now I was part of the trainers where I was training a full classroom of people on my own," FE2 said. "It was very different in the practices, in that regard. They had so many brought on." FE2 stated "We were being convinced it was a safer opioid" that was "the overall consensus that was being told to us." FE2 stated that when the sales team complained about selling to neurologists, FE2's superiors would say that "this is a great opportunity to introduce them to the safer opioid." FE2 stated that the message that NUCYNTA was a safer opioid came from multiple people and "from different parts of the country."

559. FE3 was a Pain Sales Specialist at Depomed from November 2015 to August 2016 responsible for representing NUCYNTA. FE3 stated he was one of the dozens and dozens of new sales representatives that Depomed hired after acquiring NUCYNTA in early 2015. FE3 reported to his district manager Jessica Golino. FE3 was trained by Glenn Drummond who formerly represented Oxycontin for Purdue Pharma. FE3 said he had gone through sales training at several pharmaceutical companies prior to joining Depomed but that none of those was as intense as what he experienced with Drummond.

560. "There was always negativity associated with selling any opioid, but we believed in the molecule," FE3 said. "You weren't going to get the euphoric effect. That was discussed, that you would not see that." FE3 stated that, "I heard Jim Schoeneck talk a lot. The perception of opioids? You're selling a molecule that's not supposed to cause euphoria. You're kind of talking out both sides of your mouth. I'm selling a painkiller, but not the same as (the ones) on the street." FE3 stated, "You have to think about the molecule. Doctors didn't want to give something to patients that would give that high."

561. When asked about whether the sales representatives talked about the lower abuse of NUCYNTA to doctors, FE3 stated, "If they have specific questions about abuse, we did talk abuse. We did talk about it. Yeah, we did." When asked where FE3 heard NUCYNTA was safer and less euphoric, FE3 stated that they were told during sales training that NUCYNTA did not provide the same euphoria as other street-level opioids. "It was discussed in training. That's what made this molecule as successful as it was. There was less abuse potential. Addicts weren't going to be stealing it because they wouldn't get the buzz." FE3 added the caveat, "It was never on the marketing materials. I can't point fingers at the trainers. It was just a well-known fact you're not going to get the euphoria."

562. The fact that Depomed conspicuously omitted this training instruction from its printed training materials strongly suggests that Defendants knew that the instruction was inappropriate and improper, otherwise there would be no need to hide it in this manner. FE3 confirmed they were instructed that NUCYNTA presented less abuse potential because of its design. "Just the way it was manufactured," FE3 said. "If you tried to crush it, it was almost indestructible."

563. FE3 stated that the selling point on NUCYNTA was "because it was dual mechanism." FE3 stated that he did meet with physicians who wanted to talk about Nucynta's advantages. "They knew it was an opioid. They would ask a lot of questions about even writing an opioid," he said. "They wanted to talk about what was inside the pill. What was the deterrent in the pill."

564. FE4 was a former Specialty Pain Sales Representative at Depomed, Inc. from late 2011 to late November/early December 2016. In addition to selling NUCYNTA, FE4 was

responsible in assisting with sales training related to the new employees hired to promote NUCYNTA. FE4 indicated that "there may have been some perception" that NUCYNTA was a safer painkiller. FE4 stated, "I was a guest trainer. I worked intimately with Glen [Drummond] on multiple things. He was very serious about training, there's no doubt in my mind. He could be very challenging, I wouldn't go so far as to say difficult, and he had expectations for people going through training. The agenda was rigorous. It was long hours. Glen was very, very good. He was professional, and he expressed that there was a "gray area" when it comes to selling opioids.

565. FE4 confirmed that Depomed approached NUCYNTA by marketing the drug differently from other similar products. "Oh, absolutely," FE4 said. "The tagline was, Think Differently. That was the tagline for the marketing department. NUCYNTA is very different in its mechanism of action."

566. FE5 worked as a Sales Representative at Depomed from June 2014 – February 2018 in the Eugene, Oregon territory. FE5 was hired directly by Depomed and never worked for Quintiles. FE5 was responsible for selling the complete portfolio of Depomed products, with a quota of 90% NUCYNTA products. FE5 reported to his District Sales Manager Chris Cooper who had been responsible for Oregon, Washington, and possibly Idaho in a region referred to as Seattle-Cascades. Cooper reported to Jeff McCutcheon, who had been the regional sales director for the Western US. McCutcheon had reported first to National Sales Director Steve Greco and then to Ron Menezes. Both Greco and Menezes would have reported to whoever was CEO at the time – either Schoeneck or Arthur Higgins, depending on the time frame.

567. FE5 affirmed that Depomed engaged in off-label marketing. For example, FE5 stated that during a Depomed sales team meeting that he believed was in Dallas, Depomed told sales reps to push NUCYNTA at higher starting doses than was approved on the label. FE5 stated that Janssen promoted prescribing NUCYNTA ER at 50 mg doses twice a day, but that the Depomed sales representatives were told by their Regional Directors that they should recommend that NUCYNTA ER be prescribed at 100mg doses twice a day. FE5 indicated that this was definitely "off-label" in regards to the recommended dosage.

568. FE5 remembered being told about recommending the increased dosage at a breakout session by his Regional Director (Chris Cooper) at the sales meeting and thinking at the time that this was "illegal."

569. FE5 explained that breakout meetings entailed each District Manager meeting with the sales reps who reported to that District Manager. He estimated there were around 15 breakout rooms available for the different districts. He thinks the other District Managers communicated to their teams the same message that Cooper had conveyed. As best FE5 could recall, this directive was issued around when NUCYNTA was launched by Depomed or just a little while after the launch. FE5 believes that whatever the District Managers conveyed about recommending an increase in the NUCYNTA ER dosage was based on a directive that had been conveyed to them from "upper management."

570. When asked if the sales representatives were told to promote that NUCYNTA ER was safer, less addictive and less subject to abuse than other opioids, FE5 answered affirmatively. FE5 also said there was some data made available to sales representatives as part of their "marketing insert" for NUCYNTA ER.

571. FE5 recalled that there had been a study which represented that approximately 93% - 95% of patients who had used NUCYNTA ER did not experience any withdrawal. While this shows that NUCYNTA ER as being less prone to abuse by patients, FE5 said this was "really not the case." FE5 gave an example of an instance where he used this study and got "called out" by a doctor who had been selected as a speaker for Depomed. This doctor pointed out that the Oxycodone arm in the study that Depomed was citing showed that something like 91% of Oxycodone users did not suffer from withdrawal. FE5 stated that the doctor's point was that if Oxycodone was showing a relatively low rate of withdrawal for its users, this did not validate a low addictive risk for NUCYNTA ER given Oxycodone's well-known addictiveness. FE5 could not immediately recall the name of the study at issue, but noted that after a while this claim was removed from the marketing insert. The specific term for the marketing insert was "Comprehensive Visual Aid" or "CVA".

572. Plaintiffs in this action sent FE5 the study attached to the Complaint and referenced above. FE5 confirmed that this was definitely the item to which he had been referring to. He said it

was "the exact piece" (and that whoever had obtained the item "nailed it") that the physician referenced in the original interviews had called out. More precisely, FE5 said the piece should be referred to as a "Comprehensive Visual Aid" or CVA, and was not a package insert. The CVA would have been approved by Depomed's corporate office for use by the sales reps.

573. FE5 indicated that when looking at the study that the efficacy of the NUCYNTA molecule was not meant to be comparative to Oxycodone, although it is still necessary to "measure efficacy against something other than a placebo." FE5 indicated that citing the study in the NUCYNTA package insert was a way to establish efficacy, but that the study result was "not comparative" between NUCYNTA and Oxycodone. FE5 believes that if a doctor had really studied the package insert they could have gleaned this distinction. However, he does not think this was the case with the "sales aid" which was the main information piece that "we gravitated to". As best FE5 could remember, the sales aid did not include this distinction even "in the fine print."

574. FE5 explained that a package insert is a more substantive "sales aid" than a pharmaceutical "slim jim" and is spiral-bound "8x14" "story book" about a given pharmaceutical product. FE5 explained that a package insert was inside the slim-jim (perhaps as a folded piece of paper) and that every piece of marketing material had its own separate package insert to support it. In explaining what a "slim-jim" is (which was the term used internally at Depomed and also at numerous other pharmaceutical companies), FE5 said this was information about a given drug (e.g., NUCYNTA) that provided a "condensed version" of what was set forth in the Comprehensive Sales Aid used by the sales reps (and which was different from the CVA). To promote NUCYNTA ER, the sales representatives were supposed to follow what was in their "package insert" and "tell the story" of the drug: "here's the efficacy, side-effects" but according to FE5 this would not be the main emphasis when making presentations to prescribers. Instead, FE5 said that sales representatives would represent to the prescribers that "what we really show is here is 90% of patients having no withdrawal." FE5 said that physicians tend to "talk out of both sides of their mouth" when it comes to addictiveness of opioids because they would go ahead and prescribe bigger doses but might believe there was a lower risk in doing so because of the study.

575. FE6 is a former Depomed Specialty Sales Representative who worked at Depomed from January 2012 – September 2015. FE6 was assigned a sales territory comprised of Rhode Island, Massachusetts, and Connecticut. FE6 seems to have variously reported to a District Manager named Jessica Golino, Dave Whitehead (although the witness was not reporting to Whitehead as of the time that Depomed acquired and began selling Nucynta), and John Hardiman. FE6 represented the entire portfolio of Depomed products. In descending order of priority and volume he was expected to sell NUCYNTA, Gralise, and Zipsor. For instance, FE6 estimates that NUCYNTA represented 60% - 70% of his quota, Gralise perhaps 10% or 20% and Zipsor 10%. The quota was based on the number of prescriptions for these drugs written in his region, not a particular dollar goal, but he did not recall what his quotas had been.

576. As FE6 put it, there was a lot of looking "the other way" in regards to certain representations about NUCYNTA. He stated that there was a lot of insinuation and implication made to the sales representatives as to what they should say. For example, FE6 stated that during sales force meetings there would be breakout sessions of smaller, regional groups of sales personnel. FE6 explained that one ostensible purpose of the breakout sessions was to come up with ideas to increase sales. During such breakout sessions it was discussed that Oxycodone and NUCYNTA could each be used to treat neuropathy. However, FE6 stated that the difference was that NUCYNTA had "no street value," so "the way upper management spun it" was that the sales representatives could say that NUCYNTA "can't be abused because there was no street value" and also because patients were not coming to prescribers specifically asking for NUCYNTA, which was not the case with Oxycodone. FE6 stated that he felt this was not ethical and that he and other sales representatives always did "a double-take" when they were told this because, in fact, NUCYNTA is an opioid and just as addictive as Oxycodone, but they were supposed to ask the prescribers "when was the last time someone asked for NUCYNTA" and simply "let the doctors make the decision."

577. FE6 said that the representation about NUCYNTA not having any street value was made to him and other sales representations in the regional breakout sessions by Jessica Golino and John Hardiman. FE6 said that what was being suggested to say to the doctors in this regard was clearly wrong because it was not in the NUCYNTA package insert. FE6 said that as a sales

representative it was critical to learn what was set forth in the package insert and to adhere to that information.

578. FE6 indicated that not only was this message conveyed "whenever we went to District breakout" sessions, but it was also strongly implied and reinforced by Golino when she went for ride-alongs with FE6 to visit prescribers. As he put it, Golino would suggest using "that verbiage" (that NUCYNTA did not have street value) following visits with the prescribers. FE6 stated that Golino was "big on schematics" in terms of suggesting that FE6 "choose this word" or that word in what he said during prescriber visits.

579. FE6 also stated that representing that NUCYNTA was less euphoric for users compared to other opioids was also part of the overall way that NUCYNTA was supposed to be represented. FE6 said that NUCYNTA was to be presented as giving "less of a high" and not being as addictive as Oxycodone because Oxycodone was both physically and mentally (emotionally) addictive, but that NUCYNTA supposedly did not cause emotional addiction. However, FE6 said that to his knowledge there was no real support for this assertion and even though "we were encouraged" to make these representations, he maintains that he never did because it was not supported by the "black box" label.

580. FE6 said that Hardeman and Golino definitely wanted the sales representatives, including himself, to be proactive in making these representations (that NUCYNTA gave "less of a high" and was not as addictive to Oxycodone) to prescribers, as opposed to only making these representations in response to questions posed by the prescribers. Although FE6 could not confirm if other sales representatives made these representations, he said that sales representatives were encouraged to talk to one another to learn what they were doing to be successful and what was necessary to obtain a satisfactory employee evaluation.

581. FE7 worked at Depomed, as a Senior Specialty Neuroscience/Pain Specialist from June 2014 – February 2018. FE7 confirmed that he had been assigned to four different territories over the course of his three and a half year tenure, to include separate stints focusing on pain practices and cancer practices, although he spent most of his time in San Antonio and Houston.

582. FE7 reported to Regional Manager Jaime Nassar who reported to Jeff McCutcheon who reported to Steve Greco. According to FE7 Greco was replaced by Ron Menezes who proceeded to hire Kevin Cotton to replace Nassar who ended up getting terminated. FE7's products include the NUCYNTA line.

583. FE7 also confirmed FE5 statements. When asked about the sustainability of NUCYNTA sales without relying on off-label marketing, FE7 answered that "what [FE5] said" about increasing the recommended dosage of Nucynta ER from 50 mg twice daily to 100 mg twice daily "is true." FE7 said that recommending the dosage increase began in January 2017, but then said it had been happening before then as well.

584. In regards to the sustainability of NUCYNTA sales, FE7 said that the sales went "really downhill" when Greco was fired and replaced by Menezes. When asked if NUCYNTA sales had included off-label marketing, FE7 said, "yes, I can't lie." When asked for details regarding the nature of the off-label marketing of NUCYNTA, FE7 said that one of the main forms of off-label marketing was "that piece" (i.e., study) "that FE5 told you about" regarding NUCYNTA patients not experiencing withdrawals.

585. FE8 was a Pain Sales Specialist who worked at Depomed from beginning either the very last week of September 2015 or October 1, 2015 until the end of June 2017. As a Pain Sales Specialist, FE8 had represented NUCYNTA ER and IR, as well as Gralise, but not the other drugs in Depomed's portfolio. His territory had been comprised of part of Connecticut, as well as Rhode Island. He said the quotas were based on the number of prescriptions of the drugs he represented (as opposed to a monetary amount) and each drug had its own quota. He had reported to District Manager Jessica Golino, whose district had been all of the New England states (Rhode Island, Massachusetts, Vermont, Maine, and New Hampshire, as well as Westchester County, Connecticut). At some point in 2017, Golino began reporting to Ron Menezes.

586. FE8 explained that there were at least three major sales meetings a year: the first (at the beginning of the year) was the "POA" or "Plan of Action" meeting. This was followed in spring or early summer with a National Sales meeting and then another meeting "in the last third of the year".

587. FE8 stated that at Depomed, there would be talk in meetings of sales personnel regarding the street value of pain medications, although this was supposed to be "for your information" only. He said he had been "smart enough" to know better than to make such representations, but he said that "others probably were not that smart", although he could not say "who did or who did not" engage in off-label practices.

588. FE8 went on to say that at periodic corporate sales training meetings he attended there would be informational discussions about "cross-titration" and the street value of opioids. As best FE8 could recall, one key individual who had made these ostensibly informational presentations had been Anna Copeland, although he was not positive. At another of these sales training meetings, he recalled that an individual who had not been in a sales training role had come to talk about NUCYNTA. As best FE8 could recall, this individual had been of Indian background and talked about the street value of Nucynta, but said it was "just for your information."

589. In regards to cross-titration, FE8 said this pertained to titrating a patient from one opioid to another (i.e., NUCYNTA). For instance, if a patient were using OxyContin, cross-titration entailed reducing the dosage of OxyContin while introducing a low dose of NUCYNTA and gradually replacing the OxyContin completely with NUCYNTA. The supposed benefit of going to NUCYNTA from OxyContin was that OxyContin had "a lot more abuse potential and withdrawal" risks compared to NUCYNTA. By cross-titrating, a patient could supposedly be taken off of OxyContin "without a lot of pain" and even "no withdrawal." However, according to FE8 cross-titration was not supported by the package insert for NUCYNTA and the only allowed method of switching a patient over to NUCYNTA from OxyContin was for the patient to first stop using OxyContin (or whatever opioid they were using) completely and then start the patient on NUCYNTA. But, again, FE8 indicated that Depomed indicated that the cross-titration information was said to be "just for information" purposes.

590. FE8 recalled hearing at one of the sales training meetings that while NUCYNTA could supposedly cause some euphoria, the MU part of the drug was supposed to counteract this.

591. When asked about Depomed's study on NUCYNTA ER, FE8 indicated that he "vaguely remembers" this and that the study was "something about people stopping cold turkey"

from opioid use and the percentage that experienced withdrawal symptoms. As he recalled, this claim came from a study in which people had been cut off "cold turkey". His recollection was that the percentage of users experiencing withdrawal was supposed to be lower with NUCYNTA than it had been with other opioids, like OxyContin.

592. FE8 indicated that he believed that this was "legally allowed" to be said, because it had been approved by Depomed's legal department, so he assumed it was permissible to say. FE8 indicated that during sales calls he would talk about the study and what the study said, but if he were asked if the study meant something one way or another, his stock answer was that "the data is what it is" and that the questioner needed to draw his or her own conclusions.

593. FE8 would say whatever the withdrawal rate was per the study and if someone questioned him whether NUCYNTA was safer, he would answer that he could not speak to that. But he thinks that Depomed was trying to infer without actually saying it that NUCYNTA was safer because of the dual receptor. He said this went back to the "just for your information" types of presentations during the sales training meetings.

594. FE9 worked at Depomed as a Senior Specialty Pharmaceutical Representative from July 2012 to September 2016. FE9 indicated that on October 28, 2016 he had written notes in his iPhone of "every unethical marketing practice" Depomed had engaged in because he had thought at the time he might need this information in the future. In the ensuing discussion, FE9 read from his iPhone and then explained what his notes meant.

595. FE9 made notes on his iPhone about Depomed's improper marketing. FE9 read from his iPhone that NUCYNTA had "less than 1% euphoria" and that this was to be told by the sales personnel to prescribers as applicable for all indications even though this was only supported by a study involving low back pain. FE9 said that there were not studies to support this low euphoria claim for other types of pain. As FE9 put it, "that's off-label."

596. The next note FE9 read was that NUCYNTA had "no street value" and that it was safe and "not really a Schedule II" drug. FE9 explained the context of this particular note. He said that Depomed had Regional Account Managers who "did managed care" and had in-depth knowledge about drug coverage. As a sales representative, FE9 would sometimes have a Regional

Account Manager accompany him as "an expert to talk about coverage" and had done so during a lunch meeting with a potential prescriber. During this particular meeting, the Regional Account Manager – Kristen Knight – had told the prescriber that NUCYNTA had no street value and was not really a Schedule II drug. FE9 had asked her after the meeting where she had heard this and she told him she had heard it at a speaker program. Knight worked at Depomed for four years, first as a Senior Regional Account Manager beginning May 2015; and then as a Director of National Accounts beginning December 2016.

597. The next note that FE9 read pertained to low rates of withdrawal and euphoria with the implication being that NUCYNTA "shouldn't be Schedule II" FE9 indicated that sales representatives used this as a "wink-wink, nod-nod" implication that was based on the low withdrawal rates set forth in the lower back study. This was a comparison of data points that could be used to suggest that NUCYNTA was safe.

598. The next note FE9 read related to Depomed's off-label marketing of using NUCYNTA ER and IR together. FE9 stated that note read that NUCYNTA ER and NUCYNTA IR could be used together because the only reason they could not be used together was because their joint use had not been studied. While elaborating, FE9 indicated that his District Manager Breakstone said that the sales representatives were to say that many doctors were using NUCYNTA ER and NUCYNTA IR together. FE9 said that Breakstone indicated that while there was not a study saying the two drugs could be used together there also was not any study that said they could not be used together. As FE9 put it, this was taking "the inverse to say it was OK" to use the two drugs together.

599. The next note FE9 read indicated that although Nucynta IR did not have a defined indication for Diabetic Peripheral Neuropathy, Nucynta IR was "the same molecule" as Nucynta ER which did have the DPN indication and therefore Nucynta IR could be used for DPN. He expanded on this to say that Depomed did not have any company materials indicating that Nucynta IR could be used to treat "flare ups and neuropathic pain" but that Depomed was nonetheless saying that both ER and IR could be used for this kind of pain. He said this was another "wink-wink, nod-nod" insinuation about acute, short-acting neuropathic pain, which he said is "the giant elephant" that

Depomed apparently used when there were "guardrails" that ostensibly prevented such claims being made. FE9 explained that in essence, Nucynta ER and Nucynta IR had the same molecule and even though Nucynta IR had not been studied for the neuropathic pain indications, since Nucynta ER "had passed" (i.e., could be used for these indications), "so, why not IR?"

600. He next read a note that indicated reps were to use the low back study's claim of an overall very low rate of constipation for Nucynta ER and use the low constipation rate "regardless of the condition" for which Nucynta ER was being prescribed – i.e., not just for low back pain. But FE9 said that representations about drugs are "supposed to be held to the condition of the study" and that Depomed was seeking to "muddy waters" and make the low constipation rate claim no matter what the patient's condition was.

601. FE9 read a note related to Depomed's off-label marketing of using NUCYNTA ER and IR together. FE9 stated that note read that NUCYNTA ER and NUCYNTA IR could be used together because the only reason they could not be used together was because their joint use had not been studied. While elaborating, FE9 indicated that his District Manager Breakstone said that the sales representatives were to say that many doctors were using NUCYNTA ER and NUCYNTA IR together. FE9 said that Breakstone indicated that while there was not a study saying the two drugs could be used together there also was not any study that said they could not be used together. As FE9 put it, this was taking "the inverse to say it was OK" to use the two drugs together.

602. FE9 also read a note related to the study. FE9 stated that his last note pertained to NUCYNTA and according to FE9 was "a big one". As FE9 explained, there had been a "head to head trial" comparing Oxycodone and NUCYNTA ER. His note and recollection were not completely clear to him at this point, but as best he could recall, while the two drugs were being compared to one another, the study had not completely compared them "at every measure and point." FE9 indicated he was not totally sure at this point what exactly had been problematic about the study, but said that Oxycodone had been used as "an active control" but should not have been used to compare efficacy for pain relief.

603. These statements by the former employees show that Depomed's policy to train sales representatives to promote NUCYNTA off-label, as a safer and less addictive opioid that did not

cause the same euphoric feeling as other drugs. Defendants knew Depomed's sales representatives were promoting NUCYNTA off-label as evidenced by their public statements, and their close work with the sales team. Defendants consistently held sales conference calls and events where the sales representatives would be present and discuss the off-label benefits of NUCYNTA.

Defendants Had Vast Experience in the Pharmaceutical Industry and Therefore Knew, or Recklessly Disregarded, it was Illegal to Promote NUCYNTA Off-label

604. Defendants knew or reckless disregarded that NUCYNTA was being illegally marketed because of their vast experience in the pharmaceutical industry. For example, until Schoeneck joined Depomed, he was CEO of BrainCells, Inc. ("BrainCells"), a privately-held biopharmaceutical company. Prior to joining BrainCells, he served as CEO of ActivX BioSciences, Inc., a development stage biotechnology company. Schoeneck also served as President and Chief Executive Officer of Prometheus Laboratories Inc. ("Prometheus") for three years. Prior to joining Prometheus, Schoeneck spent three years at Centocor, Inc. ("Centocor"), where he led the development of Centocor's commercial capabilities. His group launched Remicade®, which has become one of the world's largest pharmaceutical products. Earlier in his career, he spent 13 years at Rhone-Poulenc Rorer, Inc. (now Sanofi S.A.) serving in various sales and marketing positions of increasing responsibility. According to the 2016 Proxy, the Board considered "Mr. Schoeneck's experience and expertise within the following areas relevant to Depomed and its business in concluding that he should serve on the Board: Corporate Strategy; Corporate Management; Commercial Strategy; Pharmaceutical Product Launch; Strategic Transactions; and Corporate Leadership."

605. From 2010 until his appointment at Depomed, Higgins served as a Senior Advisor to Blackstone Healthcare Partners, the healthcare team of The Blackstone Group, where he focused on product-based healthcare acquisitions. Prior to 2010, Higgins held various high-ranking positions in several different pharmaceutical companies, including joining Bayer HealthCare AG in 2004, where he served as Chair of the Board Management of Bayer HealthCare AG, a developer and manufacturer of human and animal health care products, and Chairman of the Bayer HealthCare Executive Committee. From 2001 to 2004, Higgins served as Chairman, President and CEO of

Enzon Pharmaceuticals. Prior to joining Enzon, Higgins spent 14 years at Abbott Laboratories. He also has served as a past Board member of the Pharmaceutical Research Manufacturers of America (PhRMA), of the Council of the International Federation of Pharmaceutical Manufacturers and Association (IFPMA), and President of the European Federation of Pharmaceutical Industries and Associations (EFPIA).

606. From 2004 to December 2011, Mr. Moretti served as Chief Financial Officer and Senior Vice President of Alexza Pharmaceuticals, Inc., a publicly-held pharmaceutical company. From 2001 to 2004, Mr. Moretti served as Chief Financial Officer of Alavita, Inc. (formerly Surromed, Inc.). Prior to Alavita, Mr. Moretti was a partner of Heller Ehrman LLP, an international law firm. Mr. Moretti holds a B.A. from Princeton University and a J.D. from Harvard Law School.

607. Defendants are highly intelligent individuals and experienced in the pharmaceuticals industry. Therefore, they knew, or recklessly disregarded, that it was illegal to promote NUCYNTA off-label but encouraged their sales representatives to market it as safer and less addictive anyway.

Past History of Off-Label Marketing

608. The FDA-approved labels for both NUCYNTA IR and NUCYNTA ER describe the tapentadol molecule as "a substance with a high potential for abuse similar to other opioids including fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, and oxymorphone." Nowhere on the FDA-approved label does it say or mention that NUCYNTA is safer, more tolerable, less abusive, or less addictive than other opioids. Despite this, NUCYNTA has a long history of its manufacturer claiming these off-label benefits in their sales pitches and marketing.

609. For example, Janssen promoted its branded opioids, including Duragesic, NUCYNTA, and NUCYNTA ER, through its sales representatives and a particularly active speakers program. Deceptive messages regarding low addiction risk and low prevalence of withdrawal symptoms were a foundation of this marketing campaign. Janssen also conveyed other misrepresentations, including that its opioids could safely be prescribed at higher doses and were safer than alternatives such as NSAIDs.

610. Janssen supplemented these efforts with its own unbranded website, as well as third-party publications and a Front Group website, to promote opioids for the treatment of chronic pain.

These materials likewise made deceptive claims about addiction risk, safety at higher doses, and the safety of alternative treatments. They also claimed that opioid treatment would result in functional improvement, and further masked the risk of addiction by promoting the concept of pseudoaddiction.

611. Janssen sales representatives visited targeted physicians to deliver sales messages that were developed centrally and deployed identically across the country. These sales representatives were critical in transmitting Janssen's marketing strategies and talking points to individual prescribers. In 2011, at the peak of its effort to promote NUCYNTA ER, Janssen spent more than $90 million on detailing.

612. Janssen knew that there was no credible scientific evidence establishing that addiction rates were low among patients who used opioids to treat chronic pain. There is no evidence that NUCYNTA is any less addictive or prone to abuse than other opioids, or that the risk of addiction or abuse is low. Similarly, Janssen knew that there were severe symptoms associated with opioid withdrawal including, severe anxiety, nausea, vomiting, hallucinations, and delirium, but Janssen touted the ease with which patients could come off opioids.

613. These allegations were at the forefront of the City of Chicago Complaint. The City of Chicago Complaint states that "between 2009 and 2012, NUCYNTA and NUCYNTA ER sales representatives repeatedly promoted these drugs as less addictive than other opioids. For example, Janssen sales representatives described NUCYNTA as 'not an opioid' to one Midwestern internist at least twice in 2010. Similarly, a sales representative told a Midwestern physician that NUCYNTA was 'nonopioid yet opioid like' in 2011."

614. Further, the City of Chicago interviewed a number of sales representatives from Quintiles that promoted NUCYNTA off-label. These sales representatives admit that they were instructed to push the envelope when selling NUCYNTA ER and stress that NUCYNTA ER didn't hit receptors like other opioids so it was less addictive and had fewer withdrawal issues, as well as promote NUCYNTA and NUCYNTA ER as a safer alternative to NSAIDs. Quintiles sales representatives were also trained to say that NUCYNTA and NUCYNTA ER did not offer the same euphoric feeling as other opioids.

615. Specific allegations from former sales representatives in the City of Chicago complaint corroborate the former employees' statements.

616. Sales "Representative E," who worked in Janssen's Midwest Region (the Regional Manager had offices in Naperville, Illinois), was instructed to push the envelope when selling NUCYNTA ER and ***stress that NUCYNTA ER didn't hit receptors like other opioids so it was less addictive and had fewer withdrawal issues***. She also promoted NUCYNTA and NUCYNTA ER as a safer alternative to NSAIDs and, when discussing side effects related to NUCYNTA and NUCYNTA ER, she focused on nausea, itchy skin, and vomiting. ***She told physicians that they could prescribe higher doses of NUCYNTA ER because its mechanism works differently than other opioids.***

617. Sales "Representative G," whose territory included the suburbs northwest of Chicago, recalled selling NUCYNTA and NUCYNTA ER. ***She promoted NUCYNTA and NUCYNTA ER as safe and effective for the long-term treatment of chronic pain*** and told physicians that drugs like Tylenol kill the liver and that NUCYNTA and NUCYNTA ER were cleaner by comparison and did not attack the organs.

618. Sales "Representative H," who also worked in Janssen's Midwest Region, recalls selling NUCYNTA and NUCYNTA ER. ***She recalls being trained to say that NUCYNTA and NUCYNTA ER did not offer the same euphoric feeling as other opioids***. She also recalled referring prescribers to a YouTube video that asserted that NUCYNTA was more difficult to crush than other pills, making it less likely to be abused or diverted. Representative H believed that it was common for Janssen sales representatives to downplay the addictive nature of NUCYNTA and NUCYNTA ER.

619. Depomed purchased NUCYNTA from Janssen in April 2015 despite knowing of Janssen's on-going litigation with the City of Chicago for the improper off-label marketing of NUCYNTA. On June 10, 2016, Depomed filed a Form 8-K/A stating that "Janssen has been named in a number of lawsuits alleging claims related to opioid marketing practices." Additionally, Depomed and the Defendants had "significant insight" into NUCYNTA marketing prior to purchasing NUCYNTA in April 2015. On July 12, 2016, Schoeneck stated, "When we bought the

molecule from J&J, we thought that there were some things that we could do better in terms of the marketing and selling of the molecule. Now, I know that may sound like a big task for a small company, but we had significant insight into this and did significant market research prior to actually putting in our final bid on the drug." Therefore, Schoeneck and Defendants knew about these claims prior to the purchase of NUCYNTA.

620. Further, on November 9, 2015, Depomed filed a Form 10-Q for the second quarter ending June 30, 2015. The Form 10-Q was certified and signed by Schoeneck and Moretti and stated the following:

> **City of Chicago v. Purdue Pharma L.P. et al.**
>
> On August 26, 2015, the City of Chicago (City***) named the Company as a defendant*** in a Second Amended Complaint (SAC) filed in City of Chicago v. Purdue Pharma L.P. et al., a federal case filed in the United States District Court, Northern District of Illinois (following removal from Cook County Circuit Court) in June 2014 against a number of pharmaceutical companies marketing and selling opioid pain medications and that was dismissed in May 2015 with leave to amend by the Court. ***The original complaint in the action named as a defendant Janssen Pharma and its related companies.*** Janssen, at the time the original complaint was filed, marketed and sold NUCYNTA® and NUCYNTA® ER, the U.S. rights to which were sold to the Company in a transaction that closed in April 2015. The SAC references the transaction between Company and Janssen and alleges that the Company has been listed in the SAC as a defendant in order to ensure the City can obtain complete relief. ***The essential factual allegations of the SAC concern purported misleading and otherwise improper promotion of opioid drugs to physician prescribers and consumers*** that occurred prior to the Company's acquisition of the U.S. rights to NUCYNTA® and NUCYNTA® ER. The Court has set November 20, 2015 as the date for filing motions to dismiss the SAC. Discovery is currently stayed, and no trial date has been set.

3Q15 at 26 (emphasis added).

621. The City of Chicago's second amended complaint states in pertinent part:

> Janssen promoted its branded opioids, including Duragesic, Nucynta, and Nucynta ER, through its sales representatives and a particularly active speakers program. ***Deceptive messages regarding low addiction risk and low prevalence of withdrawal symptoms were a foundation of this marketing campaign***. Janssen also conveyed other mispresentations [sic] as described in Section V.D, including that ***its opioids could safely be prescribed at higher doses and were safer than alternatives such as NSAIDs***.

> Janssen supplemented these efforts with its own unbranded website, as well as third-party publications and a Front Group website, to promote opioids for the treatment of chronic pain. ***These materials likewise made deceptive claims about addiction risk, safety at higher doses, and the safety of alternative treatments***. They also claimed that opioid treatment would result in functional improvement, and further masked the risk of addiction by promoting the concept of pseudoaddiction.
>
> * * *
>
> Janssen joined the other Defendants in propagating deceptive branded marketing that falsely minimized the risks and overstated the benefits associated with the long-term use of opioids to treat chronic pain. Like the other Defendants, Janssen sales representatives visited targeted physicians to ***deliver sales messages that were developed centrally and deployed identically across the country***. These sales representatives were critical in transmitting Janssen's marketing strategies and talking points to individual prescribers. In 2011, at the peak of its effort to promote Nucynta ER, Janssen spent more than $90 million on detailing.
>
> Janssen's designs to increase sales through deceptive marketing are apparent on the face of its marketing plans. For example, although Janssen knew that there was no credible scientific evidence establishing that addiction rates were low among patients who used opioids to treat chronic pain, [REDACTED] ***there is no evidence that Nucynta is any less addictive or prone to abuse than other opioids, or that the risk of addiction or abuse is low.*** Similarly, Janssen knew that there were severe symptoms associated with opioid withdrawal including, severe anxiety, nausea, vomiting, hallucinations, and delirium, but Janssen touted the ease with which patients could come off opioids.

622. During the Class Period, Defendants, including Schoeneck, Moretti, and Higgins, knew, or recklessly disregarded, that was on NUCYNTA's FDA-approved label and, equally important, what was not.

623. For example, on a conference call on June 23, 2015, Moretti stated that "***[a]lthough not in the label*** there's a very low abuse profile and side effect rate." Defendants repeated these statements throughout the Class Period.

624. On March 14, 2016, Depomed made a presentation at the ROTH Conference. Schoeneck and Moretti participated in the presentation on behalf of Depomed. In response to a question by ROTH analyst Scott Henry, Schoeneck stated the following:

> **Scott Henry** - ROTH Capital Partners - Analyst
> Okay, that is helpful. Are there any questions in the audience? Let's continue just a little bit more on NUCYNTA. There's been a lot of talk against opioids.
>
> I don't want to distract your CMO, but ***I think the perception is that perhaps yours may be a little less addictive***. Do you think some of that macro trend could favor

> NUCYNTA? And is that, can that be part of the marketing message in growing that product?
>
> **Jim Schoeneck** - Depomed, Inc. - President and CEO
> ***I think it's certainly part of the medical rationale on the product.*** I think the marketing messaging getting into the label in terms of the differentiation, ***much tougher standard with the agents***, with the FDA to do that.
>
> But if you look at tapentadol with the two mechanisms of action, with the norepinephrine mechanism in addition to the mu mechanism***, you do are getting of [sic] lower level of hits against the mu receptor and with that we see lower levels on respiratory depression***.
>
> ***The addiction profile is thought to be better. I can't make a claim around that because we don't actually have that in the label***. We are doing some things to be able to flesh out some of the different categories of abuse protection, if you want to call it that, with the FDA. But still in some discussions.

625. The above statements show Schoeneck's knowledge of NUCYNTA's label and that Depomed could not promote NUCYNTA as a safer, more tolerable, less addictive and less abusive opioid because it was not on the FDA-approved label. In fact, in February 2017, Schoeneck also announced that Depomed was "initiating label enhancement studies, aimed at further differentiating NUCYNTA by highlighting its respiratory depression and abuse potential profile. These labeling studies will focus on the properties of the tapentadol molecule, and its uniqueness in the pain marketplace." The purpose of this was to "be able to get it hopefully into the label." This shows that Schoeneck was attempting to get this information onto the label so they would no longer be in violation of the FDA rules.

626. Further, Higgins on May 9, 2017 stated that Depomed was "looking to strengthen our label." In February 2017, Schoeneck also announced that Depomed was "initiating label enhancement studies, aimed at further differentiating NUCYNTA by highlighting its respiratory depression and abuse potential profile. These labeling studies will focus on the properties of the tapentadol molecule, and its uniqueness in the pain marketplace." The purpose of this was to "be able to get it hopefully into the label."

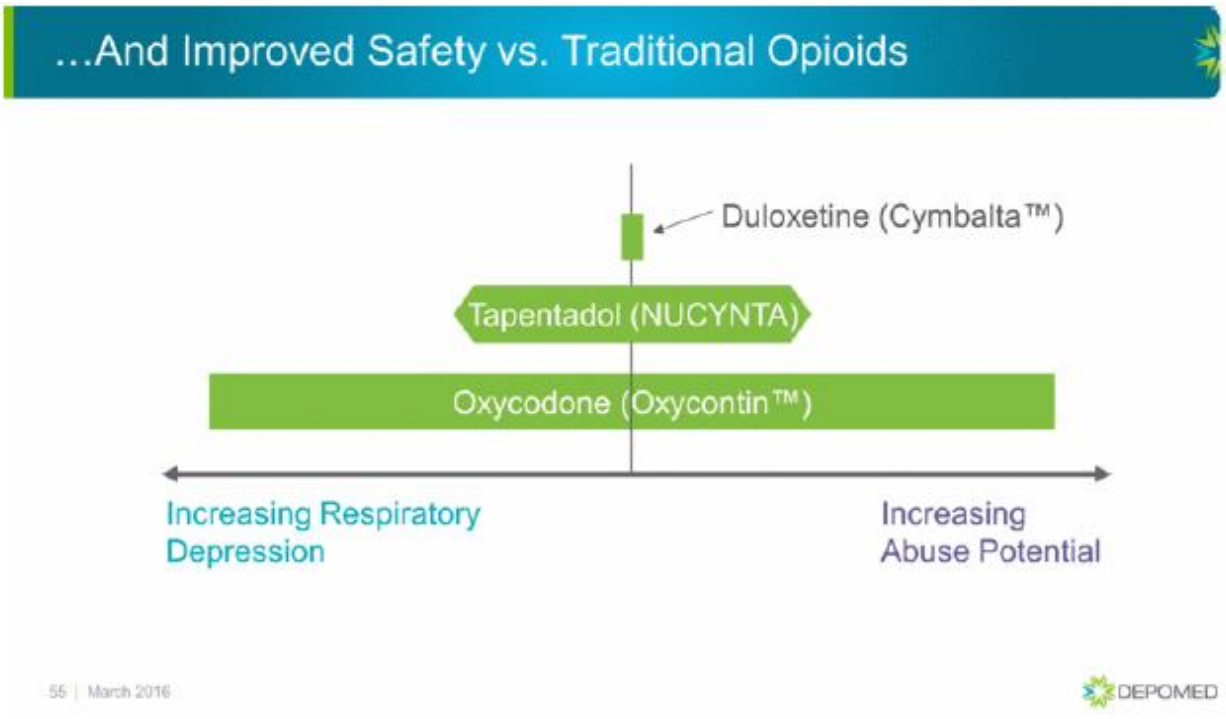
627. Knowing that it was illegal to promote NUCYNTA off-label, Defendants, including Schoeneck, Moretti, and Higgins continued to promote NUCYNTA as a safer, more tolerable, less addictive, less abusive opioid that did not have the same euphoric effect on patients.

628. First, Depomed hired many of the same representatives from Quintiles whose sales practices regarding NUCYNTA were the subject of the City of Chicago Complaint. These illicit sales methods continued under Depomed.

629. For example on a website, https://www.nucynta.com/hcp/er/safety-and-tolerability, ran by Depomed that is designed to market NUCYNTA, Depomed promotes NUCYNTA ER as more tolerable because of fewer "discontinuation rates due to treatment-emergent adverse events." Depomed goes on to set forth a number of treatment emergent adverse events and how they compare to one competitor, Oxycodone. The website also claims that NUCYNTA ER is safe because only 4.8% of NUCYNTA ER-treated patients experienced mild or moderate withdrawal. However, none of this appears on the FDA-approved label for NUCYNTA. Defendants encouraged their sales team to promote NUCYNTA off-label in the same manner.

630. Also on its' website, Depomed published an off-label study comparing the withdrawal rates of NUCYNTA side by side to Oxycodone CR. This was in direct violation of the FDA approve label.

631. Additionally, on March 23, 2016, Depomed held their Analyst and Investor Day Conference. Depomed filed with the SEC slides to accompany the presentation that depicted NUCYNTA as a safer opioid as shown below:



632. On June 21, 2016, Depomed made a presentation at the JMP Securities Life Sciences Conference. Schoeneck and Moretti participated in the presentation on behalf of Depomed. In response to JMP analyst Jason Butler's question about opioid abuse, Schoeneck promoted NUCYNTA as a safer opioid. Schoeneck stated in pertinent part:

> I think some physicians look at this drug and see it as one from the data that you don't see as much of the issues that they are looking for – or looking out for, which is ***you've got lower rates of abuse, lower rates of hospitalization*** and these are out of some of the database that the FDA uses, [RADAR] is an inflection. You see lower incidences of it.
>
> And the street price of the drug is barely above the retail price of the drug, where something like OxyContin is about $1 a milligram, we're at about $0.06 a milligram. So not particularly popular on the Street either. And some of that has to do with the fact that if you look at just the drug in the two mechanisms of action, people don't tend to get -- ***they don't get the euphoria that they get with the classic opioids.***
>
> You're not hitting the mu receptor nearly as hard because you're also hitting this other system. ***And with that you don't see the euphoria.*** And that's really what people want is they want that -- they like that good feeling and they want more of it. They start to tolerate to it, take higher and higher doses and that's where the category gets really dangerous.

633. Similarly, on an August 3, 2016 earnings call, Schoeneck states that "***the product is viewed as having low abuse potential*** and no evidence of the dose creeps seen with other opioids. . . ."

634. On March 13, 2017, Moretti made a presentation at the ROTH Conference. In response to a request from ROTH analyst Scott Henry to "talk about NUCYNTA in the concept of perhaps there are better and worse opioids with regard to addiction," Moretti stated in pertinent part:

> **August Moretti** - Depomed, Inc. - SVP and CFO
> Right. With all the appropriate caveats, my long-term view is that this is the best molecule in the category. As a dual mechanism of action, it does bind to the new opioid receptor, but at a binding strength that's 1/15th that of morphine. So as a result, ***the patient doesn't get the kind of euphoria that you get with other drugs in the category***.
>
> The second mechanism of action, norepinephrine reuptake inhibition, synergizes with the new opioid agonist and ***provides effective pain relief without the euphoria to the patient***. And as a result, you wind up with less likeability, ***less potential for***

> ***abuse***. And I think that the physicians feel that way about the drug; ***however, those claims are not in the label.***
>
> * * *
>
> Our view is that our abuse deterrents comes from the molecule itself, in that ***the molecule provides less euphoria; and, as a result, is less abusable***. It's equal pain relief but ***less threat of abuse and addiction***. But that's different from a physical barrier, or what have you -- a [hardened] pill that might support an abuse-deterrent claim for a particular route of administration.

635. At another conference one week later on March 21, 2017, Moretti again stated, "***But in the absence of the same level of euphoria and likability that other drugs in the class have***[.] So that ultimately we think that [NUCYNTA] could emerge as the opioid of choice."

636. Depomed was openly promoting NUCYNTA as a safer, less addictive, less abusive opioid without the euphoria that occurred in other opioids. These points were not approved by the FDA and did not appear on NUCYNTA's label. This supports the conclusion that, unbeknownst to investors, Defendants were also instructing their sales team to promote NUCYNTA off-label in order to increase sales.

Defendants Hired Sales Representatives from Quintiles Knowing They Engaged In Off-Label Marketing

637. Knowing that Janssen was being sued for the off-label marketing of NUCYNTA and that it was illegal to promote NUCYNTA off-label, Defendants hired the same sales team as Janssen to promote NUCYNTA at Depomed. Defendants also hired these sales representatives to train the new Depomed sales representatives knowing that they had engaged in the off-label marketing of NUCYNTA.

638. On July 29, 2015, Schoeneck stated, "Continuity was a key to our second quarter success as well as we hired Quintiles, the same contract sales organization that had marketed NUCYNTA previously to continue selling on our behalf while we completed the recruitment for positions in our expanded sales force leading up to our re-launch of NUCYNTA in June." Additionally, on November 9, 2015, in response to a question about the ability of Depomed's salesforce, Schoeneck responded, "We certainly think we vetted well when we brought people in. There was a group that actually had been selling NUCYNTA before with quintiles that we brought

onboard. So on that group we actually had direct experience in seeing what they were able to accomplish under the contract with J&J."

639. Not only did Depomed and Defendants hire Quintiles to sell NUCYNTA, but as stated by FE3, Defendants also had the former Quintiles sales representative participate in the training of the newly hired Depomed salesforce. Given Defendants knowledge of Quintiles off-label marketing and the significant insight done into the marketing of NUCYNTA, Defendants knew that their own sales representatives were marketing NUCYNTA off-label.

640. Accordingly, Defendants acted with scienter because they had actual knowledge, or recklessly disregarded that Depomed's sales force was marketing NUCYNTA off-label but portrayed the risk of exposure from off-label marketing as a mere potentiality when, in fact, Depomed was actively engaging in off-label marketing.

* * *

641. The above factors show that Depomed had a widespread policy or practice to promote NUCYNTA off-label. This campaign is evidence that Defendants knew, or recklessly disregarded, their statements relating to their "four pillars" to increase NUCYNTA sales, relating to their off-label marketing risk factors, and related to their financials were materially false and misleading.

Defendants Were Financially Motivated to Mislead Investors about Depomed's Illegal Off-label Marketing Scheme and Sensitivity to the Opioid Headwinds

642. At all times, Depomed was not a company that was motivated by the idea that NUCYNTA was helping patients, but was driven by personal profit and fear. This fear led Defendants to put Depomed gains over the public's safety, and investors ultimately paid the price.

643. Schoeneck represented at a September 16, 2015 conference, that "it really is about value . . . We're not people that are here because we started this in our garage and we want to turn it over to our kids. It really is to find things . . . where we can create value; create the value; and eventually realize that value."

644. One of Depomed's largest shareholders, Starboard Value LP, consistently pressured Defendants to do whatever it took to increase results in the face of the headwinds.

645. On April 8, 2016, Starboard Value LP, an activist investor, sent a letter to Depomed. In the letter, Starboard stated, "we are highly concerned regarding a number of actions that the Board has taken which indicate to us that meaningful change is needed to ensure the Company is acting in the best interest of all shareholders. Specifically, we have significant concerns regarding serious corporate governance deficiencies, questionable capital allocation decisions, and egregious actions taken by the Board to stymie strategic interest in acquiring Depomed. In combination, these concerns lead us to believe that management and the Board may be more interested in entrenching themselves than in delivering maximum value for all shareholders."

646. The letter also states in pertinent part:

> Given the apparent willingness of the current Board members to take extraordinary action to entrench themselves, as exemplified by the Reincorporation Proposal, we have little choice at this time but to immediately commence the process to call a special meeting of shareholders in order to preserve our rights under California law and Depomed's current bylaws. Therefore, yesterday, we delivered to the Company the documentation required under Depomed's bylaws to request that the Board set a record date for determining the shareholders entitled to call a special meeting (the "Record Date Request Notice"). Depomed's onerous special meeting bylaws require that we put forth our slate of director candidates as part of this initial step in commencing the special meeting process.
>
> Given that the Reincorporation Proposal was publicly disclosed only three days ago on April 5, 2016, and our view that the members of the Board will go to any length to entrench themselves, out of an abundance of caution, we are immediately nominating six individuals, five of whom are Starboard Value investment professionals. We intend to continue our search for a slate of director candidates that will ensure an experienced, diverse, and independent board, as has been our practice when proposing alternative board slates over the past fourteen years. However, we deemed it necessary to take this action to preserve our rights as shareholders, and to ensure compliance with Depomed's current onerous bylaw requirements, so that management cannot further manipulate the bylaws prior to our ability to take action.
>
> We are taking this extraordinary action because we cannot risk that the current Board may seek to further manipulate Depomed's bylaws to prevent a lawful special meeting request. We caution the Board against taking any steps in response to our special meeting Record Date Request Notice to further diminish or suppress the rights of its shareholders to call a special meeting under California law and the Company's bylaws.
>
> We have an ownership interest in approximately 9.8% of the outstanding shares of Depomed because we believe that significant opportunities exist to create value

> through better execution, improved capital allocation, and, potentially, a sale of the Company. We hope to have a constructive dialogue with the Company, but need to make sure that shareholders' interests remain of paramount importance. As such, we fully expect that management and the Board will halt their pattern of aggressive entrenchment behavior and take no action to further frustrate shareholders' rights. Additionally, despite recent rhetoric from management to the contrary, we believe that Depomed should not be contemplating acquisitions at this time given its levered capital structure and expensive debt.
>
> To be clear, we are not currently advocating for any one particular transaction, or any transaction at all, but we firmly believe that board change is necessary to best represent the interests of all shareholders as it relates to the ongoing business and any potential transaction opportunities in the future. Given your actions, and history of actions, we cannot take the risk that you further impair our shareholder rights. We intend to share more details with shareholders in the coming weeks regarding our views on the Company, opportunities for value creation, and Depomed's significant corporate governance deficiencies.

647. Starboard also sent letters to Depomed's shareholders on May 26, 2016, and July 26, 2016. In the July 26, 2016 letter, Starboard states:

> We continue to have significant concerns regarding serious corporate governance deficiencies, questionable capital allocation decisions, and actions taken by the Board to stymie strategic interest in acquiring Depomed. We believe the Board clearly lacks the independence, objectivity, and perspective needed to make decisions that are in the best interests of shareholders.
>
> Following our initial evaluation of well over 100 qualified potential board candidates, we have continued to meet with numerous pharmaceutical executives to supplement our slate with additional pharmaceutical experience. Unfortunately, given the extensive requirements and restrictions under the Depomed Bylaws for calling the Special Meeting, the addition of any new, highly qualified nominees to our slate at this time would effectively require us to submit a new record date request notice to Depomed, thereby restarting the clock under the Bylaws for the Special Meeting and further delaying our efforts to remove and replace the Board. Further delay is unpalatable; therefore, we have instead appointed two exceptionally qualified former senior pharmaceutical executives – Robert G. Savage and James L. Tyree – as advisors to assist in our solicitation efforts given their significant industry knowledge and experience. If our Special Meeting solicitation ultimately proves successful, we would invite Messrs. Savage and Tyree to join the Board, and they have indicated their desire to do so.

648. Starboards pressure on Defendants to maximize shareholder value led to a very real fear that they would lose their jobs. This fear came to fruition. On March 29, 2017, Depomed announced that it had replaced its chief executive and named two new directors to its board after nearly a year of activist pressure from Starboard Value LP.

649. Defendants were also financially motivated to mislead investors about the off-label marketing and opioid headwind representations. Defendants' bonuses, and in Schoeneck's case his job, was on the line. Defendants' bonuses were based on corporate objectives set forth by Depomed's Compensation Committee. These included "net product sales target of $525 million," EPS of $1.50, and "positive cash flow target of $126 million." These directly incentivized Defendants to engage in off-label marketing to increase their already lucrative compensation and cash bonuses.

650. According to the 2017 Proxy, for Fiscal 2016, Schoeneck earned $6,167,070 in total compensation from Depomed, consisting of $787,500 in salary, $2,362,290 in stock awards, $2,308,415 in option awards, $694,000 in cash bonuses and $14,865 in other compensation. Additionally, in connection with his resignation from Depomed, on March 28, 2017, Schoeneck and Depomed entered into a Waiver and Release Agreement whereby Depomed agreed to pay Schoeneck: (i) $825,000, which is equal to 12-months of his then-current base salary, payable in equal installments in accordance with Depomed's ordinary payroll practices, (ii) the full cost of the health insurance benefits provided to Mr. Schoeneck, his spouse and dependents, as applicable, pursuant to the terms of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") or other applicable law through the earlier of (a) the end of the 12 month period following the date of the Waiver and Release Agreement or (b) the date on which Mr. Schoeneck is no longer eligible for such COBRA or other benefits under applicable law and (iii) up to six months of documented, bona fide, outplacement services not to exceed $5,000 per month.

651. According to the 2017 Proxy, upon joining Depomed, it entered into a letter agreement with Higgins whereby he would receive an annual base salary of $800,000, an annual target cash bonus of 100% of his base salary, stock options that vest over a four-year-period with a value of $1.75 million and reimbursement of reasonable out-of-pocket relocation expenses. Further, on March 31, 2017, Depomed granted Higgins 139,442 restricted stock units that would vest annually in four equal tranches, with the first 25% vesting on December 1, 2017, and 315,884 stock options that vest 12.5% on September 28, 2017 and in 42 equal installments thereafter.

652. Depomed paid Moretti total compensation of $1,805,459 in 2016 and $1,490,539 in 2015.

653. Further, while in possession of material, adverse nonpublic information concerning Depomed's true business health, defendant Moretti also sold 30,000 shares of his stock for $572,797.49 in proceeds.

654. By engaging in the fraud alleged herein, the Individual Defendants benefitted themselves financially in a personal and specific manner.

Resignation of Employees

655. On March 28, 2017, the same exact day that the senate announced investigation into Depomed, Schoeneck resigned. Further, between November 2016 and June 2017, Shively (Depomed's Senior Vice-President and Chief Commercial Officer), Schoeneck (Depomed's President and Chief Executive Officer and a Director), and Rao (Depomed's Senior Vice President and Chief Medical Officer) all resigned and were rewarded lucrative severance packages by the Board, in direct violation of Depomed's Management Continuity Agreements entered into with each of the foregoing defendants, which provides severance payments for only certain voluntary/involuntary terminations, including a change in control, but does not provide any severance whatsoever where the employee voluntarily resigns, as was the case here.

656. Depomed's decision to fire these former directors and employees further implicates Defendants as having acted with scienter.

657. Depomed terminated employment with them in response to the conduct alleged herein. The nature and timing of Depomed's decision to terminate Schoeneck evidences this fact, as explained below:

- Depomed terminated Schoeneck the same day it received the letter from Senator McCaskill. The timeliness of Schoeneck's termination suggests that it was directly related to how Schoeneck promoted NUCYNTA and the misleading statements made during the Class Period;
- Schoeneck was responsible for the majority of the fraudulent statements alleged herein. The fact that Depomed terminated Schoeneck shows that wrongdoing occurred at Depomed, and that Schoeneck was responsible for the wrongdoing in some material way; and

- The current report did not contain any of the typical salutary words often found in corporate statements announcing high-level resignations, which suggests strongly that Schoeneck's departure from Depomed was involuntary and for cause.

658. Depomed's decision to terminate Schoeneck's employment shows that wrongdoing occurred in connection with Depomed's misrepresentations regarding the opioid market's effect on Depomed and Depomed's involvement in off-label marketing, which further supports the inference that Defendants acted with scienter.

Corporate Scienter

659. Depomed's public statements about the safety of NUCYNTA, off-label marking, and the opioid crisis were critical to its reputation and overall operations. Given the dramatic allegations of falsity contained herein, a strong inference exists that Depomed's corporate officials knew of the falsity of the statements at the time of publication. Specifically, the knowledge of Depomed's former CEO Schoeneck, CEO Higgins, and CFO Moretti (among other members of senior management) concerning Depomed's engagement in off-label marking and the effect of the opioid crisis on Depomed's finances, is imputed to Depomed. Depomed acted with scienter under the corporate scienter doctrine

E. Loss Causation and Economic Loss

660. Defendants' materially misleading statements and omissions during the Class Period resulted in Plaintiffs and the other Class members purchasing Depomed's shares at artificially inflated prices, and thereby directly or proximately caused, or were a substantial contributing cause, of the damages sustained by Plaintiffs and the other Class members.

661. As alleged herein:

a. the market for Depomed's stock was open, well-developed and efficient at all relevant times;

b. Defendants' above-detailed materially misleading statements and/or material omissions had the effect of creating in the market an unrealistically positive assessment of Depomed and its prospects, thus causing Depomed's shares to be

overvalued and the market price of Depomed's shares to be artificially inflated during the Class Period;

c. Defendants created an unrealistically positive assessment of Depomed and its prospects by, in part, concealing risks associated with exposure arising from Depomed's off-label marketing practices;

d. Plaintiffs and the other Class members purchased or otherwise acquired Depomed stock relying upon the integrity of the market price for Depomed shares and market information relating to Depomed;

e. The risks associated with exposure arising from Depomed's off-label marketing practices began to materialize and, in turn, investors began to discover that Defendants' public statements were materially misleading; and

f. Upon discovery of Defendants' materially misleading statements and/or material omissions, Depomed's share price suffered severe devaluation.

662. Defendants' disclosures and/or events on the below dates resulted in damages to investors.

663. **November 7, 2016**. On November 7, 2016, Depomed lowered its revenue guidance to $455 million to $465 million from $480 million to $505 million. Depomed attributed its decision to lower guidance, in part, to worsening conditions within the opioid market. Specifically, Depomed stated that "prescription demand growth for our key products that did not meet our forecast." In response to an analyst question from Ken Trbovich relating to "the commentary around the changing guidance," Depomed stated that "while we are setting records on NUCYNTA IR, and while we have made a turn on NUCYNTA, we still in our plan had it moving farther than it has to date."

664. Depomed continued: "And that is one that I will be digging into significantly over the next few weeks here on what we can do to make sure that that is accelerating as we would expect. ***I think a piece of that is certainly the opioid market***. When we came into this last year, the opioid market was -- long-acting market was growing about 1% a year. Now it's declining 4%. It looks like it's stabilized at about that 4% year-over-year decline, at least for the last three months. We will see where it continues for the rest of the year."

665. Depomed also revealed that physicians were not prescribing NUCYNTA in the off-label dosages that it had been promoting. Defendants stated, "I mentioned on our last call as well that ***we had some downtick in the milligrams per script***. That has continued as well. It hasn't gone down much farther, but it has continued at that lower level."

666. This revealed to the market that NUCYNTA was not immune to the crackdown on opioids. Prior to that point, Defendants consistently stated that their NUCYNTA marketing strategy had proven (and would continue to prove) successful, even in the face of worsening market conditions. Depomed's decision to lower its revenue estimate signaled to investors that, contrary to their prior statements, the negative sentiment towards opioids in general was affecting Depomed. On November 8, 2016, the price of Depomed stock declined from $22.89 per share to $19.01 per share. On November 9, 2017, Morgan Stanley noted that there was "financial downside associated with ongoing opioid (Nucynta) pressures."

667. **December 11, 2016.** On December 11, 2016, PiperJaffray downgraded Depomed to "underweight" citing the "trajectory of [Depomed's] business" as a "real concern." PiperJaffray also lowered its price target for Depomed stock from $17 per share to $14 per share. Significantly, PiperJaffray stated that "it has become clear to us that management, based in part on its own commentary, does not really have a new strategy in place to wring significant further volume growth out of NUCYNTA ER in the face of more challenging market dynamics." PiperJaffray's report provided investors with cause for concern, drawing suspicion around the veracity of Defendants' prior statements about Depomed's ability to weather negative market conditions (notwithstanding Defendants' assurances to the contrary). This further revealed to the market that NUCYNTA was subject to the opioid headwinds. On December 12, 2016, the price of Depomed stock declined from $20.20 per share to $18.13 per share;

668. **March 21, 2017**. On March 21, 2017, Depomed presented at the Oppenheimer Healthcare Conference. Defendants revealed for the first time that the CDC was actually presenting significant headwinds to Depomed, and not as they previously stated an additional opportunity. Defendants revealed, "In the event instead of a tailwind we have had a headwind and, again, I think because of the reinforcement of the start low, go slow mantra in the CDC guidelines the average

daily dosage has actually come down since we bought the product. So it's now down around I think the last data I saw about 257 milligrams a day. So I think the opioid market has presented us some headwinds." In response to Depomed's disclosures, the price of Depomed stock declined from $15.75 per share at open on March 21, 2017 to $14.95 per share at close on March 22, 2017.

669. **March 28, 2017.** On March 28, 2017, Senator McCaskill announced an investigation into the marketing and sales practices of the nation's top five manufacturers of prescription opioid products, including Depomed. The investigation signaled to investors that Depomed's marketing practices were not as successful or legitimate as Defendants' previously represented. Beginning on March 28, 2017 and continuing over the course of the week, the price of Depomed's stock declined from its closing price of $14.90 per share on March 27, 2017, to $14.23 per share on March 28, to $13.79 on March 29, to $12.82 on March 30, and to $12.55 on March 31. As reported by Janney, on March 29, 2017, this was directly due to the McCaskill letter and Depomed's reduced guidance.

670. May 9, 2017. On May 9, 2017, Depomed revealed for the first time that the CDC was affecting NUCYNTA's dosages. For example, Defendants stated, "the CDC announced guidelines for primary care physician prescribing of opioids. It is clear to us, though that these guidelines have resulted in a more significant decline in the opioid market than we projected, both in terms of fewer prescriptions and lower daily doses." This revealed to the market that the physicians were no longer complying with Depomed's off-label campaign to promote higher dosages. The stock price declined from a close of $10.96 on May 9, 2017 to $9.55 at open on May 10, 2017, a decline of approximately 12.8%.

671. **May 17, 2017.** On May 17, 2017, Roth Capital Partners released a report on Depomed stating that the firm was reducing its price target on Depomed stock. Roth Capital lowered the price target "based largely on a deteriorating macro environment for opioid pain treatments." Roth Capital's conclusions contradicted Defendants' statements, which gave investors further cause for concern about the accuracy of Defendants' statements prior to that point in time. On May 18, 2017, the price of Depomed stock declined from $10.82 per share to $10.20 per share; and

672. **August 7, 2017.** On August 7, 2017, Defendants revealed that, in addition to Senator McCaskill's investigation, the U.S. Department of Justice and the Office of the Attorney General for the

State of Maryland had subpoenaed Depomed in connection with Depomed's opioid marketing practices. Defendants stated in pertinent part: "We continue to operate in an environment that is challenging and rapidly evolving. The increasing public focus on opioids as well as opioid manufacturers, including by government agencies and other industry stakeholders, will continue to disrupt the opioid markets. While our flagship NUCYNTA franchise continues to outperform the long and short-acting markets, it is clearly not immune to these developments." The announcement of the subpoena and the above statement informed investors that Depomed's marketing practices were not in compliance with government regulations, *i.e.* Depomed was promoting NUCYNTA off-label.

673. In addition, Depomed revealed that it was lowering its revenue estimates to $395 million to $410 million from $405 million to $425 million. Moreover, for the first time, Depomed substantially revised "risk warning" language within its quarterly reports (Form 10-Q) as the class period progressed to discuss worsening market conditions resulting from regulatory actions, government investigations, and heightened public attention on opioid abuse. These disclosures signaled to investors that, contrary to Defendants' prior statements, Depomed faced significant exposure from risks arising from the Depomed's opioid marketing practices and worsening market conditions.

674. Finally, Defendants revealed that "Two of the more important moves we'll make in the coming quarters are: firstly, we are reducing the number of calls on targets -- or our call targets in our pain sales force by approximately 20%. The vast majority of that target reduction comes from primary care physicians, and it's becoming clear they will play a reduced role in pain management." This revealed to investors that Depomed's strategy to go against the CDC and government regulations was not working.

675. On August 8, 2017, the price of Depomed stock declined from $9.23 per share to $6.15 per share.

676. Defendants withheld material information concerning Depomed's marketing practices and, in turn, the sales results the company was generating in spite of the worsening opioid market conditions. This information included the fact that Depomed was engaging in off-label marketing. Defendants' misleading statements and omissions concealed this information from the public and precluded investors from knowing that they were subjecting themselves to significant

risks when investing in Depomed, *i.e.*, risks associated with liability exposure arising from off-label marketing.

677. **Post-Class Period Disclosures**. On February 12, 2018, after Depomed sold the rights to NUCYNTA, the above information of Depomed's improper marketing was revealed to be true. In the Homeland Security and Governmental Affairs Committee's report titled "Fueling an Epidemic," the study found that manufacturers of opioid, including Depomed, provided millions of dollars to groups that echoed and amplified messages favorable to increased opioid use. The groups also issued guidelines and policies minimizing the risk of opioid addition and promoting opioids for chronic pain, lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for over prescription and misbranding. Notably, a majority of these groups also strongly criticized the 2016 guidelines from the CDC that recommended limits on opioid prescriptions for chronic pain.

678. The report found that "[t]he fact that these same manufacturers provided millions of dollars to the groups described below suggests, at the very least, a direct link between corporate donations and the advancement of opioids friendly messaging. By aligning medical culture with industry goals in this way, many of the groups described in this report [including Depomed] may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic." Additionally, the report found that these groups that were paid by in part by Depomed, "amplified messages favorable to increased opioid use."

679. Additionally, between March 2018 and December 2018 alone, at least thirty-eight opioid lawsuits have been filed against Depomed. The lawsuits allege from extensive investigations that Depomed engaged in an intentional and deceptive marketing campaign to promote the use of prescription opioids, including NUCYNTA, and that their conduct has resulted in a national epidemic of opioid overdose deaths and addictions.

680. These lawsuits also allege that Depomed engaged in a deceptive marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain by: a) downplaying the serious risk of addiction; b) creating and promoting the concept of "pseudoaddiction" by advocating that signs of addiction should be treated with more opioids; c)

exaggerating the effectiveness of screening tools to prevent addiction; d) claiming that opioid dependence and withdrawal are easily managed; e) denying the decreased effectiveness of opioids over long-term use and the corresponding need for increased dosages; and f) exaggerating the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction.

681. The lawsuits allege that Depomed made these materially false representations directly to doctors and patients through advertising campaigns and "detailers" (sales representatives who directly targeted doctors).

682. They further allege that Depomed marketed their products indirectly to avoid FDA scrutiny and regulation. They did this through seemingly unbiased and independent third parties, including KOLs (seemingly independent doctors) and professional societies and patient advocacy groups ("Front Groups") funded in part by Depomed. They also allege that Depomed used "unbranded advertising" (promoting the general use of opioids without naming a specific drug) and manipulated published promotional materials about opioids in scientific literature to avoid FDA regulation and to give the false appearance that these were independent organizations outside of the Depomed's control.

683. The corrective disclosures during the Class period revealed to investors that Defendants engaged in a widespread off-label marketing scheme. These subsequent disclosures add to the fact that the investigations were aimed at Depomed for off-label marketing.

F. Presumption of Reliance; Fraud-On-The-Market

684. At all relevant times, the market for Depomed's common stock was an efficient market for the following reasons, among others:

(a) Depomed common stock met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient market;

(b) During the Class Period, Depomed common stock was actively traded, demonstrating a strong presumption of an efficient market;

(c) As a regulated issuer, Depomed filed with the SEC periodic public reports during the Class Period;

(d) Depomed regularly communicated with public investors via established market

communication mechanisms;

(e) Depomed was followed by many securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of brokerage firms during the Class Period. Each of these reports was publicly available and entered the public marketplace; and

(f) Unexpected material news about Depomed was rapidly reflected in and incorporated into Depomed's stock price during the Class Period.

685. As a result of the foregoing, the market for Depomed's common stock promptly digested current information regarding Depomed from all publicly available sources and reflected such information in Depomed's stock price. Under these circumstances, all purchasers of Depomed common stock during the Class Period suffered similar injury through their purchase of Depomed's common stock at artificially inflated prices, and a presumption of reliance applies.

686. Alternatively, reliance need not be proven in this action because the action involves omissions and deficient disclosures. Positive proof of reliance is not a prerequisite to recovery pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security. Here, the facts withheld are material because an investor would have considered how the opioid epidemic was impacting Depomed and Depomed's decision to engage in off-label marketing when deciding whether to purchase and/or sell stock in Depomed.

G. No Safe Harbor; Inapplicability Of Bespeaks Caution Doctrine

687. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the material misrepresentations and omissions alleged in this Complaint.

688. To the extent certain of the statements alleged to be misleading or inaccurate may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

689. Defendants are also liable for any materially false or misleading "forward-looking

statements" pleaded because, at the time each "forward-looking statement" was made, the speaker knew the "forward-looking statement" was false or misleading and the "forward-looking statement" was authorized and/or approved by an executive officer of Depomed who knew that the "forward-looking statement" was false. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions.

CLASS ACTION ALLEGATIONS

690. Plaintiffs bring this action on behalf of all individuals and entities who purchased acquired Depomed common stock on the public market during the Class Period, and were damaged, excluding Depomed, the Individual Defendants and each of their immediate family members, legal representatives, heirs, successors or assigns, and any entity in which any of the defendants have or had a controlling interest (the "Class").

691. The Class members are so numerous that joinder of all members is impracticable. Throughout the Class Period, shares of Depomed's common stock were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other Class members may be identified from records maintained by Depomed or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions. As of November 6, 2017, Depomed had 63,013,451 outstanding shares of common stock. Upon information and belief, these shares are held by thousands if not millions of individuals located geographically throughout the country and possibly the world. Joinder would be highly impracticable.

692. Plaintiffs' claims are typical of the claims of the Class members as all Class members are similarly affected by the Defendants' respective wrongful conduct in violation of the federal laws complained of herein.

693. Plaintiffs have and will continue to fairly and adequately protect the interests of the Class members and have retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

694. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by the defendants' respective acts as alleged herein;

(b) whether the defendants acted knowingly or with deliberate recklessness in issuing false and misleading statements concerning the opioid market's effect on Depomed and Depomed's involvement in off-label marketing;

(c) whether the price of Depomed common stock during the Class Period was artificially inflated because of the Defendants' conduct complained of herein; and

(d) whether the Class members have sustained damages and, if so, what is the proper measure of damages.

695. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for Class members to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

Violation of Section 10(b) and Rule 10b-5 Against All Defendants

696. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

697. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (1) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; and (2) cause Plaintiffs and other Class members to purchase Depomed common stock at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, each of the Defendants took the actions set forth herein.

698. Defendants: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers of Depomed's common stock in an effort to maintain artificially high market prices for Depomed's common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

699. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the opioid market's effect on Depomed and Depomed's involvement in off-label marketing and thus the business and future prospects of Depomed as specified herein.

700. These Defendants employed devices, schemes, and artifices to defraud while in possession of material adverse non-public information, and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Depomed's value and performance and continued substantial growth, which included the making of, or participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about the opioid market's effect on Depomed and Depomed's involvement in off-label marketing and Depomed's business and future prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business that operated as a fraud and deceit upon the purchasers of Depomed's common stock during the Class Period.

701. Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (1) Individual Defendants were high-level executives, directors, and/or agents at Depomed during the Class Period and members of Depomed's management team or had control thereof; (2) each Individual Defendant, by virtue of his responsibilities and activities as a senior officer and/or director of Depomed, was privy to and participated in the creation, development and reporting of Depomed's SEC filings and public statements concerning the opioid market's effect on

Depomed and Depomed's involvement in off-label marketing; (3) each Individual Defendant enjoyed significant personal contact and familiarity with the other Individual Defendant and was advised of and had access to other members of Depomed's management team, internal reports and other data and information about the opioid market's effect on Depomed and Depomed's involvement in off-label marketing, at all relevant times; and (4) each Individual Defendant was aware of Depomed's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

702. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing the opioid market's effect on Depomed and Depomed's involvement in off-label marketing and thus Depomed's business and future prospects from the investing public and supporting the artificially inflated price of its common stock. As demonstrated by Defendants' misrepresentations concerning the opioid market's effect on Depomed and Depomed's involvement in off-label marketing throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

703. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Depomed's common stock was artificially inflated during the Class Period. In ignorance of the fact that market prices of Depomed's publicly-traded common stock was artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the common stock trades, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other Class members acquired Depomed's

common stock during the Class Period at artificially high prices and were or will be damaged thereby.

704. At the time of said misrepresentations and omissions, Plaintiffs and other Class members were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other Class members and the marketplace known the truth regarding the opioid market's effect on Depomed and Depomed's involvement in off-label marketing, which was not disclosed by Defendants, Plaintiffs and other Class members would not have purchased or otherwise acquired their Depomed common stock, or, if they had acquired such common stock during the Class Period, they would not have done so at the artificially inflated prices that they paid.

705. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

706. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other Class members suffered damages in connection with their respective purchases and sales of Depomed's common stock during the Class Period.

707. This action was filed within two years of discovery of the fraud and within five years of each plaintiff's purchases of common stock giving rise to the cause of action.

COUNT II

The Individual Defendants Violated Section 20(a) of the Exchange Act

708. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

709. The Individual Defendants acted as controlling persons of Depomed within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, agency, ownership and contractual rights, and participation in and/or awareness of Depomed's operations and/or intimate knowledge of the false information filed by Depomed with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of Depomed, including the content and dissemination of the various statements that Plaintiffs contend are false and misleading. The Individual Defendants were provided with or had unlimited access to

copies of Depomed's reports, press releases, public filings and other statements alleged by Plaintiffs to have been misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or to cause the statements to be corrected.

710. In particular, each of the Individual Defendants had direct and supervisory involvement in the day-to-day operations of Depomed and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

711. As set forth above, Depomed and the Individual Defendants each violated Section 10(b), and Rule 10b-5 promulgated thereunder, by their acts and omissions as alleged in this Complaint.

712. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other Class members suffered damages in connection with their purchases of Depomed's common stock during the Class Period.

713. This action was filed within two years of discovery of the fraud and within five years of each Plaintiffs' purchases of common stock giving rise to the cause of action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment as follows:

(a) Determining that this action is a proper class action, certifying Plaintiffs as class representatives under Federal Rule of Civil Procedure 23 and Plaintiffs' counsel as class counsel;

(b) Awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of the defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiffs and the other Class members their reasonable costs and expenses incurred in this action, including counsel fees and expert fees;

(d) Granting extraordinary equitable and/or injunctive relief as permitted by law; and

(e) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiffs hereby demand a jury trial.

Dated: May 2, 2019

Respectfully submitted,

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