IN THE CIRCUIT COURT OF KNOX COUNTY, TENNESSEE
SIXTH JUDICIAL DISTRICT AT KNOXVILLE

STATE OF TENNESSEE,	)	
***ex rel.* HERBERT H. SLATERY III,**	)	
ATTORNEY GENERAL and REPORTER,	)	
	)	**JURY DEMAND**
Plaintiff,	)	
	)	
v.	)	**Case No.** 1-173-18
	)	
PURDUE PHARMA, L.P.,	)	
a foreign limited partnership,	)	
	)	
Defendant.	)	

COMPLAINT

[SUBJECT TO MOTION TO TEMPORARILY SEAL COMPLAINT]

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1. This civil law enforcement action is brought in the name of the State of Tennessee in its sovereign capacity by Herbert H. Slatery III, Attorney General and Reporter (State or Attorney General), pursuant to Tenn. Code Ann. § 47-18-108 of the Tennessee Consumer Protection Act of 1977, Tenn. Code Ann. §§ 47-18-101 to -131 (TCPA), against Purdue Pharma, L.P. (Purdue) to protect consumers and the integrity of the commercial marketplace in Tennessee. The State also brings suit to remedy Purdue's violations of the 2007 Agreed Final Judgment (Judgment or 2007 Judgment) and pursuant to the Attorney General's common law police power to abate and remedy the statewide public nuisance created by Purdue's interference with the commercial marketplace and endangerment of the public health.

I. GENERAL FACTUAL ALLEGATIONS

2. Opioids are synthetic or semi-synthetic drugs derived from opium. Historically, opioids were prescribed in limited circumstances because of long-standing and well-founded fears about their addictive potential and safety. Then came Purdue. Through unprecedented marketing for a narcotic, Purdue created a false narrative to reverse these attitudes among the public, health care providers, and other stakeholders in order to increase sales of its opioid products and its own market share. Time and again, Purdue placed profits over people.

3. Purdue violated the TCPA by making a series of unlawful safety, comparative, and benefit claims about its opioid products, failing to disclose its material connection to third-party pain advocacy groups it substantially funded, and unfairly targeting vulnerable populations like the elderly. Purdue advanced the deceptive narrative that its opioid products were safer than they actually were, its competitors' products were more dangerous or less effective than they actually were, its opioid products had certain qualities or benefits for which it lacked adequate substantiation, and its opioid products were safer for elderly patients than they actually were.

4. The State also brings suit based on Purdue's failure to sufficiently implement and follow an abuse and diversion detection (ADD) program as required by the 2007 Judgment. Purdue failed to take appropriate action in spite of knowing about unambiguous, credible signs of abuse or diversion. Instead, Purdue continued to direct its sales force to target the highest prescribers, many of whom had no or limited background or training in pain management.

5. For example, Purdue called on two providers *48 times* after it had been told directly by law enforcement officials that the pair was responsible for significant interstate diversion of OxyContin and called on another provider *31 times* after the provider's license was placed on restrictive probation because of issues related to his high prescribing of controlled substances. Purdue continued to make sales calls in spite of credible reports of patient overdoses, indictments, adverse licensure actions, a provider admitting he was addicted to heroin, a knife fight outside a provider's office, muggings over controlled substances outside of a pharmacy linked to a specific provider, a clinic that had no examination tables or equipment, an admission by a provider that he was running a pill mill, a provider changing the name of his practice shortly after he was notified of a state investigation into his practice, a patient being coached in the waiting room about how to fill out intake forms, armed guards in provider waiting rooms, high numbers of patients who purchased OxyContin in cash, high numbers of out-of-state or out-of-county tags in providers' parking lots, accusations of insurance fraud, choreographed urine screenings and pill counts, standing-room-only waiting rooms, and additional signs of problematic high volume practices.

6. Purdue's actions and omissions concerning its highly addictive narcotics have created and fueled a public nuisance in Tennessee by significantly interfering with the commercial marketplace and endangering the life and health of the state's residents.

PARTIES

7. The Plaintiff, State of Tennessee *ex rel.* Herbert H. Slatery III, Attorney General and Reporter, is charged with enforcing the TCPA. Pursuant to Tenn. Code Ann. § 47-18-108 actions for violations of the TCPA may be brought only by the Attorney General with approval from the Division of Consumer Affairs in courts of competent jurisdiction to restrain violations, to secure equitable and other relief, and to otherwise enforce the provisions of the TCPA. The Attorney General has all common law powers except as restricted by statute, *State v. Heath*, 806 S.W.2d 535, 537 (Tenn. Ct. App. 1990), and is expressly authorized to utilize and refer to the common law in the exercise of his duties pursuant to Tenn. Code Ann. § 8-6-109(a).

8. Defendant Purdue Pharma, L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Connecticut.

STATE COURT JURISDICTION

9. The causes of action asserted and the remedies sought in this Complaint are based exclusively on Tennessee statutory, common, or decisional law.

10. The Complaint does not confer diversity jurisdiction upon federal courts pursuant to 28 U.S.C. § 1332, as the State is not a citizen of any state and this action is not subject to the jurisdictional provisions of the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d). Federal question subject matter jurisdiction under 28 U.S.C. § 1331 is not invoked by the Complaint. Nowhere does the State plead, expressly or implicitly, any cause of action or request any remedy that arises under federal law. The issues presented in the allegations of this Complaint do not implicate any substantial federal issues and do not turn on the necessary interpretation of federal law. There is no federal issue important to the federal system, as a whole as set forth in *Gunn v. Minton*, 568 U.S. 251, 258 (2013).

11. In this Complaint, the State occasionally references federal statutes, regulations, or actions, but does so only to establish the Defendant's knowledge or to explain how the Defendant's conduct has *not* been approved by federal regulatory agencies.

SUBJECT MATTER JURISDICTION

12. As a court of general jurisdiction, the circuit court is authorized to hear this matter, based on the TCPA and nuisance claims, the amount at issue, and the relief sought pursuant to Tenn. Code Ann. §§ 16-10-101 and -110.

PERSONAL JURISDICTION

13. As set forth below, this Court has personal jurisdiction over Purdue based on its contacts in Tennessee. Among other things, Purdue has employed at least 87 sales representatives;[1] district managers, and regional managers from 2006 to 2017 to make or oversee sales calls to health care providers in Tennessee; has made numerous sales calls to health care providers in Tennessee between 2007 and 2017 for the purpose of promoting Purdue's opioid products;[2] mailed, delivered, or otherwise made marketing or promotional materials for Purdue's opioid products available to health care providers or the public in Tennessee; convened regional sales meetings in Tennessee;[3] hosted numerous speaker events in Tennessee; and participated in several conferences hosted in Tennessee for the purpose of promoting Purdue's opioid products.[4]

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[1] PWG004284992.
[2] PTN000031807; PWG004285192_A.
[3] PWG000435500.
[4] PTN000119294 ID28660 (9/5/2008) ("Gave saving card she is attending the [American Pain Society] in Nashville encouraged to stop by our booth for education[.]").

VENUE

14. Venue is proper in Knox County pursuant to the TCPA's specific state enforcement venue provision, Tenn. Code Ann. § 47-18-108(a)(3), because it is a county where the alleged violations took place and is also the county in which Purdue has conducted or transacted business.

15. Among other conduct, Purdue marketed its opioids in Knox County including to health care providers in Knox County through numerous in-person visits from its sales representatives.

PRE-SUIT NOTICE

16. The Director of the Division of Consumer Affairs of the Tennessee Department of Commerce and Insurance requested that the State file a civil law enforcement action against Purdue for violations of the TCPA. Consistent with Tenn. Code Ann. § 47-18-108(a)(2), the State has provided Purdue with 10 days' advance notice of its intention to initiate legal proceedings against it. Consistent with the 2007 Judgment, the State provided Purdue with detailed notice of violations of the Judgment at least 30 business days in advance.

TIME PERIOD

17. This enforcement action concerns violations of law that occurred after May 6, 2007—the date the Judgment was entered. References in the Complaint to conduct that occurred before this date are mentioned to establish Purdue's knowledge, a pattern of behavior, or other facts that are relevant to conduct occurring after May 6, 2007. Similarly, the State's claim for violations of the 2007 Judgment concerns conduct between June 15, 2007 and May 6, 2017, the period in which the Judgment mandated that Purdue follow an ADD program.

II. SPECIFIC FACTUAL ALLEGATIONS

Purdue's Opioid Products

18. Purdue has marketed several different extended release opioid products in Tennessee that it owns and manufactures. These products include OxyContin, Butrans, and Hysingla ER, among others. As the name suggests, extended release opioids differ from immediate release opioids in that they have a concentrated active ingredient that is supposed to be released over a longer period of time.

19. OxyContin, Purdue's highest selling and most profitable drug, is the brand name for oxycodone hydrochloride, a potent extended release opioid delivered in tablet form in 10, 15, 20, 30, 40, 60, 80, and, at one time, 160 mg doses. Butrans is the brand name for Purdue's buprenorphine skin patch available in five different strengths: 5, 7.5, 10, 15, and 20 mcg/hour doses. Hysingla ER is the brand name for Purdue's hydrocodone bitartrate, an extended release opioid delivered in 20, 30, 40, 60, 80, 100, and 120 mg film-coated tablets. Ryzolt, which Purdue no longer sells, was the brand name for tramadol hydrochloride, an opioid that had both immediate and extended release characteristics and was available in 100 mg dosing increments.

Purdue's Reliance on Continued Users and High-Dose Opioids

20. Purdue's sales model relied substantially on both continued users and high-dose opioids. For OxyContin, over 80% of Purdue's business consistently came from continued users.[5] Out of the 104,340,382 total OxyContin tablets prescribed in Tennessee from 2008 to 2017, *53.7%* of them were 40 mg or higher.[6] If 40 mg OxyContin is taken twice a day as directed, that amount

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[5] PVT0026754; PWG000324280; PWG00004088; PWG000435505.
[6] PWG003984543.

equals 120 morphine milligram equivalents (MMEs) per day, which exceeds the 90 MMEs daily amount of opioids the CDC warns against *by over 33%.*[7]

Purdue's Sales Model

21. Purdue created a sales structure that led to and fostered the proliferation of unlawful marketing claims, which was compounded by trainings in which Purdue instructed sales representatives to make select prohibited claims, lax compliance enforcement, a heavy emphasis on sales performance for compensation, and otherwise inadequate instruction.

22. Purdue employed a large sales force to market its opioid products to health care providers, pharmacies, and health care institutions in Tennessee. Purdue directed the marketing efforts of its sales representatives through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and feedback on sales representatives' "call notes" from sales visits.

23. Purdue spent significant sums to call on providers to promote its opioid products because, unsurprisingly, it had evidence that increased sales calls were "highly correlated" with more prescriptions for its products[8]—particularly among the top prescribers of those products.[9]

24. Purdue summarized the marketing for its opioid products with the tagline "We sell hope in a bottle,"[10] shown below, in one of the company's hiring guides for incoming marketing employees.

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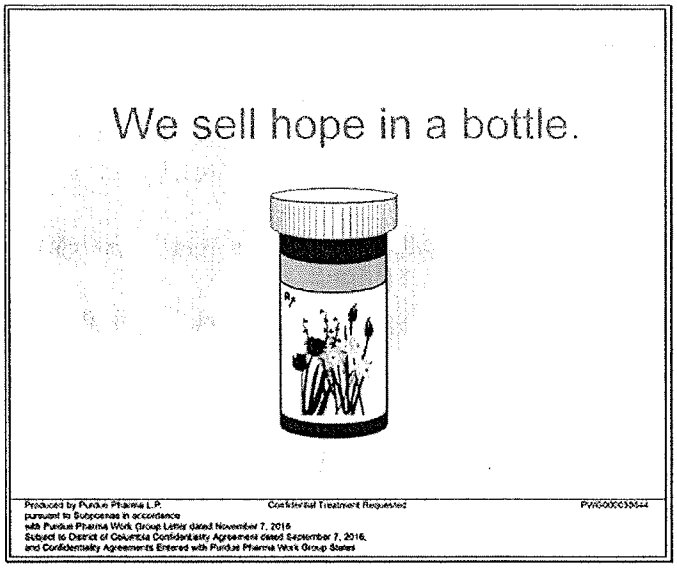
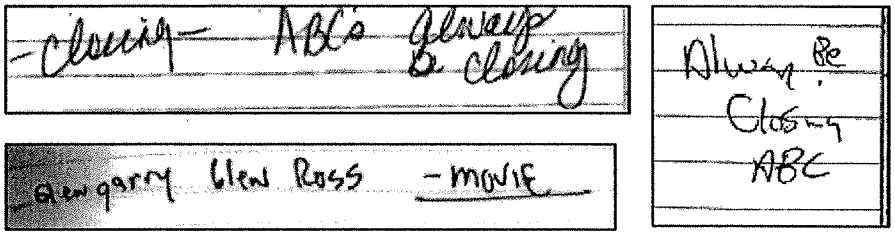
[7] https://tenncare.magellanhealth.com/static/docs/Program_Information/TennCare_MME_Conversion_Chart.pdf; https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.
[8] *See, e.g.*, PWG000324250; PWG000447858.
[9] PWG000447879.
[10] PWG000030644.



25. Purdue trained its sales representatives to be aggressive in sales calls with providers. Purdue's Tennessee sales representatives were expressly trained to "ABC," "Always be closing," a well-known phrase from *Glengarry Glen Ross*, a play and movie about highly-aggressive salesmen who use deceptive tactics to sell undesirable real estate at inflated prices. Both the phrase "Always be closing" or the movie/play's name itself appear in at least three places in training notebooks: from two different Purdue Tennessee sales representatives in 2009 and 2012[11] and from a Tennessee district manager in 2009.[12]



26. Similarly, a Purdue district manager in Tennessee in a sales training book made a note to "follow the money,"[13] as shown below.

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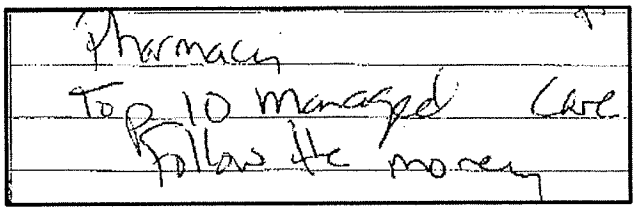
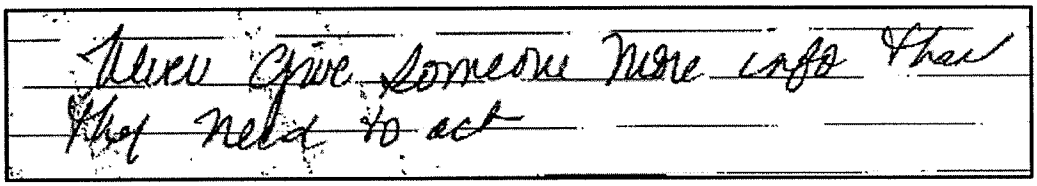
[11] ST000491 (2009 Notebook); PTN000100919 (2012 Notebook).
[12] PWG004285522.
[13] PWG004285554.



27. Among other things, Purdue expressly trained its Tennessee sales representatives to "expand the physician's definition of 'appropriate patient,'" "[d]evelop a specific plan for systematically moving physicians to move to the next level of prescribing behavior,"[14] and "never give someone more info than they need to act."[15]



28. Purdue also trained its Tennessee sales representatives to focus on providers who had more patients, were less likely to have pain management expertise, and were less likely to have time to appropriately monitor patients on opioids. Purdue trained its sales representatives about how to overcome a provider's objections, such as a provider expressing concern about the abuse of opioids or a provider stating he or she does not treat chronic pain[16]—pushing these providers to write more Purdue prescriptions.

29. Many of Purdue's Tennessee sales representatives devoted half of their sales calls in a given scheduling period to visit primary care physicians, family doctors, nurse practitioners, or physician assistants.[17] Purdue knew or should have known that these prescribers frequently had limited resources or time to scrutinize the company's claims or conduct the necessary research

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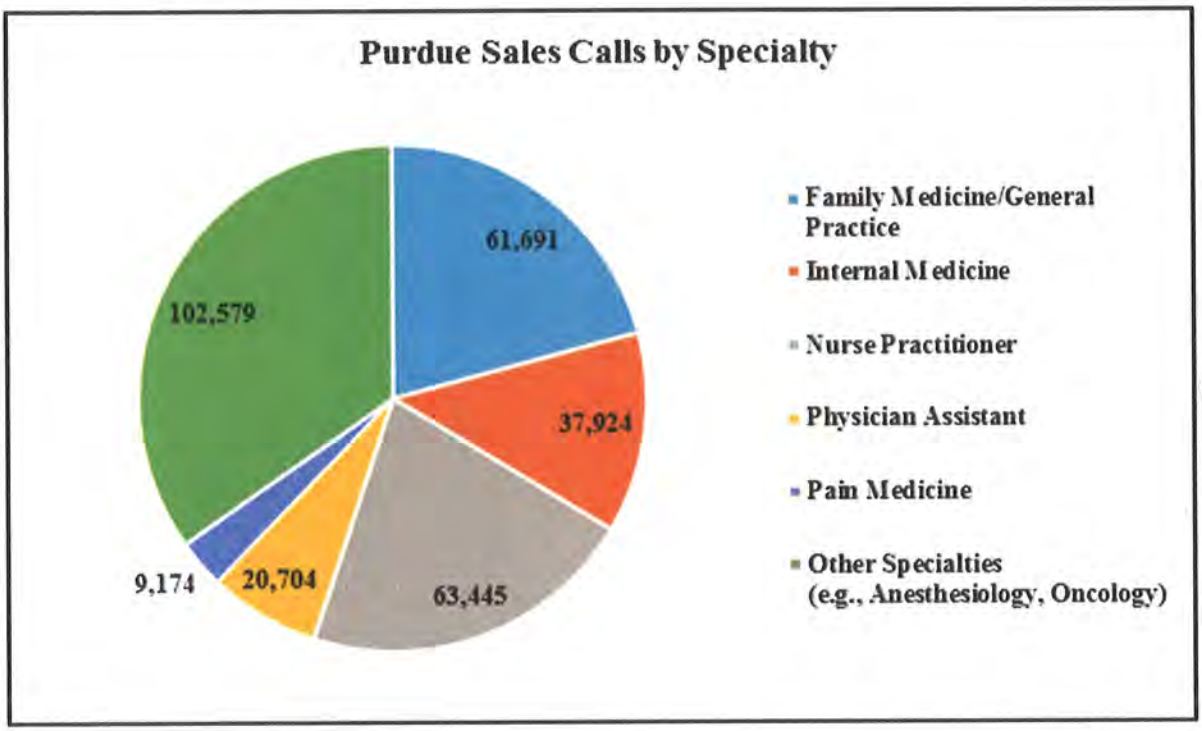
[14] PWG000346233.
[15] ST000618 (2010 Notebook).
[16] PWG000303245-51.
[17] ST000633 (2011 Notebook); PWG000071980.

about the efficacy and risks of high doses of extended release opioids themselves. Yet Purdue targeted them anyway. The below chart illustrates that Purdue's sales representatives focused at least 183,764 of at least 295,517 sales visits or 62% of sales visits to Tennessee providers to primary care physicians, internists, family doctors, nurse practitioners, and physician assistants over the last 10 years:[18]



30. Purdue targeted nurse practitioners and physician assistants specifically to increase prescribing of its opioid products. In a 2015-2016 OxyContin Brand Strategy training session, Purdue instructed that "NP/PAs [are] critical to our success; contributing to both volume and growth."[19] Likewise, in a sales and marketing PowerPoint focusing on strategies for 2012, Purdue included as a "Strategic Imperative" that the company should "*[i]ncrease/maintain volume with high value [oxycodone extended release] prescribers – These high value OxyContin prescribers*

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[18] PTN000119294.
[19] PWG000435504.

will include NPs and PAs"[20] and "[i]dentify & engage next tier of 'rising stars' to expand roster."[21] As part of its 2013 Annual Marketing Plan for OxyContin, Purdue analyzed marketing data and concluded that "[t]he only specialties still growing are NPs and PAs, which make up the fastest-growing group in both the [extended release opioid] market and the industry in general."[22] Likewise, Purdue instructed a "market insight" that "NPs and PAs desperately seek information, typically from sales representatives" in the same 2013 plan.[23]

31. Purdue's marketing strategies to target generalists as well as nurse practitioners and physician assistants worked. Between January 2007 and August 2017, these providers prescribed 65% of all OxyContin tablets in Tennessee.[24]

32. Purdue was aware at least by 2014 that prescribers often relied upon the company as "someone [sic] they can look to for the information they need to make prescribing decisions."[25] Similarly, Purdue taught its sales representatives in 2009 to assume that the "Dr does not know how to rx [prescribe] med[ication]."[26]

33. Purdue compensated its sales representatives through a salary and bonus structure that incentivized its sales representatives to make frequent sales calls to the highest volume prescribers of its opioid products, which it termed "super core" and "core" prescribers.[27] These prescribers were also more likely to be the most problematic concerning the abuse and diversion of its opioid products.[28]

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[20] PWG000062476 (emphasis added); PWG000437024. *See also* PWG000062580.
[21] PWG000062490.
[22] PWG003874196; *see also* PWG000447819; PWG000062580.
[23] PWG000062560.
[24] PWG003984543.
[25] PWG003810482.
[26] ST000556 (2009 Notebook).
[27] PWG003874461; ST000561 (2009 Notebook).
[28] PWG003874461.

34. Many of Purdue sales representatives' bonuses were based entirely on the number of prescriptions generated. Further, Purdue expressly told its sales representatives to focus on physicians who would give the best return on investment[29] and high potential prescribers.[30] Purdue subjected its sales representatives whose numbers lagged to disciplinary actions which included further sales training and strict managerial oversight, while disciplinary actions for noncompliant sales calls were rarer.

35. Predictably, this sales structure resulted in the dissemination of unlawful claims by Purdue as set forth below.

36. Purdue's sales representatives misrepresented the safety, efficacy, and benefits of its opioid products and those of its competitors to providers in Tennessee, did not provide adequate warnings to these providers, and marketed the company's opioid products to providers who were not experienced in prescribing them.

37. Unfortunately, Purdue's material misrepresentations and omissions were then passed on from these deceived prescribers to patients. For instance, patients in substance abuse treatment whose addiction began with prescriptions for opioids to treat chronic pain often have reported that they were not warned of the risk they might become addicted. A 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.[31]

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[29] ST000461 (2009 Notebook).
[30] PWG000063003; *See also* PTN000116388 (describing 80/20 rule that 20% of clinicians will write 80% of the business).
[31] HAZELDEN BETTY FORD FOUNDATION, *Missed Questions, Missed Opportunities*, (Jan. 27, 2016), available at http://www.hazeldenbettyford.org/about-us/news-and-media/press-release/doctors-missing-questions-that-could-prevent-opioid-addiction.

Purdue's Branded and Unbranded Marketing

38. Purdue created, used, and widely-disseminated a significant number of written marketing materials for its opioid products in Tennessee.

39. Purdue required its sales representatives to use sales aids, which were reviewed, approved, and supplied by the company, during sales calls with prescribers. These sales aids included both branded materials—those that referred to one of Purdue's opioid products by name—and unbranded materials—those that referred to opioids generally or a class of opioids, such as extended release opioids for which Purdue was the branded market leader.

40. Purdue's unbranded advertising was also designed to influence the prescription writing habits of providers, to increase sales of its branded opioid products, to restore "Purdue's diminished reputation as the leader in pain management,"[32] and, in some cases, to make claims about the safety or risks of opioids in general that would generate less scrutiny from the FDA than if made about a specific branded product.

41. Unbranded sales aids were integral to Purdue's overall marketing strategy. Purdue created its own specific marketing plans for its unbranded campaigns, like *Partners Against Pain*,[33] kept track of advertising metrics for these campaigns,[34] evaluated its unbranded campaigns versus those of its competitors,[35] and had its marketing team play a key role in creating unbranded content, including *Partners Against Pain*,[36] which ran in various forms from 1993 to 2016.[37]

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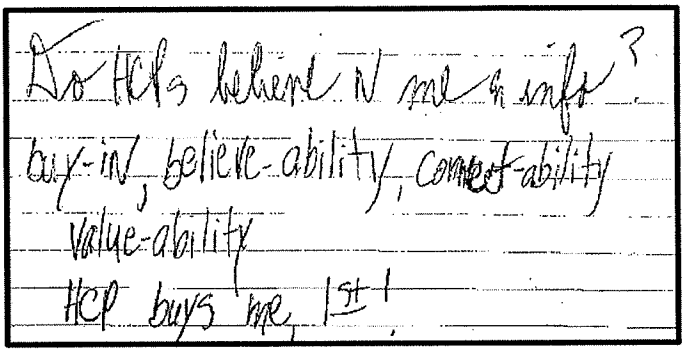
[32] PWG000209984.
[33] PWG000209977.
[34] PWG000209980.
[35] PWG000209986.
[36] PWG000209965.
[37] PWG000098224.

42. As one Purdue Tennessee sales representative noted about health care providers (HCPs), "Do HCPs believe in me on info? buy-in, believe-ability, connect-ability[,] value-ability[,] HCP buys me 1st!"[38]



43. Unbranded marketing pieces, including *Providing Relief, Preventing Abuse*,[39] *Partners Against Pain*,[40] and *In the Face of Pain*[41] were handed out or promoted by Purdue's Tennessee sales representatives as part of sales calls for specific branded products. Purdue's unbranded materials also acted as a point-of-entry for sales representatives to make contact with a provider for a sales call for a branded product.

44. Unbranded materials such as Purdue's *Partners Against Pain* and *Providing Relief, Preventing Abuse* were supposed to be left behind or referenced in sales calls—sometimes with the sales representative's business card.[42] Some unbranded materials were also designed to reach the general public. For example, Purdue's *Partners Against Pain* campaign featured celebrities such as Naomi Judd and Jennifer Grey to generate more attention for Purdue's opioid messaging.[43]

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[38] PWG004285326.
[39] PTN000119294 ID34621 (2/27/2009).
[40] PTN000082213.
[41] PTN000082213.
[42] PTN000031964.
[43] PVT0054030.

45. Purdue referred to unbranded materials as a "key tactic" to "driv[e] brand differentiation while re-energizing [the extended release opioid] market,"[44] "unbranded HCP promotion to dispel the misperception of [extended release opioids],"[45] and part of Purdue's Sales and Marketing Department's focus to "bring Value to customers."[46]

46. Purdue even expressly characterized its "Patient education material," "Patient Savings Coupon Program," and "Non-branded material ([Continuing Medical Education], abuse & diversion, etc)" as part of its overall sales and marketing plan dating back to October 2007, mere months after Purdue entered into the May 2007 Judgment regarding deceptive marketing for OxyContin..[47] The company described unbranded advocacy pieces it created such as *Partners Against Pain* and *In the Face of Pain* as part of Purdue's primary marketing strategy whose "overarching objective" was to get health care providers to "view Purdue as the leading pain management resource/company"[48] and to allow "[p]ain patients and healthcare professionals [to] have a resource to obtain information regarding proper pain management."[49] Purdue referred to unbranded campaigns, such as *Partners Against Pain*, in marketing trainings for sales representatives regarding specific branded products like OxyContin.[50]

47. Purdue also created and offered materials for providers that were disguised as "educational," but were in reality vehicles for more subtle marketing to providers.[51] Purdue expressly referenced some of these offerings in sales calls for specific branded products[52] and even

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[44] PWG000062804.
[45] PWG000062007.
[46] PWG000063003.
[47] PWG000063003.
[48] PVT0044940.
[49] PVT0044940.
[50] PVT0044939.
[51] PTN000005311.
[52] PTN000119294 ID27756 (8/14/2008).

instructed compensated physician speakers about specific marketing terms that would benefit the company. In one example, Purdue trained its speaker as follows:

> Interaction: *In order to create a sense of urgency for appropriately assessing and managing low back pain* [(which happened to be one of the types of chronic pain Purdue heavily targeted and for which its opioid products were most often prescribed)], the speaker may use this discussion opportunity to further describe the impact of unrelieved pain or have participants provide their perspective on the impact of unrelieved pain on the patient, healthcare provider and healthcare system.[53]

48. Another example of Purdue using educational pieces to advance its marketing message was the *Complexities of Caring for People in Pain* brochure, which overstated the dangers of non-steroidal anti-inflammatory drugs (NSAIDs) that contain acetaminophen and minimized the dangers of single-entity opioids, like OxyContin.

49. Thus, Purdue's unbranded pieces were designed to increase both a health care provider's receptiveness to its sales messages for its branded products and to advocate for pain management policies that were most beneficial for sales of Purdue's opioid products.

50. Purdue also funded third party pain advocacy groups like the American Pain Society (APS), the American Pain Foundation (APF), and the American Academy of Pain Medicine (AAPM) as well as specific advocacy pieces these groups published that were consistent with Purdue's marketing objectives.

Sales Calls

51. One of the primary ways that Purdue marketed its opioid products in Tennessee was through in-person sales calls with health care providers, pharmacies, managed care companies, and others. Purdue required its sales representatives to document each interaction through call

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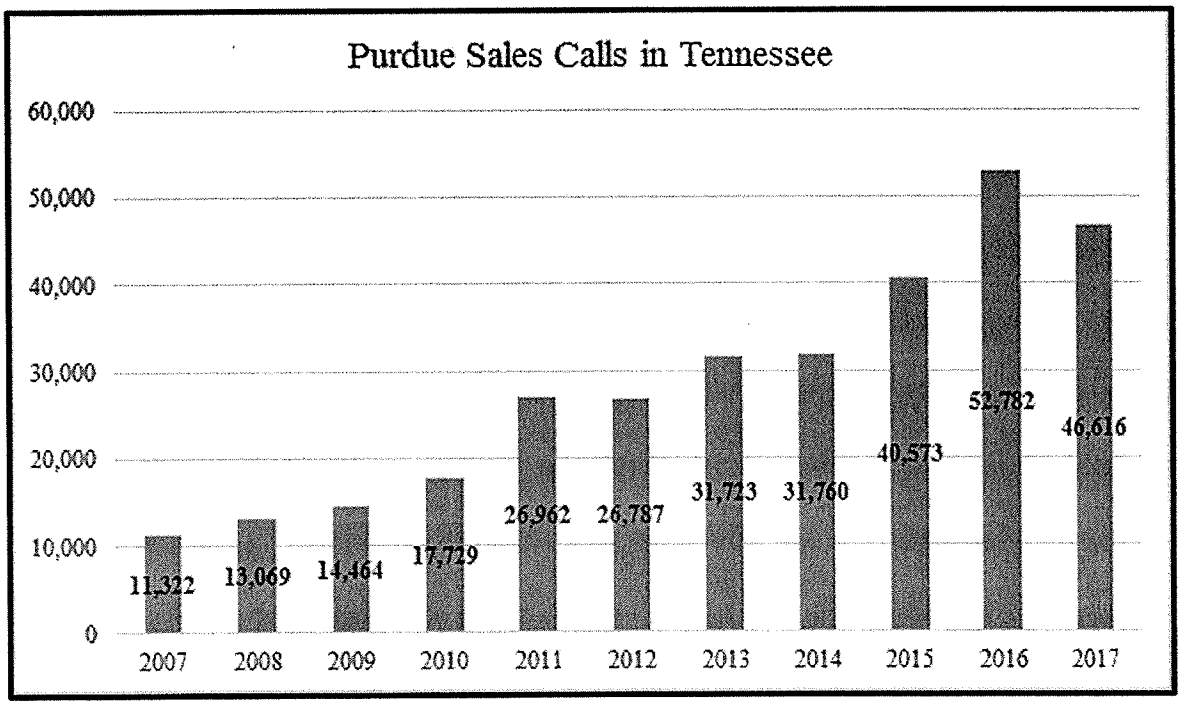
[53] PTN00005998 (emphasis added).

notes—the contents and accuracy of which Purdue relied on and used as a key part of its business. Purdue's Tennessee sales representatives engaged in approximately 300,000 sales calls to Tennessee health care providers between May 7, 2007 and December 2017[54]—meaning that Purdue's sales representatives averaged *well over 100 sales calls to Tennessee providers per day* to promote its opioid products. Notably, Purdue increased its primary marketing tool in recent years in Tennessee even after receiving civil investigative demands and subpoenas from Tennessee and other Attorneys General, being sued in litigation across the country, and as the devastating effects of the opioid epidemic became better known. Purdue increased the volume of sales calls dramatically in Tennessee over the last 10 years—particularly after the reformulation of OxyContin. The number of sales calls by Purdue sales representatives in Tennessee steadily increased from 11,322 in 2007 to a high of 52,782 in 2016 as shown in the chart below:[55]



[54] PTN000119294.
[55] PTN000119294.

52. Purdue trained its Tennessee sales representatives about how to compose a call note properly, which it told sales representatives was important because the call note was "[t]he only record we have of your interaction with Healthcare Professionals (HCPs)[.]"[56]

53. Purdue trained its sales representatives to "[p]repare a concise call note that captures the key points of the dialogue between the Representative and Customer,"[57] "ensure that call reporting clearly reflects the sales presentation,"[58] "[r]e-read every word of your call report to make sure that it is clear and accurate,"[59] "[a]lways review a call note before saving the record to ensure that it accurately reflects the important events that took place during the call,"[60] and complete the call note shortly after the sales call to ensure accuracy.[61]

54. Purdue also required its sales representative managers, known as district managers, for a time to "review the call notes for every call recorded during the previous week."[62] In addition, Purdue required its district managers to certify that they had carefully reviewed call notes from sales representatives,[63] and use a software program to track the number and percentage of sales representative call notes that were reviewed.[64]

55. Purdue *reprimanded only eight Tennessee sales representatives* despite many other sales representatives in Tennessee entering numerous call notes referencing noncompliant and misleading conduct. Sales Representative 1 was reprimanded on June 17, 2011;[65] Sales

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[56] PWG000035029.
[57] PWG000035025.
[58] PWG000035028.
[59] PWG000035035.
[60] PWG000035041.
[61] PTN000001729.
[62] PTN000010631 (emphasis omitted).
[63] PTN000063827.
[64] PTN000035907.
[65] PTN000045516.

Representative 5 on October 27, 2011;[66] Sales Representative 6 on November 4, 2013;[67] Sales Representative 12 on December 22, 2008;[68] Sales Representative 17 on September 26, 2011;[69] Sales Representative 4 on September 30, 2010;[70] Sales Representative 18 on September 2, 2011;[71] and Sales Representative 16 on December 7, 2012.[72]

56. The call notes referenced in this Complaint are word-for-word excerpts. Some call notes are referenced in multiple locations in the Complaint if multiple actionable claims were made in one sales call. Because of the sheer volume of call notes Purdue produced from its Tennessee sales representatives, only an illustrative sample of call notes are included in this Complaint.

A. DECEPTIVE SAFETY CLAIMS AND MATERIAL OMISSIONS

57. In its marketing in Tennessee, Purdue misrepresented the safety and potential adverse health risks of its opioid products—especially the increased risk of addiction, which it sought to minimize or failed to disclose entirely. Purdue did this in numerous ways, namely by: (1) representing without qualification that OxyContin did not have a dose ceiling; (2) advancing the concept of pseudoaddiction; (3) overstating the efficacy of addiction mitigation tools; (4) representing that its opioid products produced fewer peaks and valleys than short acting opioids leading to less euphoria or more effective pain relief; (5) misrepresenting the abuse-deterrence properties of OxyContin and Hysingla ER; (6) understating the risk of addiction; (7) failing to disclose the increased risk of addiction at higher doses of its opioid products; (8) failing to disclose

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[66] PTN000045520–21.
[67] PTN000045527–28.
[68] PTN000045529.
[69] PTN000045534.
[70] PTN000045538.
[71] PTN000045543–44.
[72] PTN000045556–57.

the lack of evidence concerning the effectiveness of long-term use of opioids; and (9) making sweeping, unqualified safety claims about its opioid products.

Safety Claims: Unqualified No Dose Ceiling Claims

58. Purdue represented without qualification that OxyContin did not have a dose ceiling when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

59. OxyContin has a dose ceiling that is imposed by adverse reactions to patients taking increased doses of the drug, including overdose, respiratory depression, somnolence, addiction, and other serious adverse effects.

60. While the FDA approved a limited statement on OxyContin's Full Prescribing Information making clear that OxyContin's dose ceiling *was* imposed by adverse reactions, Purdue's Tennessee sales representatives routinely asserted that OxyContin had no dose ceiling *at all*. Further, Purdue failed to discipline or correct sales representatives who made such claims.

61. While not an exhaustive list, illustrative examples of these claims are set forth below.

62. Sales Representative 3 documented his sales call with a Morristown-based family doctor on August 15, 2007, as follows:

> has pt pancreatic ca - med d – can't remb whgich plan - not sure if going to cover - woman is in lot of pain and 20 q 12 not touching her - went to 40 mg q 12 just today - gave PI - rev assymetric dosing - asked me what top dose is ? - *rev in PI that no max dose as is pure opiod*[.][73]

63. On March 31, 2008, Sales Representative 2 called on a Knoxville-area nurse practitioner and recorded his interaction as follows:

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[73] PTN000119294 ID15510 (8/15/2007) (emphasis added).

> Reviewed line of new strength she said that she had written for a 60 and was comfortable prescribing OxyContin *discussed no ceiling with single enity opioids*[.][74]

64. Sales Representative 2 documented his sales call with a Knoxville-based neurologist on November 5, 2008, as follows:

> He said that he does not start pt on morphine that he did not believe pt responded as well to morphine as compared to Duragesic or OxyContin. He asked about maximum dosing said he had a pt at 160mg a day of Oxycontin. *Discussed benefit of SEO's is there is no dosing limit said he would be uncomfortable going over 240 mg a day.*[75]

65. Likewise, Sales Representative 3 made a sales call to a Lenoir City-area family physician on March 3, 2009, and wrote the following about his interaction:

> establishing a pain mgmt office in the area - nurse anes for procedures, he to medical manage - no deisre for huge pain practice just trying to fill what need in community - doesnt see many willing to prescribe - asked me what max dose - *discussed no ceiling limit* –[.][76]

66. Likewise, Sales Representative 1 made a sales call to a McKenzie-area family physician on January 21, 2010, and wrote the following about her interaction:

> dr said he likes oxycontin tablet options because it usually takes 2-3 months to get patient adjusted to therapeutic dose. dr said most patients are on lower strengths but has a few on 80mg. said he would never write over 80mg for a patient. *discussed that oxycontin is [single entity opioid] and that there is no max dose if he ever needed higher strength for a patient.* discussed that oxycontin is not for everyone and importance of writing for appropriate patients[.][77]

67. Sales Representative 1 documented his sales call with a Lexington-based family physician on February 3, 2010, as follows:

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[74] PTN000119294 ID23107 (3/31/2008) (emphasis added).
[75] PTN000119294 ID31257 (11/5/2008) (emphasis added).
[76] PTN000119294 ID34696 (3/3/2009) (emphasis added).
[77] PTN000119294 ID47892 (1/21/2010) (emphasis added).

> dr said insurance plans won't approve oxycontin over the max dose. *i asked what he meant by max dose and he said 80mg q12h.explained that there is no max dose with oxycontin since it is [single entity opioid].* he said he recognizes that but insurance plans still won't approve. he said they also won't approve q8h.asked if he has many patients dosed q8h. he said no that he only prescribes q12h but he has seen the other[.][78]

68. Likewise, Sales Representative 1 made a sales call to a Bolivar-area nurse practitioner on February 16, 2010, and wrote the following about his interaction:

> discussed tablet options. he said he has more people at the higher doses because patients don't usually stay at the low end because everyone builds up tolerance eventually. said if patient is using breakthru meds more than 20 days per month then he will increase the dose. *talked about no max dose because [single entity opioid]. asked him if patients build up tolerance to SA opioids too.* he said yes. discussed indication which includes mod to severe chronic pain and asked him to write oxycontin for those patients who he trusts and meets indication.[79]

69. Sales Representative 1 documented her sales call with a Paris-based family physician on April 26, 2010, as follows:

> dr said he refills hydrocodone many times per day. asked him if any of those patients are persistent pain patients who can benefit from q12h dosing. he said yes. dr said he does not have a cut off time or dose where he converts. dr said he is torn between getting a patient off SA to LA early but then has concerns about what to do with that patient when they have been on oxycontin for years-then where does he go. *discussed that there is no max dose for oxycontin* and that there is no apap. dr askekd how many copays is it for patient taking 160mg if the patient has to take 2 80mg. told him i thought one but would check with pharmacist and confirm with him. we also discussed difference between physical dependence and addiction.[80]

70. Likewise, on May 13, 2013, Sales Representative 6 called on a Knoxville-area family doctor and recorded his interaction as follows:

> Discussed OxyContin and he asked if there was a maximum dose for OxyContin. I told him there has been no maximum dose established in our

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[78] PTN000119294 ID48505 (2/3/2010) (emphasis added).
[79] PTN000119294 ID49024 (2/16/2010) (emphasis added).
[80] PTN000119294 ID52449 (4/26/2010) (emphasis added).

> clinical trials. He says he has one patient taking five of the 80 mg tablets a day. Acknowledgedthat's an exception and is a high-dose compared to the other patients he has on OxyContin. We discused the dosing conversion chart from Percocet and I asked him to consider in any patient who's not comfortable with Q6 dosing or having to get up in the middle the night to take their medication.[81]

71. On July 2, 2015, Sales Representative 1 called on a Jackson-based nurse practitioner and stated the following:

> [Provider] said a lot of her new pts are on high doses of meds. One pt is on 60mg morphine q12 and also takes 40mg percocet for breakthru. She said she told pt after her pain blocks she would be eliminating the breakthru meds. I asked why not consolidate her to an oxycontin q12 dose. Explained tablet options and that 80mg is highest tablet dose *but there is no max dose of oxycontin for tolerant pts*. Reminded her she can titrate down as pain improves with procedures. [Provider] asked if oxycontin can be dosed tid. I told her q12 is the only FDa approved dose and that if pt needs more than 2 breakthru doses then the oxycontin dose should be increased. [Provider] said she goes with the lower of the 2 total daily doses: 40mg q12 over 30mg tid.[82]

72. Substantially similar claims were made by Sales Representative 7 to a Johnson-City-based anesthesiologist on November 20, 2009;[83] Sales Representative 2 to a Knoxville-area pharmacy on April 30, 2010;[84] Sales Representative 1 to a Jackson-area hematologist on June 28, 2010,[85] a Jackson-area oncologist on September 29, 2010,[86] and a Dyersburg-based nurse practitioner on October 26, 2010;[87] Sales Representative 3 to a Lenoir City-area internist on

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[81] PTN000119294 ID130004 (5/13/2013) (emphasis added).
[82] PTN000119294 ID201790 (7/2/2015) (emphasis added).
[83] PTN000119294 ID45510 (11/20/2009) (emphasis added).
[84] PTN000119294 ID52728 (4/30/2010).
[85] PTN000119294 ID55446 (6/28/2010).
[86] PTN000119294 ID60562 (9/29/2010).
[87] PTN000119294 ID61732 (10/26/2010).

October 25, 2011;[88] Sales Representative 6 to a Knoxville-area family doctor on September 27, 2013.[89]

73. Elsewhere, Purdue's Tennessee sales representatives routinely questioned health care providers who had set low dose ceilings for OxyContin.[90] For example, in response to a Tennessee health care provider who stated that he did not go past the 20 mg OxyContin dose and did not prescribe OxyContin unless he had to, Sales Representative 4 planned to "discuss further his reasoning for placing a ceiling on his oxycontin doses."[91]

74. Likewise, in response to a nurse practitioner who was hesitant to prescribe OxyContin beyond 20 mg a day, Sales Representative 4 planned to "[g]et into why she has ceiling limits on the dosing for oxycontin."[92]

Safety Claims: Pseudoaddiction

75. Purdue downplayed the problem of addiction by simply re-labeling it as "pseudoaddiction." Purdue promoted this concept as part of its marketing for its opioid products in Tennessee when it was false, deceptive, and/or unsubstantiated at the time the claims were made.

76. The term pseudoaddiction was coined by Dr. David Haddox, who later became Purdue's vice president of health policy, and was popularized for opioid treatment by Purdue. It referred to patients who exhibited drug-seeking behavior due to undertreated or uncontrolled pain, as opposed to addiction. Purdue consistently used this concept in sales calls and written educational materials to teach providers in Tennessee to actually prescribe more or higher doses of opioids for

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[88] PTN000119294 ID87656 (10/25/2011).
[89] PTN000119294 ID142806 (9/27/2013).
[90] *See, e.g.*, PTN000031807 ID25899 (4/15/2009); PTN000031807 ID27888 (4/21/2009); PTN000031807 ID29235 (2/10/2009) ("Once again asked doc why he has established a ceiling dose for oxycontin[.]").
[91] PTN000031807 ID22897 (4/15/2009).
[92] PTN000031807 ID27888 (4/21/2009).

purportedly "pseudoaddicted" patients, who would then allegedly cease drug-seeking behavior once their pain was controlled.

77. Some of Purdue's Key Opinion Leaders (KOLs), doctors hired by Purdue to help spread Purdue's marketing messages to other providers, concede that pseudoaddiction is not a valid concept. Purdue KOL Dr. Lynn Webster later acknowledged: "[Pseudoaddiction] obviously became too much of an excuse to give patients more medication. It led us down a path that caused harm. It is already something we are debunking as a concept."[93] Likewise, Dr. Russell Portenoy, a pain specialist with close ties to Purdue, later admitted that the concept of pseudoaddiction in chronic pain was not supported by the evidence. He stated, "The term has taken on a bit of life of its own. That's a mistake."[94]

78. Purdue sent annual "Dear Healthcare Provider" letters to Tennessee health care providers who prescribed opioids and enclosed copies of the *Providing Relief, Preventing Abuse* brochure Purdue drafted, which had four versions.[95]

79. The first edition of Purdue's *Providing Relief, Preventing Abuse*, which was first disseminated in 2007 following entry of the 2007 Judgment, states:

> **Pseudoaddiction**: describes the misinterpretation by members of the health care team of relief-seeking behaviors in a person whose pain is inadequately treated as though they were drug-seeking behaviors as would be common in the setting of abuse. The lack of appropriate response to the behaviors can result in an escalation of them by the patient, in an attempt to get adequate analgesia. Patients with unrelieved pain may:
>
> Become focused on obtaining medications
>
> "Clock watch"

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[93] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, MILWAUKEE WISC. J. SENTINEL (Feb. 19, 2012).
[94] *Id.*
[95] PTN00003564; PTN000003535; and PTN00003625.

Display behaviors (eg, doctor shopping, deception) to obtain relief

Pseudoaddiction can be distinguished from addiction in that the behaviors resolve when pain is effectively treated.[96]

80. Purdue asserts in the second edition of *Providing Relief, Preventing Abuse*:

> Some patients may exhibit behaviors aimed at obtaining pain medication because their pain treatment is inadequate. The term *pseudoaddiction* has emerged in the literature to describe the inaccurate interpretation of these behaviors in patients who have pain that has not been effectively treated. Pseudoaddiction can be distinguished from addiction by the fact that, when adequate analgesia is achieved, the patient who is seeking pain relief demonstrates improved function, uses the medications as prescribed, and does not use drugs in a manner that persistently causes sedation or euphoria. Such behaviors may occur occasionally even with successful opioid therapy for pain; a pattern of persistent occurrences should prompt concern and further assessment.[97]

81. The third edition of Purdue's *Providing Relief, Preventing Abuse*, while no longer using the term pseudoaddiction by name, states:

> [s]ome patients may exhibit behaviors aimed at obtaining pain medication because their pain treatment is inadequate. Such behaviors may occur occasionally even with successful opioid therapy for pain; a pattern of persistent occurrences should prompt concern and further assessment.[98]

82. Purdue widely disseminated *Providing Relief, Preventing Abuse* in Tennessee. Purdue sent the brochure in a letter form to the following number of health care providers in Tennessee in each of the years indicated: 1,984 in 2007, 1,424 in 2008, 1,130 in 2009, 952 in 2010, 808 in 2011, 799 in 2012, 1,055 in 2013, 956 in 2014, 715 in 2015, and 458 in 2016.[99] Purdue distributed at least 10,281 copies of *Providing Relief, Preventing Abuse* by mail to providers in Tennessee.

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[96] PTN000003807 (emphasis in original).
[97] PTN00003542 (emphasis in original).
[98] PTN000003632.
[99] PTN000045907; *see also* PWG004285193_A.

83. Purdue's sales representatives also distributed and referred to the document in sales calls for its branded products.[100] Purdue provided over 7,000 copies of *Providing Relief, Preventing Abuse* to Tennessee sales representatives and district managers to distribute in person.[101]

84. In fact, the definitions Purdue included in *Providing Relief, Preventing Abuse* were so ingrained in Purdue marketing that Sales Representative 5, who had been retired for over a year when interviewed, immediately authenticated the *Providing Relief, Preventing Abuse* brochure, stated that he regularly used the definitions in the brochure in sales calls, and flipped *without prompting* to page 13 of the brochure to identify the definitions of pseudoaddiction and addiction during his investigative sworn testimony. Sales Representative 5 testified that the brochure had been extremely helpful in educating Tennessee providers, many of whom were inexperienced in pain management.

85. Purdue advanced the notion of pseudoaddiction in numerous other ways. In 2013, Purdue, through its partnersagainstpain.com website, linked to materials including a consensus document created by the American Academy of Pain Medicine (AAPM), the American Pain Society (APS), and the American Society of Addiction Medicine (ASAM), that defined pseudoaddiction as:

> [a] term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may "clock watch," and may otherwise seem inappropriately "drug seeking." Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when pain is effectively treated.[102]

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[100] *See, e.g.*, PTN00031807 ID12887 (5/17/2007); PTN00031807 ID15483 (11/5/2007); PTN000031807 ID22842 (10/21/2008); PTN000031807 ID13035 (10/16/2007).
[101] PWG004285193_A.
[102] PWG000085183.

86. Call notes from Purdue's Tennessee sales representatives likewise show that the concept of pseudoaddiction and the distribution of the *Providing Relief, Preventing Abuse* brochure were frequently used in sales calls with providers regarding Purdue's opioid products.

87. While not an exhaustive list, illustrative examples of these claims are set forth below.

88. Sales Representative 5 made a sales call to a Nashville-area internist on May 17, 2007, and wrote the following about his interaction:

> *discussed the differences between pseudoaddiction and addiction*--doc agreed that abuse of medication in susceptible patients can lead to addiction. will consider oxycontin for persistent pain patients.[103]

89. On October 16, 2007, Sales Representative 17 called on a Clarksville-area orthopedic surgeon and recorded his interaction as follows:

> Conversions and titration with OxyContin 20 mg tablet, OxyContin Savings Cards #30096, doctor said the new TN Rxing program works great, and tells patients upfront he will be monitoring their Rx's. His long term OxyContin patients come in monthly and they are no problems. *Talked about pseudo-addiction.*[104]

90. Likewise, Sales Representative 3 documented his sales call with a Crossville-based hematologist on November 5, 2007, as follows:

> is signed up for pmp program - talked with [providers] - *discussed pseudoaddiction and how pmp may reveal some that are simply undertreatetd* [.][105]

91. On October 21, 2008, Sales Representative 5 called on a Nashville-area family doctor and recorded his interaction as follows:

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[103] PTN000119294 ID12683 (5/17/2007) (emphasis added).
[104] PTN000119294 ID17410 (10/16/2007) (emphasis added).
[105] PTN000119294 ID18181 (11/5/2007) (emphasis added).

> doc said that going over pain management definitions helps to clarify what issues are,really, going on; ie, physical dependence, addiction , *pseudoaddiction*. appreciated information.[106]

92. Sales Representative 14 called on a Brighton-area family physician on December 9, 2008, and recorded his interaction as follows:

> Is it pain? in-service with Doc. *[Provider] listened to the presentation and commented that it is very difficult at times to distinguish between addicted and pseudoaddicted patients.* He asked if there is any magic strategy for identifying drug seekers. I explained that other physicians have found pain treatment agreements, regular assessment, and regular urine drug screening to be helpful in ensuring patient compliance. He agreed and added that the TN. prescription drug monitoring tool has been helpful as well. I asked doc about his current oxyconitn treated patients. He said that everyone he is currently treating is stable on the current dose. He added that he is making more of an effort to use the coupon cards. I reminded him about the 10mg q12H dose being a reasonable starting dose for appropriate opioid naiive patients. He said he will keep this dose in mind.[107]

Safety Claims: Overstating the Efficacy of Tools to Mitigate Addiction

93. In order to make health care providers more willing to prescribe its addictive opioid products, Purdue overstated the efficacy of abuse and diversion mitigation tools like patient contracts, urine drug testing, pill counts, and similar strategies. [108] These statements were false, deceptive, and/or unsubstantiated at the time they were made.

94. These claims were especially harmful because Purdue made them to nurse practitioners, physician assistants, general practitioners, internists, and family doctors who, generally speaking, lack the time and expertise to closely manage higher-risk patients on opioids.

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[106] PTN000119294 ID30606 (10/21/2008) (emphasis added).
[107] PTN000119294 ID32318 (12/9/2008) (emphasis added).
[108] ST000435.

95. Moreover, these misrepresentations by Purdue were critical to assure health care providers, who were beginning to see or hear about the rising tide of opioid addiction, that they could safely prescribe opioids in their own practices and that addiction was avoidable—the result of the failure of other providers to rigorously manage and weed out problem patients.

96. The 2016 Center for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain[109] (2016 CDC Guideline) confirms the lack of adequate substantiation to support Purdue's claims regarding the utility of screening tools and patient management strategies in managing addiction risk. The 2016 CDC Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies such as screening tools, patient agreements, urine drug testing, or pill counts—"for improving outcomes related to overdose, addiction, abuse, or misuse."[110] As a result, the 2016 CDC Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients at low or high risk for [opioid] abuse or misuse" and instructs that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[111]

97. As recently as 2016, Purdue created sales training content for its sales representatives, including a piece called "General Objection Handler," that was supposed to help representatives respond to common objections from health care providers, ease these providers' concerns about prescribing potent opioids, and make them more likely to prescribe Purdue's opioid products.[112]

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[109] McDowell, Deborah MD, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016,* CENTERS FOR DISEASE CONTROL AND PREVENTION, 65(1), available at https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm (hereinafter 2016 CDC Guideline).
[110] 2016 CDC Guideline, at 11.
[111] 2016 CDC Guideline, at 28.
[112] PWG000303245-51.

98. Purdue also created content that overstated the efficacy of opioid abuse and diversion tools that were used as part of sales calls for its opioids products and made publicly available. One example of this content was Purdue's unbranded *Partners Against Pain* campaign. Purdue highlighted the use of mitigation tools including pain diaries,[113] a pain management log, a daily pain diary, and an "opioid risk tool" in this campaign through a *Partners Against Pain* Pain Management Kit, a dedicated website at partnersagainstpain.com,[114] a magazine titled "Pain,"[115] and other materials.

99. The opioid risk tool was a five question, one-minute screening tool created by Purdue KOL Dr. Lynn Webster that relies on patient self-reports to purportedly allow health care providers to manage the risk that their patients will become addicted to or abuse opioids. Because of the very nature of addiction, self-reporting facts indicative of addiction are not effective.

100. In national trainings, Purdue instructed sales representatives to use a "selling message" for the *Partners Against Pain* Pain Management Kit, which Purdue then distributed to providers. Purdue's overarching purpose for the Pain Management Kit was "[t]o educate HCPs [health care providers] and gain clinical practice implementation of the tools contained in the Kit."[116] The Pain Management Kit was so central to Purdue's marketing that it was part of materials automatically shipped to sales representatives, at least as of 2009.[117] In sales calls for Purdue's opioid products, Purdue's Tennessee sales representatives handed out the Pain Management Kit and other materials containing mitigation tools and used it as an integral part of Purdue's sales messaging.

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[113] PTN000031963; PWG000320723.
[114] *See* PWG000014427.
[115] PTN000015454.
[116] PTN000031962.
[117] PTN000031942.

101. Purdue also claimed in multiple presentations given to providers that mitigation tools, including controlled substance agreements, pill counts, and urine drug testing, could be used effectively by providers to mitigate the risk of abuse and diversion.[118]

102. While not an exhaustive list, illustrative examples of call notes deceptively referencing mitigation tools are set forth below.

103. On May 15, 2007, Sales Representative 4 called on a McKenzie-area family physician and recorded his interaction as follows:

> *Reviewed pain toolkit with him and comparison to his current pain contract. Said ours had a lot of surefire wording to help protect him and he would implement these into his own contract.*[119]

104. Sales Representative 4 documented his sales call with a Germantown-based family physician on May 23, 2007, as follows:

> *Continued discussion of having a "sound" pain contract and reviewed conversion table with him.* Had questions about patients on methadone and why? Explained that oxycontin provides better compliance and with 3rd party payers it is accessible[.][120]

105. Likewise, Sales Representative 4 made a sales call to a McKenzie-area family doctor on May 31, 2007, and wrote the following about his interaction:

> *Reviewed the Purdue patient pain toolkit and reviewed some changes he could make in his contract.* Said he needs to to try having patients sticking with the same pharmacist to help eliminate patients going everywhere to refill and help him keep better reigns on his patients that are on oxycontin and other long acting oxycontin[.][121]

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[118] PTN000006737; PTN000006794.
[119] PTN000119294 ID12583 (5/15/2007) (emphasis added).
[120] PTN000119294 ID12856 (5/23/2007) (emphasis added).
[121] PTN000119297 ID13071 (5/31/2007) (emphasis added).

106. Following a June 7, 2007 sales call with a Nashville-based physician assistant, Sales Representative 5 made a note to "focus on urine drug screen information" the next time he called on this provider.[122]

107. Similarly, Sales Representative 3 made a sales call to a Lafollette-area internist on July 30, 2007, and wrote the following about his interaction:

> stated tries not to write oxycontin - hears that brand is worth more on the street - asked if profit margin of someone that would misuse really mattered - replied no - *discussed UDT , pill counts - ways that doc kit can asssit in addressing some issues - gave doc kit cd rom*[.][123]

108. On July 18, 2007, Sales Representative 4 called on a Memphis-area family physician and recorded his interaction as follows:

> *Pain documentation kit and using the pain contracts effectively.* Said that her and her husband document but they don't have an official pain contract that they use[.][124]

109. Likewise, Sales Representative 4 made a sales call to a Memphis-area internist on September 12, 2007, and wrote the following about his interaction:

> *Followed up with him on documenting pain. Reviewed the documentation kit and sample of contract.* Said he documents but never felt the need to have patients sign a contract. Said he has good control of his patients and never felt the need to do this. Said it shows initial mistrust. *Discussed preventing abuse and the insurance of having the contract on board*[.][125]

110. Sales Representative 4 documented his sales call with a Savannah-based internist on September 13, 2007, as follows:

> Said most of her patients on oxycontin come from the hospital ER. Said that physicians in the are really have to focus on documentation because abuse

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[122] PTN000031807 ID13334 (6/7/2007).
[123] PTN000119294 ID14934 (7/30/2007) (emphasis added).
[124] PTN000119294 ID14530 (7/18/2007) (emphasis added).
[125] PTN000119294 ID16378 (9/12/2007) (emphasis added).

> of narcotics in the area is huge. *Reviewed documentation material from Purdue and pain contract to put in place in her practice.*[126]

111. Likewise, Sales Representative 14 documented his interaction with a Brighton-area family doctor on December 9, 2008 as follows:

> Is it pain? in-service with Doc. [Doctor] listened to the presentation and commented that it is very difficult at times to distinguish between addicted and pseudoaddicted patients. He asked if there is any magic strategy for identifying drug seekers. *I explained that other physicians have found pain treatment agreements, regular assessment, and regular urine drug screening to be helpful in ensuring patient compliance.* He agreed and added that the TN. prescription drug monitoring tool has been helpful as well. I asked doc about his current oxyconitn treated patients. He said that everyone he is currently treating is stable on the current dose. He added that he is making more of an effort to use the coupon cards. I reminded him about the 10mg q12H dose being a reasonable starting dose for appropriate opioid naiive patients. He said he will keep this dose in mind.[127]

112. On March 22, 2013, Sales Representative 3 documented his encounter with a Knoxville-based internist as follows:

> [d]elivered communication insight message - *delivered PAP web key and showed tools that were avavilable such as pt diaries, pain agreements, consent forms and how they were customizable to their individual practice* -- [Doctor] looked up and asked me to repeat what it was (rare that he even speaks in ths setting) - I explained briefly again and all seemed interested – [128]

113. Substantially similar claims were made by: Sales Representative 4 to a Germantown-area internist on August 27, 2007;[129] Sales Representative 12 to a Manchester-area family doctor on October 24, 2007;[130] Sales Representative 5 to a Madison-based internist on

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[126] PTN000119294 ID16399 (9/13/2007) (emphasis added).
[127] PTN000119294 ID32318 (12/9/2008) (emphasis added).
[128] PTN000119294 ID125222 (3/22/2013) (emphasis added).
[129] PTN000119294 ID15869 (8/27/2007) (emphasis added).
[130] PTN000119294 ID17711 (10/24/2007) (emphasis added).

November 27, 2007, [131] a Nashville-based physician assistant on November 27, 2007,[132] and to a Springfield-based internist on December 7, 2007;[133] Sales Representative 14 to a Cordova-area internist on May 8, 2008;[134] Sales Representative 13 to a Livingston-area family doctor on October 28, 2008[135] and a Springfield-area family doctor on October 30, 2008;[136] Sales Representative 1 to a Dyersburg-area internist on May 4, 2010[137] and a Jackson-area nurse practitioner on May 7, 2010.[138]

Safety Claims: Misrepresentations as to "Peaks and Valleys"

114. Purdue sought to minimize the true addictive potential of its opioid products by representing its products provide a slow-onset, stable dose without the "peaks and valleys"—encouraging health care providers to infer that these opioids are safer because they do not produce the euphoric high that fosters addiction. Further, Purdue used the term "peaks and valleys" or similar words to overstate a limited finding about OxyContin's steady-state in blood levels into a claim about the purported continuous pain relief and reduced euphoric effect of its opioid products or the converse in competing products. These statements were false, deceptive, and/or unsubstantiated at the time they were made.

115. In its 2012 and 2013 Promotional Guidelines, which were supposed to be followed by Purdue's sales representatives, Purdue stated that these claims were prohibited.[139] In spite of

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[131] PTN000119294 ID18858 (11/27/2007).
[132] PTN000031807 ID12398 (11/27/2007).
[133] PTN000119294 ID19269 (12/7/2007).
[134] PTN000119294 ID24432 (5/8/2008).
[135] PTN000119294 ID30876 (10/28/2008).
[136] PTN000119294 ID31016 (10/30/2008).
[137] PTN000119294 ID52847 (5/4/2010).
[138] PTN000119294 ID53146 (5/7/2010).
[139] PWG000008024–64 (p. 41 of 71); PVT0058288–323 (36 of 64).

this, Purdue sales representatives in Tennessee represented that its products provided a slow-onset, stable dose without euphoric "peaks and valleys."

116. Sales Representative 14 documented his sales call with a Bartlett-based internist on June 5, 2008, as follows:

> Asked doc if he has any patients taking percocet 5mg doses either q4 or q6H atc month after month. He said yes. I talked to him about the benefits of Oxycontin, if appropriate, over Percocet for these patients. He agreed, but said that the biggest challenge is that people get used to the Euphoria they feel with [short acting] meds and as a result feel that LA agents don't work as well b/c they don't cause euphoria. *I acknowledged his concern, but pointed out that the spike in blood plasma levels that occurs with SA agents is many times what causes the euphoria, but that these agents then subsequently dip back out of the therapeutic window and the cycle must be repeated every 4-6H. I explained that a LA agent like Oxycontin is better b/c the patient gets pain relief with a more steady blood plasma level and a more convenient dos*e. He agreed and said that he will continue trying to convince his SA patients to give Oxycontin a shot. Reminder for coupon cards.[140]

117. On August 14, 2008, Sales Representative 7 called on a group of five Johnson City-area health care providers and recorded his interaction as follows:

> [H]is first question was about a 30% dose dump and the euphoric feeling the patient feels when takeing the medicine. I wnet off of the PI showing steady state and *explaining that if the patient is taking the product correctly, they should not have this feeling all the time.* Which led into daily titration and the fact that there are 3 new strengths that they were not aware of that would provide an appropriate daily titration which the competitors could not provide. Went over Med. Edu. Resource Catalog. All prescribers were interested in these.[141]

118. On November 24, 2008, Sales Representative 5 called on a Nashville-area internist and recorded his interaction as follows:

> discussed barry cole's ten tips to prescribing opioids. residents felt all points were pertinent to what they are doing. they said short acting meds are used

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[140] PTN000119294 ID25283 (6/5/2008) (emphasis added).
[141] PTN000119294 ID27756 (8/14/2008) (emphasis added).

> , first, for patients in clinic. switch to long acting, like oxycontin, when in pain clinic. *I mentioned peaks and troughs of short acting meds could pose a challenge for patients with persistent pain.* appreciated package insert.[142]

119. Sales Representative 18 documented his sales call with a Knoxville-based internist on April 12, 2011, as follows:

> *reminded him of our previous conversations of the peaks and valleys he stated that happen with short actings and for the patients with chronic pain.* He stated that he has not used Butrans yet. He stated that he will he just gets b usy and tends to forget. I asked if I need to come in more often and he chuckled.[143]

120. On April 21, 2011, Sales Representative 18 called on a Knoxville-area internist and recorded his interaction as follows:

> *Reminded him of the peaks and valleys he discussed with the [short actings].* He stated that he remembered our conversation and stated that he will use Butrans. I asked when. He stated he will and told me to be patient. I stated I bet he will see a patients that will fit Butrans and he stated probabley I asked for that patient.[144]

121. Sales Representative 15 documented her sales call with a Memphis-based internist on February 21, 2013, as follows:

> Discussed "discontinuation insight". Doctor said he did see a high rate but he blames it on patients seeking the euphoric feeling. *I asked him if his goal in treating pain was euphoria or pain relief.* Doctor said he needs to remind patients of this goal. Discussed lack of efficacy and "determining appropriate dose" marketing piece. Reminded doc that butrans is a CIII which needs to be monitored for abuse. *Discussed dosing,* 72-hour steady state, *supplemental analgesia and titration.* ... Discussed patient education which he wanted me to put in the waiting room.[145]

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[142] PTN000119294 ID31896 (11/24/2008) (emphasis added).
[143] PTN000119294 ID72356 (4/12/2011) (emphasis added).
[144] PTN000119294 ID72985 (4/21/2011) (emphasis added).
[145] PTN000119294 ID122481 (2/21/2013) (emphasis added).

122. In another Purdue unbranded marketing piece titled *In the Face of Pain*, which was referenced during sales calls with Tennessee providers, Purdue told pain sufferers the following:

> Knowledge is power. *Many people living with pain and even some health care providers believe that opioid medications are addictive. The truth is that when properly prescribed by a health care professional and taken as directed, these medications give relief – not a "high."*[146]

Safety Claims: Abuse-Deterrence Misrepresentations

123. Opioid abuse takes several forms, the most common of which is oral abuse, which includes not only using drugs without a prescription, but also swallowing higher or more frequent doses than prescribed. Other forms of opioid abuse include crushing or liquefying the drug in order to snort or inject it.

124. Purdue falsely represented that OxyContin could not be abused in certain ways.

125. As one example, on March 25, 2008, Sales Representative 2 called on a Knoxville-area family doctor and recorded his interaction as follows:

> *Doctor asked about OxyContin and if it could be crushed and put in gtube told docotr it could not* but that he could check with phamracist to see if another product could be used He is using oxycodone liquid pt cannot swallow[.][147]

126. In 2010, Purdue received approval from the FDA for a new formulation of OxyContin that had certain abuse-deterrent properties (ADPs) that resisted abuse from snorting or injecting. In its medical review of Purdue's application, however, the FDA found that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of

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[146] PVT0037244 (emphasis added).
[147] PTN000119294 ID22883 (3/25/2008) (emphasis added).

abuse)" and that "[w]hile the reformulation is harder to crush or chew, possibly mitigating some accidental misuse, oxycodone HCl is still relatively easily extracted."[148]

127. After OxyContin and Hysingla ER were reformulated to include limited abuse-deterrent properties, Purdue used these features as a primary selling point, but failed to disclose that the abuse-deterrent properties of its opioids do not impact or prevent the most common form of abuse—oral ingestion.

128. In 2013, Purdue persuaded the FDA to permit a reference to some of the abuse-deterrent properties in the OxyContin label. When Hysingla ER launched in 2015, Purdue included similar references in the product label.

129. In sales calls with Tennessee health care providers, Purdue misrepresented the extent of the abuse-deterrent properties of its opioids that went beyond a limited acknowledgment on the 2013 revised OxyContin Full Prescribing Information approved by the FDA.[149]

130. Purdue even documented that Tennessee sales representatives in sales calls for both Hysingla ER and OxyContin *did not* "convey that ADPs do not prevent or reduce the risk of addiction of OxyContin and that abuse is still possible by intravenous, intranasal, and oral routes."[150]

131. Purdue failed to disclose that the ADPs of OxyContin and Hysingla ER did not impact oral abuse despite knowledge that its consultant conducted interviews in which some prescribers voiced concerns that the "technology does not address oral abuse."[151]

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[148] New Drug Application 22-272, OxyContin, Division Director Summary Review for Regulatory Action, at 7 (Dec. 30, 2009), available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022272s000MedR.pdf.
[149] PWG003788164.
[150] *See, e.g.*, PTN000068899.
[151] PWG000447841 (document is referenced both as a final report and working draft).

132. In 2011, Purdue published a version of *Providing Relief, Preventing Abuse* that it distributed in sales calls for its opioid products and to at least 808 individuals by mail.[152] Purdue's pamphlet deceptively depicted the signs of addiction by emphasizing the signs of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa—without clearly disclosing that the most common way to abuse opioids is through oral use.[153]

Safety Claims: Understating the Risk of Addiction

133. The vast majority of the "source of business" for OxyContin came from patients who continued to use the product. For example, from August 2009 to March 2011, over 80% of Purdue's business for OxyContin came from continued users.[154] During a six-month period later in 2011, 86.3% of Purdue's business from OxyContin sales came from continuing prescriptions.[155] During an eight-month period in 2015, 87% of Purdue's business for OxyContin sales came from patients who continued to use the product.[156]

134. In order to sell more of its opioid products and keep continued users on its products, Purdue sought to change the narrative about the addictive potential of its opioids in ways that would generate less scrutiny from the FDA. On a website that Purdue controlled, Purdue promoted material from a third-party pain advocacy group to which Purdue significantly contributed financially through projects it specifically funded that grossly misrepresented the risks of addiction from opioids. These statements were false, deceptive, and/or unsubstantiated at the time they were made.

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[152] PTN000045907; *see also* PWG004285193_A.
[153] PTN000003544.
[154] PVT0026754; PWG000324280.
[155] PWG00004088.
[156] PWG000435505.

135. *Exit Wounds* was a publication, which Purdue specifically funded,[157] that was targeted to veterans seeking pain relief. The publication could be directly accessed through a Purdue website, www.inthefaceofpain.com,[158] and was attributed to the American Pain Foundation (APF), which Purdue also substantially funded.[159] APF submitted grant proposals to Purdue for media responses in priority markets, including Nashville and Memphis, "with a high incidence of negative news coverage, *as identified by Purdue*" that utilized *Exit Wounds* as well as other APF materials.[160]

136. On www.inthefaceofpain.com, Purdue held *Exit Wounds* out as an authoritative resource for veterans seeking pain relief. Purdue promoted its *In the Face of Pain* campaign and website on written material that contained express references to Purdue's opioid products including OxyContin and Butrans.[161] Purdue also promoted *In the Face of Pain* and linked to the website, www.inthefaceofpain.com, on Purdue's more comprehensive corporate website, www.pharma.com,[162] and its mobile-friendly version,[163] both of which also contained marketing for Purdue's opioid products, such as OxyContin, by brand name.

137. *Exit Wounds* contained numerous misrepresentations about the addictive potential of opioid products. As an example, *Exit Wounds* states:

> The pain-relieving properties of opioids are unsurpassed; they are today considered the "gold standard" of pain medications, and so are often the main medications used in the treatment of chronic pain. Yet, despite their great benefits, opioids are often underused. For a number of reasons, healthcare providers may be afraid to prescribe them, and patients may be

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[157] PTN000023060; PWG000048316.
[158] PWG000190216, -305.
[159] PWG00096255.
[160] PTN000026567 (emphasis added).
[161] PWG000088580–85.
[162] PWG000126647.
[163] PWG000131838; PWG000131841.

> afraid to take them. At the core of this wariness is the fear of addiction, so I want to tackle this issue head-on.
>
> If your body adjusts to a drug or medication, it may become less effective over time. This is called tolerance. This is simply a physiological process that doesn't occur for all people or with all medications. Many people with persistent pain, for example, *don't* develop tolerance and stay on the same dose of opioids for a long time. ...
>
> Opioid medications can, however, be abused or used as recreational drugs, and some people who use these drugs this way *will* become addicted. ...
>
> Long experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications. When used correctly, opioid pain medications *increase* a person's level of functioning; conversely, when a drug is used by somebody who is addicted, his or her function *decreases*.[164]

Failing to Disclose Increased Risk of Addiction at Higher Doses

138. As recognized by the CDC, taking opioids for longer periods of time or in higher doses increases the risk of addiction, among other serious risks and side effects.[165]

139. Aside from express representations, Purdue also downplayed the increased risk of addiction from higher doses of its opioid products through material omissions, which the company has recognized are actionable in sales trainings.[166]

140. In its marketing, including branded materials, unbranded materials, and sales calls with providers and others in Tennessee, Purdue failed to disclose the material fact that there is an increased risk of addiction at higher doses of its opioid products.

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[164] PTN000023114 (emphasis in original).

[165] *Opioid Prescribing: Where You Live Matters*, CENTERS FOR DISEASE CONTROL AND PREVENTION, available at https://www.cdc.gov/vitalsigns/opioids/index.html.

[166] PWG000190154 (stating "Promotion includes written materials, what is said and even what is NOT said. [District Managers] – Pause for a moment to consider the last statement with your team. When could it be that there is an omission of material fact? Not including the risks statements, Not providing fair balance, Not correcting a misstatement or misimpression of a customer (and remember...describe the discussion in your call notes!)[.]").

141. The ability to escalate doses was critical to Purdue's efforts to market opioids for long-term use to treat chronic pain. Unless health care providers felt comfortable prescribing increasingly higher doses of opioids to counter their patients' building of tolerance to the drugs' effects, they may not have chosen to initiate opioid therapy at all. Moreover, without disclosing the increased risk of addiction, Purdue regularly encouraged providers in Tennessee to increase the dose of its opioids, or "titrate up," products like OxyContin rather than prescribe them more frequently.

142. High dose opioids have continuously been a significant part of Purdue's business in Tennessee—particularly for OxyContin. While Purdue instructed sales representatives to emphasize low-dose starts, Purdue sold disproportionately high amounts of its 40 mg and above tablets of OxyContin.

143. To put this in context, one OxyContin 40 mg tablet taken every 12 hours equates to 120 MMEs per day, a standardized unit of opioid potency.[167] 120 MMEs is 30 MMEs *over* the 90 MME and above daily threshold that the CDC states providers should avoid or carefully justify.[168]

144. Of the 104,340,382 total tablets of OxyContin prescribed in Tennessee from 2008 to 2017, 56,058,315 or *53.7%* of these units were 40 mg or higher.[169]

145. Of the approximately 1,471,006 prescriptions written for Purdue's OxyContin in Tennessee from 2008 to 2017, 708,315 or *48.15%* of these prescriptions were for doses of OxyContin 40 mg or higher.[170]

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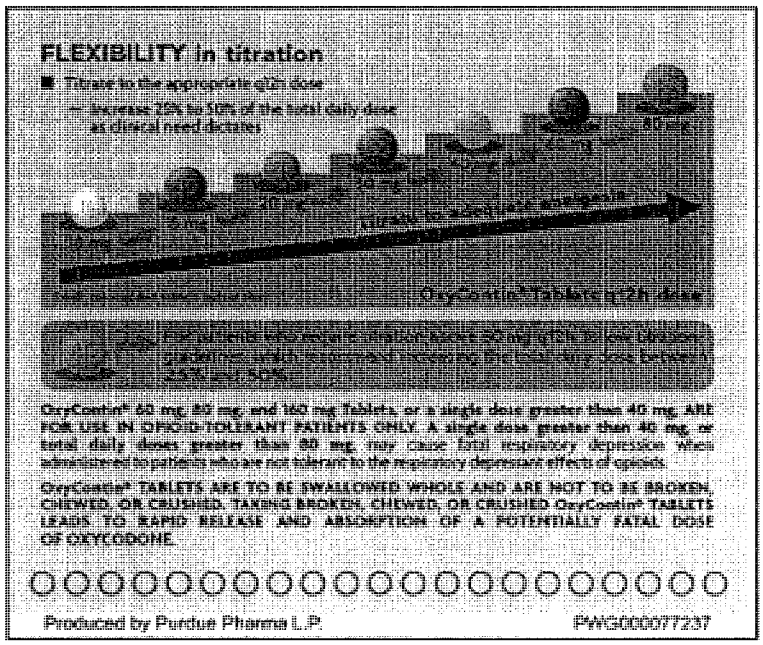
[167] https://tenncare.magellanhealth.com/static/docs/Program_Information/TennCare_MME_Conversion_Chart.pdf
[168] https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.
[169] PWG003984543.
[170] PWG003984537.

146. Purdue made the escalating dosing strengths a centerpiece of its marketing for OxyContin, stating, "OxyContin is the only ER oxycodone available in 7 tablet strengths."[171] Purdue stated in internal marketing presentations that OxyContin's availability in seven tablet strengths was a key selling message.[172]

147. Numerous Purdue written marketing materials that were widely disseminated in Tennessee depict the seven OxyContin tablet strengths—in a line or a series of upward steps—and instruct health care providers that they can increase the dose by titrating upwards without disclosing the increased risk of addiction at higher doses.[173]

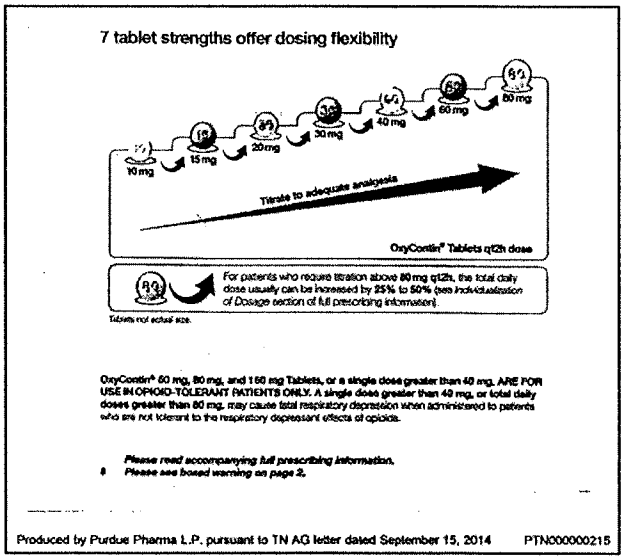
148. As an example, Purdue's Conversion and Titration Guide for OxyContin, which was widely disseminated in Tennessee,[174] contains references to titrating with OxyContin's seven dosage strengths, a statement to "[t]itrate to the appropriate q12h dose – increase 25% to 50% of the total daily dose as clinical needs dictates," the statement "[f]or patients who require titration



[171] PTN000072961.
[172] PWG000435171.
[173] PWG000290890.
[174] PWG000077224.

above 80 mg q12h, follow titration guidelines, which recommend increasing the total daily dose between 25% and 50%," and graphics featuring stair-step depiction of titrating only upwards to higher doses of OxyContin—all without disclosing the increased risk of addiction from higher doses.

149. Another version of Purdue's Conversion and Titration Guide for OxyContin also claims the "7 tablet strengths [of OxyContin] offer dosing flexibility," features a stair-step titration graphic going only upwards, and contains a reference to titration above 80 mg every 12 hours—without disclosing the increased risk of addiction from higher doses of OxyContin (excerpt below).[175]



150. Purdue's Conversion and Titration Guide was such a central part of the company's marketing for OxyContin that each sales representative was automatically shipped 50 copies to distribute to providers in Tennessee.[176]

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[175] PTN00000215.
[176] PTN000031942, -57 (referring to Lit Code: 000PO5 (version N4898)).

151. Purdue also used visual aids, like 0PO479, in sales calls with providers in Tennessee that depicted a modified titration stair-step for Purdue's first 5 doses that also did not disclose the increased risk of addiction at higher doses.[177]

152. Purdue had similar titrating up messaging in other marketing materials. For example, Purdue again referenced the seven dosing strengths of OxyContin and featured a similar stair-step titration graphic in a publication titled "Chronic Pain Has Many Faces – Maggie's Story," which likewise did not disclose the increased risk of addiction at high doses of OxyContin.[178]

153. Purdue's titration principles were based on cancer pain management guidelines that Purdue conceded were no longer current as of 2011. In a 2011 training document for sales representatives, Purdue stated:

> How were the Titration Principles initially established? Purdue developed them based on the AHRQ (Agency for Health Research & Quality) Cancer Pain Management Guidelines. However, AHRQ guidelines are no longer considered current.[179]

154. Purdue's Tennessee sales representatives frequently referred to high doses of OxyContin or other opioids without disclosing the increased risk of addiction at higher doses.

155. Purdue taught Tennessee sales representatives at national meetings to "close" with questions to providers about the benefit of OxyContin at higher doses. For instance, at one training workshop Purdue's sales representatives were taught: "Doctor, you see the benefit of OxyContin for the patient who requires 40 mg a day and higher?"[180]

156. Similarly, Purdue instructed its sales representatives:

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[177] PWG000109649.
[178] PTN000072954-61.
[179] PWG000042615.
[180] PWG000109650.

> The second objective is to continue getting appropriate patient starts on OxyContin Tablets with the 10 mg, 15 mg & 20 mg tablets, *as well as conversion to the 30 mg, 40 mg, 60 mg & 80 mg tablets from other opioids, when appropriate*.[181]

157. While not an exhaustive list, illustrative examples of call notes in which Purdue's Tennessee sales representatives recorded making these claims to providers are set forth below.

158. Sales Representative 4 documented his sales calls with a Memphis–based family doctor on May 23, 2007, in which he discussed the safety of OxyContin at higher doses without disclosing the increased risk of addiction. The call note reads as follows:

> Said that he will only go to 40mg of oxycontin unless absolutely necessary. Reviewed APS guidelines and *safety at the higher doses of oxycontin*[.][182]

159. Sales Representative 4 documented his sales call with a Germantown-based internist on August 13, 2007, in which he discussed the titration of OxyContin from a low dose to 40 mg or 80 mg every 12 hours and did not disclose the increase risk of addiction at higher doses. The call note states as follows:

> *Reviewed of titration guide and principles*. Asked about when to go from 10mgq12h to a higher dose and if it was ok to jump from low dose to 40 or 80mgq12h. Reviewed the 3/2 principle and make sure she is evaluating the patient[.][183]

160. On December 5, 2007, Sales Representative 5 called on a Gallatin-area family physician in which the sales representative discussed titrating patients to higher doses of OxyContin without disclosing that there is an increased risk of addiction at higher doses of opioids. The call note reads as follows:

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[181] PTN000031939 (emphasis added).
[182] PTN000119294 ID12888 (5/23/2007) (emphasis added).
[183] PTN000119294 ID15378 (8/13/2007) (emphasis added).

doc said he has no problem in titrating to higher strengths of oxycontin if it is warrented in his chronic pain patients.[184]

161. Likewise, Sales Representative 5 made a sales call to a Nashville-area family physician on December 10, 2007, in which he discussed higher doses of OxyContin without disclosing the increased risk of addiction at higher opioid doses. The call note reads as follows:

> *doc said he reserves oxycontin for those that need 40/80mg strengths.* probably would not write lower strengths for osteoarthritis.[185]

162. Likewise, Sales Representative 4 made a sales call to a Memphis-area internist on March 12, 2008, and had the following discussion with the provider without disclosing the increased risk of addiction at higher doses. The call note reads as follows:

> [S]aid he doesn't see any real benefit in the new strengths. Said that oxycontin is not a tru 12 hr drug and he will typically add two breakthrough meds if necessary on a patient that is taking oxycontin tid and still having some pain through the night. Said that a lot of formularies don't accept oxycontin in his practice. *Told him a lot has to do with how he is writing it.* Said he wrote one patient 80mgbid plus two short acting and windsor healthcare told him it was too much. *Asked why he didn't just write for 160mg* and he said that was a bad thought and I should really stop telling physicians that oxycontin is a q12h drug[.][186]

163. Sales Representative 14 documented his sales call with a Cordova-based internist on July 24, 2008, in which the sales representative discussed a patient for a 60 mg OxyContin dose without disclosing the increased risk of addiction at higher doses. The call note reads as follows:

> Doc badly behind, so time was limited. *Reminded him about the added flexibility that the extended line offers.* He echoed what he said on last call *when he mentioned a patient of his that may be a candidate for the 60mg dose.* Also, reminded him about the coupon cards.[187]

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[184] PTN000119294 ID19180 (12/5/2007) (emphasis added).
[185] PTN000119294 ID19322 (12/10/2007) (emphasis added).
[186] PTN000119294 ID22397 (3/12/2008) (emphasis added).
[187] PTN000119294 ID26972 (7/24/2008) (emphasis added).

164. On August 14, 2008, Sales Representative 7 called on a group of five Johnson City-area health care providers and referenced three new strengths of OxyContin and daily titration without disclosing the increased risk of addiction at higher doses. The call note reads as follows:

> Lunch- I am going to use the same note for this office as all providers came in at the same time and st at the table. This was a very good lunch and I feel we are going to see some results. His first question was about a 30% dose dump and the euphoric feeling the patient feels when takeing the medicine. I wnet off of the PI showing steady state and explaining that if the patient is taking the product correctly, they should not have this feeling all the time. *Which led into daily titration and the fact that there are 3 new strengths that they were not aware of that would provide an appropriate daily titration which the competitors could not provide.* Went over Med. Edu. Resource Catalog. All prescribers were interested in these.[188]

165. On January 27, 2009, Sales Representative 12 called on a Chattanooga-area nurse practitioner and referenced titrating upwards without disclosing the increased risk of addiction at higher doses. The call note reads as follows:

> Reviewed and discussed how she could/would use the lower doses of 10 and 15 for appropriate patients. She still said most patients come in on higher doses. *Asked if she ever wanted to develop a trust with lower doses and titrate up.* She said she did and might be a good idea. Reminded of the savings cards and the Seno S for patients on pain medication.[189]

166. Sales Representative 1 called on a Paris-area family doctor on April 26, 2010 and recorded the following about her discussion:

> [d]iscussed that there is no max dose for oxycontin and that there is no apap. *dr askekd how many copays is it for patient taking 160mg if the patient has to take 2 80mg. told him i thought one but would check with pharmacist and confirm with him. we also discussed difference between physical dependence and addiction.* discussed ryzolt positioning statement and coverage[.]

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[188] PTN000119294 ID27756 (8/14/2008) (emphasis added).
[189] PTN000119294 ID33429 (1/27/2009) (emphasis added).

167. On May 13, 2013, Sales Representative 6 made a sales call to a Knoxville-area family doctor and recorded his interaction as follows:

> Discussed OxyContin and he asked if there was a maximum dose for OxyContin. I told him there has been no maximum dose established in our clinical trials. *He says he has one patient taking five of the 80 mg tablets a day. Acknowledgedthat's an exception and is a high-dose compared to the other patients he has on OxyContin.* We discused the dosing conversion chart from Percocet and I asked him to consider in any patient who's not comfortable with Q6 dosing or having to get up in the middle the night to take their medication ....[190]

168. Substantially similar claims were made by: Sales Representative 7 to a Mountain Home-area pharmacy on June 1, 2009;[191] Sales Representative 5 to a Ashland City-based internist on December 12, 2007,[192] a Hendersonville-area emergency medicine provider on December 21, 2007,[193] and a Nashville-area internist on July 15, 2009;[194] Sales Representative 11 to a Lebanon-area physical medicine and rehabilitation specialist on September 3, 2009[195] and to three Hermitage-based providers on September 3, 2009;[196] Sales Representative 2 to a Knoxville-based physician assistant on September 22, 2008[197] and a Knoxville-area neurologist on November 5, 2008;[198] Sales Representative 11 to a Lebanon-area internist on October 5, 2009,[199] a Gordonsville-based family doctor on October 5, 2009,[200] and a Lebanon-area physical medicine and rehabilitation specialist on October 5, 2009;[201] Sales Representative 4 to a Memphis-area

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[190] PTN000119294 ID130004 (5/13/2013) (emphasis added).
[191] PTN000119294 ID38263 (6/1/2009).
[192] PTN000119294 ID19416 (12/12/2007).
[193] PTN000119294 ID19690 (12/21/2007).
[194] PTN000119294 ID39709 (7/15/2009).
[195] PTN000119294 ID41710 (9/3/2009).
[196] PTN000119294 ID41712 (9/3/2009).
[197] PTN000119294 ID29383 (9/22/2008).
[198] PTN000119294 ID31257 (11/5/2008).
[199] PTN000119294 ID43232 (10/5/2009).
[200] PTN000119294 ID43233 (10/5/2009).
[201] PTN000119294 ID43235 (10/5/2009).

anesthesiologist on October 23, 2009;[202] Sales Representative 1 to a Dyersburg-based nurse practitioner on November 20, 2009,[203] and a Dyersburg-area pulmonary specialist on November 20, 2009;[204] and Sales Representative 7 to a Bristol-area nurse practitioner on March 3, 2014.[205]

169. Purdue's district managers told sales representatives in Tennessee to focus on the seven dosing strengths of OxyContin and titration. For example, on May 27, 2016, District Manager 1 e-mailed sales representatives from the entire Nashville District and told the representatives, among other things, to "[f]ocus on product attributes, *7 dosing strengths, and the ability to titrate up and down as necessary*," without any indication that sales representatives were supposed to disclose the increased risk of addiction at higher doses.[206]

Failing to Disclose Lack of Evidence for Long-Term Use of Opioids

170. To convince Tennessee prescribers and patients that opioids should be used to treat chronic pain, despite the unavoidable risk of addiction, Purdue had to persuade them that there is a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o 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)" and that other treatments were more or equally

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[202] PTN000119294 ID44097 (10/23/2009).
[203] PTN000119294 ID45493 (11/20/2009).
[204] PTN000119294 ID45494 (11/20/2009).
[205] PTN000119294 ID155137 (3/3/2014).
[206] PTN000088254–55 (emphasis added).

beneficial and less harmful than long-term opioid use.[207] Moreover, the FDA stated in 2013 that it was "not aware of adequate and well-controlled studies of opioid use longer than 12 weeks."[208]

171. Similarly, the U.S. Health and Human Services Agency for Healthcare Research and Quality, in an Evidence Report that assessed the current evidence on effectiveness and harms of opioid therapy for chronic pain focusing on long-term (≥1 year) outcomes, concluded that the evidence regarding long-term opioid therapy for chronic pain is "very limited but suggests an increased risk of serious harms that appears to be dose-dependent."[209]

172. Purdue has long been aware of the disconnect between the academic literature, which assesses efficacy of extended release opioids only as far out as 12 weeks, and the reality—which it helped create—that many patients use OxyContin and other opioids for months or years. For example, a 2011 internal email among Purdue researchers discussed the need for "new research studies of not less than 12 months duration to determine the long-term effectiveness of opioids for chronic non-cancer pain"[210]—an acknowledgment that such evidence did not exist.

173. Nevertheless, building on its earlier marketing, Purdue has continued to tout the purported benefits of long-term opioid use, while falsely and misleadingly implying that these benefits are supported by scientific evidence. In their sales conversations with Tennessee providers, Purdue sales representatives do not disclose the lack of evidence supporting long-term

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[207] 2016 CDC Guideline at 15, 19.
[208] Ltr. from U.S. Food and Drug Administration to Andrew Kolodny, M.D., Physicians for Responsible Opioid Prescribing, 10 (Sept. 10, 2013), available at http://www.supportprop.org/wp-content/uploads/2014/12/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf.
[209] Roger Chou, M.D., F.A.C.P., *The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain*, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY; U.S. DEPARTMENT OF HEALTH AND HUMANS SERVICES, abstract available at https://www.ncbi.nlm.nih.gov/books/NBK258809/.
[210] PTN000022184.

use. And Purdue promotional materials likewise promote long-term use without disclosing the absence of long-term studies.

174. For example, the OxyContin Conversion and Titration Guide, which sales representatives widely disseminated in Tennessee, implies that opioid use can continue safely for years. One version of the Guide that was widely-disseminated in Tennessee states, "The need for ATC opioid therapy should be reassessed periodically (e.g., every 6 to 12 months) as appropriate for patients on chronic therapy"[211] without disclosing the lack of evidence for long-term use. A later 2014 version of the Guide omits the parenthetical "(e.g., every 6 to 12 months)," but states that prescribers should "periodically reassess the continued need for the use of opioid analgesics."[212] This 2014 version still conveys, however, that chronic opioid therapy is appropriate without disclosing the lack of evidence for use beyond 12 weeks.

175. Purdue's Tennessee sales representatives frequently referred to long-term use of Purdue's opioid products without disclosing the increased risk of addiction at higher doses. While not an exhaustive list, representative examples of these call notes are set forth below.

176. On August 4, 2010, Sales Representative 7 called on a Johnson City-area physical medicine and rehabilitation specialist and discussed the long-term use of Purdue's opioids without disclosing the lack of scientific evidence for long-term use. The call note states:

> The providers in this practice are very conservative. They have a less is better philosophy. *I said i understand and asked how many patients they have on pain medicine "long-term"*. They admitted that they do have quite a few on continuing therapy. *I went over ir/sa therapy vs q24hr therapy and the possibilities er therapy can offer.*[213]

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[211] PTN00000214; PWG0001275880 ("The need for around-the-clock opioid therapy should be reassessed periodically (eg, every 6 to 12 months) as appropriate for patients on chronic therapy.").
[212] PWG000052738.
[213] PTN000119294 ID57473 (8/4/2010) (emphasis added).

177. Sales Representative 15 documented her sales call with a Bartlett-based internist on September 4, 2012, in which she discussed the use of Purdue's opioids for patients with long-term around the clock pain without disclosing the lack of scientific evidence for long-term use. The call note states:

> Introduced myself as Butrans/OxyContin rep. *Asked physician what his treatment algorithm was for patients with long-term ATC pain.* He said that he did not have any algorithm because everyone was different. Dr said that he uses IR in some patients and ER in other patients. *I asked what triggers him to switch from IR to ER.* Dr said "when it feels right."[214]

178. Likewise, Sales Representative 15 made a sales call to a Germantown-area orthopedic surgeon on October 23, 2012, in which she discussed the long-term use of Butrans without disclosing the lack of scientific evidence about long-term use. The call note reads:

> Asked Dr how he had Butrans and OxyContin positioned. Dr said he doesn't use much long-acting for fear of abuse. Reminded Dr that Butrans is a 7-day transdermal patch, CIII with potential for abuse, indicated for moderate to severe ATC pain. Asked him to keep Butrans in mind for his total hip/total knee patients that still present with pain after surgery. He said he had not thought of using it there until now. Also discussed hydrocodone patients that are not controlled at 1-2 tablets/day. He said he uses hydrocodone but tries to wean patients off of it and not use it long-term for fear of patients getting addicted. Showed him a placebo patch and reminded him it is matrix technology. Asked him to give patients the option of Butrans and give trial cards so patient can try it for free.[215]

179. On April 9, 2013, Sales Representative 6 called on a Knoxville-area family doctor and discussed the long-term use of Purdue's opioids without disclosing the lack of scientific evidence for long-term use. The call note states:

> Good discussion around Butrans-he likes concept and feels it makes most sense with opioid-naive pts. We discussed dosing for those pts and reinforced savings card for commercial pts. I offered the Scott profile and pts not controlled on Tramadol. He said that he would consider that. He

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[214] PTN000119294 ID109956 (9/4/2012) (emphasis added).
[215] PTN000119294 ID113996 (10/23/2012) (emphasis added).

> ended discussion by committing to prescribing Butrans for a couple of his pts. *He likes oxycontin and does treat long-term pain when appropriate. Reinforced the dose availability and he mentioned the 30 mg dose as helpful.*[216]

Safety Claims: General Safety Claims

180. Purdue made a series of unqualified safety claims in Tennessee that represented that the company's opioid products were safer than they actually were. These claims were false, deceptive, and/or unsubstantiated at the time they were made. While not an exhaustive list, representative examples of these claims are set forth below.

181. On May 7, 2007, Sales Representative 2 called on a Knoxville-area pain medicine specialist and recorded his interaction as follows:

> [Provider] said he preffered to not use OxyContin first line because he feels once a pt is put on Oxycontin they never will try anything else becuase they like the drug . *i aksed if that was a bad thing* he siad that the hard part was to ifgure out if it was due to releif or a buzz[.][217]

182. Sales Representative 4 documented his sales call with a Cordova-based internist on May 10, 2007, as follows:

> discussion involving todays settlement announcements. *Reassuring oxycontin's safety* and her success with oxycontin[.][218]

183. Likewise, Sales Representative 5 made a sales call to a Dickson-area pharmacy on February 20, 2008, and wrote the following about his interaction:

> pharmacy tech was riding me about oxycontin being a bad drug. *corrected her by saying good drug, bad people abusing it.* pharmacist said he sees 20/10mg written to get 30mg. will order 30 and 60mg.[219]

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[216] PTN000119294 ID126688 (4/9/2013) (emphasis added).
[217] PTN000119294 ID12181 (5/7/2007) (emphasis added).
[218] PTN000119294 ID12407 (5/10/2007) (emphasis added).
[219] PTN000119294 ID21584 (2/20/2008) (emphasis added).

184. On January 8, 2009, Sales Representative 11 called on a Lebanon-area physical medicine and rehabilitation specialist and recorded his interaction as follows:

> *asked if he was aware that oxycodone was 100 years old and the fact we only improved on the delivery system with oxycontin. he said he agreed and said if the pt is on oxycodone he will use oxycontin.* he said he is using more now that the media is not saying it was a bad drug. he said his problem is when the pt wont take becasue what they heard on the news. he also asked about the generic situation. he said some pts did not like the different colors and sizes. he also said for workmans comp he is using the mail order. comp pts make up 80 percent of his practice.[220]

185. Sales Representative 11 made a sales call to a Brentwood-area anesthesiologist on March 26, 2009, and wrote the following about his interaction:

> in office today i talked about pts taking lortab or percocet 10mg with apap 500mg. *discussed apap use over a year and they were concerned with that much apap over a year. discussed pts to then titrate per indication over to oxycontin q 12*[.][221]

186. Sales Representative 1 documented her sales call with a Jackson-based anesthesiologist on November 8, 2010, as follows:

> went over state board of medical examiners leave behind piece and discussed importance of proper documentation. *also discussed that there is not a "bad drug" list, that they are all good when properly prescribed& administered.* he said when the state talks about bad drugs they use oxycontin synonymously for all bad drugs. he then said someone told him about an article that stated which drugs are most likely to cause overdose. he asked me to find that article and then we could discuss statistics. i told him i am not allowed to talk about anything that has not been approved by purdue and the fda but that he could complete a yellow card if he wanted any data specifically related to overdose and oxycontin. he signed the yellow card and his NP worded the question. then he told me that he bet 90% of the patients mentioned in that article were oxycontin deaths. i asked him why he thought that and if he has seen those statistics in his practice. he said no. he said he had a colleague..[222]

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[220] PTN000119294 ID33023 (1/8/2009) (emphasis added).
[221] PTN000119294 ID35491 (3/26/2009) (emphasis added).
[222] PTN000119294 ID62441 (11/8/2010) (emphasis added).

187. Sales Representatives 7 and 20 documented their sales call with a Nashville-based anesthesiologist on May 20, 2014, as follows:

> Discussed Oxycontin and Butrans. Dr said he likes to use Butrans on his patients he does not trust. *Explained Butrans is not just for his train wrecks.* Dr said he likes fentanyl. Does not like to use high doses for his patients, most patients taking lortab 5 mg q8h. Asked if Butrans patch will stay on, left him placebo patches.[223]

188. Purdue also promoted OxyContin's time on the market as an implied safety claim. For example, at an OxyContin Brand Strategy meeting in Nashville on September 16, 2015, Purdue stated that OxyContin should be positioned "For HCPs who treat chronic pain, make OxyContin® the preferred brand and extended-release oxycodone because it offers powerful efficacy, 20 years of clinical experience, abuse-deterrent properties and claims, and excellent managed care access" and that emphasizing OxyContin's 20 year experience was a strategic imperative for the brand.[224]

B. DECEPTIVE COMPARATIVE CLAIMS

189. Purdue has admitted on multiple occasions that it does not possess substantiated data, comparative trials, or head-to-head studies evaluating its products versus other products including in training documents from 2010,[225] 2011,[226] 2012,[227] and 2013.[228]

190. For example, in 2011 Purdue indicated to sales representatives that "Statements cannot represent or suggest that a drug is safer/more effective (or make any other sort of

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[223] PTN000119294 ID162582 (5/20/2014) (emphasis added).
[224] PWG000435507.
[225] PTN000090502 (emphasis in original) (stating "Remind you that Purdue has no comparative trials or substantiated data- thus no comparisons to other products are allowed[.]").
[226] PWG000190160.
[227] PVT0058319 (emphasis in original) (stating "Comparisons cannot represent or suggest a drug is safer/more effective unless there is **substantial evidence/clinical trials.** [-] **We have no drugs that satisfy this standard.**").
[228] PWG00008056 (stating "Comparisons cannot represent or suggest a drug is safer/more effective unless there is **substantial evidence/clinical trials.** Purdue Products do not have any comparative data that satisfy this standard.").

comparative claim) unless there is substantial evidence/clinical trials supporting the statement – **We have no drugs that satisfy this standard**[.]"[229]

191. In spite of this, Purdue made claims that competing products were more dangerous than they actually were, less effective than they actually were, or that its products were equivalent to or superior to competing opioids and non-opioids when these claims were false, deceptive, and/or unsubstantiated at the time they were made.

192. Purdue did this in eight main ways, namely: (1) broadly representing that its own products were superior to competing opioid products; (2) representing that OxyContin was safer, more effective, as effective, or superior to other extended release opioids such as (a) Opana, (b) Duragesic, (c) methadone, and (d) Avinza; (3) representing that OxyContin was safer, more effective, as effective, or superior to immediate release opioids generally as well as (a) Dilaudid, (b) hydrocodone, (c) immediate release opioids containing acetaminophen, (d) hydrocodone combinations, (e) Lortab and Vicodin, and (f) Percocet; (4) representing that OxyContin was safer, more effective, as effective, or superior to non-opioids; (5) representing that Butrans was safer, more effective, as effective, or superior to immediate release opioids such as hydrocodone, hydrocodone combinations, Darvocet, tramadol, and Lortab; (6) representing that Ryzolt was safer, more effective, as effective, or superior to immediate release opioids generally, as well as Percocet and Lortab specifically; (7) representing that Ryzolt was safer, more effective, as effective, or superior to other tramadol products including tramadol and Ultram ER; and (8) representing that Hysingla ER was safer, more effective, as effective, or superior to immediate release opioids including hydrocodone combinations and those containing acetaminophen.

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[229] PWG000190160 (emphasis in original).

Comparative Claims: OxyContin's General Superiority over Other Products

193. Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to other products when those claims were false, deceptive, and/or unsubstantiated at the time they were made. While not an exhaustive list, illustrative examples of these claims are set forth below.

194. Sales Representative 3 documented his sales call promoting OxyContin with a Greeneville-based family doctor on May 7, 2007, as follows:

> stated hates it because of name - *asked what was safer* - didn;t have an answer - waved me off[.][230]

195. Sales Representative 4 documented his sales calls with a Collierville-based family doctor on May 22, 2007, as follows:

> *Discussed the athlete and the use of oxycontin being beneficial. Better compliance, improved rehab time and don't have to worry about heat being a factor as you would with patient on the patch.* Said that was a valid point and there is a lag sometimes in pain control when it comes to the patch[.][231]

196. Sales Representative 4 documented his sales call with a Huntingdon-based family doctor on May 30, 2007, as follows:

> *Discussed dosing and lag time with fentanyl and cost difference disadvantages vs. oxycontin.* Review of oxycontin PI safety and indications.[232]

197. Sales Representative 4 documented his sales call with a Huntingdon-based family doctor on August 10, 2007, as follows:

> Told me he was tired of me getting on him about paying attention to the patient's insurance and utilizing the savings card. *Explained that he can treat patients with chronic pain more effectively by ensuring brand with*

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[230] PTN000119294 ID12240 (5/7/2007) (emphasis added).
[231] PTN000119294 ID12844 (5/22/2007) (emphasis added).
[232] PTN000119294 ID12989 (5/30/2007) (emphasis added).

DAW and making sure it happens at the pharmacy by giving out the savings cards.[233]

198. Likewise, Sales Representative 5 made a sales call to a Nashville-area oncologist on September 6, 2007, and wrote the following about his interaction:

> doc asked me why he should prescribe oxycontin. *Told him most effective and well tolerated.* doc agreed. will write.[234]

199. On November 13, 2007, Sales Representative 5 called on a Nashville-area hematologist and recorded his interaction as follows:

> doc shot passed me in the hallway--*asked him what is more effective and better tolerated than oxycontin for moderate to severe pain.* could not respond.[235]

200. Purdue Representative 3 documented his sales call with a Knoxville-based pain medicine specialist on April 17, 2008, as follows:

> re- intro call - feels that name oxycontin keeps him from prescribing it more often - feels too many people divrt or abuse - stated continues to prescribe for those who are alrady on it - *asked how concludes other long acting opiods are safer* - says matrix (delivery) system makes it easier to abuse than other such as "any" - others harder to crush or have gel like matrix that makes it harder to abuse - *agreed but asked if has gone on line and looked at how-to websites - I made the point that a cII is a cII* –[.][236]

Comparative Claims: OxyContin v. Other ER Opioids

OxyContin v. Opana

201. In its marketing in Tennessee, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to Opana ER, an extended release opioid analgesic

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[233] PTN000119294 ID15356 (8/10/2007) (emphasis added).
[234] PTN000119294 ID16158 (9/6/2007) (emphasis added).
[235] PTN000119294 ID18436 (11/13/2007) (emphasis added).
[236] PTN000119294 ID23662 (4/17/2008) (emphasis added).

tablet containing oxymorphone hydrochloride when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

202. Purdue's Tennessee sales representatives were taught to differentiate OxyContin from Opana ER in sales calls to providers based on (1) the warning on Opana ER's label for the consumption of alcohol; (2) the effect of food on Opana ER; and (3) the 3–7 day titration period for Opana ER compared with the 1–2 day period for OxyContin.[237] While not an exhaustive list, illustrative examples of these claims are set forth below.

203. Sales Representative 11 made a sales call concerning OxyContin to an Hermitage-area physical medicine specialist on May 22, 2007, and wrote the following about his interaction:

> he had another quesion about the case discussed per email. then he asked me about opana and if the drug is doing well. *i said no because of the alcohol issue on the delivery system and the food affect*[.][238]

204. Likewise, Sales Representative 2 made a sales call to a Lebanon-area hematologist regarding OxyContin on June 11, 2007, and wrote the following about his interaction:

> saw doctor breifly, and *did discuss morphine vs oxycontin*, and also had questions about opano. *did not know about thee alcohol and the food affect*[.][239]

205. Sales Representative 2 documented his sales call with a Lebanon-based internist on June 21, 2007, as follows:

> asked me how oxycontin compared to opana. *discussed alcohol and the food affect issues. did not know about them.* reminded of new starts[.][240]

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[237] ST000407–08 (2009).
[238] PTN000119294 ID12830 (5/22/2007) (emphasis added).
[239] PTN000119294 ID13426 (6/11/2007) (emphasis added).
[240] PTN000119294 ID13466 (6/11/2007) (emphasis added).

206. Likewise, Sales Representative 4 made a sales call to a Cordova-area anesthesiologist on June 21, 2007, and wrote the following about his interaction:

> *Discussed and reviewed the opana PI vs. oxycontin and disadvantages of bioavailability and issues with food and alcohol. Said he was unaware of this and the representative didn't make mention of the issues either*[.][241]

207. On June 22, 2007, Sales Representative 4 called on a Memphis-area anesthesiologist and recorded his interaction as follows:

> PI review for opana. Said the reps didn't tell him about the concerns for alcohol and food effect. *Pointed out to him that oxycontin is a much more effective drug for treating pain and with the methadone he writes he doesn't need another drug that he has to monitor*[.][242]

208. Sales Representative 11 documented his sales call with a Franklin-based anesthesiologist on June 26, 2007, as follows:

> called me today. said he could not find the savings cards and wondered where they were. i went to office and found them for him. *did discuss opana vs oxycontin.* he said the rep is really trying to get him to use . *i discussed comparisons. he did not know about the alcohol or food issue.*[243]

209. On July 3, 2007, Sales Representative 4 called on a Germantown-area obstetrician/gynecologist and recorded his interaction as follows:

> *Asked about his use of opana.* Said that he has tried some of it and for the most part patients either don't want to take it because they never heard of it or they started feeling funny on it. Said he is now going to it when oxycontin or another long acting doesn't work. *Reminded him that the bioavailability of opana is much lower and there should be concerns of food and alcohol consumption when taking opana.* Said he still hasn't given out any savings cards. Reminded him that they are beneficial for existing patients and not just new starts and to have nurses place in chart upon patient follow up[.][244]

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[241] PTN000119294 ID13816 (6/21/2007) (emphasis added).
[242] PTN000119294 ID13910 (6/22/2007) (emphasis added).
[243] PTN000119294 ID14004 (6/26/2007) (emphasis added).
[244] PTN000119294 ID14131 (7/3/2007) (emphasis added).

210. Sales Representative 4 documented his sales call with a Cordova-based internist on July 5, 2007, as follows:

> Not much time with her. *Tried to get into discussion concerning opana and asked about food alcohol effect.* Said she was somewhat aware, but rep didn't make mention off[.][245]

211. Likewise, Sales Representative 14 made a sales call to a Millington-area family physician on July 12, 2007, and wrote the following about his interaction:

> *Talked to doc about the food effects on Oxycontin vs. the food effects on Opana. Stressed that food has no effect on Oxycontin while food has to be considered with Opana.* Doc agreed that compliance is a big issue and that a medicine that is not affected by food is easier to stay compliant with than one that it is. *I asked if he would keep this in mind when making decisions on which LA agent to choose. He agreed.*I also made him aware of the recent formulary win with Tricare. He said that was good news b/c he sees a lot of Tricare patients. Also, reminded him about the coupon cards. He said that he had been using them and hadn't heard from anyone that the cards didn't work.[246]

212. Sales Representative 4 documented his sales call with a Jackson-based family doctor on July 12, 2007, as follows:

> *Discussion on opana and PI awareness. oxycontin pi review/indications and safety section.* Said she waited on opana and has tried it a few times. Said that patients haven't called or been back to see if they are doing any better[.][247]

213. Substantially similar claims were made by: Sales Representative 4 to a Knoxville-based pharmacist on July 13, 2007,[248] a Cordova-area internist on July 16, 2007,[249] a Memphis-area anesthesiologist on July 19, 2007,[250] and a Jackson-area family doctor on July 24, 2007;[251]

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[245] PTN000119294 ID14164 (7/5/2007) (emphasis added).
[246] PTN000119294 ID14394 (7/12/2007) (emphasis added).
[247] PTN000119294 ID14370 (7/12/2007) (emphasis added).
[248] PTN000119294 ID14418 (7/13/2007).
[249] PTN000119294 ID14439 (7/16/2007).
[250] PTN000119294 ID14612 (7/19/2007).
[251] PTN000119294 ID14745 (7/24/2007).

Sales Representative 11 to a Hermitage-area physical medicine and rehabilitative doctor on July 24, 2007;[252] Sales Representative 14 to a Millington-area family doctor on July 25, 2007;[253] Sales Representative 11 to a Lebanon-based physical medicine and rehabilitation specialist on July 27, 2007;[254] Sales Representative 4 to a Germantown-area internist on July 30, 2007;[255] Sales Representative 2 to a Knoxville-based nurse practitioner on August 6, 2007;[256] Sales Representative 11 to a Franklin-based anesthesiologist on August 10, 2007;[257] Sales Representative 14 to a Millington-area family doctor on September 18, 2007;[258] Sales Representative 11 to an Antioch-based internist on October 19, 2007;[259] Sales Representative 5 to a Hendersonville-area internist on October 23, 2007;[260] Sales Representative 11 to an Antioch-based physician assistant on October 26, 2007;[261] Sales Representative 4 to a Memphis-area internist on December 7, 2007;[262] Sales Representative 11 to a Murfreesboro-area oncologist on July 21, 2008;[263] Sales Representative 2 to a Newport-area internist on November 10, 2008;[264] Sales Representative 7 to a Knoxville-area family doctor on November 13, 2008[265] and a Johnson City-based anesthesiologist on December 3, 2009.[266]

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[252] PTN000119294 ID14718 (7/24/2007).
[253] PTN000119294 ID14788 (7/25/2007).
[254] PTN000119294 ID14896 (7/27/2007).
[255] PTN000119294 ID14927 (7/30/2007).
[256] PTN000119294 ID15177 (8/6/2007).
[257] PTN000119294 ID15362 (8/10/2007).
[258] PTN000119294 ID16557 (9/18/2007).
[259] PTN000119294 ID17553 (10/19/2007).
[260] PTN000119294 ID17688 (10/23/2007).
[261] PTN000119294 ID17841 (10/26/2007).
[262] PTN000119294 ID19278 (12/7/2007).
[263] PTN000119294 ID15843 (8/27/2007).
[264] PTN000119294 ID31409 (11/10/2008).
[265] PTN000119294 ID31565 (11/13/2008).
[266] PTN000119294 ID45510 (12/3/2008).

OxyContin v. Duragesic

214. In its marketing in Tennessee, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to Duragesic, the brand name for an extended release fentanyl skin patch, when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

215. While not an exhaustive list, illustrative examples of call notes in which Purdue's Tennessee sales representative compared OxyContin and Duragesic are set forth below.

216. On June 7, 2007, Sales Representative 11 called on a Franklin-area family physician and recorded his interaction as follows:

> looked through my sample box, and he wanted to discuss laxative. and the slow mag. and colace. *only was able to discuss duragesic vs oxycontin.* said he uses duragesic if pt has a hard time remembering to take med or likes the patch. *showed aps oral route prefered because of convenience, flexability, and steady blood level.* Agreed[.][267]

217. Sales Representative 11 called on a Murfreesboro-area anesthesiologist on June 12, 2007, and recorded his interaction as follows:

> saw in surgery center. *he was going out did get in a good discussion of duragesic . he had a question about the patch. after he agreed with the aps oral is the better route.*[268]

218. Likewise, Sales Representative 4 documented his sales call with a McKenzie-based family physician on June 26, 2007, as follows:

> Closing down for a half day today. said that he is starting to see some issues with patients being able to or not getting their oxycontin. Starting to pay attention to what they are getting substituted with and in the past has resorted to going to fentanyl. *Explained the occurrence of lag time with*

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[267] PTN000119294 ID13346 (6/7/2007) (emphasis added).
[268] PTN000119294 ID13510 (6/12/2007) (emphasis added).

> *fentanyl and ease or oral dosing from APS and encouraging use of oxycontin more often*[.][269]

219. Sales Representative 4 documented his sales call with a Memphis-based internist on July 5, 2007, as follows:

> Said that he uses duragesic when the patient asks for it or if oxycontin doesn't work. *Explained to him the importance of recommending what is best even when the patient request something else. Convenience of oral dosing vs. fentanyl/Lag time and adhesion in the summer problems and disadvantage*[.][270]

220. Likewise, Sales Representative 11 made a sales call concerning OxyContin to a Smyrna-area physical medicine specialist on September 4, 2007, and wrote the following about his interaction:

> *discussed moprhine and duragesic and oxycontin.*she said she uses morphine for pts that have to get because of insurance and she has been using less duragesic. said pts dont like taking a patch vs oral. i said that is *what the aps says that oral is the best route becuase of convenience , steady blood levels, and easy to titrate.* she agreed[.][271]

221. Sales Representative 14 documented his sales call with a Memphis-based family physician on October 31, 2007, as follows:

> Continued discussion on doc's preference for Duragesic. *I gave doc a copy of the APS guidelines for treating acute and cancer pain and stated that the guidelines speak to the oral route of administration being the preferred route when effective and available.* He agreed to review the guidelines.I also reminded him about the coupon cards. He thanked me for the reminder and said he would try to remember to use the cards.[272]

222. Sales Representative 11 documented his sales call with a Hermitage-based nurse practitioner on November 28, 2007, as follows:

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[269] PTN000119294 ID13996 (6/26/2007) (emphasis added).
[270] PTN000119294 ID14161 (7/5/2007) (emphasis added).
[271] PTN000119294 ID16086 (9/4/2007) (emphasis added).
[272] PTN000119294 ID17993 (10/31/2007) (emphasis added).

> had a discussion of the substance data base . *discussed comparisons to duragesic morphine and oxcontin.* she said she is using more oxycontin lately. she does have more side effects with morphine, and pts seem to not like the patch compared to oral. *i mentioned that oral is the preferred route because of convenience*[.][273]

223. On February 11, 2008, Sales Representative 5 called on a Hendersonville-area family physician and recorded his interaction as follows:

> doc feels duragesic is a safer opioid than oxycontin. *told him it would not be C11 if it were safer.*[274]

224. In a July 31, 2008 sales call, Sales Representative 4 recorded the following discussion with a general practitioner in Erwin, which is excerpted below:

> [I]asked about duragesic. Hesaid low rate of constipation and easy for elderly patients to use. Also said long acting. I said I understood, *but duragesic has a 3day titration period vs 1 and with oxycontin there is no patch to abuse.*[275]

225. Sales Representative 5 made a sales call to a Nashville-area internist on June 16, 2008, and wrote the following about his interaction:

> doc said he likes duragesic because he feels it is safer. *told him it holds C-II scheduling. all opioids in that category have same potential for abuse and diversion.* told him patient selection is very important.[276]

226. On July 31, 2008, Sales Representative 7 documented the following discussion with a general practitioner based in Erwin as follows:

> Is the medical director for 5 nursing homes and 2 hospices. Suggested that I talk to the hospice administration in Stoney Creek. Said that he tries not to write for chronic pain in his practice but uses more in hospice or nursing home setting. *Iasked about duragesic.* Hesaid low rate of constipation and easy for elderly patients to use. Also said long acting. *I said I understood,*

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[273] PTN000119294 ID18893 (11/28/2007) (emphasis added).
[274] PTN000119294 ID21191 (2/11/2008) (emphasis added).
[275] PTN000119294 ID27254 (7/31/2008) (emphasis added).
[276] PTN000119294 ID25639 (6/16/2008) (emphasis added).

> *but duragesic has a 3day titration period vs 1 and with oxycontin there is no patch to abuse.*[277]

227. Likewise, Sales Representative 11 made a sales call to a Hendersonville-area pain medicine specialist, an anesthesiologist, and a nurse practitioner on August 28, 2008, and wrote the following about his interaction with each:

> *today in clinic my objective was to discuss duragesic and oxycontin.* each said they use duragesic for those pts that need a patch instead of a pill . did discuss the pts that would be in practice . they said between 20 to 30 percent. *i said well than well for the other 70 to 80 percent use oxycontin because of the convenience of many mg options and the best delivery system.* they said they have been using more oxycontin with good results. did close on the 15mg pt. [Providers] both said they used this week closed on senokot and Colace[.][278]

228. Substantially similar claims were made by: Sales Representative 11 to a Shelbyville-area family doctor on May 14, 2007;[279] Sales Representative 4 to a Germantown-area nurse practitioner on August 15, 2007;[280] Sales Representative 14 to a Bartlett-based internist on October 31, 2007[281] and a Memphis-area internist on December 14, 2007;[282] Sales Representative 7 to an Erwin-based family doctor on January 27, 2009.[283]

OxyContin v. Methadone

229. In its marketing in Tennessee, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to methadone, another Schedule II extended release

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[277] PTN000119294 ID27254 (7/31/2008) (emphasis added).
[278] PTN000119294 ID28393 (8/28/2008) (emphasis added).
[279] PTN000119294 ID12540 (5/14/2007) ("discussed duragesic vs oxycontin. Agreed the benefit of oral is better . said I do use oxxycontin . easier to titrate, convenience and better blood levels per aps[.]").
[280] PTN000119294 ID15515 (8/15/2007).
[281] PTN000119294 ID18005 (10/31/2007).
[282] PTN000119294 ID19519 (12/14/2007).
[283] PTN000119294 ID33465 (1/27/2009).

opioid used primarily for opioid addiction treatment, but also prescribed to treat pain, when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

230. While not an exhaustive list, illustrative examples of call notes in which Purdue's Tennessee sales representative compared OxyContin and methadone are set forth below.

231. Sales Representative 5 documented his sales call with a Gallatin-based family doctor on May 11, 2007, as follows:

> *discussed benefits of oxycontin as opposed to methadone.* long half-life of drug with frequent dosing poses a problem for some patients. doc said good points were made.[284]

232. Sales Representative 4 documented his sales calls with a Memphis-based pain doctor on May 11, 2007, as follows:

> *Asked about the advantages of oxycontin vs. methadone. Discussed steady state achieved quicker, less metabolism time, cleaner side effect profile, and ease of use for the patient.* Reviewed oxycontin safety profile from PI[.][285]

233. On July 24, 2007, Sales Representative 11 called on an Hermitage-area physical medicine and rehabilitative doctor and recorded his interaction as follows:

> *had a discussion of methodone, morphine, opana, and oxycontin.* said he does still think oxycontin is the best tolerated and the one that works great. said to start to use as his opioid of choice. said he will now that he knows that oxycontin has better insurance covereage[.][286]

234. On August 2, 2007, Sales Representative 4 called on a Memphis-area anesthesiologist and recorded his interaction as follows:

> Reviewed preventing abuse guide *and equivalent chances of abuse with both oxycontin and methadone.* Said he just likes methadone and it is guranteed to work in his opinion and often better than oxycontin[.][287]

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[284] PTN000119294 ID12429 (5/11/2007) (emphasis added).
[285] PTN000119294 ID12432 (5/11/2007) (emphasis added).
[286] PTN000119294 ID14718 (7/24/2007) (emphasis added).
[287] PTN000119294 ID15120 (8/2/2007) (emphasis added).

235. Sales Representative 4 documented his sales call with a Memphis-based pain medicine doctor on August 29, 2007, as follows:

> Inquired about the difference and benefits of oxycontin vs. methadone. *Just discussed the fact of the black box warning with methadone and the disadvantage of long half life and tapering a patient off of methadone vs. safety of oxycontin*[.][288]

OxyContin v. Avinza

236. In its marketing in Tennessee, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to Avinza, the brand name for an extended release morphine sulfate drug that was discontinued in 2015, when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

237. While not an exhaustive list, illustrative examples of call notes in which Purdue's Tennessee sales representatives compared OxyContin to Avinza are set forth below.

238. On May 31, 2007, Sales Representative 4 called on a general practitioner based in McKenzie and recorded the following:

> Senokot sampling and recommendation. *Review/compare of Avinza to oxycontin* and better formulary access of oxycontin. Said he has a lot of United Healthcare. Pointed out to him tier status and copays and using the savings cards[.][289]

239. For his next call objective, Sales Representative 4 wrote, "Continue with cost savings message and PI comparisons of oxycontin/avinza."[290]

240. Sales Representative 11 documented his sales call with a Lebanon-based physical medicine and rehab specialist on July 27, 2007, as follows:

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[288] PTN000119294 ID15962 (8/29/2007) (emphasis added).
[289] PTN000119294 ID13073 (5/31/2007) (emphasis added).
[290] *Id.*

> asked about case again. discussed per email. asked about opana. *discussed food and alcohol affect.* said rep said that alcohol does not affect delivery system, and showed a study. he then looked up in package insert and looked at the black box warning for himself. then he asked about avinza and *i said they too have the same black box warning. did discuss avinza, va patch, vs oxycontin.* did say he does think oxycontin is very well tolerated and when he uses does very well. did review formulary grid and changes discusssed savings cards too. said he will daw and start to use the cards[.][291]

241. On August 27, 2007, Sales Representative 11 called on a Murfreesboro-area oncologist and recorded his interaction as follows:

> *discussed avinza, vs opana vs oxycontin. discussed the alcohol and food affect with avinza and opana's delivery system.* he did not know about that info. discussed generic situation daw and savings cards. he said he will daw and use the cards. discussed formulary changes too. ie aetna, and Tricare[.][292]

242. Likewise, following a September 7, 2007 call on a Lebanon-based physical medicine and rehabilitation specialist and his nurse practitioner, Sales Representative 11 recorded the following:

> discussed savings cards with [Provider] and his [Nurse Practitioner]. *went over comparisons to avinza, opana, and methadone.* both said the felt oxycontin was the best of all the opioids, and have been using first if insurance covers. asked both to start to daw and use savings cards where approprate.[293]

243. Sales Representative 4 called on a Memphis-based addiction specialist on September 26, 2007, and recorded his interaction as follows:

> *Asked me about the Action study comparing avinza to oxycontin. Said that the study is flawed and doesn't cover a good patient population and variety to make an even comparison to oxycontin. Said the study is garbage.*

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[291] PTN000119294 ID14896 (7/27/2007) (emphasis added).
[292] PTN000119294 ID15843 (8/27/2007) (emphasis added).
[293] PTN000119294, ID16234–35 (9/7/2007) (emphasis added).

> Reminded him again of areas he can write oxycontin such as part d plans for Cigna, Human, Healthspring in his practice[.][294]

244. On June 19, 2008, Sales Representative 11 called on a Hermitage-based family physician and recorded the following:

> *discussed avinza, and opana because doc asked about if it was true concerning the black box of the alcohol warning.* said he will use kadian and oxycontin. said he is using more oxycontin lately and pts doing great on controling the pain and being well tolerated. did go over the pt info sheet on oxycontin and the generics going away. closed with the 15mg pts that would have pain per pi and be on 40mg of hydrocodone. said he is using that way[.][295]

245. On July 17, 2008, Sales Representative 7 called on a family physician in Johnson City and recorded the following:

> Gave patient savings cards and explained how they work and the benefits they can provide certain patient populations. *Also discussed abuse and diversion with oxycontin vs kadian and avinza. Stated that he knows the same abuse is there and there is no way to stop it completely.* Reminded of new strengths.[296]

246. Likewise, on a July 24, 2008 sales call with a Kingsport physician assistant, Sales Representative 7 recorded his interaction as follows:

> Said that their corporation will not allow him to write oxycontin. Talked to him for awhile and finally asked what he does write. *He said morphine, opana, kadian and avinza or whatever. Went over all of them and he finally agreed that oxycontin is a more flexible and convenient opioid.* This practice is owned by a physician out of Franklin, TN ....[297]

247. Sales Representative 11 called on a pain doctor in Nashville on August 6, 2008, and recorded the following:

> was able to sit down with [Provider] a and go thru the pain managment resouce guide. liked several and said how do i order. i went thru the ordering

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[294] PTN000119294 ID16916 (9/26/2007) (emphasis added).
[295] PTN000119294 ID25743 (6/19/2008) (emphasis added).
[296] PTN000119294 ID26681 (7/17/2008) (emphasis added).
[297] PTN000119294 ID26934 (7/24/2008) (emphasis added).

process. did discuss the tn board guidelines. did not see before. discussed all the steps and the pt consent form. did go over the new doses and benefit to pt and doc. he said they will now be doing medical managment for pts. did say he has several on oxycontin, but did say some pts he would not put on oxycontin. did not elaborate or answer my question. he did bring up our old palladone and *said he did not like to use medications that alcohol affects the delivery system. then i said well then avinza and opana have similar black box warnings.* he did not know this. he then got paged and asked if i could set up a follow up meeting. did say he was going to the scotland meeting. i said we will be there supporting[.][298]

Comparative Claims: OxyContin v. Immediate Release Opioids

248. In its marketing in Tennessee, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to immediate release, also known as short-acting, opioids when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

249. Substantiation aside, comparing OxyContin to immediate release opioids made financial sense. As of 2008, 93.4% of switches to oxycodone extended release from other products came from immediate release opioids.[299] Purdue closely tracked and monitored those providers in Tennessee who were most likely to switch a patient from an immediate release opioid to an extended release opioid.[300]

250. At a national sales meeting attended by Tennessee sales representatives, Purdue trained its sales staff to ask the following question of a provider:

Positioning:

- "Doctor, do you realize (or are you aware) that initiating 10 mg q12h of OxyContin is comparable to initiating a 5 mg hydrocodone/oxycodone q4-6h after trying tramadol, *while also giving the patient all the benefits of less frequent dosing and providing a single entity opioid*?

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[298] PTN000119294 ID27453 (8/6/2008) (emphasis added).
[299] PWG000109609.
[300] *See, e.g.*, PTN000108184.

- You will be providing a more convenient q12h dosing regimen. Doctor since these are established opioid patients with persistent ATC moderate to severe pain doesn't this make sense?[301]

251. While not an exhaustive list, illustrative examples of call notes in which Purdue's Tennessee sales representatives compared OxyContin and immediate release opioids are set forth below.

252. Sales Representative 4 documented his sales call with a Memphis-based family doctor on June 6, 2007, as follows:

> Said she has had much chronic pain come through outside of the patients she already has on oxycontin. Reviewed oxycontin indications and PI with her again and *pointed out patients with back pain that are maxing out on their short acting or NSAID that they may be on as targets*[.][302]

253. Likewise, Sales Representative 11 made a sales call to a Nashville-area rheumatologist on October 18, 2007, and wrote the following about his interaction:

> discussed elderly and pain per oxycontin pi. said he is concerned with falls of the elderly. *discussed advantages of long acting over short acting.* showed pi and the elderly data. said he liked the info and said he should use more oxycontinn for his pts with oa ra. he did get the oa ra aps book. sealed. he did say oxycontin has its bad publicity. i said look at the science of the drug for legitamat pts. he said your right.[303]

254. On November 14, 2007, Sales Representative 14 documented his sales call with a Covington-based family doctor as follows:

> Discussed appropriate patient types for 10mg Oxycontin dose. Asked doc specifically if he sees any diabetic peripheral neuropathy, severe OA, or post herpetic nearalgia. He said he does. *I followed up from last call and stressed the advantages of Oxycontin over SA combos for appropriate patients with these ailments whose pain is in line with the Oxycontin indication.* He said he would keep it in mind. Followed on TN prescription monitoring database and he said that the state had started promoting the

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[301] PWG000109659 (emphasis added).
[302] PTN000119294 ID13313 (6/6/2007) (emphasis added).
[303] PTN000119294 ID17522 (10/18/2007) (emphasis added).

database. He said he is using it. Reminder for coupon cards and informed him about extension. Thanked me for update.[304]

255. Likewise, Sales Representative 14 made a sales call to a Brighton-area family doctor on April 21, 2008, and wrote the following about his interaction:

> *Discussed the advantages of converting appropriate chronic pain patients from SA combos to Oxycontin.* Shared visual from conversion guide. *Doc agreed in the significant different in the number of pills b/t SA combos and Oxycontin in some cases. Asked him to keep this in mind when he sees patients back that have continually been getting refills on the SA medicine.* He agreed. Reminded him about the coupon cards. He said that he had given a coupon card out today. Thanked him for making the effort and asked that he continue. He agreed.[305]

256. Sales Representative 11 made a sales call to a Lebanon-area nurse practitioner on June 21, 2008, and wrote the following about his interaction:

> *discussed adv of long acting vs short acting.* she made comment of switching 2 patients that were taking too much lortab/apap. *i then asked if she does see alot of elderly.* she said yes. asked about oa ra pts. she said many. discussed those pts taking a few lortab and not functioning . said she would start low dose 10mg or 15mg for those pts . she remembered our last call on conversions. she said yes the coversion multiplier is .9. discussed coverage for those medicare part d pts. liked coverage and said she would use oxycontin for those oa ra pts and pts taking too much lortab/apap.[306]

257. On November 24, 2008, Sales Representative 5 called on a Nashville-area practice group and recorded his interaction as follows:

> discussed barry cole's ten tips to prescribing opioids. residents felt all points were pertinent to what they are doing. they said short acting meds are used , first, for patients in clinic. switch to long acting, like oxycontin, when in pain clinic. *I mentioned peaks and troughs of short acting meds could pose a challenge for patients with persistent pain.* appreciated package insert.[307]

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[304] PTN000119294 ID18454 (11/14/2007) (emphasis added).
[305] PTN000119294 ID23745 (4/21/2008) (emphasis added).
[306] PTN000119294 ID26748 (7/21/2008) (emphasis added).
[307] PTN000119294 ID31905 (11/24/2008) (emphasis added).

258. On December 9, 2008, Sales Representative 14 called on a Covington-area physician assistant and recorded his interaction as follows:

> Followed up on appropriate patients for the lower doses of Oxycontin. [Provider] said that she isn't taking any new pain patients, but has no problem treating pain in her current patient population. *She agreed that low dose oxycontin makes more sense than SA combos for appropriate patients suffering from chronic pain.* She added that she believes tolerance many times results when chasing the pain with a SA combo. I *asked if she would keep this in mind and initiate therapy with the 10mg q12H dose instead of first going to a SA combo atc for appropriate patients with pain indicative of oxycontin's indication.* She agreed[.][308]

259. On January 29, 2009, Sales Representative 7 called on a Johnson City-area family doctor and recorded his interaction as follows:

> *Went over converting to long acting at an earlier time. Presented patients on 7.5 short acting taking 3 times /day. converting to oxycontin. No apap, leaving meds at home, etc.* I think he liked it, but we will see. Reminded of snokot-s for med induced constipation.[309]

260. Sales Representative 7 documented his sales call with a Johnson City-based neurologist on January 30, 2009, as follows:

> ... *Went over lowdose conversion comparisons from short acting combos to q12h oxycontin. He agreed that it is best to have the patient take fewer doses and eliminate the apap as well*[.][310]

261. Sales Representative 18 documented his sales call with a Knoxville-based internist on April 12, 2011, as follows:

> *reminded him of our previous conversations of the peaks and valleys he stated that happen with short actings and for the patients with chronic pain.* He stated that he has not used Butrans yet. He stated that he will he

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[308] PTN000119294 ID32317 (12/9/2008) (emphasis added).
[309] PTN000119294 ID33548 (1/29/2009) (emphasis added).
[310] PTN000119294 ID33599 (1/30/2009) (emphasis added).

just gets b usy and tends to forget. I asked if I need to come in more often and he chuckled.[311]

262. On April 21, 2011, Sales Representative 18 called on a Knoxville-area internist and recorded his interaction as follows:

> *Reminded him of the peaks and valleys he discussed with the sa.* He stated that he remembered our conversation and stated that he will use Butrans. I asked when. He stated he will and told me to be patient. I stated I bet he will see a patients that will fit Butrans and he stated probabley I asked for that patient.[312]

263. Likewise, on July 2, 2014, Sales Representative 6 called on a Knoxville-based physician assistant and documented his call as follows:

> *[Q]uick reminder of OxyContin as an option for appropriate pts on 3-4 doses of a short-acting oxycodone. We talked about the opportunity to use the 10/15 mg doses that will maintain pts well under the morphine equivalency level.*[313]

264. Substantially similar claims were made by: Sales Representative 14 to a Covington-area family doctor on November 26, 2007;[314] and Sales Representative 6 to a Knoxville-area family doctor on June 18, 2014,[315] a Knoxville-based nurse practitioner on June 23, 2014,[316] and a Knoxville-area internist on June 30, 2014.[317]

OxyContin v. Dilaudid

265. In its marketing in Tennessee, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to Dilaudid, the brand name of an immediate

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[311] PTN000119294 ID72356 (4/12/2011) (emphasis added).
[312] PTN000119294 ID72985 (4/21/2011) (emphasis added).
[313] PTN000119294 ID166132 (7/2/2014) (emphasis added).
[314] PTN000119294 ID18775 (11/26/2007).
[315] PTN000119294 ID165173 (6/18/2014).
[316] PTN000119294 ID165541 (6/23/2014).
[317] PTN000119294 ID165972 (6/30/2014).

release opioid consisting of hydromorphone that is manufactured by Purdue among others and which has been on the market since 1984, when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

266. Substantiation aside, comparing OxyContin to an immediate release opioid Purdue also owned made financial sense because it encouraged the use of more expensive opioid products that would have to be taken over a longer time period.

267. While not exhaustive, an illustrative example of a call note in which Purdue's Tennessee sales representative compared OxyContin and Dilaudid is set forth below.

268. Sales Representative 14 documented his sales call with a Memphis-based physical medicine and rehabilitation doctor on August 23, 2007, as follows:

> *Talked to doc today about the advantages of Oxycontin over SA meds like Dilaudid for appropriate patients.* Walked doc through conversions from Dilaudid per the conversion guide. Doc nodded in agreement[.][318]

OxyContin v. Hydrocodone

269. In its marketing in Tennessee, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to immediate release hydrocodone when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

270. While not an exhaustive list, illustrative examples of call notes in which Purdue's Tennessee sales representative compared OxyContin and hydrocodone are set forth below.

271. Sales Representative 2 documented his sales call about OxyContin with a Knoxville-based general practitioner on June 6, 2007, as follows:

> *Discussed feature of q12 and benefit over hydrococone* pt who has a pain crisis while sleeping[.][319]

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[318] PTN000119294 ID15773 (8/23/2007) (emphasis added).
[319] PTN000119294 ID13276 (6/6/2007) (emphasis added).

272. Sales Representative 4 documented his sales call with a Savannah-based family physician on June 8, 2007, as follows:

> On his way out for the day. Reviewed titration and conversion principles with him and *switching patients earlier to oxycontin once they have maxed out on hydrocodone*[.][320]

273. Sales Representative 5 documented his sales call with a Nashville-based physical medicine and rehabilitative doctor on December 19, 2007, as follows:

> doc asked about conversion of hydrocodone to oxycontin. *agreed some patients can have a better quality of life by taking something q12h as opposed to q4-6h*[.][321]

274. On October 20, 2008, Sales Representative 19 called on a Lexington-area physician assistant and recorded her interaction as follows:

> She said she just had a patient she saw of [Another Provider] on Oxycontin 30mg today. She told me she is new to treating chronic pain. She was not aware of the 15mg or the 60mg of the new strengths so I told her about them. She asked me when she would prescribe hydrocodone vs another agent. I reminded her of Oxycontin's indication. I showed her the page in the sales aid that shows a patient taking 240 tabs of hydrocodone vs. 60 of Oxycontin 15mg q12h. *I reinforced Oxycontin's convenience of fewer tablets than immediate release for the patients with q12h dosing.* She said she would prescribe the 15mg for the elderly, osteoarthritic patients. She said she has not had enough opportunity yet to prescribe long acting agents. I also talked to her about the savings cards for Oxycontin. She told me she would try to use them. I left Colace samples and asked her to recommend OTCs for constipation.[322]

275. Sales Representative 19 documented her sales call with a Germantown-based pain management specialist on February 23, 2009, as follows:

> Doctor said he has pts taking hydrocodone q4-6h that could benefit from Oxycontin's q12h dosing and the possible convenience of fewer tablets.

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[320] PTN000119294 ID13398 (6/8/2007) (emphasis added).
[321] PTN000119294 ID19637 (12/19/2007) (emphasis added).
[322] PTN000119294 ID30499 (10/20/2008) (emphasis added).

> Said that these pts meet the indication of having moderate to severe pain and who require ATC analgesic. *Said he has pts taking hydrocodone 5mg q6h that are appropriate for conversions to Oxycontin 10mgq12h when their pain becomes persistent instead of titrating them to hydrocodone 7.5mg tablets. Reminded him of the intermediate strengths* and he said he will prescribe them when appropriate. Savings cards reminder and preferred formulary status for Oxycontin. Transitioned to medicine induced constipation and asked him to recommend Senokot S. Also discussed Colace for straining due to constipation from postoperative conditions.[323]

276. Likewise, Sales Representative 19 made a sales call concerning OxyContin to a Decaturville-area general practitioner on March 30, 2009, and wrote the following about her interaction:

> *Asked doctor when pts are taking hydrocodone 5mgq4-6h and their pain becomes persistent if he will convert appropriate pts to Oxycontin 10mgq12h instead of titrating hydrocodone to 7.5mg and 10mg tablets.* Said he will convert pts sooner to Oxycontin 10mgq12h when they meet the indication. Said many of his pts are taking higher doses of hydrocodone so the conversions to Oxycontin are usually higher than Oxycontin 10mgq12h. Savings cards reminder. Said cards are beneficial for third party pts. Transitioned to medicine induced constipation and asked him to recommend Senokot S. Also asked him to recommend Senokot for occasional constipation. Said many of his pts suffer from both and will recommend to his pts.[324]

277. Sales Representative 11 documented his sales call with four providers from a Lebanon-based physical medicine and rehabilitation practice group on July 9, 2009, as follows:

> talked to [practice group]. only [one of the providers] has used ryzollt and has had used on two pts with good results. everyone else said they forgot about ryzolt. did get committments to use ryzolt. did go over 321, positioning of ryzolt, dual matrix, and formulary changes. *did close on the oxycontin savings cards with each clinician and ask for new pts with the oxycontin 15mg in pts needing more than 40mg of hydrocodone* and pt has pain per oxycontin pi with atc chronic mod to severe pain.[325]

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[323] PTN000119294 ID34399 (2/23/2009) (emphasis added).
[324] PTN000119294 ID35605 (3/30/2009) (emphasis added).
[325] PTN000119294 ID39502–06 (7/9/2009) (emphasis added).

278. On July 9, 2009, Sales Representative 11 called on a Lebanon-area nurse practitioner and recorded his interaction as follows:

> second call on ryzolt. she said she will use ryzolt and liked our positioning of ryzolt , and *for oxycontin discussed pts on 40mg of hydrocodone* taking atc for pain per oxycontin pi.[326]

279. Likewise, Sales Representative 11 made a sales call concerning OxyContin to a Lebanon-area family physician on August 25, 2009, and wrote the following about his interaction:

> ... *did discuss those pts on 40mg of hydrocodone that are taking atc for a persistent problem.* to convert per oxycntin pi to oxycontin 15mg q12. closed with laxatives[.][327]

280. Sales Representative 11 documented his sales call with 4 providers from a Lebanon-based physical medicine and rehabilitation practice group on September 24, 2009, as follows:

> so far in this clinic 2 of the 5 clinicians have tryed ryzolt. [The] PA, and [the] NP. [NP] said he has not seen the pt back yet. [PA] said his was a pt that ryzolt was not covered. did go over ryzolt detail piece with all and discussed dual matrix, 231, formulary status.all said they would trail ryzolt. gave and discussed oxycontin conversion and titration guide. *asked for new pts that are on 40mg of hydrocodone taking atc* and pain per oxycontin pi to use oxycontin 15mg q12. closed with laxatives[.][328]

OxyContin v. Products Containing Acetaminophen

281. In its marketing in Tennessee, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to other pain-relieving products containing acetaminophen when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

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[326] PTN000119294 ID39507 (7/9/2009) (emphasis added).
[327] PTN000119294 ID41218 (8/25/2009) (emphasis added).
[328] PTN000119294 ID42679 (9/24/2009) (emphasis added).

282. Despite not having head-to-head studies comparing the safety of its opioid products with those containing acetaminophen, Purdue emphasized the dangers of excessive levels of acetaminophen in the context of promoting its opioid products despite repeatedly recognizing that such claims were unsubstantiated comparative claims.

283. Purdue admitted in its Guidelines on Product Promotion that referring to OxyContin's "No Defined Maximum Dose" or "Single Entity Opioid Status" "could imply superiority of OxyContin® to non opioid/opioid combination products"[329] despite having a marketing piece titled "OxyContin Single-Entity Opioid Flashcard," which was created "[t]o help communicate to prescribers that OxyContin® is a single-entity opioid that does not contain acetaminophen, aspirin, or ibuprofen[.]"[330]

284. Similarly, on July 20, 2009, Purdue's Product Manager sent a bulletin to the company's entire sales force that stated among other things: "You must also remember never to discuss the maximum daily doses of APAP [acetaminophen] or ASA [aspirin] as this may lead to claims of implied superiority."[331] Elsewhere Purdue's 2013 Guidelines on Product Promotion stated, "Any discussion or reference to dosing limitations of another agent may lead to a claim of implied superiority."[332]

285. In its 2013 Guidelines on Product Promotion, Purdue specifically listed unsubstantiated superiority claims as including:

> Asking the HCP if they could think of 1-2 Percocet® around-the-clock patients who could benefit from no acetaminophen.
>
> Stating to an HCP that they should start a patient on Butrans® or OxyContin® when they want to get patients off of acetaminophen.

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[329] PVT0058322.
[330] PWG000099907.
[331] PTN000032056.
[332] PWG000008057.

> Discussing the benefits of no acetaminophen and q12h dosing with OxyContin® or 7 day dosing with Butrans®.[333]

286. Yet, Purdue's marketing materials widely disseminated these same unsubstantiated claims in Tennessee.

287. Purdue created and/or distributed several written materials to warn providers and managed care companies about the dangers of too much acetaminophen. These included the following Purdue documents (identified by Purdue's coding): OMC103, PAP058, A5530R, PO400, and PAP005.[334]

288. One of these unbranded marketing pieces distributed by Purdue, titled "Maximum Recommended Daily Doses of Opioid Analgesics Containing APAP (acetaminophen) or ASA (aspirin)," listed the maximum dosage of competing opioid products[335] and was often used by Purdue sales representatives to emphasize, directly and implicitly, that OxyContin had no maximum dosage.

289. On websites that it controlled, Purdue linked to materials that misrepresented the potential dangers between both non-opioid and opioid products containing acetaminophen and opioid products like OxyContin that do not contain acetaminophen. For example, on Purdue's *In the Face of Pain* website, it linked to the APF guide for veterans, *Exit Wounds*, which misrepresented these potential dangers.

290. *Exit Wounds* stated in relevant part:

> [A]ceteminophen can relieve mild to moderate pain and treat fever; but it is *not* an NSAID and will not reduce swelling. It produces few, if any, side

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[333] PWG000008059.
[334] PWG000325822; PWG000089678; *see also*, PWG000325457 (Mgd Care Tab showing OMC103 approved 1/14/2008); PWG000320843 (spreadsheet showing cease distribution attached to e-mail dated May 13, 2009).
[335] PWG000089678.

effects at the doses that can relieve pain, **but it can damage the liver when used in large doses, especially if used with alcohol.**

....

[A]cetaminophen is often combined with an opioid medication—usually, in the same pill or capsule—to treat moderate to severe pain. Be sure to check the amount with your doctor or pharmacist. Don't decide on your own to take extra acetaminophen if a combination pain medicine is not controlling your pain, because you could end up using too much acetaminophen, and that could cause liver damage. **Currently, there is concern in the medical community about the growing rate of liver damage associated with large doses of acetaminophen.**

....

Possible side effects of acetaminophen include: Possible liver damage at high doses[;] – Liver damage and stomach bleeding if used in combination with alcohol[.]

....

The pain-relieving properties of opioids are unsurpassed; they are today considered the "gold standard" of pain medications, and so are often the main medications used in the treatment of chronic pain. Yet, despite their great benefits, opioids are often underused. For a number of reasons, healthcare providers may be afraid to take them. At the core of this wariness is the fear of addiction, so I want to tackle this issue head-on.

....

Opioid medications can, however, be abused or used as recreational drugs, and some people who use these drugs this way *will* become addicted. Addiction is a disease state in which people can no longer control their use of a drug that is causing harm. They continue to crave and use the drug despite the harm it may be causing to their health, their relationships, or their ability to function in other spheres of life.

....

Long experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid medications. When used correctly, opioid pain medications *increase* a person's level of functioning; conversely, when a drug is used by somebody who is addicted, his or her function *decreases*.[336]

291. Purdue's Tennessee sales representatives likewise made claims comparing OxyContin and other products containing acetaminophen. While not an exhaustive list, illustrative

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[336] PTN0000023114 (bold emphasis added, italicized emphasis in original).

examples of call notes in which Purdue's Tennessee sales representative compared OxyContin and products containing acetaminophen are set forth below.

292. Sales Representative 5 documented his sales call with a Nashville-based family physician on May 10, 2007, as follows:

> *doc agreed that many patients are taking too much apap and with oxycontin that would be one less concern.* wants to discuss titration on next visit.[337]

293. Sales Representative 5 documented his sales call with a Nashville-based orthopedic surgeon on September 10, 2007, as follows:

> *doc agreed that many patients are taking too much apap with prescription drugs and over the counter analgesics. one less concern with oxycontin.*[338]

294. Sales Representative 5 documented his sales call with a Portland-based internist on October 11, 2007, as follows:

> doc said too much acetaminophen is being consumed by OTC and prescription pain medication. *agreed that was one advantage of prescribing oxycontin.*[339]

295. Sales Representative 5 documented his sales call with a Nashville-based orthopedic surgeon on August 22, 2008, as follows:

> doc agreed that some postop pain could be severe for a few weeks. *said 15mg oxycontin could help some of those patients without the concern of receiving too much acetaminophen.* will consider.[340]

296. Likewise, Sales Representative 4 made a sales call to a Memphis-area internist on October 20, 2008, and wrote the following about his interaction:

> *Me and Dr. K discussedreducing pill burden and reducing APAP limits by going to long acting oxycontin sooner.* Said that he had a patient that was

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[337] PTN000119294 ID12383 (5/10/2007) (emphasis added).
[338] PTN000119294 ID16300 (9/10/2007) (emphasis added).
[339] PTN000119294 ID17262 (10/11/2007) (emphasis added).
[340] PTN000119294 ID28151 (8/22/2008) (emphasis added).

> taking vicodin/percocet q6h and wasn't seeing any results. Said at first he thought it was drug seeking because the patient was going throug them so fast. Said he moved the patient to 60mg of oxycontin and the patient was finallyseeing some pain control and stopped taking the both of the short actings[.][341]

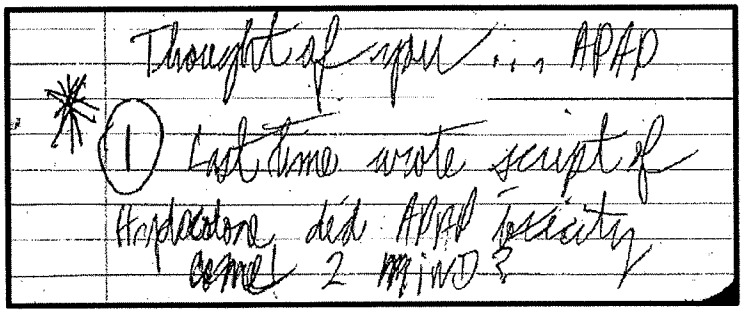
297. Likewise, Sales Representative 1 made a sales call to a Bolivar-area nurse practitioner on April 7, 2010, and wrote the following about her interaction:

> discussed oxycontin q12h dosing and fewer pills per day than SA meds. *also discussed seo for patients on maximum levels of apap.* discussed ryzolt positioning statement; coverage[.][342]

OxyContin v. Hydrocodone Combinations

298. As the name suggests, hydrocodone combinations are opioids containing hydrocodone and other active ingredients including acetaminophen, aspirin, or other compounds. In its marketing in Tennessee, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to hydrocodone combinations when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

299. Purdue instructed its Tennessee sales representatives to ask providers, "Last time [you] wrote [a] script of hydrocodone did APAP toxicity come [to] mind?"[343]



[341] PTN000119294 ID30536 (10/20/2008) (emphasis added).
[342] PTN000119294 ID51666 (4/7/2010) (emphasis added).
[343] PWG004285362.

300. While not an exhaustive list, illustrative examples of call notes in which Purdue's Tennessee sales representative compared OxyContin and hydrocodone combinations are set forth below.

301. On November 19, 2007, Sales Representative 4 called on a Memphis-area rheumatologist and recorded his interaction as follows:

> *Discussion of short acting hyrdocodone and dangers of maxing out the APAP.* review of safety in elderly from oxycontin PI[.][344]

302. Sales Representative 14 documented his sales call with a Brighton-based family medicine physician on April 21, 2008, as follows:

> Quick hit reminder on the benefits of the extended line and introduced the new conversion guide to him. *Asked him to keep patients continually getting refills on hydrocodone combos in mind as potentially being more effectively treated with Oxycontin. He said okay.* Remidner for coupon cards.[345]

303. Sales Representative 1 documented her sales call with a Savannah-based internist on May 3, 2010, as follows:

> asked her what an oxycontin new start would be like. she said a patient with severe pain whom she trusts and can prove legitimate pain. *asked her how many mg of hydrocodone she would be converting from.* she said they would be maxed out at 10mg 4x per day. showed her conversion to 15mg q12h. *discussed fewer tablets with oxycontin and treating without apap. asked was apap a concern for her. she said yes in some patients.* also showed her indication which includes moderate atc pain so not limited to just severe pain[.][346]

304. Likewise, Sales Representative 1 documented her sales call with a McKenzie-based internist on May 6, 2010, as follows:

> dr said he considers a patient to be chronic when they are taking 3 or more hydrocodone per month. *discussed q12h dosing and treating without apap.*

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[344] PTN000119294 ID18620 (11/19/2007) (emphasis added).
[345] PTN000119294 ID23746 (4/21/2008) (emphasis added).
[346] PTN000119294 ID52772 (5/3/2010) (emphasis added).

> *asked him if he would convert appropriate patients who are at that max number of pills who have chronic, atc pain.* showed conversion ratio and that patients taking 30mg or less will convert to 10mg q12h. dr said he had a new ryzolt start yesterday.[347]

305. On June 4, 2010, Sales Representative 1 called on a Jackson-area internist and recorded her interaction as follows:

> showed dr that 5 of his 6 top plans have oxycontin covered at 2T which means the lowest branded copay for patients and no pa for his staff. *asked him why would he treat a chronic pain patient with hydrocodone when patients can get oxycontin affordably and take fewer pills with no apap.* he said he didn't know coverage was so good. said he would look for appropriate conversions. discussed ryzolt coverage as well[.][348]

306. Sales Representative 1 called on a Jackson-area family physician on June 6, 2010, and recorded her interaction as follows:

> dr said he is currently starting oxycontin for low back, oa pain patients when they are maxed at 40mg hydrocodone or if he can tell that going from 7.5mg to 10mg isn't going to make much difference. dr said he really likes lower doses of oxycontin. *showed him 30mg and 40mg conversions. discussed fewer pills and no apap.* showed dr coverage and explained top 3 of 4 plans have oxycontin at lowest branded copay. discussed ryzolt for cigna patients.[349]

OxyContin v. Lortab or Vicodin

307. In its marketing in Tennessee, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to Lortab or Vicodin, two brand name examples of hydrocodone combination products, when those claims were false, deceptive, and/or unsubstantiated at the time they were made. While not an exhaustive list, illustrative examples of

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[347] PTN000119294 ID53021 (5/6/2010) (emphasis added).
[348] PTN000119294 ID54433 (6/4/2010) (emphasis added).
[349] PTN000119294 ID54617 (6/9/2010) (emphasis added).

call notes in which Purdue's Tennessee sales representative compared OxyContin to Lortab or Vicodin specifically are set forth below.

308. On May 8, 2007, Sales Representative 4 called on a Collierville-area internist and recorded his interaction as follows:

> *Asked him about how many patients have imprv.oed pain scores at least 4 points using lortab.* Said many perceive it is working because they are taking it more often. Doesn't hear much back from some patients and if he does its to request him to raise the dose. *Explained the benefit of better efficacy and less dosing of oxycontin.* Said he would give it a try again[.][350]

309. Sales Representative 11 called on an Antioch-based pain specialist on June 13, 2007, in which the sales representative recorded his interaction as follows:

> objective of day was to get them to go to long acting when approprate. *discusseed pts on high dose short acting ie 10mg lortab taking 4 to 5 a day. showed [American Pain Society Guidelines] on long acting. less end of dose pain and pts sleep better* . all did say that would be using a prn for a persistent pain problem. will start to review pts one at a time to see if long acting is a appropriate per oxycontin pi[.][351]

310. Sales Representative 14 documented his sales call with a Memphis-based internist on August 8, 2007, as follows:

> Discussed language from the PI that speaks to reasonable starting doses for opioid naiive patients. Also, walked doc through various conversions using the conversion guide. *Emphasized indication and the similarities in analgesia b/t Vicodin 5/500 q4-6H and Oxycontin 10mg q12H and asked doc to give strong consideration to Oxycontin over SA combos when the pain requires ATC therapy for a continuous, extended period of time.* Doc agreed.Also reminded doc about the coupon cards.[352]

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[350] PTN000119294 ID12300 (5/8/2007) (emphasis added).
[351] PTN000119294 ID13549 (6/13/2007) (emphasis added).
[352] PTN000119294 ID15249 (8/8/2007) (emphasis added)

311. Likewise, Sales Representative 11 made a sales call to a Brentwood-area anesthesiologist and his nurse practitioner on March 26, 2009, and wrote the following about his interaction:

> in office today *i talked about pts taking lortab or percocet 10mg with apap 500mg. discussed apap use over a year and they were concerned with that much apap over a year. discussed pts to then titrate per indication over to oxycontin q 12*[.][353]

312. Sales Representative 4 documented his sales call with a Memphis-based family doctor on January 15, 2010, as follows:

> Doc said that she doesn't have many new starts on oxycontin. I reviewed with her conversion formula and relayed the basis 1 to 1 conversion for her hydrocodone patients. When asked doc said that she doesn't really know how long she has patients on a lortab or vicodin and figures that many are on either 5 or 7.5 mg dose. *Told doc these are new oxycontin patients and to focus on cutting down the amount of pills these patients are taking and more effective pain control with switching to 10 or 15mg dose for oxycontin.* Doc didn't commit but said that is interesting and she never looked at it that way[.][354]

OxyContin v. Percocet

313. In its marketing in Tennessee, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to Percocet, the brand name for a combination short-acting opioid product containing oxycodone and acetaminophen, when those claims were false, deceptive, and/or unsubstantiated at the time they were made. While not an exhaustive list, illustrative examples of call notes in which Purdue's Tennessee sales representatives compared OxyContin and Percocet are set forth below.

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[353] PTN000119294 ID35490–91 (3/26/2009) (emphasis added).
[354] PTN000119294 ID47548 (1/15/2010) (emphasis added).

314. On May 21, 2007, Sales Representative 4 called on a Germantown-area obstetrician/gynecologist and recorded his interaction as follows:

> Said the cards are coming in handy for the patients she has on oxycontin. Said she has a few that pay cash for theirs and the $50 is still beneficial even for them. *Discussed the patients on percocet and upgrading to oxycontin when they are reaching APAP limitations*[.][355]

315. Sales Representative 2 documented his sales call with a Knoxville-based physical medicine and rehabilitation doctor on August 6, 2007, as follows:

> *asked for pt taking percoet around the clock that needed dose increase and problem sleeping* he said that was one place he uses Oxycontin reminded of Saving Card program[.][356]

316. Sales Representative 2 documented his sales call with a Knoxville-based oncologist on August 20, 2007, as follows:

> Said he thought OxyCOntin was a good drug unfortunately it has received bad press *discussed using for pt who can no longer tolerate morphine and pt first line who are doing well with percocet* and need to be on long acting for pain relief[.][357]

317. Sales Representative 7 documented his sales call with a Rogersville-based family medicine physician on February 18, 2009, as follows:

> Had a new doc that is going to be starting there when done with residency [Provider]. We went over low dose conversions from propxyphene, lortab and percocets. *Went over the fewer tablets, atc pain control and no apap.* Both agreed. I also pointed out appropriate starting dose for opiate naive patient. He asked how much oxycontin cost, I said did you know that it is available on most insurance plans for a 2nd tier co-pay.[358]

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[355] PTN000119294 ID12773 (5/21/2007) (emphasis added).
[356] PTN000119294 ID15174 (8/6/2007) (emphasis added).
[357] PTN000119294 ID15675 (8/20/2007) (emphasis added).
[358] PTN000119294 ID34223 (2/18/2009) (emphasis added).

318. Sales Representative 4 documented his sales call with a Memphis-based anesthesiologist on March 10, 2010, as follows:

> Reviewed with him and nurse [Provider] what the actual copay scenario would be for a UHC/AARP patiennt and making sure that for these patients he is writing oxycontin .Doc reminded me again that he is not writing any new oxycontin prescriptions. *Pointed out that even though they are not new patients he is still refilling and has plenty patients that are candidates for switching to oxycontin sooner because of the high doses of percocet they are taking and apap limitations*[.][359]

319. On July 14, 2010, Sales Representative 1 made a sales call to a Jackson-area nurse practitioner and wrote the following about her interaction:

> *[W]e discussed that oxycontin offers the efficacy of oxycodone but allows him to treat with fewer pills than with percocet and without apap.* showed him conversion formula and .9 conversion ratio from hydrocodone. asked him if there are patients in the jackson clinic with commercial and med d insurance and he said lots. we looked at formulary grids and explained coverage. *asked him if he would write oxycontin instead of percocet for patients with those plans we discussed.* he said certainly.[360]

320. Sales Representative 6 made a sales call to a Knoxville-area family doctor on May 13, 2013, and wrote the following about his interaction:

> Discussed OxyContin and he asked if there was a maximum dose for OxyContin. I told him there has been no maximum dose established in our clinical trials. He says he has one patient taking five of the 80 mg tablets a day. Acknowledgedthat's an exception and is a high-dose compared to the other patients he has on OxyContin. *We discused the dosing conversion chart from Percocet and I asked him to consider in any patient who's not comfortable with Q6 dosing or having to get up in the middle the night to take their medication.*[361]

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[359] PTN000119294 ID50182 (3/10/2010) (emphasis added).
[360] PTN000119294 ID56266 (7/14/2010) (emphasis added).
[361] PTN000119294 ID130004 (5/13/2013) (emphasis added).

321. Likewise, Sales Representative 6 made a sales call to a Knoxville-area family physician on June 18, 2014, and wrote the following about his interaction:

> [I] also reminded [Provider] of the opportunity in patients with declining hepatic function who may not be appropriate for a hydrocodone formulation containing acetaminophen. He agreed and thought that was a good point. Quick reminder of OxyContin *and the opportunity to convert appropriate patients on three or more doses a day of the short-acting oxycodone.* [Provider] agreed an extended release is appropriate in that situation but they tend to refer many of those patients out to a pain clinic. *I asked them to consider in elderly patients who they're not comfortable sending to a pain clinic and he agreed to consider.*[362]

322. On June 23, 2014, Sales Representative 6 called on a Knoxville-area emergency medicine physician and recorded his interaction as follows, along with comments from his district manager two-and-one-half weeks later:

> Discussed OxyContin use in appropriate patients. *Reviewed the Percocet conversion chart and discussed opportunities inappropriate patients on three or more doses a day of the short-acting oxycodone.* [Provider] agreed that getting patients on an extended release makes sense and will consider in his patients. I reminded him of the formulary coverage and savings card discount for cash pay pts. He said he's not taking any new pain patients so any use of OxyContin or Butrans will have to come from his current patient population. iPhone up on his newest patient on Butrans. [Provider] said he's not heard from patient and doesn't know if they're still taking the Butrans or not. We talked about the updated and expanded coverage for Medicare D and appropriate elderly patients who might be candidates for Butrans. I mentioned specifically patients with declining hepatic function who may not be appropriate for an opioid with acetaminophen. [Provider] thought that was a good idea and Butrans would be a consideration. Left him the Butrans Tear-off sheets for application guidelines.[District Manager 3] added notes on 07/11/2014[Sales Representative 6], *Per our discussion today...In discussing the elderly patient, you should not reference acetaminophen bc it may imply superiority.* When discussing the elderly patients, you may want to go to section 8.5 in the FPI and in this case include section 8.6 for Hepatic Impairment information[.][363]

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[362] PTN000119294 ID165158 (6/18/2014) (emphasis added).
[363] PTN000119294 ID165523 (6/23/2014) (emphasis added).

323. Substantially similar claims were made by: Sales Representative 11 to a Lebanon-area nurse practitioner on July 27, 2007;[364] Sales Representative 8 to a Murfreesboro-area physician on December 16, 2010;[365] Sales Representative 6 to a Knoxville-area physician assistant on June 22, 2013;[366] Sales Representative 20 to a McKenzie-area internist on March 13, 2014[367] and a Paris-area medical practice group on March 13, 2014;[368] Sales Representative 6 to a Knoxville-area physician assistant on May 29, 2014,[369] a Knoxville-area family doctor on June 12, 2014,[370] a Maryville-area family doctor on June 12, 2014,[371] a Knoxville-area physician assistant on June 16, 2014,[372] a Knoxville-based family doctor on June 16, 2014,[373] a Knoxville-area internist on June 16, 2014,[374] a Knoxville-area family doctor on June 16, 2014,[375] a Knoxville-based nurse practitioner on June 16, 2014,[376] a Knoxville-area family doctor on June 16, 2014,[377] a Knoxville-area family doctor on June 17, 2014,[378] a Knoxville-based physician assistant on June 17, 2014,[379] a Knoxville-area family doctor on June 17, 2014,[380] a Knoxville-area family doctor on June 17, 2014,[381] a Knoxville-area family doctor on June 18, 2014,[382] a Knoxville-based family

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[364] PTN000119294 ID14893 (7/27/2007).
[365] PTN000119294 ID64554 (12/16/2010).
[366] PTN000119294 ID136151 (7/22/2013).
[367] PTN000119294 ID156115 (3/13/2014).
[368] PTN000119294 ID156161–62, –63, –65 (3/13/2014).
[369] PTN000119294 ID163287 (5/29/2014).
[370] PTN000119294 ID164714 (6/12/2014).
[371] PTN000119294 ID164713 (6/12/2014).
[372] PTN000119294 ID164933 (6/16/2014).
[373] PTN000119294 ID164914 (6/16/2014).
[374] PTN000119294 ID164915 (6/16/2014).
[375] PTN000119294 ID164916 (6/16/2014).
[376] PTN000119294 ID164939 (6/16/2014).
[377] PTN000119294 ID164995 (6/16/2014).
[378] PTN000119294 ID165089 (6/17/2014).
[379] PTN000119294 ID165140 (6/17/2014).
[380] PTN000119294 ID165089 (6/17/2014).
[381] PTN000119294 ID165094 (6/17/2014).
[382] PTN000119294 ID165221 (6/18/2014).

doctor on June 18, 2014,[383] a Maynardsville-area nurse practitioner on June 19, 2014,[384] a Knoxville-area nurse practitioner on June 19, 2014,[385] a Maynardsville-based general practitioner on June 19, 2014,[386] a Knoxville-area internist on June 20, 2014,[387] a Knoxville-area family doctor on June 20, 2014,[388] a Knoxville-area emergency medicine physician on June 23, 2014,[389] a Knoxville-based family doctor on June 30, 2014,[390] a Knoxville-based family doctor on June 30, 2014,[391] a Knoxville-based family doctor on June 30, 2014,[392] a Knoxville-area physician assistant on June 30, 2014,[393] a Knoxville-based family doctor on June 30, 2014,[394] a Knoxville-area nurse practitioner on July 1, 2014,[395] and a Knoxville-based physician assistant on July 7, 2014;[396]and Sales Representative 1 to a Paris-area physician assistant on July 15, 2015.[397]

Comparative Claims: OxyContin v. Non-opioids

324. In its marketing in Tennessee, Purdue represented that OxyContin was safer than, more effective than, as effective as, or superior to non-opioids for the treatment of pain when those claims were false, deceptive, and/or unsubstantiated at the time they were made. While not exhaustive, an illustrative example of a call note in which Purdue's Tennessee sales representative compared OxyContin and non-opioids is set forth below.

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[383] PTN000119294 ID165172 (6/18/2014).
[384] PTN000119294 ID165277 (6/19/2014).
[385] PTN000119294 ID165276 (6/19/2014).
[386] PTN000119294 ID165278 (6/19/2014).
[387] PTN000119294 ID165404 (6/20/2014).
[388] PTN000119294 ID165468 (6/20/2014).
[389] PTN000119294 ID165523 (6/23/2014).
[390] PTN000119294 ID165880 (6/30/2014).
[391] PTN000119294 ID165980 (6/30/2014).
[392] PTN000119294 ID165880 (6/30/2014).
[393] PTN000119294 ID165929 (6/30/2014).
[394] PTN000119294 ID165980 (6/30/2014).
[395] PTN000119294 ID166091 (7/1/2014).
[396] PTN000119294 ID166421 (7/7/2014).
[397] PTN000119294 ID202815 (7/15/2015).

325. On May 8, 2007, Sales Representative 4 called on a Savannah-area pharmacy and recorded his interaction as follows:

> Had questions about use of oxycontin in nerve pain and how effective. *Discussed gimbel reprint and my knowledge of neurontin and lyrica in comparison to oxycontin. Discussed receptor sites and difficulty in dosing neurontin in comparison to ease of use with oxycontin*[.][398]

Comparative Claims: Butrans v. Immediate Release Opioids

Hydrocodone and Hydrocodone Combinations

326. In its marketing in Tennessee, Purdue represented that Butrans, its buprenorphine opioid product prescribed to treat pain, was safer than, more effective than, as effective as, or superior to hydrocodone and hydrocodone combinations when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

327. Purdue's sales representatives generally claimed that Butrans was better than hydrocodone or hydrocodone combinations because of its lack of acetaminophen—especially for the elderly. While not an exhaustive list, illustrative examples of call notes in which Purdue's Tennessee sales representatives compared Butrans to hydrocodone and hydrocodone combinations is set forth below.

328. Sales Representative 1 documented her sales call with a Dyersburg-based internist on April 26, 2011, which was commented on by her district manager. The note reads as follows:

> asked dr how he feels about writing hydrocodone for atc pain. he said he hates it. showed him butrans indication. reminded him of c3 which allows him to write refills and call in rx but also carries black box warning and showed him warnings. *asked him to try butrans since he hates writing hydrocodone. asked him for just 1 trial.* he said he would and then began to walk off. he turned around and asked if i had a coupon because he has a patient in a room now he was going to write it for.<b>[District Manager 2] query on

[398] PTN000119294 ID12366 (5/9/2007) (emphasis added).

> 05/05/2011[Sales Representative 1],*Be careful that you are not making comparative claims or claims of superiority versus hydrocodone.* Asking him about his feelings on hydrocodone and then placing Butrans could insinuate that Butrans is safer or less abuseable. This is not factual. You should position Butrans based on its indication and ask for patinets that meet the indication. *The fact that you asked him to try Butrans because he hates hydrocodone is not appropriate.* On your next call you need to clarify this issue.[Sales Representative 1's] response on 05/06/2011ok. i see what you mean. i will clarify on my next call.[District Manager 2] added notes on 05/08/2011Thanks.[399]

329. On September 21, 2011, Sales Representative 7 called on a Bristol-area internist and recorded his interaction as follows:

> Reviewed the 5 point message, pointed out that this is the first time he has had the opportunity to prescribe a single entity long acting CIII. He said he has been prescribing short acting hydrocodone so he doesn't have to prescribe a CII. *I asked him what hydrocodone would be scheduled if it didn't have acetaminophen. He said he would assume it to be a CIII. I let him know that actually it is a CII if there is no acetaminophen. He said he didn't know that. I pointed out again that Butrans is a single entity 7 day CIII. He said this is interesting.* I asked if would prescribe or give a try, he said he would but needed to know where he could use it, is it covered by any plans. I provided him with a formulary grid for Butrans and went over the savings cards. I asked him where he is going to use in his practice, he said he has many patients who dint like using tablets. He said he is going to use in those patients.[400]

330. Likewise, Sales Representative 6 made a sales call to a Knoxville-area internist on June 16, 2014, and wrote the following about his interaction:

> Discussed Butrans use in appropriate patients. [Provider] asked me about a recent patient who has been dealing with some cancer pain who he had changed to Butrans. The patient had returned to her oncologist at Vanderbilt and was switched back to an oxycodone regimen. [Provider] asked if there were contraindications in this type of patient and we reviewed the PI and I showed him that there should be no reason to switch that if patient was doing well. *I also reminded him of the opportunity in appropriate elderly patients with declining liver function who might be Butrans candidates to*

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[399] PTN000119294 ID73289 (4/26/2011) (emphasis added).
[400] PTN000119294 ID85000 (9/21/2011) (emphasis added).

> *avoid taking a hydrocodone formulation with acetaminophen.* [Provider] agreed that makes sense.[401]

331. Sales Representative 6 documented his sales call with a Knoxville-based family physician on June 16, 2014, as follows:

> [R]eviewed the Butrans expanded Medicare D formulary coverage grid and *linked to appropriate elderly pts with declining liver function. Discussed the opportunity to try Butrans and avoid using the hydrocodone formulation with acetaminophen.* [Provider] agreed.[402]

332. Likewise, Sales Representative 6 made a sales call to a Knoxville-area family physician on June 17, 2014, and wrote the following about his interaction:

> [F]ollowed up on Butrans use in appropriate patients. Reviewed the Medicare D formulary grid and *discussed appropriate elderly patients also with declining renal function who may not be appropriate candidates for any hydrocodone formulation with acetaminophen. He agreed.* [Provider] also said he had a patient last week that he initiated on Butrans but couldn't remember the patient situation. He's very pleased so far with the results he seen and feels like it gives him a good option to other opioid medications.[403]

333. On June 17, 2014, Sales Representative 6 called on a Knoxville-area family physician and recorded his interaction as follows:

> She was busy today. Had to be quick. Reviewed the expanded Medicare D formulary grid and *discussed appropriate elderly patients that might be candidates for Butrans therapy. I asked her about patients with declining liver function whom need a long-term around-the-clock analgesic. She did comment that Butrans might be a viable option for those pts since she won't use a hydrocodone formulation with acetaminophen*[.][404]

334. Likewise, Sales Representative 6 made a sales call to a Knoxville-area family physician on June 18, 2014, and wrote the following about his interaction:

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[401] PTN000119294 ID164915 (6/16/2014) (emphasis added).
[402] PTN000119294 ID164994 (6/16/2014) (emphasis added).
[403] PTN000119294 ID165093 (6/17/2014) (emphasis added).
[404] PTN000119294 ID165094 (6/17/2014) (emphasis added).

> Followed up on previous discussion around Butrans and the opportunity to get it on the hospital formulary. I gave [Provider] the updated Medicare D formulary grid and he appreciated the info. He said he would be using that in two weeks when his committee discusses potential med additions to their pain management formulary. *We talked about the opportunity to use Butrans in the elderly patients where a once a week dosing regimen may be appropriate. I also reminded [Provider] of the opportunity in patients with declining hepatic function who may not be appropriate for a hydrocodone formulation containing acetaminophen.* He agreed and thought that was a good point[.][405]

335. Sales Representative 6 documented his sales call with a Knoxville-based family doctor on June 18, 2014, as follows:

> *Transitioned to Butrans* and reviewed the updated Medicare D formulary coverage. We talked about the appropriate elderly patient who he's considering for hydrocodone therapy. *I mentioned potential candidates who have declining hepatic function who might not be appropriate for a hydrocodone formulation with acetaminophen.* [Provider] said that makes sense. He said he initiated a patient within the last two weeks. He said he likes the profile of Butrans for the elderly patient and the fact that he's not adding additional pills to their current regimens.[406]

336. On June 23, 2014, Sales Representative 6 called on a Maryville-area internist and recorded his interaction as follows:

> *Discussed Butrans use in appropriate patients.* Reviewed the expanded Medicare D formulary coverage and discussed appropriate elderly patients who might be candidates for Butrans therapy. [Provider] said he initiated a patient last week and said he gave the patient information guide to the pt that was helpful in explaining how to apply the patch. *We talked about additional patients with declining liver function who might not be candidates for meds containing acetaminophen. He thought that was a good thought and would definitely consider. We also talked about the opportunity in the nursing home for use in appropriate patients.* He said he's seen good results in that setting.[407]

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[405] PTN000119294 ID165158 (6/18/2014) (emphasis added).
[406] PTN000119294 ID165172 (6/18/2014) (emphasis added).
[407] PTN000119294 ID165522 (6/23/2014) (emphasis added).

337. On June 30, 2014, Sales Representative 6 called on a Knoxville-area internist and recorded his interaction as follows, which was commented on by his district manager 12 days later:

> He was really backed up today after having come back from a weeks vacation. Followed up with him on OxyContin use in appropriate patients. Discussed his tapering efforts and reminded him of the seven dosing strengths for patients he has over 200 mg of morphine equivalency. Hundred him of the savings card and available formulary coverage. Ask him to consider converting appropriate patients on three or more doses a day of the short acting if formulary is not a hurdle. *Quick reminder of Butrans and discussed appropriate patients.* Reviewed the expanded formulary coverage and *linked to appropriate elderly patients who cannot take an acetaminophen formulation.*[District Manager 3] added notes on 07/11/2014[Sales Representative 6], *Per our discussion today...In discussing the elderly patient, you should not reference acetaminophen bc it may imply superiority.* When discussing the elderly patients, you may want to go to section 8.5 in the FPI[.][408]

338. Sales Representative 6 documented his sales call with a Knoxville-based physician assistant on July 7, 2014, as follows:

> Reviewed the expanded Medicare D coverage grid for Butrans and discussed appropriate elderly patients. *Reviewed the efficacy data seen in the opioid na∩ve trial and discussed appropriate elderly patients who may not be candidates for an acetaminophen formulation.*[409]

339. Substantially similar claims were made by: Sales Representative 6 to a Seymour-area nurse practitioner on June 16, 2014,[410] a Knoxville-based nurse practitioner on June 16, 2014,[411] a Maynardsville-based general practitioner on June 19, 2014,[412] a Knoxville-area internist on June 20, 2014,[413] a Knoxville-area family doctor on June 20, 2014,[414] a Knoxville-area

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[408] PTN000119294 ID165972 (6/30/2014) (emphasis added).
[409] PTN000119294 ID166421 (7/7/2014) (emphasis added).
[410] PTN000119294 ID164972 (6/16/2014).
[411] PTN000119294 ID164939 (6/16/2014).
[412] PTN000119294 ID165278 (6/19/2014).
[413] PTN000119294 ID165404 (6/20/2014).
[414] PTN000119294 ID165468 (6/20/2014).

emergency medicine physician on June 23, 2014,[415] a Knoxville-based internist on June 23, 2014,[416] a Knoxville-area family physician on June 24, 2014,[417] a Knoxville-area nurse practitioner on June 27, 2014,[418] a Nashville-based internist on June 30, 2014,[419] a Knoxville-area family doctor on June 30, 2014,[420] a Knoxville-area physician assistant on June 30, 2014,[421] a Knoxville-area family doctor on June 30, 2014,[422] a Powell-area family doctor on June 30, 2014,[423] a Knoxville-area nurse practitioner on July 1, 2014,[424] a Knoxville-area nurse practitioner on July 1, 2014,[425] a Knoxville-area nurse practitioner on July 1, 2014,[426] a Knoxville-area nurse practitioner on July 1, 2014,[427] and a Knoxville-based physician assistant on July 2, 2014.[428] In spite of these claims and a prior reprimand in November 2013,[429] Sales Representative 6 was not terminated or even reprimanded for these claims.

Comparative Claims: Butrans v. Darvocet or Tramadol

340. In its marketing in Tennessee, Purdue represented that Butrans was safer than, more effective than, as effective as, or superior to other opioids including Darvocet, a combination narcotic pain reliever and fever reducer consisting of propoxyphene and acetaminophen, or

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[415] PTN000119294 ID165523 (6/23/2014).
[416] PTN000119294 ID165570 (6/23/2014).
[417] PTN000119294 ID165678 (6/24/2014).
[418] PTN000119294 ID165820 (6/27/2014).
[419] PTN000119294 ID165880 (6/30/2014).
[420] PTN000119294 ID165928 (6/30/2014).
[421] PTN000119294 ID165929 (6/30/2014).
[422] PTN000119294 ID165980 (6/30/2014).
[423] PTN000119294 ID165997 (6/30/2014).
[424] PTN000119294 ID166017 (7/1/2014).
[425] PTN000119294 ID166035 (7/1/2014).
[426] PTN000119294 ID166076 (7/1/2014).
[427] PTN000119294 ID166091 (7/1/2014).
[428] PTN000119294 ID166132 (7/2/2014).
[429] PTN000045527.

tramadol when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

341. While not an exhaustive list, illustrative examples of call notes in which Purdue's Tennessee sales representatives compared Butrans to Darvocet or tramadol are set forth below.

342. Sales Representative 7 and District Manager 3 called on an Oneida-based family physician on March 30, 2011, and the Sales Representative recorded their interaction as follows:

> *[A]sked him where he sees a fit for butrans* - stated that we discussed b4 he is unsuer where fits - sd most peoppekl dont seem to need a moderate pain med - has other choices more aligned with cost needs for pts not needing a patch and other products much stronger analgeisa wise for those needing greater strength -I advised perhaps I did not hear that concern earlier - I advised will like to set up lunch and explain where might be better fit -- *asked if would consider for a pt taking darvocet or tramadol on a chronic basis* - sd yes does make sense and has a pt in mind[.][430]

343. Sales Representative 6 documented his sales call with a Knoxville-area family physician on June 18, 2014, as follows:

> He didn't have much time today. I gave him the updated Medicare D formulary grid for Butrans and *discussed appropriate elderly patients whose pain is not controlled on tramadol. We talked about those patients with declining hepatic function who he wants to avoid using acetaminophen in. I reminded him of the schedule three rating for Butrans.* Discussed the appropriate dosing and titration. He said he would consider.[431]

Comparative Claims: Butrans v. Lortab

344. In its marketing in Tennessee, Purdue represented that Butrans was safer than, more effective than, as effective as, or superior to Lortab when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

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[430] PTN000119294 ID71443 (3/30/2011) (emphasis added).
[431] PTN000119294 ID165173 (6/18/2014) (emphasis added).

345. While not exhaustive, an illustrative example of a call note in which Purdue's Tennessee sales representative compared Butrans to Lortab is set forth below.

346. Sales Representative 15 and District Manager 2 made a sales call to a Memphis-area internist on June 6, 2013, and wrote the following about their interaction:

> *I asked Doctor how he sees Butrans fitting in his practice*. He said that he considers it for pain. discussed Lortab patients and he said he wants "to get rid of them" because they are problems. Looked at placebo patches. *I asked him to initiate Butrans earlier in his treatment algorithm like after tramadol and not let his patients get to high doses of Lortab.* Discussed Intermezzo and reviewed Intermezzo "reassess" marketing piece and asking appropriate questions of his insomnia patients.[432]

Comparative Claims: Ryzolt v. Immediate Release Opioids

347. In its marketing in Tennessee, Purdue represented that Ryzolt, an extended release tramadol hydrochloride product, was safer than, more effective than, as effective as, or superior to immediate release opioids, such as Percocet and Lortab, when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

348. Purdue sold Ryzolt from 2009 until it was pulled from the market. When it was sold, Purdue used a "2-3-1" message for Ryzolt meaning that it had 2 acting delivery systems, 3 modes of action, and 1 daily dose.[433]

349. While not exhaustive, illustrative examples of call notes in which Purdue's Tennessee sales representatives compared Ryzolt to short-acting opioids, such as Percocet and Lortab, are set forth below.

350. Sales Representative 11 made a sales call concerning OxyContin to a Lebanon-area family physician on August 25, 2009, and wrote the following about his interaction:

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[432] PTN000119294 ID132304 (6/6/2013) (emphasis added).
[433] ST000414.

discussed ryzolt's positioning statement before lortab , dual matrix, 231, and formulary status. he wanted me to leave one in the bin so he could check status of formulary coverage.[434]

351. On September 3, 2009, Sales Representative 7 called on a Kingsport-area family physician and recorded his interaction as follows:

> *Introduced* [Provider] *to ryzolt via the 231 message and the benfits.* Also, Discussed product positioning and formulary coverage and value cards. Gave him a new oxycontin conversion guide. *After going over the indications of ryzolt*, he siad that he is probably going to use in fibromyalgia patients. *I again went over the indication for moderate to moderately severe chronic pain in adults.* He said he understands, but fibromyalgia is where he is going to use. *Also went over positioning again to use before starting patient on short acting combos.*[435]

352. Sales Representative 7 made a sales call to a Johnson City-area spine specialist on November 2, 2009, and wrote the following about his interaction:

> Discussed ryzolt dual matrix and really tied in the positioning of ryzolt into his practice... He said he has tried ryzolt in a few patients so far but is getting mixed reactions. he said in naive patients it seems to do just fine, in tolerant patients it doesnt seem to do too well. I explained that a product like ryzolt is going to have that group of patients that it just isnt going to be effective in, like perhaps an opiate tolerant patient. *I explained that not all patients need or want to be on percocet or lortabs and perhaps ryzolt may be just what they need.* He said the is worth probably trying it on a good percentage of his patients. I also went over the prescription solutions information and the formulary grids. He said that he really likes the 15mg strength and has started using it more lately. As a matter of fact, he said he really likes the fact that the 15,30 and 60mg strengths are avalilable now.[436]

Comparative Claims: Ryzolt v. Other Tramadol Products

353. In its marketing in Tennessee, Purdue represented that Ryzolt, a branded tramadol product, was safer than, more effective than, as effective as, or superior to other tramadol products,

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[434] PTN000119294 ID41218 (8/25/2009) (emphasis added).
[435] PTN000119294 ID41755 (9/3/2009) (emphasis added).
[436] PTN000119294 ID44518 (11/2/2009) (emphasis added).

such as generic tramadol and branded Ultram ER, when those claims were false, deceptive, and/or unsubstantiated at the time they were made. While not an exhaustive list, illustrative examples of call notes are set forth below.

354. On May 20, 2009, Sales Representative 2 called on a Sevierville-area family physician and recorded his interaction as follows:

> He asked difference from Ultram ER *discussed dual matrix delivery system and value card program* he said that the value card program was a benefit[.][437]

355. Sales Representative 14 documented his sales call with a Memphis-based family physician on June 11, 2009, as follows:

> Introduced Ryzolt to [Provider]. We discussed the key points from the PI and I shared the value card program with him. I asked where he could see Ryzolt fitting into his practice. He said he has treated with tramadol products some in the past and some patients have done really well with them. He said insurance coverage has always been a struggle. *I asked which of his patients have done well with tramadol in the past.* He said those with pain that wasn't bad enough for a stronger opioid. *I asked if he would treat with Ryzolt for those patients.* He agreed. I followed up on his point about insurance coverage and shared the latest formulary grid with him. He thanked me for the tool. I stressed importance of value cards and he agreed.[438]

356. Sales Representative 7 documented his sales call with a Kingsport-based neurologist on December 21, 2009, as follows:

> Introduced to ryzolt via the 231 message and value cards. *He said he hasnt had much success with ir tramadol. I asked how much, he said up to 400mg/day. I asked if he would try ryzolt up to 300 mg/day. Perhaps er would control pain all day and maybe that is why the short acting didnt work.* He said that is a good point and would give a try.[439]

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[437] PTN000119294 ID37821 (5/20/2009) (emphasis added).
[438] PTN000119294 ID38736 (6/11/2009) (emphasis added).
[439] PTN000119294 ID47090 (12/21/2009) (emphasis added).

Comparative Claims: Hysingla ER v. Acetaminophen Products and Hydrocodone Combinations

357. In its marketing in Tennessee, Purdue represented that Hysingla ER, its branded hydrocodone hydrochloride drug that did not contain acetaminophen, was safer than, more effective than, as effective as, or superior to opioids containing acetaminophen products and hydrocodone combinations when those claims were false, deceptive, and/or unsubstantiated at the time they were made. While not an exhaustive list, illustrative examples of call notes are set forth below.

358. Sales Representative 1 made a sales call to an Atoka-area nurse practitioner on March 16, 2015, and wrote the following about her interaction:

> [Provider] said he hasn't written hysingla. *I had him read the "contains no apap" bullet on of 3 of cva and asked his opinion.* He said this is a big concern and pts have no idea about the dangers of apap because they can get it without an rx. He said many of his pts also drink alcohol while taking apap combination products. *I asked if he could identify a pt he has on hydrocodone/apap that he wants to convert to hysingla based on apap concerns*. He said despite his concerns, he still can't write hysingla if the pts insurance plan won't pay for it. He couldn't name his top 3 plans but said amerigroup seems to be growing and since its an obamacare plan, they don't take referrals so he gets stuck treating their pain and can only write generics. Discussed portfolio positioning and coverage.[440]

359. On a March 30, 2015 sales call with a Sevierville nurse practitioner, Sales Representative 9 documented the following discussion:

> During this call with [Provider] I reviewed insight number 19. *I asked her if any of her patients were at a high risk for taking more than the daily recommendations of acetaminophen? She stated that she was sure several of her patients were and will convert those patients to either Butrans or Hysingla.* She asked that managed-care coverage for Hysingla. The call was cut short when she had to take a phone call. [Provider] stated that they have several patients who are now taking Hysingla and doing well.[441]

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[440] PTN000119294 ID189666 (3/16/2015) (emphasis added).
[441] PTN000119294 ID191289 (3/30/2015) (emphasis added).

360. On May 27, 2016, District Manager 1 e-mailed the entire Nashville District of sales representatives and instructed them about the following sales messaging, in relevant part:

> Hysingla ER:
>
> Need to focus on the efficacy of the product on every call. Q24 dosing, delivery of hydrocodone over 24 hours, ensure appropriate 1 to 1 conversions, how to titrate, *and no APAP.*[442]

C. DECEPTIVE BENEFIT CLAIMS

361. In its marketing materials, Purdue made a series of representations about the benefits and characteristics of its opioid products that were not approved by the FDA and for which it lacked substantiation. Purdue did this in three main ways, namely by (1) representing that its products improved a patient's quality of life; (2) representing that its products would improve a patient's function; and (3) representing that its opioid products helped a patient sleep.

Benefit Claims: Quality of Life

362. Purdue sales representatives in Tennessee claimed that Purdue's opioid products could improve a patient's quality of life when these claims were false, deceptive, and/or unsubstantiated at the time they were made.[443]

363. The CDC Guideline concluded after a "systematic review of the best available evidence" by an expert panel free of conflicts of interest that no study exists to show opioids are effective for outcomes related to quality of life.[444] Further, powerful narcotics that can kill patients

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[442] PTN00088254 (emphasis added).
[443] PTN000031807 ID13076 (10/31/2007); PTN000031807 ID161903 (11/19/2008); PTN000031807 ID162774 (11/21/2008); PTN000031807 ID14930 (12/19/2007); PTN000031807 ID24848 (1/8/2009); PTN000031807 ID38655 (5/7/2010).
[444] 2016 CDC Guideline, at 9.

and commit them to a life of addiction or recovery cannot be said to broadly improve a patient's quality of life.

364. In its 2012 Guidelines on Product Promotion, Purdue has stated and trained its sales representatives that "[y]ou cannot make a quality of life claim unless supported by substantial evidence – We have no drugs that meet this standard," and "[y]ou cannot ask a questions of the HCP that causes him/her to make a quality of life conclusion about a Purdue product."[445]

365. Similarly, in its 2013 Guidelines on Product Promotion, Purdue stated and trained its sales representatives that:

> A quality of life claim is a claim that a person's well-being, or certain aspects of a person's well-being, will be improved by using a certain product. You cannot make a quality of life claim unless supported by substantial evidence.
>
> *We have no drugs with clinical studies that satisfy this standard.*[446]

366. Despite having no evidence to support these claims, Purdue trained its Tennessee sales representatives to make quality of life claims in sales calls to health care providers, which they did routinely.[447]

367. While not an exhaustive list, illustrative examples of call notes in which Purdue's Tennessee sales representative made broad quality of life claims concerning its products are shown below.

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[445] PVT0058330.

[446] PWG000008070 (emphasis added).

[447] PWG000007356 (Introduction to Pain Management 2013 Level 100 Sales Training) (Jan. 9, 2013) (stating in a Purdue sales training presentation that a "Comprehensive Evaluation" includes, among other things, a "Pain Assessment" in which one should "Discuss qualities of pain" and "Evaluate impact of pain on physical and psychological function"); PTN000031807 ID13076 (10/31/2007); PTN000031807 ID161903 (11/19/2008); PTN000031807 ID162774 (11/21/2008); PTN000031807 ID14930 (12/19/2007); PTN000031807 ID24848 (1/8/2009); PTN000031807 ID38655 (5/7/2010).

368. Sales Representative 5 recorded his discussion with a Clarksville-based neurologist on November 19, 2008, as follows:

> [D]iscussed the problem with persistent pain and how it reduces a patient's quality of life. *oxycontin can help restore quality of life.* doc agreed.[448]

369. On November 21, 2008, Sales Representative 10 called on a Manchester-area pain specialist and recorded her interaction as follows:

> After our talk he said that the 15 mg may change some of his rxing habits because he has always only saved oxycontin for "big gun needs" like cancer pts. I thanked him for his compassion to the ca pts. *I asked him to consider conversion doses and providing the same quality of life advantages that he is reserving for his cancer pts for some of his other suffering pts in pain who have also been assessed and need atc management of moderate to severe pain and he deems them responsible enough to take an opioid*. He said that was a good point and he should not hold oxycontin out just for a few based on the actions of a few . I provided pi, and conversion chart.[449]

370. Sales Representative 5 called on a Nashville doctor and recorded his interaction on December 19, 2007, as follows:

> doc asked about conversion of hydrocodone to oxycontin. *agreed some patients can have a better quality of life by taking something q12h as opposed to q4-6h.*[450]

371. Likewise, Sales Representative 5 made a sales call to a Nashville-area nurse practitioner on February 19, 2009, and wrote the following about his interaction:

> [Provider] mentioned that oxycontin is effective for many of their failed back pain patients. *long duration of action allows patients to be productive and improves quality of life.*[451]

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[448] PTN000119294 ID31733 (11/19/2008) (emphasis added).
[449] PTN000119294 ID31858 (11/21/2008) (emphasis added).
[450] PTN000119294 ID19637 (12/19/2007) (emphasis added).
[451] PTN000119294 ID34285 (2/19/2009) (emphasis added).

Benefit Claims: Improved Function

372. Purdue represented that its opioid products would improve a patient's function when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

373. While opioids may initially improve function by providing pain relief in the short term, Purdue's claim that opioids improve patients' function in the long term is unsubstantiated.

374. The 2016 CDC Guideline concluded that "there is *no good evidence* that opioids improve pain or function with long-term use." The CDC reinforced this conclusion throughout the Guideline, finding that "[n]o 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," "[a]lthough opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term therapy," and "evidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."[452]

375. Despite the lack of evidence, Purdue represented in its written marketing materials that its opioid products could improve patients' function.

376. In an advertisement originally posted on *The Atlantic* magazine's website in 2015 titled *Take My Pain Away . . . A Physician's Perspective of Prescription Opioids and Pain Management*, Purdue made the unsubstantiated claim that all physicians who treat chronic pain with opioids have a significant number of patients that experience quality of life improvements.

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[452] 2016 CDC Guideline, at 12, 15, 18, and 20.

Purdue used a paid consultant and past president of the American Academy of Pain Medicine, a third party pain advocacy group that Purdue substantially funded, to author this sponsored content.

377. Specifically, Purdue stated in *Take My Pain Away*:

> *Today, all physicians who treat chronic pain with opioids have a significant number of patients in our practices that are back at work as full-time employees or back at school as full-time students because their pain is tolerable and under control. I have a group of patients who take opioids on a regular, sustained basis, and no one could pick them out of any group of their friends, neighbors, or coworkers.* They look and act like anyone else. They have no cognitive impairment and no sign of sedation or drowsiness because their treatment is under control, they are appropriate patients for the treatment, and they are monitored by their treating physician or healthcare professional.
>
> ....
>
> Pain makes people less able to continue their normal activities and, eventually, if untreated, pain can ruin their lives. . . . Pain can make a patient depressed, and depression leads to more physical pain.
>
> ....
>
> But for patients who don't respond to other pharmacological agents, or to physical or complementary therapies, *it is very good to know that there is a class of potent medications [high-dose opioids] that, when used carefully with the right patients, might allow them to live more comfortable, active, and normal lives.*[453]

378. While the piece did not mention OxyContin by name, Purdue used *Take My Pain Away* as an advertisement for OxyContin that was consistent with Purdue's brand strategy for OxyContin to "[e]levate the importance of abuse deterrence as key driver for ERO prescribing"[454] and "[g]enerate supporting data and related promotional materials on abuse deterrence."[455]

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[453] www.theatlantic.com/sponsored/purdue-health/take-my-pain-away/202 (emphasis added); PWG000214678 (2014 draft with revisions) (p. 3).
[454] PWG000029073.
[455] PWG000063473.

379. *Take My Pain Away* recommended opioids with abuse deterrent properties, a category in which OxyContin was the clear market-leader[456] and the first opioid to receive "Tier 1 and Tier 3 labeling that describes abuse-deterrent characteristics."[457]

380. The emphasis on abuse deterrent properties within the piece was amplified in tag-along correspondence in which Purdue encouraged recipients to read and share *The Atlantic* articles including the *Take My Pain Away* piece and emphasized "recent technological approaches to developing opioid medications with abuse-deterrent properties."[458]

381. As of March 2015, Purdue's *Take My Pain Away* had at least 26,236 page views, 21,998 unique visitors to the website, and led to 37,681 impressions on Twitter.[459] Purdue's *Take my Pain Away* is currently still online.

382. Likewise, Purdue's Tennessee sales representatives claimed in sales calls that its opioid products could improve a patient's function. While not an exhaustive list, illustrative examples of call notes are shown below.

383. On May 8, 2007, Sales Representative 4 called on a Collierville-area family physician and recorded his interaction as follows:

> Said many of her patients have some form of difficulty performing regular duties as fast as they would like. *Discussed oxycontin in improving patient function* and normal sport activities becasue of patient having improved or even tolerable pain after activity.[460]

384. Sales Representative 12 documented his sales call with an Athens-based nurse practitioner on June 12, 2007, as follows:

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[456] PWG000029073 (referencing Purdue's "ADF leadership" concerning OxyContin).
[457] PWG000029079.
[458] PWG000133628.
[459] PWG000204609.
[460] PTN000119294 ID12302 (5/8/2007) (emphasis added).

> Said she only still prescribes opioids for a few appropriate patients. She seemed to not want to speak about appropriate pain patients. *She agreed with the improve function is the goal.*[461]

385. Sales Representative 12 documented his sales call with a Chattanooga-based neurologist on June 12, 2007, as follows:

> Asked what was the greatest challenge in treating patients in pain. He said his concern when they get on the medicine they never seem to get off. *Asked if he has seen improved function with most of his appropriate patients.* He said he had. *I asked him if that was good or bad if appropriate patients are on medicine and improved function.* He said probably not. Reemphasize the savings card. He was going to start giving Seno S with all patients in pain.[462]

386. In a September 7, 2007 sales call with a Knoxville internist, Sales Representative 2 recorded his discussion as follows:

> Elderly pt profile from PI and asked for appropiate pt who now needs a long acting analgesic *Oxycontin benefit* is good rest and *better activity during day*[.][463]

Benefit Claims: Sleep Aid

387. Purdue represented that its opioid products would act as a sleep aid when those claims were false, deceptive, and/or unsubstantiated at the time they were made.

388. While Purdue's opioids may relieve pain, and some are dosed every 12 hours as opposed to shorter intervals, the claim that opioids improve a patient's sleep is unsubstantiated. Indeed, one of the most significant risks of OxyContin and other opioids is respiratory depression, which is more difficult to detect or counteract during sleep.

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[461] PTN000119294 ID13520 (6/12/2007) (emphasis added).
[462] PTN000119294 ID13522 (6/12/2007) (emphasis added).
[463] PTN000119294 ID16174 (9/6/2007) (emphasis added).

389. While not an exhaustive list, illustrative examples of call notes in which Purdue's Tennessee sales representatives made claims that its opioid products could improve a patient's sleep are shown below.

390. On June 21, 2007, Sales Representative 11 called on a Nashville-based internist and recorded the following discussion:

> [D]iscussed new starts and when to go to long acting. *showed aps* less end of dose pain *and pts sleep better at night.* said if you see pain is persistent and per oxycontin pi then long acting. discussed 10mg usage in some of those patients. said he did not know we had a 10mg tablet[.][464]

391. Sales Representative 5 called on a Hendersonville-based family physician on June 22, 2007, and recorded his interaction as follows:

> *APS 5th edition--supports use of oxycontin for patients going to bed in pain.doc said he would inquire, more, of his patients on how pain disrupts getting a good nights rest.*[465]

392. Likewise, Sales Representative 5 made a sales call to a Gallatin-area family physician on June 25, 2007, and wrote the following about his interaction:

> *doc agreed with APS 5th edit. that people with around the clock pain will need a good night's sleep.* short acting pain medication, will not keep them out of pain for the full night. *oxycontin is good for those patients.*[466]

393. Sales Representative 5 documented his sales call with a Nashville-based family physician on July 3, 2007, as follows:

> *discussed APS 5th edition--doc agreed that around the clock pain can disrupt a person's sleep. oxycontin --one less concern.*[467]

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[464] PTN000119294 ID13833 (6/21/2007) (emphasis added).
[465] PTN000119294 ID13905 (6/22/2007) (emphasis added).
[466] PTN000119294 ID13918 (6/25/2007) (emphasis added).
[467] PTN000119294 ID14142 (7/3/2007) (emphasis added).

394. Sales Representative 2 documented his sales call with a Knoxville-based physical medicine and rehabilitation doctor on August 6, 2007, as follows:

> *asked for pt taking percoet around the clock that needed dose increase and problem sleeping* he said that was one place he uses Oxycontin reminded of Saving Card program[.][468]

395. Sales Representative 11 documented his sales call with a Nashville-based rheumatologist on June 23, 2008, as follows:

> rheumatologist attending. gave the oa ra aps book. we talked about pts that are not functioning due to pain and have pain per oxycontin pi. *agreed to start to ask about sleep too. agreed to start to use oxycontin for those pts.*[469]

396. On July 14, 2008, Sales Representative 11 called on a Lebanon-area internist and recorded his interaction as follows:

> talked to [two providers] at the same time. i asked if they have pts on a prn that do have persistent pain . pts taking 120 shorts, pts on sleep meds becasue they wake up in pain. they both said a few . *i said does it then make sense to try low dose oxycontin in those pts and maybe they would not wake up in pain.* they said it is worth a try. closed with senokot and Colace[.][470]

397. Sales Representative 11 made a sales call to a Lebanon-area internist on October 9, 2008, and wrote the following about his interaction:

> *asked if he has pts that can't sleep and have mod to severe pain and the pts may be on lortab, and a sleep aid.*he said he does have some like that. *asked if he would go to a long acting before a sleep aid* . said that made sense and would try[.][471]

398. Likewise, Sales Representative 11 made a sales call to a Lebanon-area physical rehabilitation practice group on April 17, 2009, and wrote the following about his interaction:

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[468] PTN000119294 ID15174 (8/6/2007) (emphasis added).
[469] PTN000119294 ID25833 (6/23/2008) (emphasis added).
[470] PTN000119294 ID26493 (7/14/2008) (emphasis added).
[471] PTN000119294 ID30242 (10/9/2008) (emphasis added).

> in office today i showed conversion and titration guide and the pic of the pills of lortab, and percocet. *i discussed appropriate pts per oxycontin pi that wouild benefit from long acting. atc control, sleep etc.* all agreed that they do have several pts that are on 4 or 5 of the lortab 10mg and percocet 10mg that should be on long acting ie oxyconntin[.][472]

D. DECEPTIVE CLAIMS ABOUT OPIOID USE IN THE ELDERLY

399. Purdue misrepresented the safety of OxyContin in the elderly through a series of affirmative statements and material omissions. Purdue specifically and unfairly targeted providers who worked with nursing homes or who had large elderly patient populations—presumably because Medicare Part D had favorable coverage for some of Purdue's opioid products.

400. Purdue overstated OxyContin's safety in elderly patients in spite of the fact that OxyContin's product label recognizes respiratory depression is "the chief hazard from oxycodone," and "is a particular problem in elderly or debilitated patients."[473]

401. Purdue likewise misrepresented the safety of Butrans in elderly patients with affirmative statements and material omissions. The label for Butrans states "[w]hile no dose adjustment is recommended on the basis of age, administer Butrans with caution in elderly patients."[474]

402. Purdue designated providers "LTC" for long term care, included these providers on target lists for sales representatives to visit, and established prescribing goals for LTC providers that sales representatives were supposed to meet.[475]

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[472] PTN000119294 ID36384–87 (4/17/2009) (emphasis added).
[473] PTN00000087.
[474] PWG003467787.
[475] PTN000116404-18.

403. Purdue's sales representatives called on nursing homes[476] and Purdue instructed them to "have a specific business plan in place for key institutions" including long-term care facilities like nursing homes that "should be geared towards appropriately maximizing demand for Ryzolt™, OxyContin® Tablets, and Colace® Capsules."[477]

404. Purdue misrepresented the safety of its products in the elderly by (1) omitting the material fact that there is a greater risk of respiratory depression from OxyContin and Butrans in elderly patients; (2) omitting the material fact that low-dose starts of OxyContin in elderly patients most often lead to higher doses of OxyContin where risks are increased; (3) making unsubstantiated comparative claims about OxyContin and its extended release competitor, Duragesic, which was popular for providers to prescribe to elderly patients; and (4) making unsubstantiated comparative claims about Butrans and competing products with acetaminophen.

405. In addition to examples of Purdue's unsubstantiated comparative claims discussed above, illustrative examples of call notes showing Purdue's targeting of elderly patient populations and material omissions about the safety of opioids in the elderly are shown below.

406. Sales Representative 12 recorded a sales call with a Cleveland-based internist on May 17, 2007, as follows:

> *Told the nurse of the generic situation and asked if most of his pain patients are at the nursing home.* Said she was unsere. *Asked if they have a transition plan from generic to brand. MCO coverage is the main emphasis.*[478]

407. On October 29, 2007, Sales Representative 14 documented his sales call with a Memphis-based internist as follows:

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[476] *See, e.g.*, PTN000119294 ID26652 (7/17/2008) ("this is NHC health Care. they do not have a pharmacy at location. just a nursing home").
[477] PTN000031935.
[478] PTN000119294 ID12711 (5/17/2007) (emphasis added).

> *Talked to doc today about treating elder patients. He said that a lot of his patients are older (has a nursing home population).* We talked through the language in the PI on geriatric patients. Doc said he was clear on everything and thanked me for the reminder. He said he uses OxyContin where appropriate.[479]

408. Likewise, Sales Representative 11 made a sales call to a Lebanon-area nurse practitioner on July 21, 2008, and wrote the following about his interaction:

> discussed adv of long acting vs short acting. she made comment of switching 2 patients that were taking too much lortab/apap. *i then asked if she does see alot of elderly.* she said yes. *asked about [osteoarthritis or rheumatoid arthritis] pts.* she said many. discussed those pts taking a few lortab and not functioning . said she would start low dose 10mg or 15mg for those pts . she remembered our last call on conversions. she said yes the coversion multiplier is .9. *discussed coverage for those medicare part d pts. liked coverage and said she would use oxycontin for those oa ra pts and pts taking too much lortab/apap.*[480]

409. On September 8, 2008, Sales Representative 4 recorded his call with a Memphis-based internist this way:

> New doc/intro call. Said that she uses some oxycontin but moreso outside of the clinic. *Said that she uses more of it in the nursing homes. Said she sees patients at [nursing home] further down on Madison.* Said she refers a lot of patients to [Provider] at the [pain clinic]. *Made her aware of intermediate strengths.*[481]

410. In a call on December 2, 2008, with a McMinnville family physician, Sales Representative 11 recorded his discussion as follows:

> still said he sends pts to pain clinic but did say he will treat the elderly. *did show where the 10mg and 15mg would benefit for last line to increase function in the elderly that have oa ra.* he agreed[.][482]

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[479] PTN000119294 ID17905 (10/29/2007) (emphasis added).
[480] PTN000119294 ID26748 (7/21/2008) (emphasis added).
[481] PTN000119294 ID28709 (9/8/2008) (emphasis added).
[482] PTN000119294 ID32108 (12/2/2008) (emphasis added).

411. Sales Representative 11 called on a Franklin-based internist on March 23, 2010, and documented the discussion as follows:

> *he works several of the nursing hoomes and he said being on AARP second tier was great. this plan is the biggest one in the nursing homes. discussed 7 doses of oxycontin too.* for ryzolt he said many of his pts are elderly with med d plans. he said he will keep in mind for the plans ryzolt is covered. closed on laxatives[.][483]

412. Likewise, on August 19, 2010, Sales Representative 11 called on a Nashville-based family physician and documented his interaction this way:

> [Provider] has not seen the REMS info in his mail. did go over this piece. goals for pt and doctor. medication guide. mail in confirmation. he said he does use more Oxycontin in the nursing homes. *Did mention med D plans that cover Oxycontin and commercial plans. did go over 7 doses of Oxycontin.*[484]

413. On October 26, 2010, Sales Representative 16 called on a Sevierville family physician and recorded her interaction as follows:

> Lunch and Learn with [Provider] today. *Asked Dr if he prescribes Oxycontin.* Dr said that yes, he does prescribe Oxycontin to a few patients. Dr said that the patients he prescribes to are typically patients who have seen him for many years. Some of these patients are in the nursing homes he covers. *I asked Dr which nursing homes he is now Director of and Dr said that he is Medical Director of of 3 facilities:* [names of facilities]. Dr also sees patients at [name of health care center] and [name of assisted living center]. Dr said that he now takes all of Wednesday off for nursing home patients. Introduced Ryzolt. I told Dr that I noticed he had value cards in his sample closet and asked if he ever prescribed Ryzolt. Dr said no. I asked why and Dr said that he was not sure. Provided FPI and conversion guide for Dr to review. Also discussed laxative line. Provided Dr med ed info sheets.[485]

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[483] PTN000119294 ID50746 (3/23/2010) (emphasis added).
[484] PTN000119294 ID58400 (8/19/2010) (emphasis added).
[485] PTN000119294 ID61709 (10/26/2010) (emphasis added).

414. On March 8, 2011, Sales Representative 7 called on an Oak Ridge-area family doctor and recorded his interaction as follows:

> *asked if has tried butrans yet - has not - asked if any reason why* - sd hasnt remembererd and really didnt see it as a great advantage - he told me he has had difficulty with most patch products coming off - advised may with this as well but unproven as of yet - *I told him that this could really be a "game changing" drug in treating chronic pain* - he replied that he did not see it that way - *I asked him to simply consider the fact that buprenorphine is a partial mu agonist and is limited to 20 mcg/hr as not such a negative characteristic and possibly even a positive one as may prove beneficial in treating elderly in chronic pain - perhaps someone who does not remember to take their meds or has to depend on someone else to deliver their medication - advised maybe not all pts but certainly are some that could benefit from once every 7 day delivery system*[.][486]

415. Sales Representative 1 called on a Dyersburg-based pulmonologist on April 18, 2011, and documented her discussion as follows:

> while i was waiting on dr, the receptionist was telling me that he spends his day off making nursing home & hospice rounds. *i asked dr how he butrans fitting in for nursing home patients.* he said he thinks it would be great especially if they were taking multiple pain pills a day that butrans would be a lot easier on them. reminded dr that butrans isn't appropriate for pts taking higher doses of pain meds and showed him the conversion chart. discussed starting patients after nsaids/celebrex when appropriate. he said that would be great but most nursing home patients are med d. *asked him if there is an open formulary for first 100 days as with most nursing homes.* he said no. explained where butrans does have coverage. *also explained oxycontin med d coverage for patients who need >20mcg butrans*[.][487]

416. Substantially similar claims were made by: Sales Representative 11 to a Lebanon-based nurse practitioner on July 16, 2007;[488] Sales Representative 7 and District Manager 3 to a Johnson City-based pharmacist on July 8, 2008;[489] Sales Representative 2 to a Knoxville-based

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[486] PTN000119294 ID69677 (3/8/2011) (emphasis added).
[487] PTN000119294 ID72610 (4/18/2011) (emphasis added).
[488] PTN000119294 ID14473 (7/16/2007).
[489] PTN000119294 ID26270 (7/8/2008).

family doctor on November 8, 2007;[490] Sales Representative 4 to a Collierville-area family physician on August 28, 2007;[491] Sales Representative 14 to a Bartlett-based internist on September 16, 2008;[492] Sales Representative 7 to a Johnson City-area institutional client on September 26, 2008;[493] Sales Representative 12 to a Cleveland-based supplier on May 21, 2009;[494] Sales Representative 1 to a Lexington-based pharmacist on November 4, 2009;[495] Sales Representative 3 to a Tazewell-based health care institution on December 1, 2009;[496] Sales Representative 13 to a Columbia-based internist on September 14, 2010;[497] Sales Representative 24 to a Memphis-based geriatric medicine specialist on November 4, 2010;[498] Sales Representative 1 to a Humboldt-based pharmacist on November 11, 2010;[499] and Sales Representative 25 to a Columbia-area family physician on May 10, 2011.[500]

E. OMISSIONS OF MATERIAL CONNECTIONS

417. Purdue routinely referred to positions that third party pain advocacy groups would take with respect to a health care issue without clearly and conspicuously disclosing the material fact that Purdue was a substantial financial contributor to the third party group.

418. This material omission had the effect of making the third party pain advocacy group's position appear more credible or more neutral than it otherwise would had the material fact of Purdue's substantial monetary contribution been disclosed.

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[490] PTN000119294 ID18326 (11/8/2007).
[491] PTN000119294 ID15907 (8/28/2007).
[492] PTN000119294 ID29114 (9/16/2008).
[493] PTN000119294 ID29712 (9/26/2008).
[494] PTN000119294 ID37885 (5/21/2009).
[495] PTN000119294 ID44685 (11/4/2009).
[496] PTN000119294 ID45908 (12/1/2009).
[497] PTN000119294 ID59806 (9/14/2010).
[498] PTN000119294 ID62232 (11/4/2010).
[499] PTN000119294 ID62706 (11/11/2010).
[500] PTN000119294 ID74421 (5/10/2011).

419. Purdue was the predominant financial contributor to the American Pain Society (APS). Between 2012 and 2017, Purdue gave APS 56% of its total funding, providing $542,259.52, compared with $420,465 combined from four other opioid manufacturers.[501] From 2006 to 2016, Purdue gave APS at least $628,925 in educational grants.[502] Between 1997 and 2012, Purdue gave APS $3,091,264.[503]

420. Purdue was also the predominant financial contributor of the American Academy for Pain Medicine (AAPM). Between 2012 and 2017, Purdue provided 60% of AAPM's total funding, providing $725,584.95 compared with just $473,825 from four other large branded-opioid manufacturers.[504]

421. Purdue also significantly funded the American Pain Foundation (APF), which was highly dependent on pharmaceutical company funding and produced numerous publications touting the use of opioids to treat chronic pain. Between 2006 and 2016, Purdue gave APF $1,356,000.[505] Between 1999 and 2012, Purdue was one of APF's biggest donors, with donations totaling $3.6 million.[506]

422. With Purdue's financial backing, APF created several documents that advanced messages that were favorable to Purdue. For example, APF published *Treatment Options: A Guide*

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[501] PWG004285195; Senate Report available at: https://www.mccaskill.senate.gov/media-center/news-releases/breaking-millions-in-payments-among-findings-of-mccaskill-opioid-investigation-into-ties-between-manufacturers-and-third-party-advocacy-groups-.

[502] PWG000096255.

[503] PTN000017361.

[504] PWG004285195; Senate Report available at: https://www.mccaskill.senate.gov/media-center/news-releases/breaking-millions-in-payments-among-findings-of-mccaskill-opioid-investigation-into-ties-between-manufacturers-and-third-party-advocacy-groups-.

[505] PWG00096255.

[506] PTN000017361.

for People Living with Pain[507] that downplayed and omitted the serious risks of opioids while overstating the risks of non-steroidal anti-inflammatory drugs (NSAIDs) and acetaminophen.[508]

423. Unsurprisingly, APF took actions that were directly in Purdue's interest. As shown in internal emails, Purdue even worried that APF would be perceived as acting too much on its behalf where APF's position was consistent with branded manufacturers, as opposed to positions more consistent with general pain patient advocacy.[509]

424. APF took action that directly benefited Purdue. For example, APF responded to an article titled "Grieving Mother Pushing Oxy Ban – 18-year-old son died of overdose" in a Florida newspaper.[510]

425. APF and Purdue were so connected that Dr. Richard Sackler, who was one of the principal owners of Purdue, even e-mailed Dr. David Haddox, Purdue's Vice President of Health Policy, upon learning that APF shut down in May 2012 after a Congressional investigation launched, stating, "*What is the story here? We were founding funders.*"[511]

From:	Sackler, Dr Richard
To:	Haddox, Dr. J. David
Sent:	5/8/2012 11:44:42 PM
Subject:	FW: Important Announcement

What is the story here? We were founding funders.

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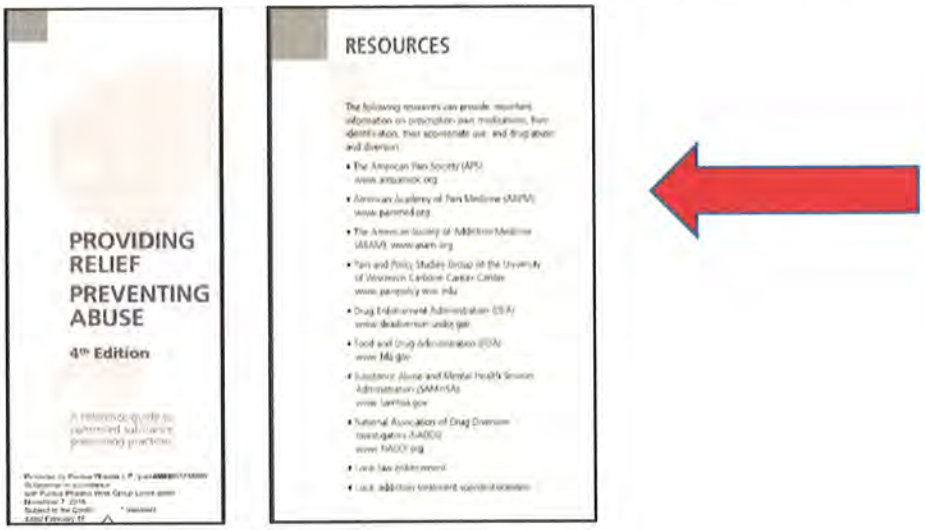
[507] PWG009243973.
[508] PWG009243990-91.
[509] PTN000024706.
[510] PTN000023984.
[511] PTN000023246 (emphasis added).

426. Purdue referred to third party groups in its marketing materials without disclosing its financial connection to the groups alongside authoritative, unbiased sources.



427. *Providing Relief, Preventing Abuse* brochures, as shown in the excerpt above, that were handed out to the general public in Tennessee, included APS and the AAPM along with references to federal regulatory and law enforcement agencies such as the DEA and FDA without disclosing Purdue's funding connection to APS or AAPM.[512]

428. Similarly, Purdue's www.partnersagainstpain.com website referenced APS and AAPM as authoritative resources without disclosing Purdue's financial connection to the groups.[513]

429. In standardized presentations Purdue created to give to health care providers and other groups, Purdue held out APS and AAPM, among others as "Resources for Appropriate Pain

[512] PWG003738850, –61.
[513] PWG000085182.

Management and Responsible Prescribing Practices" without disclosing Purdue's funding connection to these groups.[514]

430. Purdue also linked to deceptive APF materials like *Exit Wounds* on its pain advocacy website, www.inthefaceofpain.com, without disclosing Purdue's significant funding of the group.[515]

431. Purdue's Tennessee sales representatives frequently referenced recommendations from other pain advocacy groups that Purdue significantly funded without clearly and conspicuously disclosing this material fact.

432. For example, Purdue instructed its sales representatives to use the APS guidelines to advance its own branded marketing message. As with materials published by other pain advocacy groups, the APS guidelines advanced Purdue's position by emphasizing the superiority of delivery of the opioid by oral use and attempting to legitimize high doses of opioids, defining a "high" dose to be > 200 MME per day.[516]

433. On May 8, 2007, Sales Representative 4 called on a Collierville-area internist and recorded an interaction in which the sales representative discussed the APS Guidelines without disclosing Purdue's funding connection to APS. The call note from the interaction states as follows:

> Discussed the limitations again with using so much tylenol #3. Said that is just has less of a bad perception with many patients, however she realizes the dosing limitations and will go to oxycontin next once the patient *is exceeding the APS guidelines*[.][517]

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[514] PWG000290879.
[515] PWG000058550.
[516] PWG000225448.
[517] PTN000119294 ID12301 (5/8/2007) (emphasis added).

434. On May 21, 2007, Sales Representative 4 called on a Germantown-area gynecologist and documented an interaction in which the sales representative discussed APS recommendations concerning fentanyl, a competing opioid product, without disclosing Purdue's funding connection to APS. The call note from the interaction states as follows:

> Recommendation of senokot-s for pain med patients and patients that are pregnant because of gentleness and specific delivery system. Never thought about it as a preference but said good point because of the stool softner on board. *Discussed from APS lag time of fentanyl.* Mentioned that he has some problems with this with patients saying it doesn't last as long and adhesion issues.[518]

435. Sales Representative 4 documented his sales calls with a Memphis-based family doctor on May 23, 2007, as follows:

> Said that he will only go to 40mg of oxycontin unless absolutely necessary. *Reviewed APS guidelines and safety at the higher doses of oxycontin*[.][519]

436. On June 7, 2007, Sales Representative 11 called on a Franklin-area family physician in which the sales representative told the provider that APS recommended oral ingestion of opioids without disclosing Purdue's funding connection to APS. The call note reads as follows:

> looked through my sample box, and he wanted to discuss laxative. and the slow mag. and colace. *only was able to discuss duragesic vs oxycontin.* said he uses duragesic if pt has a hard time remembering to take med or likes the patch. *showed aps oral route prefered* because of convenience, flexability, and steady blood level. agreed[.][520]

437. On June 12, 2007, Sales Representative 11 called on a Murfreesboro-area anesthesiologist in which the sales representative told the provider that APS recommended oral

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[518] PTN000119294 ID12771 (5/21/2007) (emphasis added).
[519] PTN000119294 ID12888 (5/23/2007) (emphasis added).
[520] PTN000119294 ID13346 (6/7/2007) (emphasis added).

ingestion of opioids without disclosing Purdue's funding connection to APS. The call note reads as follows:

> saw in surgery center. he was going out *did get in a good discussion of duragesic* . he had a question about the patch. *after he agreed with the aps oral is the better route.*[521]

438. On June 13, 2007, Sales Representative 11 called on an Antioch-based pain doctor and his physician assistant in which the sales representative showed the providers APS materials concerning long-acting opioids when discussing patients on high dose short acting such as Lortab taken multiple times a day without disclosing Purdue's connection to APS. The call note reads as follows:

> objective of day was to get them to go to long acting when approprate. discusseed pts on high dose short acting ie 10mg lortab taking 4 to 5 a day. *showed aps on long acting. less end of dose pain and pts sleep better* . all did say that would be using a prn for a persistent pain problem. will start to review pts one at a time to see if long acting is a appropriate per oxycontin pi[.][522]

439. On June 13, 2007, Sales Representative 14 called on a Memphis-based internist and showed the provider APS materials that referred to the potential benefits of OxyContin for patients who failed on NSAIDs without disclosing Purdue's connection to APS. The call note reads as follows:

> *Quick hit reminder on the APS guidelines for treating OA pain. Stressed the language that speaks to the potential benefits of low dose oxycontin for patients that have previously not responded to NSAIDs.* He said he would keep it in mind.[523]

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[521] PTN000119294 ID13510 (6/12/2007) (emphasis added).
[522] PTN000119294 ID13549 (6/13/2007) (emphasis added).
[523] PTN000119294 ID13580 (6/13/2007) (emphasis added).

440. Similarly, on June 14, 2007, Sales Representative 14 called on another Memphis-based internist and showed the provider APS materials that referred to the potential benefits of OxyContin for patients who failed on NSAIDs without disclosing Purdue's connection to APS. The call note reads as follows:

> *Covered the APS guidelines for treating OA pain. Stressed the language that speaks to the potential benefits that can be seen when NSAID failures are treated with 10mg Oxycontin q12H.* Doc thanked me for the information and said that he continues to use Oxycontin where appropriate.[524]

441. On June 21, 2007, Representative 11 called on a Nashville-based internist and referenced APS materials that purportedly showed that long-acting opioids produce less end of dose pain and allow patients to sleep better at night, without disclosing Purdue's connection to APS. The call note reads as follows:

> discussed new starts and when to go to long acting. *showed aps less end of dose pain and pts sleep better at night.* said if you see pain is persistent and per oxycontin pi then long acting. discussed 10mg usage in some of those patients. said he did not know we had a 10mg tablet[.][525]

442. On June 22, 2007, Sales Representative 5 called on a Hendersonville-based family physician in which the sales representative referred to APS materials supporting the use of OxyContin for patients going to bed in pain without disclosing Purdue's connection to APS. The call note reads as follows:

> *APS 5th edition--supports use of oxycontin for patients going to bed in pain.doc* said he would inquire, more, of his patients on how pain disrupts getting a good nights rest.[526]

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[524] PTN000119294 ID13584 (6/14/2007) (emphasis added).
[525] PTN000119294 ID13833 (6/21/2007) (emphasis added).
[526] PTN000119294 ID13905 (6/22/2007) (emphasis added).

443. Substantially similar claims without disclosures were made by: Sales Representative 5 to a Gallatin-area family physician on June 25, 2007;[527] Sales Representative 4 to a Germantown-area nurse practitioner on August 15, 2007[528] and a Collierville-area family physician on August 28, 2007;[529] and Sales Representative 11 to a Smyrna-area physical medicine and rehabilitation specialist on September 4, 2007.[530]

F. VIOLATIONS OF 2007 AGREED FINAL JUDGMENT

444. Under the 2007 Judgment that Purdue entered into with the State of Tennessee, Purdue was supposed to establish, implement, and follow an Abuse and Diversion Detection (ADD) program in which it would identify and act upon facts received from the field that were indicative of abuse or diversion from June 15, 2007 to May 6, 2017.

445. The non-exclusive facts referenced in the 2007 Judgment include:

- an apparent pattern of an excessive number of patients for the practice type, such as long lines of patients waiting to be seen, waiting rooms filled to standing-room-only capacity, or patient prescriber interactions that are exceedingly brief or non-existent;
- an atypical pattern of prescribing techniques or locations, such as repeated prescribing from an automobile, or repeated prescribing at atypical times, such as after usual office hours when the Health Care Professional is not on call;
- information from a highly-credible source or several sources (*e.g.*, pharmacists, law enforcement, other health care workers) that a Health Care Professional or their patients are abusing or diverting medications;
- sudden unexplained changes in prescribing or dispensing patterns that are not accounted for by changes in patient numbers or practice type;
- a Health Care Professional who has a disproportionate number of patients who pay for office visits and dispensed medications with cash;

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[527] PTN000119294 ID13918 (6/25/2007).
[528] PTN000119294 ID15515 (8/15/2007).
[529] PTN000119294 ID15907 (8/28/2007).
[530] PTN000119294 ID16086 (9/4/2007).

- multiple allegations that individuals from a particular practice have overdosed; or
- unauthorized individuals signing prescriptions or dispensing controlled substances.

446. Purdue also identified the following specific examples of suspicious conduct for abuse and diversion in a training document describing its ADD program:

- On a consistent basis, a long line of patients waiting to get prescriptions;
- A waiting room filled to capacity or standing room only;
- Patient contact with a prescriber that is exceedingly brief or non-existent;
- A volume of prescriptions that seems to significantly exceed what you would expect from geographical data and the type of ... practice;
- Repeated prescribing at atypical times, such as after usual office hours when the Prescriber ... is not on call;
- Very restricted office hours yet significant volume of prescriptions;
- Practices ... heavily populated with young patients (teens and early 20's);
- Practices ... in which more than 35% of the patients pay for their prescription with cash;
- A pediatrician, dentist, podiatrist (or other unusual specialty for a prescriber of opioid analgesics) who starts writing prescriptions for OxyContin® Tablets;
- A prescriber with no history of writing OxyContin or other Schedule II controlled substances begins writing multiple 80 mg OxyContin prescriptions;
- A sudden increase in OxyContin prescriptions where no new HCP or Prescriber joined the practice;
- A credible allegation that a Prescriber ... , staff member or patient has abused or is actively abusing substances, such as alcohol, illicit drugs or prescription medications;
- A Prescriber's practice ... with a large number of patients who travel significant distances, for example, across state lines, to obtain and/or fill their prescriptions without a rational explanation;
- Numerous out-of-state license plates on cars in the parking lot;

- Patients traveling from areas where there are pain management or other trained healthcare professionals to visit a practice that lacks an outstanding reputation;
- A prescriber's practice ... where there are reports that patients make frequent early requests for new prescriptions significantly in advance of the time the initial prescription would normally be completed;
- A credible allegation that a law enforcement or regulatory authorities are conducting an active investigation regarding a Prescriber ... related to their prescribing activities, diversion or substance abuse;
- A Prescriber that moves his or her practice ... from one city or state to another on more than one occasion within a couple of years without obvious explanation;
- A Prescriber ... with an atypical patient population based on Prescriber's ... location and other attendant circumstances;
- A Prescriber ... with an atypical patient population based on Prescriber's ... location and other attendant circumstances; and
- A disproportionate number of younger patients for the nature of the practice, among others.[531]

447. The 2007 Judgment required Purdue to take appropriate steps based on these facts, including the cessation of promotion of Purdue products to a specific health care provider if Purdue had knowledge of this suspicious conduct.

448. Purdue stated in a training document that the purpose of this ADD program was "to enhance the likelihood that the Company *does not promote its opioid products to a Prescriber about whom Purdue has a concern relating to the prescribing or dispensing of controlled substances.*"[532]

449. As part of its ADD program, Purdue required its sales representatives to submit reports of concern (ROCs) if they witnessed any of the above-listed factors and prohibited them from calling on providers they reported until they received further instruction from Purdue. Purdue

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[531] PWG003811623–32.
[532] PWG00381617 (emphasis added).

then made the decision to place a health care provider in either "cease calling" status,[533] a designation in which Purdue's Law Department directed its sales representatives not to call on a specific provider, or keep the provider in "continue calling" status.

450. Overall, Purdue routinely did not place a provider into cease calling status despite credible information indicative of abuse or diversion. Instead, Purdue usually did so only *after* a provider was subject to adverse licensure action, a criminal charge, conviction, or guilty plea, *if at all*. Notably, Purdue requested the provider's sales data as part of its decision process.[534]

451. Purdue's ADD program had inherent structural deficiencies. In establishing, implementing, and following its ADD program, Purdue:

- failed to take appropriate action based on unambiguous, credible signs of abuse or diversion;
- failed to consistently implement a cease calling directive once issued;
- systematically placed a specific health care provider in cease calling status and not the provider's clinic or supervisees who also prescribed opioids—aside from rare exceptions;
- failed to respond or make decisions in a timely manner to reports or questions from sales representatives and district managers about suspicious providers;
- created disincentives for sales representatives to report suspicious provider activity to Purdue's Law Department; and
- structured sales representative bonuses to heavily incentivize calls on high-volume prescribers of Purdue's opioids.

452. As illustrated below, Purdue had knowledge of credible information that various providers and practices were engaging in the abuse or diversion of OxyContin or other opioids and

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[533] *See* PTN000031810.
[534] *See, e.g.*, PTN000042234 (cease call directive); PTN000042243 (continue call directive).

failed to act on this information. Purdue's lack of action under the ADD program was especially true for Purdue's highest volume prescribers of OxyContin.

453. At various times, Purdue's Phoenix database, which Purdue's sales representatives used to identify health care providers to target, still included providers who had been placed in cease calling status as potential targets.[535]

454. Purdue's sales representatives repeatedly called on health care providers *after* they had been placed in cease calling status.[536] Purdue sales representatives called on one provider who was previously identified by law enforcement as being one of the most problematic prescribers in the area at least *13 times while he was in cease calling status*.[537]

455. According to internal Purdue documents, Purdue only reprimanded one sales representative in Tennessee for calling on prescribers in cease call status or after a report of concern was submitted.[538]

456. In addition, except for isolated examples, Purdue merely made recommendations to cease calling on suspicious health care providers, not to cease calling on specific clinics, offices, or even any of the provider's supervisees who also prescribed opioids.[539] This practice allowed a Purdue sales representative to continue calling on the provider's supervisees or the provider's

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[535] *See, e.g.*, PTN000038690–91; PTN000036364; PTN000040179.

[536] *See, e.g.*, PTN000038008; PTN000039266; PTN000039267; PTN000040179; PTN000031807 ID111986 (10/1/2013); PTN000119294 ID159232 (4/16/2014); and PTN000039271. *See also*, PTN000119294 ID137939 (8/8/2013) (notification that doctor was supervising physician at Pain Clinic A; PTN000119294 ID168024 (7/25/2014) (report that doctor was still the supervising physician at Pain Clinic A); PTN000119294 ID142209 (9/23/2013); PTN000119294 ID144696 (10/17/2013); PTN000119294 ID146491 (11/6/2013); PTN000119294 ID147280 (11/13/2013); PTN000119294 ID150180 (12/18/2013); PTN000119294 ID151387 (1/13/2014); PTN000119294 ID154177 (2/19/2014); PTN000119294 ID155218 (3/4/2014); PTN000119294 ID158660 (4/8/2014); PTN000119294 ID161081 (5/5/2014); PTN000119294 ID163625 (6/2/2014); PTN000119294 ID166526 (7/8/2014); and PTN000119294 ID169020 (8/6/2014).

[537] *See* PTN000119294.

[538] PTN000045549–51.

[539] PTN000038691; *see also*, PTN000036379.

clinic even when the entire clinic was suspected of abuse or diversion or there were other red flags that were not limited to a single provider. On numerous occasions, Purdue kept calling on a provider's supervisees when the supervisor had been placed in cease calling status or on other providers from a clinic when there were red flags that were not limited to a single provider.[540]

457. Purdue's home office frequently failed to timely respond to reports and questions about suspicious providers from sales representatives and district managers even after repeated prompts.[541]

458. In one example, Purdue had direct reports from a sheriff and a narcotics detective on July 18, 2007 that two providers had questionable prescribing practices[542] and had been disciplined by the Tennessee Board of Medical Examiners,[543] as well as reports from sales representatives that contained classic red flags such as high numbers of cash paying patients, crowded waiting rooms, and reports of patients dying from overdoses.[544] Despite these reports, Purdue waited one and one-half years before making a decision to cease calling on these two providers. Even then, Purdue only made the decision the day after news broke on February 4, 2009 of the providers' arrests and indictments for illegally supplying large quantities of prescriptions to hundreds of people, including a visibly pregnant woman whose child was later born with neonatal abstinence syndrome.[545]

459. Similarly, on October 30, 2008, Purdue received both a report that a provider was being investigated by the Tennessee Board of Medical Examiners[546] and a report that local

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[540] *See, e.g.*, PTN000031807 ID111986 (10/1/2013); PTN000031807 ID194150 (4/16/2014).
[541] *See, e.g.*, PTN000038690–91; PTN000038338 and PTN000031810 (48 days until cease calling status).
[542] PTN00039938–39.
[543] PTN00038268; PTN000038275.
[544] PTN000038288; PTN000038298.
[545] PTN000031810; PTN000038290–91; PTN000038311–12.
[546] PTN000042203–04.

pharmacists were seriously questioning the prescribing practices of the same provider.[547] Purdue waited a full year and a half to make a decision until April 5, 2010. In the meantime, that provider had at least one patient die from an overdose of OxyContin[548] and the provider was disciplined by the Tennessee Board of Medical Examiners for his inappropriate prescribing of controlled substances.[549]

460. Likewise, in 2013, Purdue waited 48 days to make a cease calling decision after receiving a firsthand report from one of its sales representatives that a 40 year-old patient was being closely coached on how to fill out intake forms by a much younger woman the patient came in with, both the patient and the younger woman were visibly nervous, and the clinic had a new sign stating that it provided MRIs for $270 cash.[550]

461. All of these providers mentioned above were among the top prescribers of OxyContin in Tennessee and were specifically and continuously targeted by Purdue sales representatives.

462. Purdue's ADD program in many instances conflicted with Purdue's primary focus: sales. Purdue's Marketing Department attributed declines in its market share in part due to Region 0, a term often used interchangeably with Purdue's ADD program. In its Data and Market Insights for 2011, Purdue stated its OxyContin brand share declined 0.6 points and attributed Region 0 as one of the factors.[551]

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[547] PTN000042206.
[548] PTN000042043; PTN000042099; PTN000042139–41.
[549] PTN000042074.
[550] PTN000031810; PTN000038338.
[551] PWG000324230.

463. In addition to Purdue's sales representative compensation program that always had prescription sales from targeted providers as a primary component, Purdue also created internal policies to actually dis-incentivize sales representatives from reporting suspicious providers.

464. For example, Purdue's Incentive Bonus Program, which was effective January 1, 2013, made clear that sales representatives would not receive a bonus based on sales from providers whom the sales representatives reported to Purdue's Law Department that were placed in cease calling status. However, under this Program, Purdue sales representatives would potentially still receive a bonus based on prescribers' sales data that sales representatives did not initially report but who were later placed in cease calling status by the Law Department.[552] The Incentive Bonus Program stated:

> 5.1.3.2 Where the Sales Representative reports a prescriber pursuant to RSOP 1.7.1 and the Law Department ultimately determines that the Sales Representative should cease calling on that prescriber, the sales and sales history attributable to that prescriber will remain removed from the Sales Representative's bonus calculations.
>
> 5.1.3.3 Conversely, where the Law Department determines that a Sales Representative should cease calling on a prescriber who was not initially reported by the Sales Representative, the sales history attributable to that prescriber may be manually added back into the Sales Representative's bonus calculations at the company's discretion following a review of the circumstances.[553]

465. While some Purdue sales representatives provided superiors with reports about suspicious prescribers, they did so in spite of the Incentive Bonus Program or their general compensation structure and far less often than they engaged in activity that undermined Purdue's ADD duties.

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[552] PWG003874628.
[553] PWG003874628.

466. As an illustrative example, Sales Representative 3 made a sales call to a Kingston-area family doctor on July 20, 2007, and wrote the following about his interaction:

> very interested in pain mgmt - *told me prescribes a lot of oxycontin but not brand due to street value - asked him why it mattered if thought was going to end on street ?* - point well received - interested in itmes to assist in pt selection[.][554]

467. As an additional part of the bonus system, Purdue held a yearly national sales contest in which members of the sales force competed to be in the "Topper's Club," by either finishing the contest year as a district leader or in the top 10% of all representatives in the nation, generally based on the number of opioid prescriptions attributed to that representative. Sales personnel who were in the Purdue Topper's Club won trips as well as money.

468. Purdue also structured bonuses for its sales staff to focus on its highest volume prescribers, which it termed "super core" and "core" prescribers.[555] Purdue used a point system to allocate bonuses that rewarded sales representatives who had the highest percentage of total sales calls with super core or core prescribers, who were also more likely to be the most problematic prescribers.[556] Purdue repeatedly emphasized in memoranda to its sales representatives, "*It is extremely important that all Sales Force colleagues* maintain a high energy level, and *continue the focus solely on Core and Super Core selected prescribers.*"[557]

469. Sales Representative 11's career with Purdue demonstrates this perverse incentive. He was a member of the Purdue Topper's Club[558] for at least six years and earned a total of $35,238 in related bonuses. Sales Representative 11 was also ranked first nationally as the "OxyContin

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[554] PTN000119294 ID14658 (7/20/2007) (emphasis added).
[555] *See, e.g.*, PWG003874461 ("District Manager Incentive Program").
[556] PWG003874461.
[557] *See, e.g.*, PTN000033091 (emphasis added).
[558] PTN000056968.

Product Leader" in Purdue's contest based on OxyContin prescription numbers, for several years running.[559] Purdue rewarded his success in selling its opioids. In 2010, Sales Representative 11's base salary was $110,743.11, yet he earned and additional $128,592 in bonuses.[560] In 2014, Sales Representative 11 participated as a member of Purdue's Sales and Marketing Advisory Council.[561]

470. Sales Representative 11 called on a large number of highly problematic providers who ended up in cease calling status, criminally indicted, and/or had adverse licensure action taken against them, including many of the ones discussed below. For example, he called on Dr. Michael Rhodes, Dr. James Pogue, Dr. Mireille Lalanne, Dr. Visuvalingam Vilvarajah, Dr. Donald Boatright, among many others, as well as problematic pain clinics, such as Pain Clinic F, and pharmacies. Sales Representative 11 also ranked as high as second among all Purdue sales representatives for redemptions of OxyContin savings cards by patients of prescribers he called upon.[562] The savings cards provided up to a $90[563] discount off the purchase of OxyContin, could be used repeatedly, and were closely associated with cash-paying patients and high volume practices.

471. Other Purdue sales representatives who called on these same problematic providers filed some ROCs to Purdue. Yet Sales Representative 11, despite calling on some of these providers for years and having access to other sales representatives' call notes for these providers, almost never reported them to Purdue. Purdue never disciplined Sales Representative 11 for failing to report abuse and diversion, despite ample evidence of it. Instead, they rewarded his blind eye.

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[559] *See, e.g.*, PTN000032549.
[560] PTN000036126.
[561] PTN000033821.
[562] PWG000046398.
[563] PTN00001279.

472. In other cases, Purdue ignored suspicious behavior. For example, in 2016 after a sales representative reported that a large health insurance company was "pulling credentials for prescribing patterns" for a pain clinic, Purdue's Law Department responded:

> This appears to be an insurance-related issue, not an SOP 1.7.1 issue, therefore we will not be opening an ADD inquiry and you can continue calling on this practice. If you do learn of or observe any SOP 1.7.1 concerns, please be sure to report them immediately.[564]

Purdue employees used the term SOP 1.7.1 or 1.7.1 to refer to the section in Purdue's Standard Operating Procedures that established circumstances in which sales representatives were not supposed to make a sales call on a provider. During the time the ADD program was in effect, 1.7.1 was used interchangeably to describe the ADD program itself.

473. The inadequacy of Purdue's ADD program and its failure to take appropriate steps is set forth in the following illustrative examples with specific health care providers and practices in Tennessee.

Dr. Michael A. Rhodes, Sr.
Cease Calling Status Date: November 3, 2015

474. Dr. Michael Rhodes was a family doctor in Springfield and one of Purdue's top prescribers of OxyContin in Tennessee. From 2006 to 2015, Dr. Rhodes prescribed 102,166 tablets of 80 mg OxyContin—one of Purdue's highest doses.[565] From 2006 to 2015, Dr. Rhodes prescribed 319,560 total tablets of OxyContin.[566] Purdue had knowledge that at least 217 of Dr. Rhodes's patients paid with cash for OxyContin in 2008.[567]

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[564] PTN000079780–81.
[565] PTN000031809.
[566] PTN000031809.
[567] PTN000056674.

475. Dr. Rhodes wrote 297 prescriptions for OxyContin in 2007; 1,082 in 2008; 1,204 in 2009; and 1,307 in 2010. Between 2006 and August 2016, he wrote a total of 4,921 prescriptions for OxyContin, 3,593 of which were written in a three-year span.[568]

476. Purdue first called on Dr. Rhodes on February 10, 2004,[569] and would call on him at least *126* additional times between January 30, 2006 and August 27, 2015[570] though there are indications that Purdue called on him more often than reflected in the call notes.[571]

477. *Purdue even called on Dr. Rhodes 31 times after the Tennessee Board of Medical Examiners placed his license on restrictive probation on May 22, 2013.*[572]

478. Purdue reviewed ROCs filed by sales representatives and affirmatively decided to keep Dr. Rhodes in continue calling status on April 5, 2010, November 14, 2012, and August 26, 2013—the last of which occurred after his license was placed on probation.[573]

479. As outlined below, before Purdue finally moved Dr. Rhodes to cease calling status on November 3, 2015,[574] it had knowledge of reports of patient overdose deaths from Dr. Rhodes's prescription of OxyContin, a knife fight outside his office, choreographed urine screenings, several relevant investigations by the Tennessee Board of Medical Examiners that led to disciplinary actions and ultimately the revocation of his medical license, an accusation of insurance fraud, his high patient volume, and that Dr. Rhodes was contemplating a business name change after discovering he was being investigated by the State.

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[568] PTN000052837.
[569] PTN000042047.
[570] PTN000031807.
[571] *See* PTN00042221 (ROC Sales Representative 5 filed on 10/23/15 saying Dr. Rhodes informed him that his license was suspended); PTN000031807 (listing last call note for Dr. Rhodes on 8/27/15).
[572] PTN000042209–10.
[573] PTN000031810.
[574] PTN000031810.

480. While other Purdue sales representatives had been calling on him for years, Sales Representative 13 began calling on Dr. Rhodes on April 14, 2008.[575] Sales Representative 13's notes indicate that during this first meeting, Dr. Rhodes told her that "he heard Oxycontin is 80 dollars a pill on the street ... [d]id not reveal source," and she "[r]eminded him of the appropriate patient and the indications for Oxycontin."[576]

481. That same day, Sales Representative 13 also called on a pharmacy, where she and the pharmacist "[d]iscussed the [prescription] writers in town and she confirmed I was going to the right places. Said Dr. Rhodes uses much TNcare and she is usally having to be on the phone for long periods of time for his patients."[577]

482. On May 8, 2008, District Manager 1 accompanied Sales Representative 13 on her call with Dr. Rhodes and he stated: "*Documentation resources presented, doctor agreed to implement and have staff print, new strengths presented, agreement for 30mg and 60mg*, Snokot S samples and dosing."[578]

483. A month later on June 26, 2008, Sales Representative 13 submitted an ROC about Dr. Rhodes which stated:

> Had lunch today and went over the new savings cards and ordered cme's for Dr. Rhodes, *as I was sitting in his office, there were two patients in a knife fight outside the office's front door, I overheard one of the patients saying he wanted his ID. Many patients were lottery the office as they have the past two times I was in there. Concerned the doctor is being taken advantage of by some drug seekers. Dr. Rhodes said he does urine drug screens but tells the patient when he will do the next drug screen.* Said he was trying to get the pain management forms together. Said he has many patients saying that their doctors are referring patients to him because they can't write any narcotics but he can, he asked me why they cannot write it.

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[575] PTN000042087.
[576] PTN000042087.
[577] PTN000119294.
[578] PTN000035268 (emphasis added).

> *Said his patient load that morning was 40 people for the morning that someone overbooked him.*[579]

484. Purdue's Sales and Marketing Department forwarded this ROC to Purdue's Risk Management the next day on June 27, 2008.[580]

485. Sales Representative 13 submitted another ROC about Dr. Rhodes to Purdue on July 2, 2008, which stated:

> On Monday evening, I was in the back yard with my sister-in-law in Clarksville, TN. *Her neighbor a Nurse Practitioners, told me that she has been sending many of her patients, who are asking for pain medication to Dr. Boatwright's office, where Dr. A has been prescribing narcotics for them. She said she had heard that if you offer enough money Dr. A will write whatever you ask for. Dr. A is not in my territory but his partner , Dr. Boatwright has several other locations with Dr. Rhodes from Springfield, TN. Dr. Boatwright and Dr. Rhodes are in my territory.*
>
> A report was made last week, by me. I have [] heard that Dr. Boatwright is in physical medicine and he will not write narcotics.[581]

486. This ROC was also forwarded to Purdue's Risk Management department on July 2, 2008.[582]

487. On September 3, 2008, Sales Representative 5 called on an Ashland City pharmacy, where the pharmacist told him that "most of the high dose oxycontin prescriptions are coming from drs rhode and [another provider]."[583]

488. Despite documenting her concerns, Sales Representative 13 continued to regularly make sales calls to Dr. Rhodes.[584] Sales Representative 13's October 30, 2008 call note for Dr. Rhodes stated: "Went over the Drug monitoring program for Tn and Kentucky, *said he has not*

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[579] PTN000042217–18 (emphasis added).
[580] PTN000042217.
[581] PTN000041565 (emphasis added).
[582] PTN000041565.
[583] PTN000119294.
[584] PTN000042087–88.

beening [sic] doing those but will. Said he is changing the name of the clinic from pain clinic to medical clinic because he is having to submit some patients charts to the TN Boards."[585]

489. Notably, on that same day, Sales Representative 13 also submitted three separate ROCs to Purdue's Sales and Marketing Department concerning Dr. Rhodes.[586] In the first ROC, Dr. Rhodes was listed as the reporter and Sales Representative 13's summary of the event stated: "*[He s]aid the Tn medical board is investigating him on some of his patient records and he is concerned. Said he feels he has been treating too many pain patients and he is going to have to change the name of his clinic from pain clinic to medical clinic.*"[587]

490. Sales Representative 13's second ROC on October 30, 2008 stated:

> Talked with [pharmacists], [pharmacist] said she is concerned *Dr.Michael Rhodes may not be doing the right thing for his patients, she felt that he was just giving the patients whatever they want. [Pharmacist] said he tore up two scripts of Oxycontin yesterday from Dr. Micheal Rhodes clinic, one from the doctor and one from the NP within 10 days apart, called Dr. Rhodes and asked him to tear up the script.*[588]

491. The third ROC submitted by Sales Representative 13 on October 30, 2008 stated:

> Doctor new to this practice and as we discussed the 10 point plan and Oxycontin, said *asked if Dr.Rhodes was my highest prescriber for Oxycontin, I told her many physicians treat pain with Oxycontin. This made me quite uncomfortable.*[589]

492. A little over a week later, on November 7, 2008, Sales Representative 5 called on Dr. Rhodes.[590]

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[585] PTN000042088 (emphasis added).
[586] PTN000042203–06.
[587] PTN000042204 (emphasis added).
[588] PTN000042206 (emphasis added).
[589] PTN000119294 (emphasis added).
[590] PTN000042058.

493. On November 12, 2008, an attorney in Purdue's Law Department emailed Sales Representative 13 with a request to call her at Sales Representative 13's earliest convenience to discuss the second ROC.[591] While the content of the call is not known to the State, Sales Representative 13 again called on Dr. Rhodes on December 11, 2008, and she and Sales Representative 5 continued regularly calling on Dr. Rhodes.[592]

494. On January 1, 2009, Purdue printed Sales Representative 13's call notes for Dr. Rhodes from July 26, 2007 to December 11, 2008—the same ones referenced above.[593]

495. Sales Representative 13 submitted another ROC to Purdue on February 6, 2009, which read:

> [Provider] asked if we recommend oxycontin to be taken more often than q12h, I stated no our product insert states clearly, we are only indicated q12h, *he asked me to share that with Dr. Rhodes because he has seen him write it q8h and q6h. Told [Provider] I have shared that with Dr. Rhodes and will share that with him again.*[594]

496. Sales Representative 13 entered a call note on March 4, 2009, which read, "[Pharmacist] *told me most of the high dose oxycontin prescriptions are coming from drs. rhodes* [and other Provider]."[595] Multiple other pharmacies made similar statements to Purdue's Sales Representatives 5 and 13.[596]

497. A call note entered by Sales Representative 13 on April 28, 2009 read as follows:

> Went over the conversion guide and reminded of the 15mg strength tablets. Said he would use the 15mg. *Also went over the PI and the highest dose studied with oxycontin, said that information did help to see the average*

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[591] PTN000042205.
[592] PTN000042058.
[593] PTN000042086–88.
[594] PTN000119294 (emphasis added).
[595] PTN000119294.
[596] PTN000119294.

dose of the study was 105mg strength. Reminded of the savings cards as well.[597]

498. On August 17, 2009, Purdue printed a report from NewsChannel 5 titled "Mother accuses Springfield doctor of prescribing pain medication for no reason."[598]

499. The report, which was dated four days earlier on August 13, 2009, stated:

> *Tonight serious concerns about a pain clinic and whether prescriptions for powerful narcotics are written for no good medical reason.* New at six, *a young man is dead and a mother is grieving.* But the doctor in question tells us he did nothing wrong.
>
> [Patient A's Mother] says she lost her son to prescription narcotics.
>
> *Patient A died in January.* Each week his mother cleans his headstone and asked herself why.
>
> *[Patient A's Mother] says her son did not suffer from chronic pain, yet he was able to obtain prescriptions for oxycodone from among other, Dr. Michael Rhodes Sr. at this Springfield pain clinic.*
>
> *Dr. Rhodes is still practicing medicine at the clinic in Springfield, but the state board of medical examiners has taken notice, citing problems with nine different patients.*
>
> *They issued a formal reprimand citing the doctor for unprofessional or unethical conduct, gross malpractice or negligence in the course of medical practice, and dispensing, prescribing any controlled substance not in good faith to relieve pain and suffering.*
>
> [Clinic manager] says Dr. Rhodes sees many patients who have nowhere else to go, most of them on TennCare, and many seeking relief from pain.
>
> Dr. Rhodes says he does not prescribe narcotics for no medical reason...[599]

500. On August 24, 2009, Purdue documented that Patient A's mother called the company and reported that:

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[597] PTN000042026 (emphasis added).
[598] PTN000042043.
[599] PTN000042043 (emphasis added).

- her son's autopsy revealed he had accidentally overdosed on OxyContin given by Dr. Rhodes;
- Dr. Rhodes had given her son 90 80 mg OxyContin tablets and 60 Lyrica 75 mg tablets despite a history of addiction to OxyContin;
- Dr. Rhodes started her son on 40 mg of OxyContin instead of 10 mg;
- Dr. Rhodes still had his license but was reprimanded and charged with negligence and gross and repeated malpractice with 10 patients; and
- "Dr. Rhodes is feeding addicts."[600]

501. Purdue submitted an FDA-required adverse event form on August 31, 2009 that stated that Patient A's death was an accident and though he had previously taken Lyrica and Suboxone as concomitant medications, he died "from the toxic effects of OxyContin."[601]

> The patient died on 08JAN2009 from the toxic effects of OxyContin. The manner of death was accidental.

502. Purdue also sent a letter to Dr. Rhodes concerning the adverse event report around the same time.

503. Before it submitted the adverse event form on August 31, 2009, Purdue received and reviewed a copy of the state medical examiner's report, excerpted below, that stated, "*[i]n my opinion, the cause of death is toxic effects of oxycodone*. The manner of death is accident."[602]

> This 26-year-old white man, with a history of drug abuse, was found unresponsive in his residence.
>
> Autopsy reveals pulmonary edema. The postmortem blood contains an elevated level of oxycodone.
>
> In my opinion, the cause of death is toxic effects of oxycodone. The manner of death is accident.

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[600] PTN000042139–41.
[601] PTN000042103.
[602] PTN000042110 (emphasis added).

504. Sales Representative 5 next called on Dr. Rhodes on September 25, 2009 during which Dr. Rhodes "told [the sales representative that] he received a letter from Purdue. must have been an adverse event. will be cautious in prescribing oxycontin."[603] The letter Purdue sent to Dr. Rhodes on September 1, 2009 informed him that Patient A had overdosed on OxyContin and that Patient A's mother had given Purdue permission to contact Dr. Rhodes for more information.[604]

505. In addition to the NewsChannel 5 report that referenced the disciplinary action, Purdue's internal records indicate that Purdue had knowledge no later than September 25, 2009 that the Tennessee Board of Medical Examiners formally disciplined Dr. Rhodes on July 21, 2009.[605]

506. The Tennessee Board of Medical Examiners found that Dr. Rhodes "*[p]rescribed controlled substances without documenting appropriate medical histories and/or performing adequate physical examinations to justify the medical necessity and/or duration of the medications.*"[606] As a result, the Board took action against Dr. Rhodes's license and fined him.[607]

507. In spite of this disciplinary action by the Board and direct knowledge of his patient's overdose death from OxyContin, *Purdue continued to call on Dr. Rhodes.*

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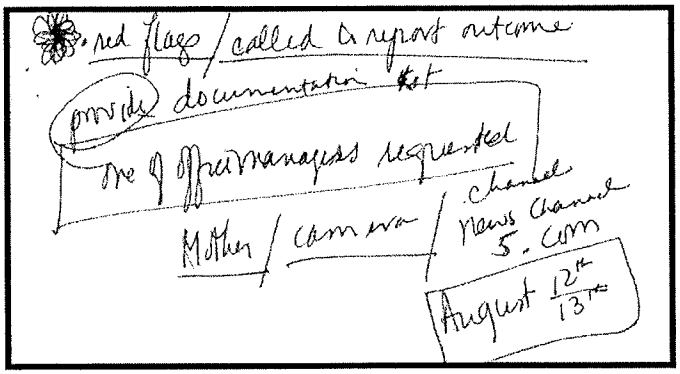
[603] PTN000042056.
[604] PTN000042099.
[605] PTN000042074.
[606] PTN000042074 (emphasis added).
[607] PTN000042074.

508. Handwritten notes, shown below, provided by Purdue show that the company was aware of and classified the events as red flags and suggested that sales representatives provide Dr. Rhodes with a documentation kit.[608]



509. On December 2, 2009, Sales Representative 5 called on Dr. Rhodes and recorded that Dr. Rhodes "told me some of the staff in the office don't trust me, but he has no problem because I gave him resources to help him in prescribing oxycontin."[609]

510. Despite all of this information, Purdue closed its 17-month long investigation into Dr. Rhodes on April 1, 2010 and directed its sales representatives *that they could continue calling on Dr. Rhodes.*[610] Sales representatives had not ceased calling on Dr. Rhodes during Purdue's investigation, however, but instead called on him no fewer than *24 times* during this period, once with a district manager present. Purdue never reprimanded or disciplined any of the sales representatives or district managers who called on Dr. Rhodes.

511. On July 26, 2010, Sales Representative 5 called on Dr. Rhodes and was accompanied by District Manager 1, who wrote the following:

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[608] PTN000042074–75.
[609] PTN000119294.
[610] PTN000042068; PTN000031810.

> Reviewed the updated OxyContin fpi, *discussed patient selection and documentation, doctor agreed on importance.* Bridged to Ryzolt, doctor asked percentage of patients who receive efficacy with product. [Sales Representative 5], good job with the Ryzolt fpi and discussing the clinical data within this document and the current indication. *Doctor agreed and requested additional savings cards.* Reminder on the Senokot S for opioid induced constipation, dosing, and provided samples.[611]

512. On January 4, 2011, Purdue's Law Department received an email from District Manager 1 that referenced another interaction with Patient A's mother during which she said that her son died of an overdose from OxyContin originally prescribed by Dr. Rhodes. The body of the e-mail stated:

> Today, I was conducting a training meeting at the Hampton Inn and Suites in Mt. Juliet, TN. *I was approached by the employee working the front desk and her name is [Patient A's mother's first name]. She saw that Purdue Pharma was on the schedule for one of the meeting rooms and notified me that her son died of an overdose on OxyContin two years ago. She stated that he bought the drug off the street and that the drug was originally prescribed by Dr. Michael Rhodes of Springfield, TN. She said that she was on the television news two years ago on a segment regarding this physician. In addition, she has been working to change the Tennessee Intractable Pain Law that according to her does not allow prescribers to be criminally held responsible. She has also mentioned that she spoke to [Purdue] in the past regarding this situation.*[612]

513. Purdue continued to pressure Dr. Rhodes to prescribe more and more opioids, even when he expressed concerns regarding his own ability to competently do so. For example, on August 9, 2011, Sales Representative 5 called on Dr. Rhodes and recorded that "[h]e found the Butrans dinner meeting as information overload. *He felt Butrans is too complicated to prescribe.* He wants to decrease patient's use of short acting medication. *I told him to prescribe Butrans. He is very reluctant.*"[613]

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[611] PTN000035268 ID1554 (emphasis added).
[612] PTN000042037 (emphasis added).
[613] PTN000119294 (emphasis added).

514. On March 30, 2012, Purdue verified Dr. Rhodes's licensure status via the Tennessee Department of Health's website which indicated that the Tennessee Board of Medical Examiners had reprimanded Dr. Rhodes for "unprofessional conduct."[614]

515. On April 23, 2012, District Manager 1 accompanied Sales Representative 5 on a sales call and wrote the following comment:

> *Good job of finding Dr. Rhodes new practice. He had at least 20 patients waiting and he stated he did not have time today.* Reminded him of OxyContin and Butrans, he stated he is seeing more Primary Care patients, asked you to come back in two weeks.[615]

516. Sales Representative 5 recorded the following for the same sales call:

> *I reminded dr. rhodes that I continue to promote Butrans and oxycontin. He told me he is no longer in pain mgmt.., but primary practice. He refers his patients to a pain clinic.* Doc told me to come back in two weeks and we will discuss his practice.[616]

517. Sales Representative 5 called on Dr. Rhodes again on June 18, 2012, and Dr. Rhodes, again, told Sales Representative 5 that he was "not a pain clinic and will not prescribe Butrans or oxycontin."

518. On August 28, 2012, the next time Sales Representative 5 called on him, Dr. Rhodes once again "said he is referring his pain patients to pain clinics. He said he is not prescribing Butrans or oxycontin. He is maintaining patients on what they are presently on, but no new prescriptions."[617]

519. On August 27, 2012, District Manager 1 accompanied Sales Representative 5 on a sales call for Dr. Rhodes and wrote the following comment:

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[614] PTN000042040.
[615] PTN000035268.
[616] PTN000119294 (emphasis added).
[617] PTN000119294.

> [Sales Representative 5], we need to wait a few months to see if this HCP is able to register as a Pain Clinic in Tennessee. *He has been reported to the Law Department in the past and we have been allowed to continue sales calls.* Based on the information provided directly by the HCP this morning, he claims to not have any new pain patients in his practice and is getting away from treating pain. Please continue to provide any new information to the Law Department regarding changes to this practice as per the ADD policy.[618]

520. Purdue had knowledge of additional red flags about Dr. Rhodes's prescribing problems. On October 9, 2012, Sales Representative 5 emailed Purdue's Law Department and District Manager 1 to report that "*Dr. Rhodes told me he is meeting with his lawyer, on tomorrow, because Americhoice has accused him of fraud. He mentioned that he wrote a wrong date on the chart, which led to the accusation.*"[619]

521. On November 14, 2012, Purdue *yet again determined that sales representatives may continue calling on Dr. Rhodes.*[620]

522. On May 22, 2013, the Tennessee Board of Medical Examiners disciplined Dr. Rhodes for the second time and placed his license on restrictive probation for five years.

523. Among other things, Dr. Rhodes admitted to:

> *prescribing narcotics and other medications and controlled substances in amounts and/or for durations not medically necessary, advisable, or justified for a diagnosed condition[;] ... prescrib[ing] controlled substances for pain for his patients without a clear objective finding of a chronic pain source to justify the ongoing and increasing prescribing[;] ... prescrib[ing] controlled substances and other medication without documenting a written treatment plan with regard to the use of controlled substances and other medication;* ... fail[ing] to properly or consistently monitor for or seek out and respond to signs of substance abuse on the part of his patients[;] ... [and] provid[ing] few modalities of treatment other than the prescription of controlled substances.[621]

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[618] PTN000035268 (emphasis added).
[619] PTN000042076 (emphasis added).
[620] PTN000042046.
[621] PTN000042209–10 (emphasis added).

524. District Manager 1 emailed Purdue's Law Department on June 19, 2013 to report: "*I was informed today that Michael Rhodes officially lost his medical license. He has [been] reported numerous times for various reasons.*"[622]

525. In spite of this information, on August 26, 2013, Purdue's Law Department sent an email stating that "*[s]ales representatives may continue to call of Dr. Michael Rhodes. If, however, any negative relevant information about Dr. Rhodes' prescribing or his practice comes to light, the sales force should contact the Law Department for review and recommendation.*"[623]

526. Sales Representatives continued to report red flags to Purdue, such as Dr. Rhodes's office being open on Christmas Eve in 2013, which Sales Representative 5 noted as "[o]ne of the few offices open."

527. As stated above, Purdue's sales representatives called on Dr. Rhodes at least *31 times after his license was placed on restrictive probation.*[624]

528. For example, Sales Representative 5 and District Manager 1 called on Dr. Rhodes on May 22, 2014 and continued to encourage him to write more prescriptions, despite his objection:

> Good delivery of Insight #16, developed constructive tension, *doctor gave the getting out of Pain Management objection. Good job refocusing him to appropriate patients for OxyContin because he still sees Pain Patients.*[625]

529. On September 18, 2015, the Tennessee Board of Medical Examiners revoked Dr. Rhodes's license for repeatedly violating the Board's orders.

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[622] PTN000042201 (emphasis added).
[623] PTN000042089 (emphasis added).
[624] PTN000031807.
[625] PTN000035268 (emphasis added).

530. On October 22, 2015, Sales Representative 5 informed Purdue of the Board's action by submitting another ROC. It stated that "*Dr. Rhodes informed me that his medical license has been taken (revoked) by the Tennessee Medical board and his practice is currently closed.*"[626] This report was forwarded to Purdue's ADD-Legal, Drug Safety, and Pharmacovigilance, and Risk Management departments the next day, and Purdue verified his licensure that day as well.[627] Purdue also printed Dr. Rhodes's "Current Prescriber TRx" on October 23, 2015, which showed him still prescribing hundreds and hundreds of narcotic painkillers per month.[628]

531. On November 3, 2015, six weeks after Dr. Rhodes lost his license to practice, Purdue finally placed him in cease calling status and instructed sales representatives that they "should not call on" him.[629]

Dr. James Pogue
Cease Calling Status Date: July 30, 2012

532. Dr. James Pogue, a family doctor practicing in Brentwood, was the number one prescriber of OxyContin tablets in Tennessee from 2006 to 2016—despite not prescribing any tablets from 2013 to 2016.[630] Dr. Pogue's prolific prescribing habits and use of OxyContin prescription savings cards for cash paying patients were indicative of red flags of which Purdue had knowledge.

533. Between insurance, cash, Medicaid, and Medicare Part D payors, Dr. Pogue prescribed a total of 562,703 tablets of 80 mg OxyContin[631]—one of Purdue's highest doses—and

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[626] PTN000042221 (emphasis added).
[627] PTN000042221–22.
[628] PTN000042038.
[629] PTN000042091.
[630] PTN000031809.
[631] PTN000031809.

which translates into 240 MMEs per day when taken as directed.[632] During a six month period in 2009, Dr. Pogue alone generated *$655,106.19* in revenue for Purdue.[633]

534. From 2009 to 2012, Dr. Pogue's patients redeemed approximately 2,733 OxyContin savings cards to pay in part for their prescriptions.[634] Approximately 1,808 of those savings cards handed out by Dr. Pogue were used for 80 mg OxyContin prescriptions.[635] From January to October 2010, Dr. Pogue's patients redeemed 1,808 OxyContin savings cards,[636] compared with a total redemption of 4,714 *for all prescribers in his territory.*

535. Data from savings card redemptions that Purdue collected and tracked also shows that Dr. Pogue wrote numerous, incredibly high dose prescriptions of OxyContin to younger patients. According to Purdue's savings card data, the average age for Dr. Pogue's patients who used savings cards was 39 and the average number of pills per prescription was 85.[637]

536. Purdue's savings card data for specific days tell a similar story. As a representative example, Purdue knew through its savings card data that Dr. Pogue prescribed *1,990* OxyContin 80 mg tablets and 180 OxyContin 60 mg tablets[638] to 20, mostly younger patients that redeemed savings cards at pharmacies on April 19, 2010 as indicated in the chart below:

April 19, 2010 Savings Card Redemptions

Patient Age and Gender	Dose Strength	Number of Tablets	Days' Supply
47 F	80 mg	240	30
59 M	80 mg	180	30

[632] https://tenncare.magellanhealth.com/static/docs/Program_Information/TennCare_MME_Conversion_Chart.pdf.
[633] PTN000039192.
[634] PTN000056673.
[635] PTN000056673.
[636] PTN000108464.
[637] PTN000056673.
[638] PTN000056673.

29 M	80 mg	160	26
24 M	80 mg	120	30
30 M	80 mg	120	30
30 M	80 mg	120	30
30 F	80 mg	120	30
32 F	80 mg	120	30
35 M	80 mg	120	30
38 M	80 mg	120	30
39 M	80 mg	120	30
44 M	80 mg	120	30
27 F	60 mg	120	30
45 M	80 mg	90	30
26 M	80 mg	60	30
35 F	80 mg	60	30
42 F	80 mg	60	30
68 M	80 mg	60	30
26 M	60 mg	60	30
28 F	40 mg	60	30

537. High quantities of high dose OxyContin, such as those obtained on April 19, 2010 through OxyContin savings cards, are especially troubling because they pose a greater risk of abuse or diversion. While the street value of OxyContin can vary by geographic location, the U.S. Drug Enforcement Administration (DEA) has previously found that diverted OxyContin generally sells for $1 per milligram.[639] At $1 per milligram, the prescription referenced above for a 30 day supply

[639] https://www.justice.gov/archive/ndic/pubs10/10550/10550p.pdf.

of 240 80 mg OxyContin tablets if diverted would have a street value of *$19,200 by itself.* As known to Purdue, Dr. Pogue also prescribed a 30-day supply of 240 tablets of 80 mg OxyContin that was purchased using a Purdue savings card with the same unique patient identifier on February 18, 2010, March 22, 2010, May 17, 2010, June 17, 2010, and July 13, 2010.[640] At $1 per milligram, these prescriptions would have a street value of $115,200.

538. Purdue knew through the savings card data that it collected of other examples of many other high quantity/high dose prescriptions from Dr. Pogue that were extremely likely to have been diverted. Purdue compiled savings card data showing that Dr. Pogue wrote a 24 year-old male a 12-day prescription for 150 tablets of 80 mg OxyContin —equivalent to 1,000 mg or *1,500 MMEs* a day. Dr. Pogue also wrote a 12-day prescription for 180 tablets of 80 mg OxyContin, which equals 16 tablets per day, or *1,920* MMEs per day, *over 21 times the CDC's 90 MME cautionary limit.*[641]

539. Dr. Pogue or someone at his office repeatedly asked for additional OxyContin or other prescription savings cards or coupons that his patients could use repeatedly to save up to $60 on co-pays at the time on January 2, 2008, September 30, 2008, February 12, 2009, July 20, 2009, July 30, 2009, November 6, 2009, March 2, 2010, April 16, 2010, and April 27, 2010.[642]

540. Purdue reviewed Dr. Pogue's status on October 8, 2009, December 13, 2010, and April 29, 2011, and each time Purdue decided to keep him in continue calling status.[643]

541. Before moving Dr. Pogue to cease calling status on July 30, 2012, Purdue devoted substantial resources to Dr. Pogue. Purdue sales representatives called on Dr. Pogue at least *53*

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[640] PTN000056673 ID636 (2/18/2010); PTN000056673 ID1547 (3/22/2010); PTN000056673 ID2868 (4/19/2010); PTN000056673 ID4702 (5/17/2010); PTN000056673 ID6922 (6/17/2010); and PTN000056673 ID8730 (7/13/2010).
[641] PTN000056673.
[642] PTN000039164; PTN000039189.
[643] PTN000031810.

times from December 8, 2005 to May 1, 2012—*more than half of those occurring after his license was reprimanded in 2009.*[644] Sales Representative 11 also called on Dr. Pogue at least 5 times while Purdue was conducting an investigation, but Purdue never disciplined him for it.

542. In contrast, Purdue immediately took action after it was told that an insurance provider was not approving any long acting opioids for Dr. Pogue. On April 3, 2009, Sales Representative 11 checked internally with the Purdue Senior Account Manager of Managed Markets, after Dr. Pogue "mentioned that americhoice is not approving any of [Dr. Pogue's] long actings including morphine and opana in march. I did call [Purdue's Senior Account Manager] and told him about this."[645]

543. Aside from this, Purdue had knowledge of facts indicative of abuse or diversion of OxyContin at Dr. Pogue's practice for years before placing him in cease calling status. In a sales call on October 22, 2007, Sales Representative 11 documented a discussion with Dr. Pogue in which he stated "he did not know about the [state's] prescription [drug] monitoring program."[646]

544. Sales Representative 11's call notes reference Dr. Pogue being rushed, too busy, or only being able to talk through the waiting room window on June 23, 2006, August 21, 2006, January 2, 2008, August 22, 2008, and September 30, 2008.[647]

545. According to an Internal Review Memo, during a three month period in 2009, Purdue documented that Dr. Pogue had 14% of patients receiving single entity opioids pay cash and *52% of patients receiving single entity opioid generics paid cash.*[648] Purdue had knowledge

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[644] PTN000031807.
[645] PTN000039164.
[646] PTN000039167.
[647] PTN000039164–67.
[648] PTN000039171.

that *424 patients* of Dr. Pogue paid in cash in 2010.[649] Another Purdue report regarding Dr. Pogue's prescribing data indicated that *23.49% of 479 transactions were in cash* during a three month period in 2010.[650]

546. The Tennessee Board of Medical Examiners disciplined Dr. Pogue on September 15, 2009 for engaging in unprofessional conduct related to treatment of pain with human growth hormone and preprinted patient records.

547. Purdue had repeated notice of this disciplinary action as early as October 8, 2009 and again on December 13, 2010,[651] April 29, 2011,[652] May 25, 2011,[653] and July 25, 2011,[654] yet Purdue decided to allow sales representatives to continue calling on him.

548. On April 5, 2010, Sales Representative 16 submitted an ROC to Purdue which stated: "[Pharmacist] then expressed concern about Dr. Pogue. He said the patients he gets coming into his pharmacy is paying cash for their Oxycontin."[655]

549. Sales Representative 25 entered a call note on January 2, 2012, which read, "[Pharmacist] said most of his scripts come from Dr. Pogue and Dr. Cochran downtown Nashville."[656]

550. Less than two weeks later, on January 13, 2012, Sales Representative 13 submitted an ROC to Purdue which stated: "[Pharmacist] said he has seen a few of his patients move from a

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[649] PTN000056674.
[650] PTN000039189.
[651] PTN000039169.
[652] PTN000039139 (print date April 29, 2011); *see also* PTN00039133 (Metadata lists last modified date as of 4/29/2011).
[653] PTN000039190.
[654] PTN000039194 (Metadata lists last modified date as 7/25/2011).
[655] PTN000119294.
[656] PTN000119294.

long acting opioids that was working to SA Oxycodone. The two doctors that stand out [Pharmacist] stated Dr. Cochren and Dr. Pogue."[657]

551. On May 16, 2012, District Manager 1 forwarded a media report from Nashville's CBS affiliate about Dr. Pogue titled "Undercover Pain Clinic Video Shocks Lawmakers"[658] that referenced "*people sitting in their cars and standing near the clinic instead of waiting inside an often full waiting room*," people waiting at the clinic between 6 and 9 ½ hours before seeing the doctor, patients sharing pills, a patient describing how she sells the drugs Dr. Pogue prescribed her, and patients snorting crushed pills in a car after filling a new prescription.[659]

552. Dr. Pogue was the only doctor at the clinic and pharmacy records for one patient showed the doctor had "prescribed him 180 Oxycontin [sic] pills and 180 Oxycodone pills, month after month last year." District Manager 1 stated in his May 16, 2012 email to Purdue's Law Department, "*It appears this involves Dr. James Pogue who has been reported to your [Law] Department in the past.*"[660]

553. On June 18, 2012, Sales Representative 5 submitted a ROC which was forwarded to Purdue's ADD-Legal and Risk Management Departments that stated, "*Dr. Rhodes brought to our attention that a Dr. Pogue was videotaped, by channel 5 news, prescribing large quantities of Oxycontin* and Roxicodone."[661]

554. On June 22, 2012, Sales Representative 8 submitted another ROC to Purdue concerning Dr. Pogue: "*Pharmacy also reported Dr. James Pogue, located in Brentwood, TN.*

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[657] PTN000119294.
[658] PTN000039188.
[659] PTN000039161–63 (emphasis added).
[660] PTN000039188 (emphasis added).
[661] PTN000039181 (emphasis added).

Pharmacy stated that Dr. Pogue is under investigation for misuse and abuse for prescribing pain medications. Pharmacy will not fill Dr. Pogues rxs."[662]

555. On July 6, 2012, Sales Representative 13 called on a Nashville nurse practitioner who "asked if I called on Dr. Pogue; told her no; [she] said that type of pain clinic makes it difficult for her to prescribe opioids."[663]

556. On July 30, 2012, Purdue finally placed Dr. Pogue in cease calling status[664]—*75 days* after Purdue's Law Department was made aware of the NewsChannel 5 story.

557. Purdue's placement of Dr. Pogue into cease calling status on July 30, 2012[665] came almost three years after the Tennessee Board of Medical Examiners reprimanded Dr. Pogue on September 15, 2009 for "unprofessional, unethical, or dishonorable conduct"[666] for pain treatment involving human growth hormone.

558. The Tennessee Board of Medical Examiners later suspended Dr. Pogue's license on November 28, 2012 for his prescription controlled substance practices including:

> prescribing ... any controlled substance ... not in the course of professional practice, or not in good faith to relieve pain and suffering, or not to cure an ailment, physical infirmity or disease or in amounts and/or for durations not medically necessary, advisable or justified for a diagnosed condition" and "prescribing ... a controlled substance ... if such person is addicted to the habit of using controlled substances without making a bona fide effort to cure the habit of such patient.[667]
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> 7. Between 2007 and 2010, Respondent failed to take an appropriate history or perform a medically appropriate physical examination and/or failed to document such, requisite to justify prescribing or dispensing of narcotics and other medications and controlled substances to [twenty-two patients.]

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[662] PTN000037057 (emphasis added).
[663] PTN000031807.
[664] PTN000031810; PTN000039214.
[665] PTN000031810; PTN000039214.
[666] PTN000039159.
[667] PTN000039159.

> 8. Between 2007 and 2010, Respondent failed to obtain medically appropriate diagnostic tests or obtain appropriate medical consultations and/or failed to document such, requisite for the appropriate initiation and/or continuation of care for [twenty-two patients.]
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> 9. Between 2007 and 2010, Respondent prescribed or otherwise distributed controlled substances to [twenty-one patients] when the quantity, duration and method was such that the persons would likely become addicted to the habit of taking said controlled substances, failed to provide the patient with information about the benefits and risks of narcotics and/or other controlled substances or failed to document such and failed to make a bona fide effort to cure the habit of such persons or failed to document any such effort[.]
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> 10. ... Between 2007 and 2010, Respondent prescribed controlled substances to [twenty-one patients] when such prescriptions were not in the course of professional practice, not in good faith to relieve pain and suffering, or not medically necessary, advisable or justified for a diagnosed condition[.][668]

559. Purdue kept Dr. Pogue in continue calling status for three years after his license was reprimanded and despite knowledge of red flags such as the high number of cash paying patients and the high volume of his practice. Even after the company had knowledge of a television report that stated Dr. Pogue was prescribing large quantities of OxyContin, had wait times up to nine and a half hours, and had patients waiting in the parking lot outside of his clinic, Purdue waited 75 days until placing him in cease calling status.

Dr. Allen Foster

Cease Calling Status Dates: January 9, 2007 to July 17, 2009; February 7, 2011

560. Dr. Allen Foster, an anesthesiologist who operated pain clinics in Morristown and Knoxville,[669] was one of the top prescribers of OxyContin in Tennessee, especially in high

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[668] https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1606_30361_112812.
[669] PTN000041795.

doses.[670] From 1998 to 2017, Dr. Foster prescribed 1,049,199 OxyContin tablets, of which *85%* or 892,754 were 40 mg or higher.[671]

561. During a six month period from May 3, 2008 to November 3, 2008, Dr. Foster wrote *1,410 prescriptions* for OxyContin, which generated *$758,580.83* in revenue for Purdue.[672]

562. Purdue placed Dr. Foster in cease calling status on January 9, 2007.[673] Purdue decided to move Dr. Foster back to continue calling status on July 17, 2009,[674] presumably in response to a request from one of Purdue's sales representatives.

563. Purdue placed Dr. Foster in continue calling status in 2009 in spite of a 2006 report that he was involved in a "drug ring," Purdue's own referral of Dr. Foster to the DEA, and other red flags indicative of abuse or diversion.

564. Before and during the period from 2009 to 2011 that Purdue returned Dr. Foster to continue calling status, Purdue had knowledge of reliable evidence indicative of abuse or diversion.

565. On January 16, 2007, Purdue contacted the Nashville field office of the DEA to make a referral and submit a report regarding Dr. Foster's prescribing habits of controlled substances.[675] Despite this report, Purdue decided to place Dr. Foster in continue calling status in July 2009—over two years later.

566. On November 12, 2007, Sales Representative 2 and District Manager 2 called on Dr. Foster for a site inspection and the manager's comments read:

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[670] PTN000031809.
[671] PWG003984543.
[672] PTN000041814.
[673] PTN000041803.
[674] PTN000041815.
[675] PTN000045571.

> made a site inspection call per [Purdue Law Department] on doctor. Spoke with office manager and she said they were using the pms for tn and were *dismissing pts daily for misuse or failed uds*. Spoke with both pa's and doc. they are all doing uds and they are documenting and getting informed consent. doc was very knowledgeable about pain meds and his office was fully staffed with lab on site and x-ray. *the parking lot was full*, but all tags were from the immediate area. *they have a security guard on the premises. the waiting room was full and most pts looked legit. there were several young healthy males in the office that did stand out. the rx pads were kept in a drawer in the office managers office. at one point a nurse came in and asked for a script pad and took one out of the drawer. i cannot say whether or not there are problems here for certain.* [Sales Representative 2] and i will talk with legal about the status.[676]

567. Purdue continued to call on Dr. Foster's clinic in spite of these red flags.

568. The Tennessee Board of Medical Examiners took disciplinary action against Dr. Foster's medical license in December 2010 for violations concerning controlled substances and Dr. Foster agreed to temporarily restrict his prescribing privileges.

569. On February 2, 2011, Sales Representative 3 sent the following message to Purdue's Law Department and his district manager:

> *I got an odd call yesterday from ... [Pain Clinic J] and she told me in a very pleasant voice that if I didn't come to their office with some savings cards and senokot samples the Docs were going to quit prescribing my drugs.* When I clarified who they were I determined that they are in your territory. Not sure how or why they had my #. ... *This office, I think, was started by Dr. Allen Foster who I believe was established as a 1.7.1 no-see. Not sure if the other Doc and the NP where ever made 1.7.1* but you may want to double-check by calling [Purdue's Law Department] at home office to discern if they are appropriate to call on. *I was told last week that Dr Allen Foster has recently been "asked" to retire his medical license.* Call me if you have any ?s.[677]

570. Only after the Tennessee Board of Medical Examiners suspended Dr. Foster's prescribing privileges on February 7, 2011, did Purdue finally place him back in cease calling

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[676] PTN000035268 (emphasis added).
[677] PTN000036379 (emphasis added).

status.[678] On February 7, 2011, Purdue's Law Department informed the sales force that they should not call on Dr. Foster because his "[p]rescribing privileges [were] suspended."[679]

571. Ultimately, Dr. Foster pled guilty to criminal charges of health care fraud on February 23, 2011. On February 24, 2011, Sales Representative 16 forwarded the article referencing the guilty plea to fellow sales representatives and Purdue's Law Department.[680]

572. Purdue again referred Dr. Foster and 81 other prescribers to the DEA during a meeting between Purdue and the DEA on April 12, 2011.[681]

573. Dr. Foster's license was revoked on January 27, 2012 as a result of his criminal conviction.

574. Purdue failed to place all of Dr. Foster's pain clinic in cease calling status. *Purdue's sales representatives continued calling on providers associated with Dr. Foster's clinic despite him being placed in cease calling status and even recruited one other prescriber to be a paid speaker for Purdue.*[682]

Dr. Robert Cochran
Cease Calling Status Date: February 27, 2013

575. Dr. Robert Cochran, a Nashville internist, was another one of Purdue's top OxyContin prescribers in Tennessee from 2006 to 2016, despite the fact that he retired in 2012. From 2006 to 2012, Dr. Cochran prescribed 1,171,588 tablets of OxyContin, 432,222 of which

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[678] PTN000041816; PTN000031810.
[679] PTN000041816.
[680] PTN000041810.
[681] PTN000045570.
[682] *See* PTN000030245.

were 80 mg tablets—one of Purdue's highest doses.[683] From 1998 to 2017, Dr. Cochran prescribed 1,667,270 OxyContin tablets, of which 65.8% or 1,098,509 were 40 mg or higher.[684]

576. Between June 2009 and April 2011, Dr. Cochran prescribed well over 1,000 opioids each month.[685] In 2008, 151 of Dr. Cochran's prescriptions for OxyContin were paid for with cash.[686] Purdue classified Dr. Cochran as a "key thought leader."[687]

577. Purdue reviewed Dr. Cochran's file and kept him in continue calling status on September 16, 2011[688] and March 30, 2012.[689] Purdue finally placed Dr. Cochran in cease calling status on February 27, 2013.[690] The Board of Medical Examiners issued an order for Dr. Cochran to cease and desist the practice of medicine in March 2013 stemming from his prescribing habits of controlled substances.[691]

578. According to Purdue's records, Purdue sales representatives called on Dr. Cochran *110 times* between February 5, 2006 and December 19, 2012.[692] During this time, Purdue had knowledge of facts indicative of abuse or diversion.

579. On July 1, 2011, Sales Representative 5 submitted a ROC to Purdue that stated the following:

> Doc said he will be coming to butrans dinner meeting. *He told me there is an investigation on him. No specifics. Dr Cochran was inquiring about different pain clinics in the area.* I told him of [other pain clinic providers]. He mentioned no medication. This is not an adverse event.[693]

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[683] PTN000031809.
[684] PTN003984543.
[685] PTN000037195.
[686] PTN000056674.
[687] PTN000035268 (6/20/11).
[688] PTN000037183.
[689] PTN000037203.
[690] PTN000037199.
[691] PTN000037196; https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1606_3795_031913.
[692] PTN000031807.
[693] PTN000037161 (emphasis added).

580. Despite this information about a pending investigation, Purdue informed its sales representatives on September 16, 2011 that they could continue calling on Dr. Cochran.[694]

581. The appearance of red flags regarding Dr. Cochran continued. On January 26, 2012, Sales Representative 13 submitted a ROC that a pharmacist "was concerned when a patient that presents with *an Oxycontin script written q6h. The prescriber was Dr.Robert Cochren.*"[695]

582. One month later, on February 21, 2012, Sales Representative 21 sent a ROC to Purdue that led with a nurse practitioner's concern about Dr. Cochran's practice:

> [Nurse practitioner] stated she saw a patient of Dr. Cochran's from Nashville taking six 15mg roxycodone a day. Patient was young with no updated imagining. Patient was on six 10mg hydrocodone a day with no long acting; MD switched to six 15mg roxycodone. *[Nurse practitioner] stated she has concerns about Dr. Cochran's prescribing. It is her understanding he accepts cash only, has mostly out of state license plates, and sees about 50 patients a day.*[696]

583. Nevertheless, Purdue's Law Department informed the Purdue sales force on March 30, 2012 that they may continue calling on Dr. Cochran with the caveat that "if any negative relevant information comes to light, the sales force should contact the Office of the General Counsel."[697]

584. Additional facts indicative of abuse or diversion continued to emerge. On July 23, 2012, Sales Representative 13 submitted a ROC that read:

> [Nurse Practitioner] said she had dinner with a representative and with Dr. Robert Cochran.(Dr. C) *Dr.C said he feels comfortable prescribing high doses of OxyContin; [Nurse Practitioner] said one of his patients was on a large dose of Oxycontin every 4 to 6 hours*; [Nurse Practitioner] said if she has an appropriate patient who needs higher doses of Oxycontin she may refer to Dr. C; *[Nurse Practitioner] said Dr. C said he is running a pill mill*;

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[694] PTN000037183.
[695] PTN000037186–87 (emphasis added).
[696] PTN000037202 (emphasis added).
[697] PTN000037203 (emphasis added).

> [Nurse Practitioner] *said he told her he was investigated once and it did not go anywhere; she said Dr. C said he may retired or hire a medical director.* [Nurse Practitioner] *also asked if I knew she had been investigated when she first started in pain management; told her no, I did not know that*; [Nurse Practitioner] said the case had no merit; the patients complaint was because they did not receive the prescription they wanted[.][698]

585. On February 13, 2013, Sales Representative 13 filed yet another ROC with Purdue that stated that another provider "said he has seen several patients who were under Dr. Robert Cochran's care *and then Dr. Cochran lost his prescribing licenses.*"[699] It took Purdue another two weeks before finally placing Dr. Cochran in cease calling status on February 27, 2013.[700]

586. Ultimately, Purdue knew that Dr. Cochran was being investigated by the Tennessee Board of Medical Examiners, of a report from another provider that Dr. Cochran admitted he was running a pill mill, and of concerns about Dr. Cochran's practice from other providers and a pharmacist while Purdue kept Dr. Cochran in continue calling status.

Drs. Mireille Lalanne and Visuvalingam Vilvarajah
Dr. Lalanne Cease Calling Status Date: February 5, 2009
Dr. Vilvarajah Cease Calling Status Date: February 5, 2009

587. Dr. Mireille Lalanne and Dr. Visuvalingam Vilvarajah were previously married to one another and continued to practice together in Nashville after they divorced. Dr. Lalanne, an anesthesiologist, was one of the top prescribers of OxyContin in Tennessee from 2006 to 2016, despite the fact that she only wrote three prescriptions for OxyContin from 2010 to 2016.[701] In the span of three years from 2006 to 2009, Dr. Lalanne wrote 6,595 prescriptions for OxyContin[702] totaling 305,894 tablets, 104,516 of which were 40 mg tablets paid for with cash.[703] During a six-

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[698] PTN000037184–85 (emphasis added).
[699] PTN000037188–89 (emphasis added).
[700] PTN000037199.
[701] PTN000031809.
[702] PTN000052837.
[703] PTN000031809.

month period from January 2, 2009 to June 1, 2009, she generated *$247,688.09* for Purdue from OxyContin prescriptions alone.[704]

588. Purdue had knowledge that *902* of Dr. Lalanne's patients paid in cash for their OxyContin prescriptions in 2008.[705] In 2007, *1,200* of her patients paid in cash for OxyContin.[706]

589. Purdue placed Dr. Lalanne in continue calling status from October 9, 2003 until February 5, 2009, when it finally told sales representatives to cease calling on her.[707]

590. Purdue also devoted substantial attention to Dr. Vilvarajah,[708] Dr. Lalanne's ex-husband, who likewise generated significant revenue for Purdue. In the first six months of 2009, Dr. Vilvarajah generated *$93,634.31* for Purdue based on OxyContin tablets alone.[709]

591. Purdue reviewed Dr. Vilvarajah's file and kept him in continue calling status after internal investigations on October 9, 2003 and December 27, 2004. Purdue failed to place him in cease calling status until February 5, 2009, following news of his and Dr. Lalanne's arrests.

592. Purdue sales representatives called on Dr. Lalanne and Dr. Vilvarajah *82 times* between January 20, 2006 and January 27, 2009.[710] Twenty-five of these visits were non-compliant calls made to Dr. Lalanne after an internal investigation had been opened but prior to Purdue making a decision on her call status. During this time, Purdue had knowledge of numerous facts indicative of abuse or diversion.

593. Purdue had knowledge of Dr. Vilvarajah's disturbing history well before the implementation of its ADD program in 2007, including his criminal conviction of two counts of

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[704] PTN000039971.
[705] PTN000056674.
[706] PTN000056674.
[707] PTN000031810.
[708] PTN000035268.
[709] PTN000038263.
[710] PTN000031807.

second-degree murder in 1988.[711] On August 19, 2003, Sales Representative 22 recorded that Dr. Vilvarajah told her that he had a male patient who overdosed and also wanted to know the highest dose of OxyContin that had been studied.[712] Purdue's internal notes from December 20, 2004 reveal concerns about Dr. Vilvarajah because he had "a lot of cash paying pts" and he "doesn't take a lot of medicaid."[713] Despite this information, Purdue decided to keep him in continue calling status on December 27, 2004.[714]

594. On July 18, 2007, a Purdue field researcher in the Risk Management and Health Policy Department reported to Purdue's Legal Department that she had "recently returned from a site visit to Harlan KY where the sheriff's department spoke of 3 physicians which in their opinion, had questionable prescribing practices involving OxyContin."[715] Two of the three physicians referenced in this report of concern were Dr. Lalanne and Dr. Vilvarajah.

595. The report stated:

> According to the detective and sheriff, large numbers of OxyContin and methadone prescriptions are coming into Harlan from this practice. *Dr. Lalanne is the ex-wife of Viso Vilvarajah, MD* (License #9540). Dr. Vilvarajah has been subject to disciplinary actions in the past by the TN Department of Health. ... *The sheriff and detective stated that when Dr. Vilvarajah experienced disciplinary actions he brought his ex-wife back into the practice so she could write for controlled substances.* At present, their website ... lists Dr. Vilvarajah as a "Medical Associate."[716]

596. Purdue sales representatives called on Dr. Lalanne or Dr. Vilvarajah at least *48 times after this field report was written.*

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[711] PTN000039966; PTN000038303.
[712] PTN000038315; PTN000038296 (created 2/12/2009); PTN000039979 (created 9/28/2009).
[713] PTN000038299.
[714] PTN000038313; PTN000031810.
[715] PTN000039938.
[716] PTN000039938–39 (emphasis added).

597. On September 12, 2007, a Purdue employee printed a news article from a Memphis television station that referenced Dr. Vilvarajah's previous conviction for second-degree murder of his first wife.[717]

598. On February 4, 2008, a Nashville pharmacist told Sales Representative 5 that he "see[s] scripts from lalanne, dr.v and dr. Cochran." On February 6, 2008, a Nashville pharmacist told Sales Representative 5 that "a lot of scripts [come] from drs. lalanne and V."[718] That same day, Sales Representative 5 called on a different pharmacy in White House where the pharmacist told him that he "sees a lot of scripts from dr. v and lalanne."[719] Another Nashville pharmacy told Sales Representative 5 the next day that "they get scripts from office of drs. v and lalanne."[720]

599. Sales Representative 5's September 22, 2008 call note stated that Dr. Vilvarajah mentioned to him that another patient of his died from an overdose after taking 50 tablets and that the patient's family blamed him.[721]

600. In February 2009, Dr. Lalanne and Dr. Vilvarajah were arrested and charged with three counts of engaging in organized crime, second-degree assault, and first degree wanton endangerment.[722] Dr. Lalanne pleaded guilty to facilitation of trafficking in a controlled substance in the first degree on January 11, 2010.[723] Dr. Vilvarajah also pleaded guilty to a drug charge.

601. Dr. Vilvarajah's license was summarily suspended and ultimately revoked by the Tennessee Board of Medical Examiners on January 29, 2010 and March 23, 2010 respectively.[724]

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[717] PTN000039966.
[718] PTN000119294.
[719] PTN000119294.
[720] PTN000119294.
[721] PTN000038287.
[722] PTN000038290–91; PTN000038311.
[723] PTN000039982 (Doc created/saved 10/2/2013); PTN000039959.
[724] https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1606_9540_012910.

602. Dr. Lalanne's license was summarily suspended, placed on restrictive probation, and then revoked in orders by the Tennessee Board of Medical Examiners on January 29, 2010, March 23, 2010, and June 13, 2012.[725]

603. Purdue finally placed both Dr. Lalanne and Dr. Vilvarajah in cease calling status on February 5, 2009, following news of their arrest.

604. In addition, an October 5, 2009 Field Research Signal Report for Harlan County, Kentucky, obtained by Purdue confirmed that significant amounts of diverted OxyContin were from Dr. Vilvarajah and Dr. Lalanne.[726]

605. Aside from other red flags, Purdue's sales representatives submitted call notes from visits with Dr. Vilvarajah and Dr. Lalanne that repeatedly made reference to their office being very busy, the high number of cash paying patients, and the high volume of prescription savings cards used by their patients.[727] For example, call notes reported the "office packed" on May 3, 2007,[728] "packed with patients" on April 1, 2008,[729] "packed to the brim, as usual" on May 9, 2008,[730] "very busy, as usual" on May 16, 2008,[731] and "bustling with patients" on November 25, 2008.[732] Call notes from February 6, 2008 stated that Dr. Vilvarajah "sees a large number of cash paying patients."[733] Call notes from July 8, 2008 stated that "doc mentioned that many of his cash paying patients are very appreciative of the oxycontin savings cards."[734]

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[725] https://apps.health.tn.gov/Licensure/Discipline.aspx
[726] PTN000039991.
[727] PTN000038296–98; PTN000038287–88.
[728] PTN000031807.
[729] PTN000038288.
[730] PTN000039942.
[731] PTN000038288.
[732] PTN000039941.
[733] PTN000031807.
[734] PTN000031807.

606. Sales Representative 5 also recorded a call note with a representative of Pharmacy A, located in Nashville, who told Sales Representative 5 that "[a]s long as possible, keep the office of drs. Lalanne and vilavrajah stocked with savings cards. Where most of his oxycontin business comes from."[735]

607. During the time that Purdue sales representatives called on Dr. Lalanne and Dr. Vilvarajah, Purdue had knowledge of numerous red flags that should have warranted cease calling status for both providers prior to their arrests in 2009, such as reports of questionable prescribing practices, at least two patients dying from overdoses, a high number of patients paying in cash, and, most notably, a direct report from law enforcement that specifically stated that OxyContin pills from these providers were being diverted.

Dr. Frank McNiel and Dr. C

Dr. Frank McNiel Cease Calling Status Dates: April 1, 2003 to October 5, 2007; April 7, 2011
Dr. C Cease Calling Date: April 7, 2011

608. Dr. Frank McNiel practiced family medicine at a large pain clinic in Knoxville, named Pain Clinic A, along with Dr. C.[736] From 2006 to 2016, Dr. Frank McNiel wrote *15,196 prescriptions* for OxyContin and was one of the highest prescribers of OxyContin in Tennessee.[737] During that time, he prescribed *1,655,940 tablets of OxyContin, 758,478 of which were Purdue's 80 mg dose.*[738] From 1998 to 2017, Dr. Frank McNiel prescribed 3,350,167 tablets of OxyContin, of which *79.5% or 2,662,183 were 40 mg or higher.*[739] In 2008, *779* of his patients paid for their OxyContin prescriptions in cash and in 2009, *668* of his patients paid for their OxyContin

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[735] PTN000031807; *see also* PTN000031807 (2/20/2009) (Call note with Pharmacy A post-arrests of Drs. Lalanne and Vilvarajah stating the same pharmacy reported "see[ing a] decrease in prescriptions since office of lalanne and vilvarajah closed.").
[736] *See* PTN000039869.
[737] PTN000031809.
[738] PTN000031809.
[739] PWG003984543.

prescriptions in cash.[740] Dr. Frank McNiel also prescribed a 62 year old man a 30 day supply consisting of 300 tablets of 80 mg OxyContin on 5 different occasions in 2010.[741]

609. Dr. C was known as a co-owner of Pain Clinic A who most often worked at the same practice location as Dr. Frank McNiel.[742] Dr. C practices family medicine in Knoxville and was the eighth highest prescriber of OxyContin from 2006 to 2016. During that time, she wrote *8,872 prescriptions* for OxyContin,[743] which totaled *785,599 tablets, 344,729 of which were 80 mg.*[744] From 1998 to 2017, Dr. C prescribed 1,155,706 tablets of OxyContin, of which *83.5% or 964,586* were 40 mg or more.[745]

610. Purdue sales representatives called on Dr. Frank McNiel and Dr. C at least *163 times* in less than four years between May 13, 2007 and February 15, 2011[746]—a number that does not include sales calls made to other Pain Clinic A providers or to a pharmacy closely linked to Pain Clinic A.

611. Purdue recommended that sales representatives cease calling on Dr. Frank McNiel on April 1, 2003, changed the recommendation to continue calling on October 5, 2007,[747] and changed it back to cease calling on April 7, 2011. Purdue reconsidered whether sales representatives could again call on Dr. Frank McNiel on April 27, 2012, but decided against it.[748]

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[740] PTN000056674.
[741] PWG003984543.
[742] *Cf.* PTN000031807 ID20018 (11/21/2008); PTN0000031807 ID19464 (7/28/2008) (listing 429 Bearden Drive); PTN000031807 ID9555 (6/11/2007); PTN000031807 ID8101 (6/29/2007) (both listing 5612 Kingston Pike).
[743] PTN000052837.
[744] PTN000031809.
[745] PWG003984543.
[746] PTN000031807.
[747] PTN000040534 ("Purdue has decided that the sales representative may call on Drs. Frank [McNiel] and [C]. Should the status of their medical or DEA licenses change, the sales representative should immediately notify the Law Department for further evaluation. … **Sales operations: [Drs. Frank McNiel and C] have been region zero status since 2003.").
[748] PTN000031810; *see also* PTN000039878 (Email dated 4/7/2011 containing message that sales representatives should not call on Drs. C and Frank McNiel).

612. Purdue sales representatives called on Dr. Frank McNiel after Purdue placed him in cease calling status. Sales Representative 2 called on him *at least 14 times* prior to October 5, 2007 while Dr. Frank McNiel was in cease call status and had been there for 4 years, yet Purdue never disciplined him. On April 18, 2012, when Dr. Frank McNiel was again in cease calling status, Sales Representative 16 recorded a call note with a pharmacist that stated "[the pharmacist] asked if I still called on Dr [Frank] McNiel, I discussed that no, *he was assigned to another rep.*"[749]

613. Purdue had detailed knowledge about Dr. Frank McNiel's controlled substance prescribing practices before 2007. Purdue placed Dr. Frank McNiel in cease calling status days after receiving a March 28, 2003 letter which contained a Tennessee Court of Appeals case, *Frank McNiel, M.D. and [C], M.D. v. Tennessee Board of Medical Examiners*, No. 01-A-01-9608-CH-00383, 1997 WL 92071 (Tenn. Ct. App. March 5, 1997).[750]

614. In that action, Dr. McNiel and Dr. C had been disciplined by the Tennessee Board of Medical Examiners, which had concluded that "Frank McNiel, M.D. and [C], M.D. in prescribing controlled substances to 16 patients for chronic, nonmalignant pain, incompetence, unprofessional and unethical conduct, prescribing not in good faith to cure an ailment and prescribing to addicts without an attempt to cure their addiction[.]"[751]

615. Specifically, the Board found the following with respect to Dr. Frank McNiel:

> Respondent has administered controlled, mind-altering substances to these patients, and to many additional patients as is reflected within several area pharmacy drug audits, in a rote fashion, rather than in a fashion tailored to the specific needs of the individual patient. Particularly with respect to his administration of benzodiazepines, [R]espondent has routinely administered the highest Valium dosage (10 mg) to most of his patients without ever attempting to titrate such dosages to individual patient needs.

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[749] PTN000031807 (emphasis added).
[750] PTN000040486–96.
[751] PTN000040487.

Respondent has, in many instances, administered these controlled substances in excess of the recommended daily dosage limitations as indicated by the *Physicians Desk Reference*. His chronic, repeated administration of Schedule II-IV narcotic analgesics such as Lortab, Lorcet Plus, Vicodin, Percodan, Percocet, Tylenol (#3 & #4), Darvon and Darvocet for periods of time approximating 3 years in some patients is not recommended within this treatise, nor is such chronic administration of these substances recognized as appropriate care as a family practice physician, particularly when combined with administration of sedating benzoates-pines and sedative hypnotics (Phenobarbital and Halcyon) on such a long-term, chronic basis[.] Respondent's administration of such combinations in such a chronic fashion fell below the standard of care expected of a reasonably competent primary case [sic] or family practice physician practicing in the State of Tennessee. Respondent constantly administered the combination of benzodiazepines and narcotic analgesics in a chronic fashion to most of the ten patients referred to herein (and to many others, too numerous to list), without attempting to justify or take precautions against the sedating, and potentially addictive consequences these combinations could have. In many instances, Respondent did not recognize, and in fact rewarded, drug seeking behavior manifested by his patients. This conduct on Respondent's part fell below the standard of care of a reasonably competent primary care or family practice physician practicing in Tennessee.

Respondent's chronic use of narcotic analgesics for management of non[-]malignant pain in many patients fell below the standard of care expected of a reasonably competent primary care or family practice physician practicing in the State of Tennessee, which is that narcotics are to be avoided except in limited, acute pain cases, and, only after all other specific therapies have been exhausted and the patient has been evaluated according to a multi-disciplinary approach, including referrals to orthopedists, neurological surgeons, administration of steroidal anti-inflammatory drugs, antidepressants, administration of a TENS unit, and hypnosis. None of the ten patients referred to herein suffered from malignant pain caused by organic disease, and the Respondent did not limit his administration of narcotics to short-term, intermittent, acute cases.

Respondent did not, in any of the ten cases referred to herein, or in general with respect to most other patients, either refer patients to alternative therapies or to specialists in pain management, or refrain from continuing administration of strong narcotic analgesics and benzodiazepines while the patients were simultaneously undergoing treatment by such mental health and pain specialists.

616. The Tennessee Court of Appeals ultimately overturned the Board's decision due to insufficient expert testimony, but specifically found that "[t]he records of the respondents and their testimony adequately support the specific facts found by the Board." *Frank McNiel, M.D. and [C], M.D. v. Tennessee Board of Medical Examiners*, No. 01-A-01-9608-CH-00383, 1997 WL 92071, *5 (Tenn. Ct. App. March 5, 1997).[752]

617. Purdue placed Dr. C in continue calling status from June 27, 2003 to April 7, 2011, even though she worked at the same location as Dr. Frank McNiel who was placed in cease calling status for four years [753], and in spite of specific findings by the Board that:

> The records of Dr. [C] indicate that on March 7, 1988, Patient 6 was using "too many Anexia-D" but the same entry shows the prescription for the same drug was renewed; that, on March 23, 1988, 6 "wants pills early;" that, on March 28, 1988, the same medication was re-prescribed; that on April 6, 1988, the same prescription was renewed; that, on April 20, 1988, the chart for 6 indicates "too many Anexia and Darvocet;" that, on April 21, 1988, Dr. [C] told 6 she was addicted and recommended addiction treatment and wrote on the chart "no more Anexia or Darvocet," that on May 4, 1988, Halcyon, a controlled substance, was prescribed; that on May 5, 1988, Anexia D was again prescribed; and that prescriptions for this drug continued from June, 1988 to October, 1988; that, in October 1988, Dr. [C] began injections of Buprenex and prescribed 100 Percocets every two weeks; that, on January 6, 1992, the record states "patient has been taking too many pain pills, naughty, naughty," and that 100 more Percocet pills were prescribed on the dame [sic] date.
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> Dr. [C] testified that, in June, 1992, she charted Patient 2 with a note "caution with meds," that a psychiatrist told Dr. [C] in September, 10, 1992, that 2 "doesn't need meds" and 2 was "milking Dr. [C] for meds;" that 2 was charted for "no more meds," but from September 14, 1992 through January 1993, controlled substances were prescribed for 2 without an examination.
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> Dr. [C]'s June, 1992 chart for Patient 4 reflects a plan for drug screens because of "questions" about abuse, but prescriptions for controlled substances were continued to March 23, 1993, without a drug screen.

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[752] PTN000040486–96.
[753] PTN000031810.

> Dr. [C]'s chart for Patient 5 on April 25, 1999, shows "prob. multiple substance abuse" and "no plan for substance abuse." On January 1989, the record shows recommendation for drug rehabilitation and "we will not treat her anymore." The record reflects that controlled substances were prescribed continuously throughout 1991 and 1992 without a charted physical examination.
>
> The record of Dr. [C]'s for Patient 6 states "using too many Anexia D cautioned, wants pills early – explained that she is addicted, thinks she can quit; recommended that she get help. Told her to call Jim Dunlap at New Day if she needs help; patient has been taking too many pain pills, naughty, naughty."
>
> Dr. [C] testified that "there were red flags' [sic] in respect to Patient 2, and her record on this patient stated "caution with meds?" and "no more controlled meds."
>
> The record of Dr. [C] on Patient J contains: "meds" recommended drug rehabilitation and "we will not treat her anymore," and that Dr. [C] did not read this entry 2 years later before prescribing pain relievers, but she wishes she had "because I feel it would have changed things."[754]

618. In addition to the facts that led to Purdue's 2003 cease calling recommendation, Purdue had knowledge of facts indicative of abuse or diversion before April 7, 2011 when Dr. Frank McNiel and Dr. C were in continue calling status.

619. Before the reinstatement of Dr. Frank McNiel's continue calling status in October 2007, Purdue had knowledge of suspicious OxyContin prescribing behavior by the two providers. For example, in a November 21, 2006 internal email titled "Report of 'dirty doctors,'" a field researcher in Purdue's Risk Management & Health Policy Department submitted the following investigative report *based on an interview with a Knox County Sheriff's Office detective* that:

> *the most problematic physicians being investigated right now are: Frank McNeal, MD and [C], MD – both practicing in Knoxville. Apparently, Dr. McNeal works in a pain clinic with three other physicians ([C] has a separate office), but all the prescriptions that come out of the office for*

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[754] PTN000040490–91.

> *OxyContin use his DEA number. Most prescriptions are for: 180 80 mg OxyContin Tablets, 180 40 mg OxyContin Tablets, and an unspecified amount of Xanax and Soma.*[755]

620. The response from Purdue's home office stated, in relevant part, "[W]e are familiar with the doctors you mentioned below. Our sales representatives have not been calling on these prescribers for some time, as in accordance with RSOP 1.7.1." The field researcher's findings about the couple were also contained in a December 5, 2006 field report submitted to Purdue.[756]

621. *Despite being in cease calling status until October 7, 2007*, Sales Representative 2 called on Dr. Frank McNiel *13 times* in 2007 before this date including May 7, May 14, May 15, June 6, June 18, June 25, June 29, July 9, July 16, July 30, August 23, September 12,[757] and October 2, 2007.[758]

622. During the sales call on May 15, 2007, Sales Representative 2 and Dr. Frank McNiel discussed a lawsuit in which he was involved. Purdue's representative reiterated the company's commitment to its providers. Sales Representative 2's call note stated:

> [Dr. Frank McNiel] wanted to farther discuss the results of the lawsuite and how it would effect civil liabilities *discussed in general the suit and that we wer committed to providers.*[759]

623. On October 7, 2007, Purdue authorized its sales representatives to continue calling on Dr. Frank McNiel and Dr. C—even though these sales representatives had been calling on Dr. Frank McNiel anyway.[760]

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[755] PTN000041829 (emphasis added).
[756] PTN000055997, –6000.
[757] PTN000031807.
[758] PTN000031807.
[759] PTN000031807 ID9567 (5/15/2007) (emphasis added).
[760] *See, e.g.* PTN000119294 ID15767 (8/23/2007).

624. Purdue continued to ignore red flags about the couple after October 7, 2007. On August 22, 2008, a Purdue sales representative reported an article that had appeared in Knoxville's Metro Pulse titled "Drug Zone."[761]

625. The article stated:

> An astounding fact: According to experts within the Knoxville Police Department, [Pharmacy B] dispenses the highest volume of narcotic drugs (e.g. oxycontin, hydrocodone, oxycodone) in the State of Tennessee. *According to eyewitnesses and police reports, during the spring of 2008, some pharmacy customers were mugged as they left the store and their prescriptions stolen, some at gunpoint. Several shoppers had observed drug deals taking place in the parking lot. These crimes prompted [Pharmacy B] to hire armed Knoxville Police Officers to guard the store during pharmacy hours. Just around the corner from [Pharmacy B*], [...], *is [Pain Clinic A], a clinic operated by Drs. Frank [McNiel and C]. According to one local Drug Enforcement Agency (DEA) official, this clinic, when it comes to overprescribing narcotics, is "the biggest problem in the state." According to the Knoxville Police and the DEA, [Pharmacy B] is the only pharmacy in town still accepting prescriptions from the Drs. [Frank McNiel and C]. A group of concerned neighbors has begun meeting to address this issue. Their goal is to persuade [Pharmacy B] to put neighbors first and stop honoring the Drs. [Frank McNiel and C]'s narcotic prescriptions at any of the Knoxville [Pharmacy B] pharmacies.*[762]

626. Purdue was also aware that, on December 10, 2008, Dr. Frank McNiel paid what was classified as an "above average" settlement amount for a malpractice claim as reported to the Tennessee Department of Health.[763]

627. On February 15, 2011, Sales Representative 16 and District Manager 3 called on Dr. Frank McNiel and recorded the following call note:

> This was a challenging call and [Sales Representative 16] prepared for that. Dr McNeil was down on the reformulation. *He brought up q8h dosing* but [Sales Representative 16] pointed out the PI information. He acknowledged that *he still prescribes the product*. In terms of Butrans, he was also down

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[761] PTN000039866.
[762] PTN000039868–72 (emphasis added).
[763] PTN000040485; PTN000040501.

> on it and did not see a place for it in his practice which patients are on higher doses of morphine equiv than suggested in PI. [Sales Representative 16 and District manager 3] asked him "where do you see it fitting in?" he responded with Family Practice. Submitted a MIRF for a specific question.[764]

628. Purdue sales representatives called on Dr. Frank McNiel and/or Dr. C *102 times* after Purdue received the August 22, 2008 ROC[765] until the company finally placed them in cease calling status on April 7, 2011 because their DEA registrations to prescribe controlled substances had expired.[766]

629. On April 12, 2011, Purdue referred Dr. Frank McNiel to the DEA.[767] Nevertheless, District Manager 3 still emailed Purdue's Law Department on April 3, 2012 and requested that he be able to reevaluate Dr. Frank McNiel and Dr. C in order to resume calling on them,[768] which Purdue did deny.[769]

630. Further, following the May 6, 2007 Judgment with the State of Tennessee, Purdue called on Dr. Frank McNiel repeatedly, even *after* Purdue was told that he and Dr. C were the most problematic prescribers in the area by law enforcement and *13 times after Dr. Frank McNiel was in cease calling status.*

631. On March 20, 2018, the Tennessee Board of Medical Examiners permanently revoked Dr. Frank McNiel's medical license. The Stipulations of Fact in the Consent Order read, in part, as follows:

> 2. The Department conducted an investigation of the Respondent's prescribing practices, reviewing approximately 75 patient records. *That investigation and review reflected that, from 2002 to present and while practicing at [Pain Clinic A] in Knoxville, Respondent engaged in a pattern*

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[764] PTN000035268 ID2078.
[765] PTN000031807.
[766] PTN000039878.
[767] PTN000045572.
[768] PTN000036910–11.
[769] PTN000036363.

of prescribing opioids and other controlled substances in excessive amounts and inconsistent with and below the applicable standards of care. Specifically, he prescribed controlled substances in amounts and/or for durations not medically necessary, advisable, or justified for a diagnosed condition and/or not for a legitimate medical purpose; without attempting alternative non-narcotic modalities; and without appropriately monitoring for abuse and diversion.

Further, during this time period, Respondent served as supervising physician for multiple allied practitioners (advanced practice registered nurses and physician assistants) who continued such excessive prescribing of excessive amounts and inconsistent with and below the applicable standard of care in violation of the rules adopted by the Tennessee Board of Medical Examiners and the Tennessee Board of Nursing. Respondent failed to appropriate supervise such allied prescribers whose prescriptive services were within his control and responsibility under Tennessee law and failed to appropriately respond to conduct that was below the standard of care.[770]

Pain Clinic A
Cease Calling Status Date: April 30, 2012 to date unknown
Continue Calling Date: At least by August 2017[771]

632. Pain Clinic A was a pain clinic based in Knoxville, Tennessee that had many health care providers, but was most closely identified with Dr. Frank McNiel and Dr. C in internal Purdue documents.[772] Besides Dr. Frank McNiel and Dr. C, Pain Clinic A's other providers included Dr. D, Physician Assistant Lisa Adams, Nurse Practitioner E, Nurse Practitioner Brandy Burchell, Nurse Practitioner Christina Collins, Physician Assistant AA, Nurse Practitioner BB, Nurse Practitioner CC, Nurse Practitioner Teodora Neagu, Dr. DD, Nurse Practitioner F, Nurse Practitioner G, Physician Assistant EE, and Nurse Practitioner FF.

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[770] https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1606_16119_032018 (emphasis added).
[771] *See, e.g.*, PTN000119294 ID301165 (8/1/2017).
[772] PTN000039869; PTN000039658.

633. Of these 15 health care providers associated with Pain Clinic A, *13 were placed in cease calling status by Purdue at least once*[773] and many were among the top OxyContin prescribers in Tennessee.

634. At various times, Purdue's Phoenix database continued to include health care providers who had been placed in cease calling status, including those at Pain Clinic A.[774]

635. As stated above, as a general rule, Purdue made recommendations about whether to cease calling on suspicious health care providers, not specific clinics or offices.[775] Purdue did not list Pain Clinic A on its Suspicious Doctors List from 2002 to 2016, though it listed a few other clinics.[776] At some point Purdue told sales representatives not to call on Pain Clinic A, but the earliest identified directive is from April 30, 2012.[777]

636. However, this directive to cease calling on Pain Clinic A did not last. Purdue's Phoenix database continued to list Pain Clinic A providers as potential sales targets as late as March 22, 2013.[778]

637. Further, Purdue sales representatives continued calling on providers known by Purdue to still be working at Pain Clinic A at least *13 times* after April 30, 2012.[779]

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[773] PTN000031810.
[774] PTN000038690–91; PTN000036364.
[775] PTN000038691.
[776] PTN000031810.
[777] PTN000036363.
[778] PTN000038690–91.
[779] PTN000119294 ID137939 (8/8/2013) (notification that doctor was supervising physician at Pain Clinic A; PTN000119294 ID168024 (7/25/2014) (report that doctor was still the supervising physician at Pain Clinic A); PTN000119294 ID142209 (9/23/2013); PTN000119294 ID144696 (10/17/2013); PTN000119294 ID146491 (11/6/2013); PTN000119294 ID147280 (11/13/2013); PTN000119294 ID150180 (12/18/2013); PTN000119294 ID151387 (1/13/2014); PTN000119294 ID154177 (2/19/2014); PTN000119294 ID155218 (3/4/2014); PTN000119294 ID158660 (4/8/2014); PTN000119294 ID161081 (5/5/2014); PTN000119294 ID163625 (6/2/2014); PTN000119294 ID166526 (7/8/2014); and PTN000119294 ID169020 (8/6/2014).

638. As known to Purdue, Pain Clinic A's other providers besides Dr. Frank McNiel and Dr. C prescribed high amounts of OxyContin. For example, from 2006 to 2016, Nurse Practitioner Christina Collins wrote prescriptions for 292,960 tablets of OxyContin from all payors.[780] She prescribed *142,395 OxyContin 80 mg tablets from 2006 to 2014*.[781] In 2011 alone, Ms. Collins wrote 935 prescriptions for OxyContin, 835 more than she had written in 2010.[782] She wrote 1,444 prescriptions for OxyContin in 2012.[783] Purdue placed Ms. Collins in cease calling status from April 30, 2012 until November 25, 2014, when Purdue moved her back to continue calling status[784] following a request from Sales Representative 6.[785]

639. In addition to the facts about Dr. Frank McNiel and Dr. C recited above, Purdue had knowledge of credible facts about Pain Clinic A that were indicative of abuse or diversion.

640. Purdue sales representatives made repeated sales calls to Pharmacy B, which was closely linked to Pain Clinic A, especially in 2007 and 2008.[786]

641. On May 21, 2007, Purdue's Managed Care Sales Representative recorded the following from a sales call with a managed care group:

> Rumore of a pharmacy called [Pharmacy B] doing more scripts than any other pharmacy in Tennessee. A *suggestion from the [Pharmacy Director of Managed Care Group] that it is a problem pharmacy*. Representative said they do a lot of Oxycontin in this pharmacy as well. This is a ROC report. . . .[787]

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[780] PTN000031809.
[781] PTN000031809.
[782] PTN000052837.
[783] PTN000052837.
[784] PTN000031810.
[785] PTN000039267.
[786] PTN000031807 ID9588 (5/17/2007); *see also* PTN000031807 ID104183 (7/16/2013) (referring to Pharmacy B "filling the majority of prescriptions for [Pain Clinic A].").
[787] PTN000031807 ID9564 (5/21/2007) (emphasis added).

642. On August 22, 2008, Purdue's sales representative reported an article about concerns of high OxyContin prescribing from Pain Clinic A that had appeared in Knoxville, Tennessee's Metro Pulse titled "Drug Zone,"[788] which is recited above in the section about Dr. Frank McNiel and Dr. C.[789]

643. Pain Clinic A handed out a large number of OxyContin savings cards, which were used by a significant number of cash-paying patients. In January and February 2008, Pain Clinic A accounted for 579 out of 665 $50 savings cards in the Purdue sales territory where Pain Clinic A is located.[790] Pharmacy B, which was closely associated with Pain Clinic A, redeemed 1,327 out of 1,839 OxyContin savings cards paid-to-date and 213 out of 286 for the month of January 2008 alone in the same territory.[791] By February 2008, Pharmacy B accounted for 412 out of 565 savings cards for the year to date and 1,526 out of 2,118 total in the territory.

644. In addition to calling on Pain Clinic A itself, Purdue sales representatives also repeatedly called on Pharmacy B *after* Purdue had knowledge that Pharmacy B was a problem pharmacy that was dispensing more prescriptions of OxyContin than any other pharmacy in the

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[788] PTN000039866.
[789] PTN000039868–72.
[790] PTN000070654.
[791] PTN000083350.

State,[792] *after* Purdue had knowledge about the Metro Pulse article referenced above,[793] *after* Purdue placed both Dr. Frank McNiel and Dr. C in cease calling status on April 7, 2011,[794] and even *after* Pain Clinic A was placed in cease calling status on April 30, 2012.[795]

645. After the Metro Pulse article was published in 2008, Sales Representative 2 recorded his interaction with Pharmacy B on October 22, 2009, as follows:

> *[Pharmacist] said they are filling and refilling a prescription for [Pain Clinic A] dose 300 Discussed saving card program gave some value cards for pt also asked to hold any OxyContin 60$ cards that cant be used so I can take to [Pain Clinic A].*[796]

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[792] PTN000031807 ID13543 (7/2/2007); PTN000031807 ID13488 (7/9/2007); PTN000031807 ID13512 (7/11/2007); PTN000031807 ID10664 (7/16/2007); PTN000031807 ID10779 (8/1/2007); PTN000031807 ID10781 (8/3/2007); PTN000031807 ID14220 (8/8/2007); PTN000031807 ID10883 (8/13/2007); PTN000031807 ID10805 (8/22/2007); PTN000031807 ID10028 (9/4/2007); PTN000031807 ID10993 (9/12/2007); PTN000031807 ID10062 (9/17/2007); PTN000031807 ID12484 (10/1/2007); PTN000031807 ID14123 (10/10/2007); PTN000031807 ID12400 (10/31/2007); PTN000031807 ID14303 (11/7/2007); PTN000031807 ID14335 (11/13/2007); PTN000031807 ID16462 (11/26/2007); PTN00031807 ID12940 (12/11/2007); PTN000031807 ID14833 (12/18/2007); PTN000031807 ID18582 (1/11/2008); PTN000031807 ID15772 (2/4/2008); PTN000031807 ID14080 (2/8/2008); PTN000031807 ID15993 (2/12/2008); PTN000031807 ID18157 (2/20/2008); PTN000031807 ID16203 (2/26/2008) (noting "Product not moving"); PTN000031807 ID14941 (3/6/2008); PTN000031807 ID17440 (3/18/2008); PTN000031807 ID17415 (3/31/2008); PTN000031807 ID17151 (4/15/2008); PTN000031807 ID20993 (5/8/2008); PTN000031807 ID20502 (6/5/2008); and PTN000031807 ID20007 (6/16/2008).

[793] *See, e.g.*, PTN000039866 (listing article reported to Purdue on 8/22/2008); PTN000031807 ID23500 (9/10/2008); PTN000031807 ID21001 (10/22/2008); PTN000031807 ID22234 (12/11/2008); PTN000031807 ID22235 (12/19/2008) (stating "Discussed RxPatrol and controls that protect pharmacy they said they use many including video security"); PTN000031807 ID22780 (1/7/2009); PTN000031807 ID25950 (2/9/2009); PTN000031807 ID23905 (2/24/2009); PTN000031807 ID28307 (3/13/2009); PTN000031807 ID26428 (3/30/2009); PTN000031807 ID27460 (4/17/2009); PTN000031807 ID26887 (5/4/2009); PTN000031807 ID32079 (5/18/2009); PTN000031807 ID32539 (7/8/2009); PTN000031807 ID34271 (9/14/2009); PTN000031807 ID35121 (11/2/2009); PTN000031807 ID31778 (11/19/2009); PTN000031807 ID33450 (12/1/2009); PTN000031807 ID36592 (12/9/2009); PTN000031807 ID31997 (12/24/2009); PTN000031807 ID31667 (1/15/2010); PTN000031807 ID31953 1/26/2010); PTN000031807 ID37353 (3/1/2010); PTN000031807 ID37476 (3/19/2010); PTN000031807 ID167855 (5/7/2010); PTN000031807 ID41256 (6/3/2010); PTN000031807 ID39244 (7/7/2010); PTN000031807 ID168145 (7/22/2010); PTN000031807 ID39049 (7/26/2010); PTN000031807 ID42380 (8/4/2010); PTN000031807 ID46255 (8/13/2010); PTN000031807 ID46843 (10/19/2010); PTN000031807 ID45021 (11/3/2010); PTN000031807 ID46061 (12/9/2010); PTN000031807 ID49705 (1/4/2011); PTN000031807 ID49815 (1/5/2011); PTN000031807 ID45712 (1/25/2011); PTN000031807 ID52432 (2/11/2011).

[794] PTN000031807 ID49992 (4/12/2011); PTN000031807 ID171739 (4/18/2011); PTN000031807 ID57311 (7/8/2011); PTN000031807 ID60826 (8/29/2011); PTN000031807 ID64704 (11/7/2011); PTN000031807 ID70179 (12/15/2011); PTN000031807 ID177858 (2/6/2012); PTN000031807 ID73219 (2/13/2012); PTN000031807 ID178515 (3/13/2012); PTN000031807 ID76199 (4/23/2012).

[795] PTN000031807 ID180017 (6/1/2012).

[796] PTN000031807 ID165638 (10/22/2009) (emphasis added).

646. Purdue continued to heavily promote OxyContin to providers at Pain Clinic A and focused on OxyContin savings cards. For example, on January 26, 2010, Sales Representative 2 recorded in a call note the following conversation with Pain Clinic A's Nurse Practitioner Teodora Neagu:

> She said that her pt have been asking for OxyContin value cards and *she was already out of the ten I gave her last week gave her 3 boxes* and mentioned the 10,15,30 mg tablet for titration andd initiation of therapy...[797]

647. Purdue continued to receive red flags concerning Pain Clinic A. On October 15, 2010, Sales Representative 3 reported an adverse event that stated:

> This AE may have been previously reported by another rep ! *[pharmacist's] girlfriend works at [Pain Clinic A] and they have a pt close to death in a local hospital with GI bleed that thinks is due to reformulation* - he wants to know how/why reformulation could cause. advised he unsure how but will report as an AE.[798]

648. On February 24, 2011, Sales Representative 16 submitted a ROC to Purdue, which stated:

> After Dr. [H] left the lunch room. Dr [I] asked me if [Pain Clinic A] had been closed yet. I said not to my knowledge, why? Dr [I] said that he has heard from an employee who used to work at [Pain Clinic A] that they were going to be closed. Dr [I] also said that according to the employee, *[Pain Clinic A] has been raided by the FEDS twice previously. Dr [I] said that he thinks [Pain Clinic A] should be closed. I asked why? Dr said that he think they just prescribe pills. Dr said that he has a patient who went to [Pain Clinic A] for neck pain. The patient told Dr [I] that they did a neck xray and told him that he had arthritis and prescribed him a long acting Oxycodone and a short acting Oxycodone and Soma. When the patient came to Dr [I], he ordered an MRI, saw the patient had a ruptured disc, the patient had surgery and is now fine.*[799]

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[797] PTN000031807 ID165734 (1/26/2010) (emphasis added).
[798] PTN000031807 ID169415 (10/15/2010) (emphasis added).
[799] PTN000037965–66 (emphasis added).

649. On April 7, 2011, despite having knowledge about problematic prescribing practices implicating Pain Clinic A as a whole, Purdue only placed Dr. Frank McNiel and Dr. C in cease calling status. Purdue allowed its sales representatives to continue calling on the actual clinic and the other providers at the clinic.[800]

650. Red flags continued to mount regarding Pain Clinic A and its providers. On June 21, 2011, Sales Representative 16 documented the following ROC:

> *Lab tech [K] was a former employee of [Pain Clinic A] (Frank McNiel).* [K] discussed several things. 1) *She feels that Dr Frank prescribes too much pain medication for his patients* 2) She feels that Oxycontin should have an indication for certain types of pain only. [K] feels that most patients should not be able to get Oxycontin. 3) *While working at [Pain Clinic A], she and all employees would have to be escorted into work by police when Dr Frank had death threats. [K] said that Dr Frank had several death threats while she worked there 4) [K] also said that she did not feel that the parking lot was safe. [K] said that thee were always people waiting in cars for patients to get their prescriptions, feet handing out of their cars and so on.*[801]

651. On February 22, 2012, Sales Representative 16 again submitted a ROC to Purdue with the following information:

> Buffy discussed that at the pain clinic ([Pain Clinic B]) she has been working at on Wednesday they do not take any patients from [Pain Clinic A] (Frank McNiel, [C] , and others). *Buffy said that patients from [Pain Clinic A] are prescribed unusually large quantities of both Long acting and short acting medications. Buffy said that at her new clinic that she and another NP are opening on March 1, they also will not accept patients from [Pain Clinic A].*[802]

652. According to the records produced by Purdue to the State, the earliest identified date that Purdue placed Pain Clinic A in cease calling status is April 30, 2012.[803]

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[800] PTN000039878.
[801] PTN000040515–16 (emphasis added); *see also* PTN000031807.
[802] PTN000039864–65.
[803] PTN000036363.

653. However, Purdue's Phoenix database continued to list known Pain Clinic A providers as potential targets for sales representatives as late as March 22, 2013.[804]

654. Purdue continued to call on providers known to be working at Pain Clinic A well after April 30, 2012.

655. For example, Sales Representative 16 was affirmatively told on August 8, 2013[805] and again on July 25, 2014[806] that Dr. D was the supervising physician at Pain Clinic A. Yet Sales Representative 8 called on Prescriber D on September 23, 2013,[807] October 17, 2013,[808] November 6, 2013,[809] November 13, 2013,[810] December 18, 2013,[811] January 13, 2014,[812] February 19, 2014,[813] March 4, 2014,[814] April 8, 2014,[815] May 5, 2014,[816] June 2, 2014,[817] July 8, 2014,[818] and August 6, 2014.[819]

656. Purdue's sales representatives continued to submit ROCs about Pain Clinic A even after Purdue placed Pain Clinic A in cease calling status. On June 4, 2012, Sales Representative 16 submitted the following ROC from Dr. J, which stated that Pain Clinic A was asking its patients to go to Pharmacy B in Knoxville because they would never input prescriptions into the State's prescription drug monitoring program (PDMP) website:

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[804] PTN000038691–92.
[805] PTN000119294 ID137939 (8/8/2013).
[806] PTN000119294 ID168024 (7/25/2014).
[807] PTN000119294 ID142209 (9/23/2013).
[808] PTN000119294 ID144696 (10/17/2013).
[809] PTN000119294 ID146491 (11/6/2013).
[810] PTN000119294 ID147280 (11/13/2013).
[811] PTN000119294 ID150180 (12/18/2013).
[812] PTN000119294 ID151387 (1/13/2014).
[813] PTN000119294 ID154177 (2/19/2014).
[814] PTN000119294 ID155218 (3/4/2014).
[815] PTN000119294 ID158660 (4/8/2014).
[816] PTN000119294 ID161081 (5/5/2014).
[817] PTN000119294 ID163625 (6/2/2014).
[818] PTN000119294 ID166526 (7/8/2014).
[819] PTN000119294 ID169020 (8/6/2014).

> Dr [J] asked what was happening at [Pharmacy B]? I said I did not know and asked Dr what he meant? Dr said that has noticed that several of his patients who get their pain medications filled at [Pharmacy B] never track on the PDMP website. Dr said that the patients bring their pill bottles in, so he knows they are filling the prescriptions, but they never track. Dr asked why all of the pain clinics around town are asking their patients to go to [Pharmacy B]? *I said that I was unaware that* anyone but [Pain Clinic A] *did this* ...[820]

657. On January 9, 2013, Sales Representative 16 recorded a ROC that stated that Pain Clinic A's new medical director was responsible for another pharmacy's closing. The ROC stated:

> *[Pharmacist] discussed that Dr [DD] is now the medical director of [Pain Clinic A]. Chad said that Dr [DD] is credited with [Pharmacy C] closing.* [Pharmacist] also discussed that he thinks he has filled prescriptions for 3 legitimate patients from [Pharmacy C].[821]

658. On January 10, 2014, Physician Assistant Lisa Adams, who had been a provider at Pain Clinic A, signed a Consent Order with the Tennessee Board of Medical Examiners' Committee on Physician Assistants that contained the following factual allegations:

> 2. Pursuant to a complaint, the Department conducted an investigation that included the review of thirty-two (32) patient records prepared and kept by Respondent, reflecting treatment from on or about April, 2010 to March, 2011 with controlled substances in higher amounts and/or for longer durations than the Board believes were necessary.
>
> 3. Respondent was employed as a physician assistant at [Pain Clinic A], a pain management clinic in Knoxville, Tennessee from April, 2010 through March 11, 2011, during which time Dr. Frank McNiel was her supervising physician.
>
> 4. Under Dr. McNiel's training and direction, Respondent routinely prescribed controlled substances, primarily large quantities of opioids, for treatment of patients at [Pain Clinic A]. Respondent did consistently check the Controlled Substance Monitoring Database for patients on each visit, and each patient chart included a criminal background check, numerous

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[820] PTN000031807 ID78628 (6/4/2012) (emphasis added).
[821] PTN000031807 ID88954 (1/9/2013) (emphasis added).

> urine drug screens, and contracts with each patient allowing for termination of treatment.
>
> 5. In September 2010, Respondent attended a chronic pain management seminar, at which point it became evident to her that the prescribing practices that she learned at the seminar were different from the practices under which Dr. McNiel trained her.
>
> 6. When respondent questioned Dr. McNiel about the quantities and combinations of controlled substances being prescribed at the practice after she attended the seminar, Dr. McNiel informed Respondent that higher doses generally led to a greater degree of functionality and quality of life. Thereafter, Respondent did not alter her prescribing practices through the remainder of her employment at [Pain Clinic A].
>
> 7. Respondent ceased her employment at [Pain Clinic A], citing her reason for leaving as not being comfortable with the prescribing policies at the clinic.[822]

659. Among other things, the Tennessee Board of Medical Examiners' Committee on Physician Assistants reprimanded Ms. Adams's license and barred her from practicing in a pain management clinic.

660. Sales Representative 16 filed an ROC with Purdue on April 14, 2014 stating that "a Female PA, Lisa Adams who used to work at this clinic, lost her DEA license for overprescribing while she worked at [Pain Clinic A]."[823] Purdue downloaded the Consent Order on April 16, 2014.[824] Purdue placed Ms. Adams in cease calling status on May 9, 2014.[825]

661. Despite knowledge of this history of problematic prescribers, beginning at least by August 1, 2017, Purdue began calling on Pain Clinic A again directly, including on August 1, 2017,[826] August 9, 2017, August 30, 2017, September 5, 2017, September 12, 2017,[827] September

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[822] PTN000038803–09 (emphasis added).
[823] PTN000038794.
[824] PTN000038803 (metadata).
[825] PTN000038800.
[826] PTN000119294 ID301165 (8/1/2017).
[827] PTN000119294 ID307468 (9/12/2017).

18, 2017,[828] October 3, 2017,[829] October 17, 2017,[830] November 8, 2017,[831] November 28, 2017,[832] December 4, 2017,[833] December 5, 2017,[834] and December 15, 2017.

662. When Purdue finally placed *both* Dr. Frank McNiel and Dr. C in cease calling status on April 7, 2011, despite being told *in 2006* by law enforcement that both were the most problematic prescribers in the area, the company failed to place the other providers at Pain Clinic A in cease calling status until April 30, 2012, failed to ensure that providers at the clinic were removed from targeted lists after April 30, 2012, continued to call on the pharmacy closely linked to the clinic even after April 30, 2012, and started calling directly on the clinic again at least 13 times since August 1, 2017.

Breakthrough Pain Therapy Center
Cease Calling Status Date: N/A

663. Breakthrough Pain Therapy Center (Breakthrough) was a pain clinic based in Maryville that was alleged to have been part of a wide-sweeping conspiracy to distribute oxycodone and other opioids. The Breakthrough clinic was owned by Sandy and Randy Kincaid, who were not licensed medical providers. The action by the U.S. Department of Justice led to guilty pleas in 2016 from Breakthrough providers or former providers including Drs. Deborah Thomas and James Joyner, former Nurse Practitioners Buffy Kirkland, Jamie Cordes, Sherry Fetzer, and Donna Smith, as well as former Physician Assistant David Blankenship.[835] Another

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[828] PTN000119294 ID308345 (9/18/2017).
[829] PTN000119294 ID310685 (10/3/2017).
[830] PTN000119294 ID312418 (10/17/2017).
[831] PTN000119294 ID315690 (11/8/2017).
[832] PTN000119294 ID318317 (11/28/2017).
[833] PTN000119294 ID319077 (12/4/2017).
[834] PTN000119294 ID319441 (12/5/2017).
[835] PTN000036257–58.

former Physician Assistant, David Brickhouse, who was associated with the clinic, died in an unrelated car crash before trial.

664. Purdue never placed the Breakthrough clinic in cease calling status despite knowing of the December 2010 indictments against Breakthrough's owners, Sandy and Randy Kincaid, by January 18, 2011.[836]

665. Further, despite knowledge of numerous red flags indicative of abuse or diversion as early as *2010* concerning the clinic as a whole, Purdue only placed providers Dr. Deborah Thomas[837] and Nurse Practitioner Donna Smith[838] in cease calling status before news of the indictments against Breakthrough's other providers became public in *October 2014.*

666. In 2010, Purdue had knowledge that the Breakthrough clinic was reported by at least two sources to have no examination tables, examination gloves, urine screens, or providers who performed independent pain diagnoses.[839]

667. Purdue had intimate knowledge about Breakthrough and the suspect practices of its providers. Sales Representative 16 even made a presentation to Breakthrough's unlicensed owners, Sandy and Randy Kincaid, directly handed them OxyContin savings cards and other promotional materials, and continued to call on former Nurse Practitioners Buffy Kirkland and Jamie Cordes and Physician Assistant David Brickhouse years after Purdue knew of a federal raid on the clinic where they had worked.

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[836] PTN000039573 (showing last modified date as 1/18/2011).
[837] PTN000031810 (cease calling status date: 12/10/2010).
[838] PTN000031810 (cease calling status date: 6/23/2011).
[839] PTN000042504–05; PTN000042515.

668. Well *before* it became public knowledge, Purdue knew that Breakthrough and another pain clinic were being investigated and was told that there was "some illegal activity" at these two pain clinics in Maryville.

669. On May 14, 2010, Sales Representative 16 sent the following email with the subject line "Maryville, TN Pain Clinic(s)" to Purdue's Law Department:[840]

> To Whom This May Concern:
>
> This is to report that there is some illegal activity at one or more of the new pain clinics in Maryville, TN.
>
> My son is a reporter for the Daily Times in Maryville, TN. He overheard a conversation in the newsroom yesterday that one of the reporters was going to do a story on the new pain clinics that have recently opened in Maryville. According to the reporter, the Blount county Sheriff asked them not to write a story for a couple of months. According to the reporter, the sheriff also stated that they are investigating these clinics. The sheriff also reportedly said that one or more of them are writing pain medication prescriptions for people who are filling them in Tennessee and then taking them to Florida to re-sell them. Also, the sheriff supposedly mentioned that in two months their investigation would be complete and they would have indictments at that time.

670. On October 8, 2010, *after receiving the above-referenced report from the Blount County Sheriff about Breakthrough*, Sales Representative 16 documented the following in a sales call with Sandy and Randy Kincaid, the unlicensed owners of Breakthrough:

> Met with Sandy and Randy today. Got list of all providers. Providers include: Deborah Thomas, MD; Buffy Kirkland, Don Lewis, Walt Blankenship, Donna Smith, [Physician Assistant KK][841] and Sherry Fetzer. Provided Sandy with a REMS packet for each provider. *Also provided Oxycontin patient tear off sheets, TN managed care grids, conversion guides and savings cards*. Sandy asked if the reformulated Oxycontin has effected company sales. I told Sandy that I truthfully did not know. Sandy asked what exactly changed with Oxycontin. Provided Sandy with a RFC sheet and read through first two points. *Discussed appropriate patient selection and provided Sandy with partnersagainstpain brochure and CD.* Also *provided Sandy with Ryzolt slim Jim's* and Senokot pamphlets for appropriate patients.[842]

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[840] PTN000041765 (emphasis added).
[841] [Physician Assistant KK] now works at Pain Clinic A and is supervised by Dr. C and other providers.
[842] PTN000031807 ID47210 (10/8/2010) (emphasis added).

671. One week later, on October 15, 2010, Sales Representative 3 sent an email to Purdue's Drug Safety and Pharmacovigilance and Purdue's Risk Management Departments,[843] copying Sales Representative 16, that stated:

> *While in ... Knoxville TN I was told by the office mgr, [L], that she is hearing rumors that a pain mgmt. practice called Breakthru Pain in Maryville TN owned by an individual named Sandy Kincaid is running an illegal physician practice.* When I asked why she characterizes as illegal – she reported to me that a PA she knows well told her of the following issues occurring at the clinic:
>
> > *No exam table in the office*
> > *Office records scant or non existent*
> > *a pts medical diagnosis and pt plan of care based from previous physician notes*
> > *Office does not conduct UDT*
> > *Prescriptions pre-written – often dispensed without a physician present.*
>
> Told me that Mrs. Kincaids daughter has opened another clinic South of Maryville towards Townsend TN and was duplication Breakthrus business model.[844]

672. Sales Representative 3's October 15, 2010 ROC was later forwarded to Purdue's Law Department on October 26, 2010.[845]

673. On October 20, 2010, Sales Representative 16 sent an email to Purdue's Law Department that stated:

> As follow up to our conversation yesterday, I am removing these two clinics from my call list. Since the company looks at individual providers, here is what I know about these clinics:
>
> Breakthrough Pain Therapy Center
> Owned by Sandy and Randy Kincaid (sp?)

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[843] PTN000042492.
[844] PTN000042505 (emphasis added).
[845] PTN000042492.

2211 East Broadway
Maryville, TN 37804
....
Overseeing Physician: Deborah Thomas, MD
Associated Providers:
Buffy Kirkland, FNP
Don Lewis FNP
Walter Blankenship, PA
Donna Smith, FNP
[Physician Assistant KK]
Sherry Fetzer, FNP

[Pain Clinic F]
Owned by [Owner of Pain Clinic F] and his daughter
[Male Owner of Pain Clinic F] is the ex-husband of Sandy Kincaid, and his daughter is also Sandy Kincaid's daughter
...
I will be adding call notes to each physician about our conversation yesterday and that you will let me know if these clinics should be called on at a future date.[846]

674. On November 11, 2010, Sales Representative 16 submitted a ROC to Purdue concerning Breakthrough that the pain clinic had no examination equipment, had no examining gloves, did not perform any urine drug screens, and that the physician would just ask a patient about their pain based on a previous doctor's notes, stating in relevant part:

> Office Manager [M] told me today that she spoke with the owner of [a pharmacy in the area] this morning and that he told her that he is no longer taking any more patients from Breakthrough Pain Therapy Center. *[M] also told me that she knows the MD who works at Breakthrough Pain, because she had worked with them for a couple of months. [M] said that the Dr has told her that they have no exam equipment at Breakthrough pain. [M] said that the Dr said that patients sit across from a desk in an office and the provider discussed their pain based on a previous physicians notes. [M] said that the Dr also told her that they have no gloves and that they do not do any urine drug screens.*[847]

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[846] PTN000042500–01.
[847] PTN000042515 (emphasis added).

675. On November 11, 2010, Sales Representative 16 submitted another ROC concerning Breakthrough about information she received from a nearby pharmacy. She wrote:

> *[N] said that he is unsure about Breakthrough Pain down the street.* [N] said that the clinic has been there about two years. [N] said that he has met with the owner Sandy a couple of times and talked with her about things. [N] said that she answers all of the questions he has asked with the right answers. *However, [N] said that he still wonders about the practice. [N] said that they are always busy. [N] said that he ran some errands earlier today and drove by on his way back to the pharmacy and the parking lot at Breakthrough was full. [N] said he wonders if there are really that many patients who have chronic pain issues.*[848]

676. Despite the report that Sales Representative 16 would remove Breakthrough and its providers from her call list, she continued to call on the providers who she had identified as being associated with Breakthrough well after her correspondence to her superiors at Purdue about the clinic and providers in October 2010.[849]

677. For example, on November 23, 2010, Sales Representative 16 recorded the following from a sales call with Nurse Practitioner Buffy Kirkland, a provider who was still working at Breakthrough:

> Buffy said that she got a call from someone asking her about a patient she has treated at the Breakthrough Pain Therapy Center. Buffy said that she was the last one to prescribe Oxycontin for this patient. *Buffy said that the patient ended up in the hospital with an abscess and track marks from where he had been shooting up Oxycontin. Buffy said that whoever called asked if she knew that the patient was getting medications prescribed by other providers? Buffy said that she asked who? Buffy said that they are the other prescriber's at Breakthrough Pain. Buffy said that the providers at Breakthrough do not have set appointments, that they see patients as they come in.*[850]

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[848] PTN000042497–98 (emphasis added).
[849] PTN000031807 ID49661 (1/6/2011); PTN000031807 ID50441 (4/26/2011); PTN000031807 ID58212 (6/14/2011); PTN000031807 ID60967 (9/26/2011).
[850] PTN000031807 ID48817 (11/23/2010) (emphasis added); *see also* PTN000039256 (11/23/2010 call note stating Ms. Kirkland was still working at Breakthrough on Wednesdays).

678. Purdue continued to receive reports concerning Breakthrough. On December 14, 2010, additional news broke that the U.S. Department of Justice raided Breakthrough and another clinic and arrested several people for conspiracy to distribute controlled substances, including oxycodone.[851]

679. On December 15, 2010, Sales Representative 16 sent an email to Purdue's Law Department that referenced "Breakthrough Pain Therapy Center" and another clinic in the subject line and stated:

> FYI: My son spoke with the reporter who went with law enforcement to the Breakthrough Pain Therapy Center bust yesterday. *He was told that indictments are coming for the [Drs. Deborah Thomas and James Joyner] involved.* I asked if the reporter said anything about other prescribers. My son said that he did not.[852]

680. On December 15, 2010, Purdue Sales Representative 16 also called on Jamie Cordes, a nurse practitioner who had previously worked at Breakthrough, and through her notes acknowledged that she had heard about the allegations against the clinic.[853] The call note stated:

> *[J]amie asked me if I had heard about Breakthrough Pain. I told Jamie that I had heard. Jamie said that she had worked there* and that she was shocked by all of the allegations she has heard about. *Jamie said that she knew of some of the problems (see below)*, but was unaware of many of the problems there. ... *Jamie said that Dr Thomas saw the new patients in the clinic and that the other providers would see patients for follow up visits.* Jamie said that she refused to see some patients at Breakthrough Pain when she was there. *Jamie said that she would refuse to see patients if she had asked for them to be fired from the practice, for any reason, or if the appropriate documentation was not in the chart.*[854]

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[851] PTN000039576–78; PTN000039573.
[852] PTN000039570 (emphasis added).
[853] PTN000031807 ID48324 (12/15/2010).
[854] PTN000031807 ID48324 (12/15/2010) (emphasis added).

681. Sales Representative 16 spoke with Pharmacist O about Breakthrough the same day. In a call note dated December 15, 2010, Sales Representative 16 wrote:

> Met with pharmacist … today. … *[Pharmacist] asked if I had heard about Breakthrough Pain and Maryville Pain. I told [pharmacist] that I had.* [Pharmacist] said that he would have never guessed. [Pharmacist] said that they spoke with [Prescriber O] from Breakthrough every day on the phone. [Pharmacist] said that Maryville Pain had been closed by the DEA previously and that somehow they hired a new Dr and NP and were allowed to re-open. I told [Pharmacist] my that I did not know. [Pharmacist] asked if I knew anything about [Pain Clinic F]. [Pharmacist] said that it just doesn't make sense to him that a gynecologist would run a pain clinic. *[Pharmacist] also suggested that I do not wear my name badge in public with the Purdue logo. [Pharmacist] said that many people are becoming desperate.*[855]

682. On December 20, 2010, Purdue placed "Drs. [B] and Deborah Thomas of Breakthrough Pain Clinic" in cease calling status citing "clinic raided/owners/staff arrested" as the reason.[856] *Purdue did not place the other providers who it knew to be associated with this clinic in cease calling status at this time.* Purdue's sales representatives made repeated calls to Nurse Practitioners Buffy Kirkland and Jamie Cordes, who had both worked at Breakthrough, after December 2010.[857]

683. As known by Purdue, on October 9, 2014 and October 16, 2014, news broke of indictments against Dr. Thomas and Dr. Joyner,[858] Physician Assistants David Blankenship and David Brickhouse, and Nurse Practitioners Buffy Kirkland, Jamie Cordes, Sherry Fetzer, and Donna Smith.[859]

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[855] PTN000031807 ID53611 (12/15/2010) (emphasis added).
[856] PTN000037521.
[857] PTN000031807 ID58212 (6/14/2011); PTN000031807 ID60967 (9/16/2011); PTN000039229; PTN000040722–23.
[858] Voluntarily retired license on July 22, 2015.
[859] PTN000036449–55; PTN000036592.

684. Purdue Sales Representative 16 called on Nurse Practitioner Kirkland *even after* the October 9, 2014 story broke of her indictment and indictments against multiple other Breakthrough providers.[860] Sales Representative 16 also called on providers who took over treating all of Ms. Kirkland's opioid-prescribed patients, many of whom were on OxyContin, *almost immediately* after Breakthrough closed.[861]

Buffy Kirkland, APRN
Cease Calling Status Date: October 21, 2014

685. Buffy Kirkland was a nurse practitioner who worked in Maryville at several suspect pain clinics. As known to Purdue, Ms. Kirkland worked at Breakthrough and prescribed significant amounts of OxyContin, especially between 2010 and 2014.[862] From 1998 to 2017, Ms. Kirkland prescribed 68,438 tablets of OxyContin, of which 65.6% or 44,925 were 40 mg or higher.[863]

686. Ms. Kirkland began working for another physician after the raid by federal authorities at Breakthrough. But, as Purdue knew, Ms. Kirkland also kept working for Dr. Deborah Thomas, the supervising physician at Breakthrough.

687. Ms. Kirkland also worked for another clinic that was known to Purdue to be "cash only."[864] Despite Purdue's knowledge of her role with suspect clinics and other red flags, Ms. Kirkland was only placed in cease calling status on October 21, 2014.[865]

688. Purdue continued to make sales calls to Ms. Kirkland and extended repeated dinner program invitations[866] to her in spite of facts indicative of abuse or diversion as detailed below.

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[860] PTN000039229.
[861] *See* PTN000031807 ID138911 (11/13/2014).
[862] PTN000030704 (203.08–2010), (242.3 –2012), (284.3 –2013), and (196.8–2014).
[863] PWG003984543.
[864] PTN000031807 ID176230 (11/17/2010).
[865] PTN000031810.
[866] PTN000039229; PTN000039234; PTN000039236; PTN000039244.

689. Purdue sales representatives called on Ms. Kirkland at least *158 times* between September 12, 2006 and October 13, 2014.[867]

690. Purdue had knowledge that Ms. Kirkland continued to work at Breakthrough even after receiving reports in October 2010 that the clinic was an illegal practice and had no examination equipment.[868]

691. On November 23, 2010, Sales Representative 16 recorded the following call note from a visit with Ms. Kirkland:

> Buffy told me about the patient below from Breakthrough Pain [shown below]. *Buffy said that this has made her feel bad and wonder if she should be working there on Wednesdays*. Buffy said that the patient has passed all of the urine drug screens (even at the hospital). Buffy said that they do check the PMP website and that the patient was not Dr shopping.[869]

692. As stated above, Sales Representative 16 added:

> Buffy said that she got a call from someone asking her about a patient she has treated at the Breakthrough Pain Therapy Center. Buffy said that she was the last one to prescribe Oxycontin for this patient. *Buffy said that the patient ended up in the hospital with an abscess and track marks from where he had been shooting up Oxycontin. Buffy said that whoever called asked if she knew that the patient was getting medications prescribed by other providers? Buffy said that she asked who? Buffy said that they are the other prescriber's at Breakthrough Pain. Buffy said that the providers at Breakthrough do not have set appointments, that they see patients as they come in.*[870]

693. At least by July 7, 2011, Purdue had knowledge that Ms. Kirkland was still working with Dr. Thomas, the supervising physician at Breakthrough, yet allowed its sales representatives

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[867] PTN000031807.
[868] PTN000042504.
[869] PTN000039256 (emphasis added).
[870] PTN000031807 ID48817 (11/23/2010) (emphasis added).

to keep making sales calls to Ms. Kirkland. On that day, July 7, 2011, Sales Representative 16 wrote following a sales call that:

> *Buffy stated that she is working at a new pain clinic called [Pain Clinic B]* on Gov. John Sevier Highway on Wednesdays (her day off from Dr [P]'s office). *Buffy said that Dr Deborah Thomas is working there.*[871]

694. Ms. Kirkland tried to work with other suspect providers and pain clinics besides Breakthrough. On June 14, 2011, Sales Representative 16 reported that Ms. Kirkland was interested in working for Pain Clinic A, a clinic whose providers, Dr. Frank McNiel and Dr. C, were also known by Purdue to have been problem prescribers and placed in cease calling status.[872] On that day, Sales Representative 16 wrote:

> Buffy discussed a few things: 1) *She previously worked for Breakthrough Pain on her day off from Dr [P] s's office and that she has heard that the court date for Breakthrough pain has been set for October.* 2) She said that she did not believe that any of the charges in the indictment by the Feds were true, and that the owners of Breakthrough Pain have filed a defamation of character lawsuit against the feds. 3) *She asked several questions about [Pain Clinic A], and stated that she has been thinking about going to work there.*[873]

695. Ms. Kirkland did not end up working for Pain Clinic A.

696. On February 17, 2012, Purdue Sales Representative 16 stated in a call note following a discussion with Ms. Kirkland that "*Buffy discussed that she is opening her own pain clinic with another NP in Alcoa.* Buffy discussed that she would like me to call on her there after March 1 . . . *Buffy said that our Oxycontin business would be better*, since there is a shortage of Opana. . . ."[874]

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[871] PTN000031807 ID173739 (7/7/2011) (emphasis added).
[872] PTN000031810.
[873] PTN000031807 ID58212 (6/14/2011) (emphasis added).
[874] PTN000039251 (emphasis added).

697. Purdue had knowledge that when Ms. Kirkland was working for another suspect clinic and in the process of opening her own practice, she described Pain Clinic A in more negative terms than just months before when she was considering working for that clinic.

698. On February 17, 2012, Sales Representative 16 wrote of the interaction with Ms. Kirkland:

> Buffy discussed that at the pain clinic ([Pain Clinic B]) she has been working at on Wednesdays they do not take any patients from [Pain Clinic A] ([Drs. B], [C], and others). *Buffy said that the patients from [Pain Clinic A] are prescribed unusually large quantities of both Long acting and short acting medications. Buffy said that at her new clinic that she and another NP are opening on March 1, they also will not accept patients from [Pain Clinic A].*[875]

699. Purdue also had knowledge that Pain Clinic B, the clinic where Ms. Kirkland indicated she was working on Wednesdays, was suspect. In a November 17, 2011 call note describing a visit with an orthopedic surgeon, Sales Representative 16 wrote that Pain Clinic B was "*a cash only office.*"[876]

700. Ms. Kirkland continued to associate with other providers from Pain Clinic B. Around March 1, 2012, Ms. Kirkland opened a new clinic with Nurse Practitioner LL,[877] who had worked at Pain Clinic B.[878]

701. On May 22, 2012, Sales Representative 16 stated in a call note from a visit with Nurse Practitioners Kirkland and LL that Nurse Practitioner LL was expanding and opening a clinic in another town.[879]

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[875] PTN000031807 ID69373 (2/17/2012) (emphasis added); PTN000039864.
[876] PTN000031807 ID176230 (11/17/2011) (emphasis added).
[877] *See* PTN000039251 (3/14/2012).
[878] PTN000047870.
[879] PTN000039248.

702. Ms. Kirkland continued to prescribe significant amounts of OxyContin. On May 31, 2012, Sales Representative 16 noted the following in a call note from a sales visit with Ms. Kirkland:

> *When I walked in Buffy said that she started another patient on Oxycontin this morning. Buffy said that she has started quite a few patients on Oxycontin recently.* Buffy said that the patients seem to do better. Buffy also said that she is utilizing the cards and prescribing Oxycontin every 14 days for some patients who have difficulty with the cost. ...[880]

703. Elsewhere, Purdue had knowledge that Ms. Kirkland's clinic had a suspect patient population. On July 19, 2012, Sales Representative 16 reported the following in a call note from a sales call with Ms. Kirkland:

> *Buffy discussed that two area clinics closed recently*: [Pain Clinic C] in Knoxville and a pain clinic in Vonore. *Buffy discussed that many of those patients are calling and that they are seeing some of them.* I asked what medications and doses these patients are currently taking when they come to her. Buffy said that Pts vary are from taking anything from 2 hydrocodone/day to Oxycodone, possibly morphine and so on. With conversion guide I discussed appropriate conversion from other medications to Oxycontin.[881]

704. Sales Representative 16's manager, District Manager 3, accompanied her on this sales call to Ms. Kirkland and he noted the following:

> F/B PRESENTATIONS: You presented each product. During the call, the HCP had given you the info *that there is a new influx of patients and several are on "a couple of hydros a day"* that she felt were perfect for Butrans.
>
> CLOSING: You asked for utilization in the new influx of patients.[882]

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[880] PTN000039248 (emphasis added).
[881] PTN000039247–48 (emphasis added).
[882] PTN000035268 (emphasis added).

705. On September 5, 2012, Sales Representative 16 documented another sales call with Ms. Kirkland as follows:

> *Buffy discussed that she dismissed a patient for shooting up oxycodone when she saw the track marks on the patient's arms.*[883]

706. On June 11, 2013, Purdue Sales Representative 16 made the following note about a sales call with Ms. Kirkland:

> [B]uffy discussed several issues she has had with patients recently. *Buffy discussed that she has had discharge several patients recently. Buffy discussed that she dismissed three patients this week already.*[884]

707. On September 22, 2014, Sales Representative 16 made the following note from a sales call with Ms. Kirkland:

> Brief call. … Buffy said that she has had a bad day. *Buffy discussed that she has had to dismiss two patients recently, one of whom she dismissed today.* Buffy discussed that the patient she dismissed today was a patient she never would have suspected.[885]

708. In addition to other red flags, Purdue sales representatives reported during sales calls that Ms. Kirkland or her clinic was "very busy" or words to that effect on May 9, 2012, May 15, 2012, May 28, 2013, September 16, 2013, September 17, 2013, May 22, 2014, June 23, 2014, and August 11, 2014.[886]

709. Yet Purdue continued to call on Ms. Kirkland to promote OxyContin in 2014. On June 16, 2014, Sales Representative 16 made the following note from a sales call during which Ms. Kirkland proactively solicited Purdue to get more OxyContin savings cards:

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[883] PTN000031807 ID80960 (emphasis added).
[884] PTN000039239 (emphasis added).
[885] PTN000039229 (emphasis added).
[886] PTN000031807.

> *This call was in response to a message from Buffy asking for additional OxyContin savings cards.* Provided Buffy with two packs of OxyContin savings cards. I thanked Buffy for prescribing OxyContin.[887]

710. As stated above, on October 9, 2014 news broke of indictments against several other providers at Breakthrough.[888] Sales Representative 16 even called on Ms. Kirkland on October 13, 2014, *after* news of the indictments against the other Breakthrough providers were reported.[889] On October 16, 2014, news broke of the indictment against Ms. Kirkland.[890]

711. One month later, on November 13, 2014, Sales Representative 16 was already calling on the provider who took all of Ms. Kirkland's patients. She reported:

> *[Q] discussed that they are now treating all of Buffy Kirkland's patients and that many of these patients were on oxycontin.* [Q] said that most of these patients have BCBS for insurance. Discussed Butrans for appropriate patients with Helen patient profile. [Q] asked about adverse events. Discussed adverse events with vis aid. *[Q] asked about the savings cards program. Discussed and provided cards.*[891]

712. On November 18, 2015, Nurse Practitioner Kirkland was disciplined by the Tennessee Board of Nursing, which found the following:

> Respondent worked at [Breakthrough Pain Therapy Center] part time, (one day a week) from around August 2010 to December 2010.
>
> [Breakthrough] had no protocol for the treatment of its customers and the defendant was provided no medical supervision.
>
> While Respondent worked at [Breakthrough], [Breakthrough] did not have examination tables, medical equipment, hospital gowns, or gloves.
>
> Patients of [Breakthrough] were required to pay for their visits in cash and make a follow-up appointment before being seen by a provider.

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[887] PTN000039231 (emphasis added).
[888] PTN000036592.
[889] PTN000039229.
[890] PTN000036449–55.
[891] PTN000031807 ID138911 (11/13/2014) (emphasis added).

> Some patients were treated at [Breakthrough] by Respondent and others based on old radiographic results or descriptions of the chronic pain they were feeling, with limited medical history regarding the pain and without being given a physical examination or without having been given a physical examination sufficient to meet the standard of care.
>
> Some patients seen at [Breakthrough] by Respondent and other providers were written prescriptions for Schedule II controlled substances including morphine, oxycodone, and oxymorphone, and for Schedule IV controlled substances including alprazolam, without a legitimate medical purpose.
>
> The providers at [Breakthrough] including Respondent and others, did not always engage in screening patients for aberrant or drug seeking behavior.
>
> Some patients could have been observed dealing and using illicit drugs in the parking lot.[892]

713. On June 1, 2016, Ms. Kirkland and three others formerly employed at Breakthrough each pleaded guilty to a charge of conspiracy to distribute controlled substances.

714. Overall, Purdue ignored Ms. Kirkland's connection to two suspect clinics, her continued connection to suspect providers including those that Purdue had already placed on cease calling status, and numerous other red flags indicative of abuse or diversion.

Jamie Cordes, APRN
Cease Calling Status Date: October 10, 2014

715. Jamie Cordes was a nurse practitioner who practiced at multiple clinics in the Knoxville area. As with Ms. Kirkland, Purdue knew that Ms. Cordes had been associated with the Breakthrough clinic and of other facts indicative of abuse or diversion, yet kept making sales calls to her office.

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[892] https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1702_10475_111815.

716. Ms. Cordes was once designated a "core" prescriber for Purdue sales representatives[893] due to her high volume prescribing amounts. Purdue sales representatives still called on her repeatedly after she was removed from the core list.[894]

717. According to the records Purdue produced to the State, Purdue's sales representatives called on Ms. Cordes at least 60 times between August 17, 2009 and October 7, 2014.[895]

718. Purdue finally placed Nurse Practitioner Cordes in cease calling status on October 10, 2014,[896] after news broke of her indictment in a conspiracy involving the illegal distribution of prescriptions for controlled substances.[897] Ms. Cordes later pleaded guilty to each criminal charge.[898]

719. From January to September 2010, Ms. Cordes's patients redeemed 409 $70 OxyContin savings cards, almost 20% of the 2,223 total $70 OxyContin savings cards provided to patients by all of the prescribers in her Purdue sales territory.[899]

720. Purdue knew as early as December 15, 2010 that Nurse Practitioner Cordes had worked at Breakthrough. On that date, Ms. Cordes told Sales Representative 16 that she worked at one of the clinics that was accused of engaging in abuse and diversion. As recited above, the call note stated:

> *Jamie asked me if I had heard about Breakthrough Pain.* I told Jamie that I had heard. *Jamie said that she had worked there* and that she was shocked by all of the allegations she has heard about. *Jamie said that she knew of*

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[893] PTN000040739.
[894] *See* PTN000040725.
[895] PTN000040725; PTN000031807.
[896] PTN000031810; PTN000040749.
[897] PTN000036449–55.
[898] PTN000036573–76.
[899] PTN000071735.

> *some of the problems (see below)* but was unaware of many of the problems there.[900]

721. Purdue had knowledge of other red flags about Ms. Cordes. On May 25, 2011, Sales Representative 16 recorded the following interaction with Nurse Practitioner Cordes:

> Jamie said that she will start work for [a hospital] in the local Walmart clinic. *Jamie said that she is over trying to treat chronic pain. Jamie discussed all of the pressure, concerns, etc she feels.* Jamie said that there will be a new Dr coming to practice there.[901]

722. Despite this statement, Nurse Practitioner Cordes continued working with Breakthrough. On June 8, 2012, Sales Representative 16 entered a call note which stated "Called on clinic and asked to see Jamie Cordes, FNP. The receptionist said that, "They have 15 more patients to see this morning and 5 more to come in yet."[902]

723. Additionally, on that same day, Sales Representative 16 reported the following in her ROC to Purdue concerning Ms. Cordes:

> This is approximately the fourth time I have called on this clinic. *Today was the first time I observed the following: The parking lot was full of cars. Many of the cars had people sitting in them or smoking outside. The car parked directly behind mine had a person in the passenger seat who looked stoned. The license plates on the cars were primarily from Hamblen County (2 counties away), with two from Knox County (the county the office is in) and one from Washington County (with the person in the passenger seat). Washington County is approximately 4 counties away, about 2 or more hours of a drive away.*[903]

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[900] PTN000040736 (emphasis added).
[901] PTN000040732–33 (emphasis added).
[902] PTN000119294 ID103746 (6/8/2012).
[903] PTN000040722–23 (emphasis added).

724. Despite witnessing this concerning conduct, Sales Representative 16 asked the receptionist to speak with Ms. Cordes, provided her business card, and left promotional materials for Purdue products including OxyContin and Butrans.[904]

725. Purdue kept Nurse Practitioner Cordes in continue calling status despite these continuing signs of abuse and diversion.[905] On July 14, 2014, Sales Representative 3 recorded the following in his call notes about the clinic where Nurse Practitioner Cordes worked at the time: "*[O]ffice shared with me that they have lost credentials with BCBS, UHC, and Humana.* They have laid off 17 people and others to follow. Not sure how providers will break up or where they will end up."[906]

726. On July 25, 2014, Sales Representative 3 wrote the following about his interaction with Nurse Practitioner Cordes's office: ". . . sd office hopefully returning to normal soon. . . . *Jamie cordes left and unknown whereabouts.*"[907] On September 4, 2014, Sales Representative 6 noted in a call with Nurse Practitioner LL, Ms. Kirkland's former partner who had also worked at Pain Clinic B,[908] that Nurse Practitioner Cordes had opened up a clinic with Nurse Practitioner LL.[909]

727. Additionally, the call notes from Purdue sales representatives show that Ms. Cordes had a high volume practice. On February 10, 2011, Sales Representative 16 recorded the following in her call notes: "Also spoke with practice manager [R]. [R] said that Jamie is currently seeing about 20 patients/day and that she rarely gets a break anymore."[910]

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[904] PTN000040722.
[905] PTN000040726.
[906] PTN000040726 (emphasis added).
[907] PTN000031807 ID196166 (7/25/2014) (emphasis added).
[908] PTN000047870.
[909] PTN000031807 ID130884 (9/9/2014).
[910] PTN000040735.

728. As noted above, on June 8, 2012, Sales Representative 16 recorded in her call notes: "Called on clinic and asked to see Jamie Cordes, FNP. The receptionist said that, "They have 15 more patients to see this morning and 5 more to come in yet. ..."[911] On July 30, 2013, Sales Representative 6 noted that providers including Ms. Cordes were "[t]oo busy to talk."[912] On March 19, 2014, Sales Representative 3 noted: "brief window call as again office very bz. . . . "[913]

729. Despite all of these reported signs of abuse and diversion associated with Ms. Cordes's practice and associated clinics and providers, Purdue failed to place Ms. Cordes in cease calling status until October 10, 2014,[914] after news broke of her indictment in a conspiracy involving the illegal distribution of prescriptions for controlled substances.

Pain Clinic B
Cease Calling Status Date: N/A

730. Pain Clinic B was a pain clinic based in Knoxville that Purdue never placed in cease calling status. Purdue knew that Pain Clinic B had a significant number of cash paying customers and employed providers who were the subject of ROCs, who were placed in cease calling status themselves, or who had close ties with other suspicious providers or practices including Breakthrough.

731. Purdue had knowledge of facts indicative of abuse or diversion concerning Pain Clinic B for many years. On November 17, 2011, Sales Representative 16 filed a ROC in which two providers she called on "[i]dentified two Pain clinics that are *cash only*" including Pain Clinic B.[915]

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[911] PTN000040748.
[912] PTN000040729.
[913] PTN000040727.
[914] PTN000031810; PTN000040749.
[915] PTN0000119294 ID89540 (emphasis added).

732. On January 29, 2013, Sales Representative 16 filed a ROC after she called on a doctor who "said that he has heard that *[Pain Clinic B]* … was going to be shut down. Dr said he heard that they already had to close one of their offices."[916]

733. At various times, Purdue also had knowledge of facts indicative of abuse or diversion at the clinic from the providers who worked there. Notably, Dr. Deborah Thomas, the supervising physician from Breakthrough that Purdue placed in continue calling status on December 10, 2010, worked at Pain Clinic B,[917] as well as suspect providers including Nurse Practitioners Buffy Kirkland (discussed above), Nurse Practitioner Brandy Burchell, Nurse Practitioner Christina Collins, and Nurse Practitioner II.

734. Despite Purdue's knowledge of abuse and diversion associated with the clinic's providers, Purdue failed to ever place the actual Pain Clinic B on cease calling status.

Brandy Burchell, APRN

Cease Calling Status Period April 30, 2012 to November 25, 2014

735. Brandy Burchell was a nurse practitioner who worked at Pain Clinic B,[918] but who also previously worked with Dr. Frank McNiel and Dr. C at Pain Clinic A.[919] From 1998 to 2017, Ms. Burchell prescribed 285,652 tablets of OxyContin, of which 89.8% or 256,745 were 40 mg or higher.[920]

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[916] PTN0000119294 ID120529 (emphasis added).
[917] PTN000119294 ID78705 (7/7/2011); PTN000031807 ID176230 (11/17/2011). *See also* PTN000047870 (identifying address as "Deborah Thomas, MD 2805 West Govenor [sic] John Sevier Highway" as of 9/6/2011) and PTN000031807 ID78675 (6/5/2012); PTN000031807 ID129722 (7/24/2014); PTN000031807 ID139688 (12/2/2014); PTN000031807 ID139782 (12/2/2014); PTN000031807 ID140651 (1/13/2015); PTN000031807 ID140980 (2/25/2015) (identifying same address as being associated with Pain Clinic B).
[918] PTN000040261.
[919] PTN000036363.
[920] PWG003984543.

736. Purdue placed Ms. Burchell in cease calling status on April 30, 2012.[921] This cease calling status lasted until November 25, 2014,[922] when Purdue granted Sales Representative 6's request that Ms. Burchell's cease call status be changed.

737. During the time that Ms. Burchell was in cease calling status, Purdue sales representatives still called on her. For example, on July 24, 2014, Sales Representative 6 called on Nurse Practitioner Burchell at Pain Clinic B and wrote:

> Met Brandy for the first time. She had very little time to talk. … *Reminded her of the seven dosing strengths* and discussed their tapering efforts in patients getting them to the *200 mg morphine threshold. She said they're trying hard to get most of their patients down to that level.*[923]

738. Aside from the fact that a Purdue sales representative called on Ms. Burchell while she was in cease calling status and Purdue failed to discipline the sales representative, the sales call itself is problematic because of the high MME threshold reference. The CDC has stated the risk of overdose death increases twice at just 50 MMEs and considers anything over *90* MMEs per day to be dangerous.[924]

739. Purdue Sales Representative 6 stated his "Next Objective" from this call was to "f]ollow up on OxyContin use in appropriate patients. … Review the *seven dosing strengths and discuss how their titrating their patients… Review the savings card program and discuss its application especially with cash pay pts.*"[925]

740. On October 30, 2014, while Ms. Burchell was working at Pain Clinic B,[926] Sales Representative 6 wrote that he:

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[921] PTN000031810.
[922] PTN000031810.
[923] PTN000038107 ID129722 (emphasis added).
[924] https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.
[925] PTN000040264 (emphasis added).
[926] *See* PTN000039266 (listing 2805 W. Governor John Sevier Highway as Ms. Burchell's address).

> called on [Pain Clinic B] after a lead from an office. This HCP was entered into the system and popped up as a 'No call'. This HCP used to be in the [Pain Clinic A] and is not anymore. Could this HCP be re-evaluated to see if it would be ok to resume calling on?[927]

741. In response, on November 25, 2014, Purdue emailed its sales representatives notifying them that they may resume calling on Nurse Practitioner Burchell.[928]

742. Despite knowledge of Ms. Burchell's connection to both Pain Clinic A and Pain Clinic B and the high MME doses she had prescribed her patients, Purdue continued to call on her. Even when it placed her in cease calling status, Purdue sales representatives continued to call on Ms. Burchell.

743. On November 20, 2017, Ms. Burchell was disciplined by the Tennessee Board of Nursing and found to have acted below the standard of care with respect to prescribing controlled substances to 13 patients "in amounts and/or for durations not medically necessary, advisable, or justified for a diagnosed condition" from 2011 to 2013. The Board noted that Ms. Burchell "often prescribed monthly prescriptions to individual patients exceeding a daily dosage of one thousand (1000) morphine milligram equivalents," in at least one case prescribed more than 3,000 MMEs to at least one patient, and "routinely ignored signs of abuse or diversion."[929]

Christina Collins, APRN
Cease Calling Status Date: April 30, 2012 to November 25, 2014

744. Nurse Practitioner Christina Collins,[930] who had previously worked for Pain Clinic A[931] and Pain Clinic B,[932] was one of the top prescribers of OxyContin in Tennessee.[933] Ms. Collins

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[927] PTN000039266.
[928] PTN000040265.
[929] https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1702_12829_112017.
[930] PTN000039272; PTN000039283.
[931] PTN000039267.
[932] PTN000039272; PTN000039283.
[933] PTN000031809.

had a large portion of her patients on high levels of opioids—including OxyContin.[934] As mentioned above, from 2006 to 2016, Nurse Practitioner Collins wrote prescriptions for 292,960 tablets of OxyContin from all payors.[935] She prescribed 142,395 OxyContin 80 mg tablets from 2006 to 2014.[936] From 1998 to 2017, Ms. Collins prescribed 293,739 tablets of OxyContin, of which 90.9% or 267,062 were 40 mg or higher.[937] In 2011 alone, Nurse Practitioner Collins wrote 935 prescriptions for OxyContin, 835 more than she had written in 2010.[938] She wrote 1,444 prescriptions for OxyContin in 2012.[939]

745. Purdue placed Nurse Practitioner Collins and other prescribers at Pain Clinic A[940] in cease calling status on April 30, 2012. Purdue moved Ms. Collins back to continue calling status on November 25, 2014.[941]

746. Before and during the time that Ms. Collins was placed in cease calling status, Purdue had knowledge of facts indicative of abuse or diversion. On July 24, 2014, Sales Representative 6, who had called on Nurse Practitioner Burchell when she was in cease calling status, *also called on Nurse Practitioner Collins while she was in cease calling status*. He reported: "Met Christina for the first time. … Had good discussion around their efforts and tapering patients down due to the new dosing guidelines. Christina felt she has roughly 90% of her patients at or

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[934] PTN000038107 ID167818 (5/7/2010) (call note "stated [she] has prescribed oxycntin a couple of times *but not as much as at old loaction*[.]") (emphasis added).
[935] PTN000031809.
[936] PTN000031809.
[937] PWG003984543.
[938] PTN000052837.
[939] PTN000052837.
[940] PTN000036363.
[941] PTN000039280; PTN000031810.

below the 200 mg morphine equivalency level."[942] As stated above, these doses are well above the 90 MME level that the CDC considers dangerous.[943]

747. Despite the fact that Ms. Collins was prescribing opioids to some patients at dangerously high levels even while in cease calling status, Sales Representative 6 requested that Purdue move Ms. Collins back to continue calling status.[944] Purdue granted this request on November 25, 2014 with emails from Purdue's Law Department instructing the sales representatives that they may begin calling on Nurse Practitioner Burchell and Collins again without any justification as to why it would be appropriate to resume calling on these previously identified problem prescribers.[945]

748. Based on her documentation of pain treatment and "her haphazard and unprofessional prescribing practices," the Tennessee Board of Nursing disciplined Ms. Collins on March 6, 2018 by placing her license on probation for 2 years and prohibiting her from practicing in a licensed pain management clinic as a nurse practitioner.[946]

Nurse Practitioner II
Cease Calling Status Date: N/A

749. Nurse Practitioner II was another provider who worked at Pain Clinic B in Knoxville at least by August 20, 2012.[947] After reviewing Nurse Practitioner II's file, Purdue decided to keep her in continue calling status on June 24, 2014.[948]

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[942] PTN000038107 ID196137.
[943] https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.
[944] PTN000039271.
[945] PTN000039280.
[946] https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1702_12828_030118.
[947] PTN000049448.
[948] PTN000036708.

750. Before and after Purdue made this decision, it had knowledge of facts indicative of abuse or diversion, including that 50% of Nurse Practitioner II's patients paid in cash from January 2014 to March 2014.[949]

751. On August 20, 2012, Nurse Practitioner II affirmatively called Purdue to request that a "sales rep bring OxyContin savings cards."[950]

752. Nine days later, on August 29, 2012, Sales Representative 18 stated the following in his notes from a sales call with Nurse Practitioner II:

> We went over the different doses of oxycontin and she stated that her patients will tell her the 15mg doses does not exist. I explained that it does. *She stated that it is an excuse the patients make up about the product.* She stated that *she is using the coupons.* ... She stated that she is going to go to our speakers program.[951]

753. Elsewhere, Purdue received reports of Nurse Practitioner II's patients traveling from distant counties. On May 5, 2014, Purdue District Manager 3 accompanied Sales Representative 16 when she called on Nurse Practitioner II and he recorded: "It was observed in the parking lo that *there were license plates from several counties, some as far as 3 hours away, patients waiting in cars outside of the clinic.* In the clinic, we did not see any other causes for concern but this should be reported."[952]

754. Four days later, on May 9, 2014, Sales Representative 16 submitted a ROC to Purdue concerning Nurse Practitioner II's office that said: "Prior to making this call *I noticed the following that car license plates from the following Tennessee counties were in the parking lot:*

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[949] PTN000036702–03.
[950] PTN000049448.
[951] PTN000036709 (emphasis added).
[952] PTN000035268 (emphasis added).

Gibson, Blount, Williamson, Sevier, Anderson, Knox and Bradley."[953] Some of these counties are located far from Nurse Practitioner II's clinic, and the drivers of these cars would have access to many other health care providers in cities closer to home. For example, Gibson County is approximately 321 miles *or over 5 hours driving by car to Knoxville*. Williamson County *is approximately 197 miles or 3 hours driving by car from Knoxville*.

755. Purdue continued to have knowledge of red flags after it decided to keep Nurse Practitioner II in continue calling status on June 24, 2014.[954] On July 1, 2014, Sales Representative 3 made his initial call on Nurse Practitioner II and noted that:

> *She came from [Pain Clinic B]* and has no desire to become a huge prance. She stwtd her goal is to provide pain mgmt but giving attn to pts other medical needs as well and *will not be writing huge doses and handing out Rx s indiscriminately as she has seen other NP clinics*.[955]

756. In sales call notes, Sales Representative 3 documented multiple instances in which Nurse Practitioner II was too busy for a proper sales call. He attempted calls on August 5, 2014 ("Unable to see provider"),[956] September 8, 2014 ("Brief"),[957] September 5, 2014 ("Unable to see provider"),[958] September 24, 2014 ("unable to see provider"),[959] December 9, 2014 ("Saw provi r briefly at window"),[960] February 24, 2015 ("attemptd call"),[961] April 29, 2015 ("Brief"),[962] May 1, 2015 ("Brief window call again"),[963] May 19, 2015,[964] and June 1, 2015 ("Quick Call").[965]

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[953] PTN000036713 (emphasis added).
[954] PTN000036708.
[955] PTN000031807 ID126846 (7/24/2014) (emphasis added).
[956] PTN000031807 ID128837 (8/5/2014).
[957] PTN000031807 ID130966 (9/8/2014).
[958] PTN000031807 ID196614 (9/5/2014).
[959] PTN000031807 ID197850 (9/24/2014).
[960] PTN000031807 ID140438 (12/9/2014)
[961] PTN000031807 ID144828 (2/24/2015).
[962] PTN000031807 ID150614 (4/29/2015).
[963] PTN000031807 ID150216 (5/1/2015).
[964] PTN000031807 ID151620 (5/19/2015).
[965] PTN000031807 ID204109 (6/1/2015).

757. On May 1, 2015, Sales Representative 3 visited the office in response to Nurse Practitioner II's call to Purdue requesting more OxyContin savings cards and reported it was once again a brief front desk window visit.[966]

758. Purdue failed to place Nurse Practitioner II in cease calling status despite her association with Pain Clinic B, her high number of cash-paying patients, her high volume practice, and other red flags, such as the presence of patients from distant counties at her clinic.

Teodora Neagu, APRN
Cease Calling Status Date: April 30, 2012 to May 1, 2014

759. Teodora Neagu is a nurse practitioner who works in the Knoxville area and whose license is currently on probation for over-prescribing or prescribing controlled substances in a manner inconsistent with the Tennessee Board of Medical Examiners' Rules.[967] Nurse Practitioner Neagu worked for Pain Clinic A from 2008 to 2013[968] and for Dr. MM in 2008—the same year he was placed in cease calling status.[969]

760. Despite not writing any prescriptions for OxyContin in 2006, 2007, or 2016, Nurse Practitioner Neagu was one of Purdue's top 100 OxyContin prescribers in Tennessee between 2006-2016.[970] Between 2008 and 2014, Ms. Neagu wrote 6,325 prescriptions for OxyContin, totaling 618,329 OxyContin tablets, *268,716 of which were 80 mg tablets*—Purdue's highest available dose at the time.[971] In 2008, she wrote 924 prescriptions for OxyContin.[972] Four years later in 2012, the number of OxyContin prescriptions written by Ms. Neagu increased to 1,745.[973]

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[966] PTN000031807 ID150216 (5/1/2015).
[967] https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1702_12684_111717.
[968] *See* PTN000036363; https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1702_12684_111717.
[969] PTN000031810; PTN000038024.
[970] PTN000031809; PTN000031407.
[971] PTN000031809; PTN000031407.
[972] PTN000052837.
[973] PTN000052837.

761. According to records produced by Purdue, from April 4, 2007 to December 8, 2014, Purdue sales representatives called on Nurse Practitioner Neagu at least *100 times*,[974] two of which were conducted while she was in cease call status from April 30, 2012 to May 1, 2014. While Ms. Neagu was in continue calling status, Purdue had knowledge of facts indicative of abuse or diversion.

762. On March 2, 2012, Purdue opened a file on Ms. Neagu, presumably because she let her DEA license lapse, but did not place her in cease calling status at that time.[975]

763. On April 30, 2012, Purdue determined that Ms. Neagu, along with Dr. Frank McNiel, Dr. C, and others associated with Pain Clinic A, should be placed in cease calling status.[976]

764. On October 1, 2013, Sales Representative 6 called on Nurse Practitioner Neagu *while she was in cease calling status* but Purdue did not discipline the sales representative.[977]

765. After a request from a sales representative, Purdue removed Ms. Neagu from Region 0 and allowed sales representatives to resume calling on her on May 1, 2014.[978]

766. Most recently, Ms. Neagu worked with Dr. JJ, another doctor Purdue reviewed to determine whether its representatives should continue calling on him.[979]

767. Despite her association with Pain Clinic A, her relationship with other suspect providers, and other red flags, Purdue decided to place Nurse Practitioner Neagu in continue

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[974] PTN000119294; PTN000036345.
[975] From Sales Representative 16's April 18, 2012 call note: "[Pharmacist] talked about how about a year ago, … how both [Dr. Frank McNiel and Dr. C] and Teodora Neagu did not renew their DEA licenses. [Pharmacist] discussed that after they got them renewed (about two weeks later) he asked for copies before he filled their prescriptions." PTN000031807; PTN000040480–81.
[976] PTN000036363.
[977] PTN000031807 ID111986 (10/1/2013).
[978] PTN000036362.
[979] PTN000031810.

calling status in 2014. Even when Ms. Neagu was in cease calling status, Purdue sales representatives called on her.

768. In November 2017, the Tennessee Board of Medical Examiners brought a disciplinary action against Nurse Practitioner Neagu in which she admitted "her prescribing of controlled substances was non-therapeutic in nature, neither justified nor medically necessary for patients' diagnoses, and not for a legitimate purpose."[980] In the Consent Order, which placed her license on restrictive probation, the Board found the following:

> 4. Respondent was employed as an APRN at [Pain Clinic A], a pain management clinic in Knoxville, Tennessee from 2008 to March 2013, during which time Dr. Frank McNiel was her supervising physician until he retired on December 25, 2012.
>
> 5. While working at [Pain Clinic A], Dr. McNiel informed Respondent that higher doses of opioids generally led to a greater degree of functionality and quality of life. Thereafter, Respondent prescribed controlled substances in adherence to Dr. McNiel's philosophy.
>
> 6. In each of the charts reviewed there was objective evidence, including for example X-Rays, MRIs, and small fiber conduction studies, to support that the patients at issue suffered from conditions that might cause pain. *However, Respondent's prescribing was non-therapeutic in nature, neither justified nor medically necessary for patients' diagnoses, and not for a legitimate purpose. Respondent's prescribing of controlled substances, while within adherence with Dr. McNiel's directive, fell below the minimum standard of care.*
>
> 7. Respondent typically treated patients that had been receiving care from multiple providers at [Pain Clinic A] prior to her encounter with the patient. As opposed to treating patients based upon her own medical judgement, *Respondent often mimicked the previous treatment provided. This regularly included prescribing large amounts of controlled substances for which patient charts did not provide sufficient justification.*[981]

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[980] https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1702_12684_111717.
[981] https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1702_12684_111717 (emphasis added).

Dr. Abdelrahman Mohamed
Cease Calling Status Date: N/A

769. Dr. Abdelrahman Mohamed, a neurologist based in Morristown, was one of Purdue's top prescribers of OxyContin in Tennessee before he pleaded guilty to health care fraud in 2017.[982] From 2006 to 2011, Dr. Mohamed prescribed 72,693 tablets of 80 mg of OxyContin.[983] From 2006 to 2016, he prescribed 544,202 total tablets of OxyContin.[984] Purdue regularly called on Dr. Mohamed, invited him to programs outside of the office, and sent managed market specialists to answer his questions about third-party coverage of Purdue's opioids.[985]

770. Purdue reviewed and determined that Dr. Mohamed should be in continue calling status on August 24, 2011.[986] Purdue had not placed him in cease calling status as of 2016. During the time that Dr. Mohamed remained in continue calling status, Purdue knew of facts indicative of abuse or diversion.

771. Purdue sales representatives called on Dr. Mohamed *350 times* between February 15, 2006 and April 27, 2017.[987]

772. Purdue knew early on that Dr. Mohamed was prescribing high doses of opioids—including OxyContin. On September 14, 2006, Sales Representative 3 reported that Dr. Mohamed said during a sales call that he has been getting a lot of patients from other providers "*on large doses of opioids* – is drug screening trying to assess need – hasn't seen any problems with pts yet other than simply large doses."[988]

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[982]http://www.citizentribune.com/news/local/morristown-neurologist-to-plead-guilty-in-pain-pill-conspiracy/article_f3942944-3fcd-11e7-9234-ffdce9ace522.html.
[983] PTN000031809; *see also* PTN000031373.
[984] PTN000031809.
[985] *See, e.g.*, PTN000031807 ID141986 (1/14/2015).
[986] PTN000031810.
[987] PTN000031807.
[988] PTN000031807 ID2605 (9/14/2006) (emphasis added).

773. On September 13, 2007, Sales Representative 3 reported from a sales call that Dr. Mohamed "*asked what dosing limit on [oxycontin] – advsed 160/day – wwantd tamper resist rx pad.*"[989]

774. Elsewhere, Purdue had knowledge about Dr. Mohamed's suspect patient conversions to OxyContin. On March 22, 2010, Sales Representative 16 recorded the following from a sales call with Dr. Mohamed, in which he expressed a willingness to convert a patient from Suboxone, a drug used to treat opioid use disorder, to OxyContin. She stated:

> Walked in and Dr asked if we make a 60 mg Oxycontin. Reminded Dr. about the detail piece he hung up behind him on his bulletin board. Dr asked if I had something bigger. Gave Dr. the Q12h detail piece. *Dr said that he is trying to figure out how to convert patients from Symboxone to Oxycontin.* Dr asked if I knew anything about how to convert patients. I said I did not. . . *Provided Dr. with Oxycontin conversion guide.*[990]

775. Additionally, Purdue received reports of other signs indicative of abuse or diversion. On May 26, 2011, Sales Representative 16 submitted a ROC that included the following:

> *Dr. [S] said that there have been reports of drug abuse and diversion in the parking lot of Bartlett Center in Morristown.* Dr. [S] said that some of the providers in the Center overprescribe medications. Dr [S] said that Dr William Williams, *Dr Abdelrahman Mohamed*, [QQ], FNP and [PP], PA *all overprescribe pain medications*. FYI: Dr [S] also works weekends as an ER Dr at Lakeway Regional Hospital in Morristown.[991]

776. In spite of this reported concern, Purdue's sales representatives continued to talk extensively with Dr. Mohamed about OxyContin and appear to have done nothing to act on the information concerning Dr. William Williams, who was also referenced in the ROC.

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[989] PTN000031807 ID12529 (9/13/2007) (emphasis added).
[990] PTN000031807 ID35062 (3/22/2010) (emphasis added). *See also* PTN000046511; PTN000046513.
[991] PTN000038400 (emphasis added).

777. Dr. Williams was also a significant prescriber of OxyContin from 2006 to 2016. Purdue sales representatives called on Dr. Williams at least 448 times. Dr. Williams's license was placed on probation following a Board of Osteopathic Examination consent order concerning the way in which he prescribed controlled substances and supervised others in the practice who prescribed controlled substances.[992]

778. In spite of the May 26, 2011 ROC, Purdue continued to call on Dr. Mohamed. On March 27, 2012, Sales Representative 18 recorded the following from a sales call with Dr. Mohamed:

> *He and his staff stated that we should see a big increase in oxycontin. I asked why and he stated that he likes the product and there is no supply issue.* He also stated that *he has been using the savings coupon.*[993]

779. On August 2, 2012, Sales Representative 18 recorded the following from a sales call with Dr. Mohamed:

> *He stated that most of his patients are on oxycontin.* He stated that the 20mg dose is what he uses the most with oxycontin. We discussed the different doses of oxycontin.[994]

780. On April 1, 2014, Sales Representative 9 recorded the following call note for her sales call with Dr. Mohamed:

> Dr.Mohammed stated that *he has many patients he has treated with OxyContin after taking SA opioids ATC.* He said he is *treating a variety of conditions with OxyContin and his only concern is if the patients are able to get this medicine on their insurance formulary. ...* [995]

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[992] https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1907_962_050615.
[993] PTN000031807 ID178190 (3/27/2012) (emphasis added).
[994] PTN000031807 ID180885 (8/2/2012) (emphasis added).
[995] PTN000031807 ID122458 (4/1/2014) (emphasis added).

781. Red flags continued to be reported to Purdue in 2014 and 2015. On April 29, 2014, Sales Representative 9 recorded the following call note from her sales call with Dr. Mohamed:

> *Dr. Mohamed's waiting room was standing room only and he was running behind.* I acknowledged his time constraints and *told him to make sure he had plenty of copay cards for his patients. He thanked me for recognizing his busy schedule today and stated that he has started several new patients on OxyContin since we last talked. ...* [996]

782. On May 14, 2015, Sales Representative 23 recorded her interaction with Dr. Mohamed during a sales call in which he referenced being warned by the State about his opioid prescribing habits. She reported:

> He said he likes that OxyContin has abuse deterrent labeling and he will convert a patient once they are taking 4 pills,per day. He said he doesn't convert them sooner because of the TN restrictions. *He said every now and then they send a nasty email and that they keep a close watch. He said when he converts them to and ER he has to give them an IR for breakthrough pain and then he has 2 scripts for schedule II drugs and they state watches how many scripts they write and that is why he keeps them on an IR longer.* I asked him to simply do what is approp for patient.[997]

783. On August 13, 2015, Sales Representative 23 recorded her interaction with Dr. Mohamed during a sales call as follows:

> Quickly talked to Dr. Mohamed about oxycontin and Butrans. He said he has been writing and went into his procedure. *Talked to his nurse and she' said he is def writing a lot of oxycontin* but not Butrans. Talked about approp patients for Butrans. *She said most of their patients are on high morphine equivalents than what would be approp for convert to Butrans...* [998]

784. In addition to reporting these other concerning factors to Purdue, Purdue's sales representatives regularly recorded that Dr. Mohamed was very busy, that his office was

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[996] PTN000031807 ID193933 (4/29/2014) (emphasis added).
[997] PTN000031807 ID203351 (5/14/2015) (emphasis added).
[998] PTN000031807 ID155048 (8/13/2015) (emphasis added).

"slammed," or words to that effect on April 14, 2006,[999] March 1, 2007,[1000] August 9, 2007,[1001] July 23, 2014,[1002] December 23, 2014,[1003] and January 21, 2015.[1004]

785. As of December 2016, Purdue had not placed Dr. Mohamed in cease calling status despite being told that abuse and diversion were taking place outside of his clinic, that he was overprescribing controlled substances, about his suspect conversions from an opioid use disorder treatment to OxyContin, and that his office was standing room only or very busy on multiple occasions. In 2017, Dr. Mohamed pleaded guilty to 11 federal felonies related to health care fraud.[1005] In 2018, Dr. Mohammed permanently surrendered his license following a disciplinary action by the Tennessee Board of Medical Examiners that also permanently barred him from practicing in a pain management clinic or prescribing controlled substances.[1006]

Dr. TT

Cease Calling Status Dates: April 11, 2008 to March 14, 2012; April 25, 2012

786. Dr. TT was an internist based in Clarksville who also specialized in pediatrics. He was one of Purdue's top prescribers of OxyContin in Tennessee. Between 2006 and 2016, Dr. TT prescribed 104,970 tablets of 80 mg OxyContin and 208,976 OxyContin tablets of all potencies.[1007]

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[999] PTN000031807 ID1295 (4/14/2006).
[1000] PTN000031807 ID8594 (3/1/2007).
[1001] PTN000031807 ID11630 (8/9/2007).
[1002] PTN000031807 ID126588 (7/23/2014).
[1003] PTN000031807 ID199937 (12/23/2014).
[1004] PTN000031807 ID138751 (1/21/2015).
[1005] http://www.wate.com/news/local-news/morristown-pain-clinic-owner-wife-sentenced-to-federal-prison-terms/1045160185
[1006] https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1606_31933_012418.
[1007] PTN000031809; *see also* PTN000031435.

787. A basic Google search for Dr. TT also reveals that he was indicted for health care fraud by a federal grand jury in 2005[1008] and later received pre-trial diversion.[1009] Despite this publicly available information about Dr. TT's criminal charges for health care fraud in 2005, Purdue took an additional three years until first deciding to place him in cease calling status.[1010]

788. Purdue placed Dr. TT in cease calling status on January 25, 2008, approximately 7 months after a sales representative submitted the first ROC about him.[1011] On March 14, 2012, Purdue sales representatives were instructed that they may resume calling on Dr. TT and "Sales [were] requested."[1012] This continue calling status lasted a little over a month, until April 25, 2012 when Purdue again placed Dr. TT in cease calling status.[1013]

789. Before and during the time that Dr. TT was placed in continue calling status, Purdue was aware of facts indicative of abuse or diversion.

790. On September 25, 2007, Sales Representative 17 filed a report concerning Dr. TT with Purdue's Law Department[1014] though the report itself does not appear to have been produced by Purdue to the State.

791. Purdue then instructed Sales Representative 17 that he could call on Dr. TT according to call notes entered on December 13, 2007.[1015]

[1008] https://www.claimsjournal.com/news/southeast/2005/04/21/54150.htm.
[1009] *Clarksville Doctor Cleared of Charges*, CLARKSVILLE LEAF CHRONICLE, Feb. 18, 2008, A1 (correction states that headline should have stated doctor received diversion of charges, which does not mean he was cleared of charges).
[1010] PTN000031810.
[1011] PTN000031810; PTN000042238.
[1012] PTN000042243.
[1013] PTN000031810; PTN000042234.
[1014] PTN000031807 ID14472 (12/13/2007) (referencing 9/25/2007 HCP report).
[1015] PTN000031807 ID14472 (12/13/2007).

792. On August 12, 2008, Sales Representative 5 was given a tip by a pharmacist that Dr. TT was prescribing lots of OxyContin.[1016]

793. On March 9, 2012, District Manager 1 accompanied Sales Representative 13 on a visit to Dr. TT and wrote: "DM sent in by [Law Department] to assess office under Purdue's ADD Policy. No pain products were discussed, just reviewed the staff, patients, and notices on the wall. Review sent to [Law Department] via e-mail."[1017] Five days later, Purdue placed Dr. TT back in continue calling status.

794. On March 20, 2012, two weeks after Purdue decided to resume calling on Dr. TT, Sales Representative 13 submitted a ROC which said that a nurse told her that "*there are three candy men in town*," meaning "*a patient could approach the doctor and ask for any product they wanted and the doctor would prescribe it.*"[1018] She told Sales Representative 13 that Dr. TT was one of the "three candy men."[1019]

795. On April 19, 2012, Purdue created a Microsoft Word document which in part reads:

> The Tennessee Bureau of Investigation announced on February 13[, 2008] that [Dr. TT], a licensed medical doctor in private practice, entered into a Pre-Trial Diversion Agreement in the United States District Court for the Middle District of Tennessee concerning seventeen charges, including healthcare fraud and money laundering.[1020]

796. On April 25, 2012, Purdue notified sales representatives that Dr. TT had been placed in cease calling status and noted "Sales reported."[1021] After Purdue had placed Dr. TT in cease calling status, Purdue's sales representatives continued to make sales calls to the small,

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[1016] PTN000031807.
[1017] PTN000035268.
[1018] PTN000040810–11 (emphasis added).
[1019] PTN000040811.
[1020] PTN000042228.
[1021] PTN000042234.

independent pharmacy that filled prescriptions for a large percentage of his patients as late as May 29, 2014.[1022]

797. Despite his previous criminal indictment and diversion for health care fraud, ROCs from sales representatives, and his previous cease calling status, Purdue decided to keep Dr. TT in continue calling status. When Purdue found out from another provider that Dr. TT was "one of three candy men" in town, it took almost a month to place him again in cease calling status and even then, Purdue continued to call on the small, independent pharmacy associated with Dr. TT's practice.

Physician Assistant T

Cease Calling Status Dates: September 16, 2010 to April 3, 2012; July 9, 2012

798. T was a physician assistant based in Jonesborough who worked at Pain Clinic A[1023] and wrote a significant number of prescriptions of OxyContin in Tennessee. From 2006 to 2016, he wrote 10,143 prescriptions for OxyContin; 9,665 of which were written between 2007 and 2010.[1024] From 1998 to 2017, Mr. T wrote prescriptions for 810,358 tablets of OxyContin, of which 84.7% or 687,117 were 40 mg or higher.[1025] In 2008 alone, Mr. T wrote 3,797 OxyContin prescriptions.[1026] That same year, Mr. T had 457 patients who paid in cash.[1027]

799. Purdue placed Physician Assistant T in cease calling status on September 14, 2010 after Sales Representative 3 filed a ROC stating that he had heard Physician Assistant T lost his DEA license to prescribe controlled substances.[1028] Purdue then returned Physician Assistant T to

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[1022] PTN000031807 ID194943 (5/29/2014).
[1023] PTN000031807 ID162814 (11/3/2008).
[1024] PTN000052837.
[1025] PWG003984543.
[1026] PTN000052837.
[1027] PTN000056674.
[1028] PTN000040161; PTN000040158–59.

continue calling status on April 3, 2012 following a request by Sales Representative 7.[1029] This continue calling status lasted until July 9, 2012 when Purdue placed Mr. T in cease calling status following news that he was blocked from Tennessee's state Medicaid program.[1030]

800. Before and during the time that Purdue placed Physician Assistant T in continue calling status, it had knowledge of facts indicative of abuse or diversion. As of May 29, 2008, Physician Assistant T told Purdue's sales representatives that he had patients who were trying to deceive him to obtain opioids. On that date, Sales Representative 2 recorded a discussion with Physician Assistant T that stated, "*Said he uses Opana when he feels pt is on too much oxycontin or feels pt may be pulling his le*g he feels opana does not have street value."[1031]

801. Physician Assistant T repeatedly told Purdue that he was continuing to work with Dr. Frank McNiel and Dr. C at Pain Clinic A. On September 9, 2008, Sales Representative 2 referenced in his call notes that "*[Physician Assistant T] was going to start working with [Dr. Frank McNiel and Dr. C] on Fridays.*"[1032]

802. On November 3, 2008, Physician Assistant T also referenced working with Dr. Frank McNiel and Dr. C at Pain Clinic A. Sales Representative 2 wrote about a sales call with Physician Assistant T, stating:

> *He said that he would go to 320mg He said that he had no objection to prescribing Oxycontin.* He said that had been out of town as ld explain why prescriptions down. *He is also working on Friday at [Pain Clinic A]. He said he has been trying to limit those pt on dosing.* Discussed that diversion could happen with all products he agreed that could happen with any scheduled drug.He did agree that oxycontin has always worked[.][1033]

[1029] PTN000040133; PTN000040374 (subject line refers to a request to resume calling).
[1030] PTN000031810; PTN000040134.
[1031] PTN000040149 (emphasis added).
[1032] PTN000040148 (emphasis added).
[1033] PTN000031807 ID162814 (11/3/2008) (emphasis added).

803. Physician Assistant T also told Purdue about his concern about abuse and diversion at his clinic. On January 27, 2009, Sales Representative 2 recorded the following from a sales call with Physician Assistant T:

> He feels that Oxycodone is a effective pain reliever and that OxyContin is effective *He is concerned about abuse and diversion* and will write opana he feelss has less abuse discussed that all have abuse potential similar to morphine.[1034]

804. On April 12, 2011, more than six months after placing Physician Assistant T in cease call status, *Purdue referred Physician Assistant T and 81 other prescribers to the DEA during a meeting between Purdue and the DEA.*[1035]

805. On April 28, 2011, Sales Representative 7 got a tip from a pharmacist that he should call on Physician Assistant T, who apparently had moved to the Johnson City area.[1036]

806. On March 7, 2012, Sales Representative 7 requested to resume calling on Physician Assistant T.[1037] Despite the referral to the DEA less than a year before, Purdue granted the request and moved Mr. T back to continue calling status on April 3, 2012.[1038]

807. On May 9, 2012, Purdue learned that Physician Assistant T was blocked from billing TennCare after prescribing large amounts of addictive painkillers.[1039] Two months later, on July 9, 2012, Purdue's Law Department instructed sales representatives to no longer call on Physician Assistant T[1040] because of a report of licensing action against his supervisors for overprescribing.[1041] Purdue appears to have considered changing his status again and checked his

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[1034] PTN000031807 ID27295 (1/27/2009) (emphasis added).
[1035] PTN000045569.
[1036] PTN000031807 ID56186 (4/28/2011).
[1037] PTN000040133.
[1038] PTN000040374; PTN000031810.
[1039] PTN000040134–35.
[1040] PTN000040137.
[1041] PTN000031810; PTN000041789.

DEA registration on August 29, 2013,[1042] before ultimately moving him back to continue call status in April 2017.[1043]

808. In sum, Physician Assistant T was in continue calling status after Purdue had knowledge of his connection to Pain Clinic A and suspect providers, after it knew that TennCare had blocked him for overprescribing, and after Purdue itself had even referred him to the DEA for suspicious prescribing habits, as well as other red flags. This status only changed because of reports of a licensing action against his supervisors for overprescribing. Despite all of this, Purdue sales representatives resumed calling on Physician Assistant T in early 2017.[1044]

David Brickhouse, PA
Cease Calling Status Date: October 13, 2014

809. David Brickhouse was a physician assistant in the Maryville area who was called on by at least two Purdue sales representatives:[1045] Sales Representative 2[1046] and Sales Representative 3[1047] at the same time. As shown in sales call notes, Purdue knew that Mr. Brickhouse owned at least five clinics called Pain Clinic D[1048] and approved which opioids his providers, including physicians, would prescribe.[1049]

[1042] PTN000040154.
[1043] PTN000119294 ID290037 (4/25/2017).
[1044] PTN000119294 ID290037 (4/25/2017).
[1045] PTN000031807.
[1046] PTN000031807 ID34372 (9/1/2009).
[1047] PTN000031807 ID31314 (9/21/2009); PTN000039607.
[1048] PTN000031807 ID72422 (4/24/2012).
[1049] PTN000037814–15 ("Check with David on supporting his providers to the [sic] use of OxyContin where appropriate."); PTN000039607 ("Dr. said that David (Brickhouse, PA who own the clinic) has told her it would be okay for her to prescribe Butrans."); PTN000031807 ID80752 (9/7/2012) (10/1/2012) (11/8/2012) (7/9/2013) "[H]e said he has no problem *with his providers* prescribing oxycontin in appropriate pts…") (emphasis added).

810. Purdue placed Mr. Brickhouse in cease calling status on October 13, 2014.[1050] Before being placed in this status, Purdue sales representatives called on him 40 times from September 1, 2009 to July 22, 2013, not including calls to other providers at his pain clinics.[1051]

811. Purdue had knowledge of facts indicative of abuse or diversion. Early on, Mr. Brickhouse expressed concern about the cost of OxyContin for his cash paying customers. On February 8, 2010, Sales Representative 3 recorded that Mr. Brickhouse "[w]as concerened about cost of oxycontin for *cash pay pts – gave coupon.*"[1052]

812. Elsewhere, Purdue was told by another provider that Mr. Brickhouse's office did not check the prescription drug monitoring program database before prescribing a controlled substance. Sales Representative 16 called on Dr. U on April 29, 2011, and afterwards filed the following ROC:

> Dr's office manager [V] asked me if I knew of a Dr Brickhouse. I said that I have heard of a David Brickhouse who is a PA. [V] said that they had a call from his office this morning about a patient who has been seeing him since February. [V] said that Dr [U] has seen the patient for years and had been prescribing pain medications for the patient. *[V] said that the Brickhouse office had a report that the patient was selling her medication. [V] said that the Brickhouse office did not look up the patient's PMP information until after they had a report about the patient.[V] said that they called Dr [U] today after seeing that the patient had also been getting pain medications prescribed by Dr [U]. [V] said that the Brickhouse office had been prescribing the same pain medication for the patient as Dr [U], since February.* [V] said that Dr [U] had recently called the patient for a random pill count.[1053]

[1050] PTN000031810; PTN000037828.
[1051] PTN00031807.
[1052] PTN000037821 (emphasis added).
[1053] PTN000031807 (emphasis added).

813. As of April 24, 2012, Purdue knew that Mr. Brickhouse, a physician assistant, owned five clinics and employed Nurse Practitioner Cordes, who had also worked at Breakthrough and about whom Purdue had knowledge of suspicious prescribing.[1054]

814. On October 1, 2012, Sales Representative 16 recorded a call note about a visit with Dr. W who worked in the same practice with Mr. Brickhouse.[1055] Sales Representative 16 asked Dr. W, a medical doctor, to get Physician Assistant and clinic owner Brickhouse's approval to write a controlled substance prescription.[1056]

815. Sales Representative 16 also reported that a similar situation occurred on November 2, 2012 whereby Dr. W had sought approval from Mr. Brickhouse to prescribe certain opioids.[1057] Sales Representative 16 also reported a similar situation occurred on November 2, 2012 whereby Dr. W had sought approval from Mr. Brickhouse to prescribe certain opioids. Even after Purdue knew that Dr. W worked for Mr. Brickhouse and took prescribing instructions from him, Purdue continued to call on Dr. W as well.[1058]

816. The Purdue sales representatives who called on Mr. Brickhouse made repeated references to red flags including how busy the clinic and Mr. Brickhouse appeared to be when they visited. These notes included: "office packed,"[1059] "office busy,"[1060] "visited 2x's today – office

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[1054] PTN000031807 ID72422 (4/24/2012).
[1055] PTN000039607–08.
[1056] PTN000039607.
[1057] PTN000039607.
[1058] PTN000039601 ID200691 (2/2/2015).
[1059] PTN000037821 (1/5/2010); PTN000031807 ID36283 (1/5/2010); PTN000031807 ID36630 (4/7/2010).
[1060] PTN000037820 (4/23/2010).

filled each time – unable to see prescribers,"[1061] "very busy as could see,"[1062] "simply too busy to stop today,"[1063] "slammed,"[1064] "too bz to discuss,"[1065] and "office BZ as always."[1066]

817. On October 18, 2012, Sales Representative 3 attempted to call on Mr. Brickhouse, and noted the following: "waited for approx. an hour to see mr Brickhouse … eventually told me he would be unable to see me today … was advised they adding 4 providers within a month[.]"[1067]

818. Elsewhere, Purdue sales representative reported similar issues with being unable to call on Mr. Brickhouse. For example, on April 20, 2012, Sales Representative 3 reported that Mr. Brickhouse "was hard to catch at farragut office."[1068]

819. On May 1, 2013, Sales Representative 6 reported that the nurse would update Mr. Brickhouse "when he had some free time."[1069]

820. On October 16, 2014, news broke that nine health care providers, including Mr. Brickhouse, had been indicted in a conspiracy involving illegal distribution of prescriptions for controlled substances.[1070]

821. Mr. Brickhouse died in a car crash on April 5, 2016.[1071]

822. Purdue kept Mr. Brickhouse in continue calling status despite knowledge that his office did not regularly check the prescription drug monitoring program database, that he made

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[1061] PTN000031807 ID165257 (9/15/2009).
[1062] PTN000037820 (4/7/2010).
[1063] PTN000037819 (10/25/2010); PTN000031807 ID43122 (10/25/2010).
[1064] PTN000037819 (11/22/2010); PTN000031807 ID44886 (11/22/2010).
[1065] PTN000037819 (12/22/2010).
[1066] PTN000037819 (2/4/2011); PTN000031807 ID53504 (2/4/2011).
[1067] PTN000037817.
[1068] PTN000037818.
[1069] PTN000037816.
[1070] PTN000036449.
[1071] https://www.wbir.com/article/news/local/man-accused-in-pill-mill-scheme-dies-in-crash-before-trial/122886912.

prescribing decisions for doctors who were supposed to supervise him, and of repeated references to his high volume practice, among other red flags.

Dr. X

Cease Calling Status Date: April 16, 2015

823. Dr. X was a family doctor based in the Knoxville area who was the Medical Director for Pain Clinic D by 2013.[1072] From 1998 to 2017, Dr. X prescribed 32,245 OxyContin tablets, of which 70.3% or 22,699 were 40 mg or higher.[1073]

824. In 2012, Dr. X worked at Pain Clinic E.[1074] Purdue's sales representatives, including Sales Representative 6, called on Dr. X to encourage him to prescribe OxyContin and noted "he had a lot of influence."[1075]

825. Purdue did not place Dr. X in cease calling status until April 16, 2015,[1076] following news reports that he was closely linked to a large pill mill.[1077]

826. Before this time, Purdue chose to defer to its sales representatives' discretion on whether to call on Dr. X or not. In an email dated September 20, 2012, Purdue's Law Department stated: "Sales representatives **may** cease calling on [Pain Clinic E] and employees—[X]" (emphasis in original).[1078]

827. Purdue sales representatives continued to call on Dr. X and other providers from 2013 until 2015[1079] and had knowledge of facts indicative of abuse or diversion.

[1072] PTN000031807 ID103843 (7/19/2013).
[1073] PWG003984543.
[1074] PTN000037486; PTN000037480.
[1075] PTN000031807 ID103843 (7/19/2013).
[1076] PTN000040396.
[1077] PTN000041548–52.
[1078] PTN00037480 (emphasis in original).
[1079] *See, e.g.*, PTN000031807 ID112139 (10/23/2013); PTN000031807 ID103843 (7/19/2013); PTN000031807 ID139935 (12/8/2014); PTN000031807 ID139541 (12/19/2014); PTN000031807 ID138566 (1/5/2015); PTN000031807 ID143665 (2/2/2015).

828. On August 10, 2012, Sales Representative 3 submitted a ROC to Purdue that stated he was concerned about Pain Clinic E where Dr. X then worked. He wrote:

> The office in Lenoir City has been present for approximately 2 years ?, Uses a sign out front by the name of [Pain Clinic E]. *A seeming revolving door of providers. Indicators of 1.7.1 present upon each visit (not many): crowded (and large) office waiting room, few patients past 40yoa with no noticeable disabilities, armed security guard (none noted at last visit), evasive office staff at window unwilling to provide schedule of what providers are present and what locations they typically work at, concerns voiced by local pharmacists regarding practice, large volume of short acting oxycodone only written by the prescribers I have seen data on.*[1080]

829. After this report, Purdue continued to call on Dr. X for the purpose of promoting OxyContin when he began working at Pain Clinic D.

830. As of 2013, Pain Clinic D had a policy of not prescribing OxyContin[1081] that Purdue tried to change.

831. On July 19, 2013, Sales Representative 6 recorded a call note with Dr. X in which he documented that Dr. X was the Medical Director for Pain Clinic D. Sales Representative 6 also documented that Pain Clinic D had a small number of patients who paid through commercial health insurance, which means the clinic likely had a large number of patients who paid for health expenditures in cash. The call note stated:

> [M]et with him for the first time. He's the medical director for the [Pain Clinic D]. *He practices just a couple days a week but obviously has a lot of influence.* I reinforced OxyContin and q12 dosing ... Leveraged the comments from David Brickhouse around patients on Q6 short acting opioids being transitioned to an extended release like OxyContin. He said that does make sense for some patients ... *He did acknowledge they have a small percentage of commercial patients* but though it might be an option to consider.[1082]

[1080] PTN000037486–87 (emphasis added).
[1081] PTN000031807 ID112139 (10/23/2013) ("No interest in OxyContin because of prodigal policy.").
[1082] PTN000031807 ID103843 (7/19/2013) (emphasis added).

832. On March 11, 2015, Sales Representative 16 forwarded an image of an article titled "Dozens Arrested in Federal Pill-Mill Probe" to Purdue's home office with the subject line "East Knoxville Healthcare Services, 509 Lovell Road, Knoxville, TN" noting that the article contained a photograph of the practice group's door that referenced Dr. X among other providers.[1083]

833. On March 29, 2015, the Knoxville News Sentinel published an article, which was retained in Purdue's internal records, referencing Dr. X as being part of a $400 million pill mill conspiracy in East Tennessee in which he pretended to be an owner of the pill mill in exchange for $1 million.[1084]

834. On April 1, 2015, a Purdue employee accessed an article online titled "FBI agent testifies 2 people fatally overdosed from pills prescribed from alleged pill mill in Lenoir City" that referred to Dr. X "pre-signing prescriptions."[1085]

835. Despite Purdue having knowledge for several years of suspicious conduct by Dr. X, including working at a clinic with an armed security guard and a crowded waiting room, Purdue waited until after Dr. X was publicly known to be under criminal investigation to move him to cease calling status.

836. On April 16, 2015, Purdue instructed sales representatives not to call on Dr. X.[1086]

837. While Dr. X was placed in cease calling status and was under criminal investigation, Purdue still failed to include him on the list Purdue kept of suspicious providers.[1087]

[1083] PTN000040393.
[1084] PTN000036220.
[1085] PTN000041548–52.
[1086] PTN000040396.
[1087] PTN000031810.

Pain Clinic F
Cease Calling Status Date: N/A

838. Purdue sales representatives regularly called on providers employed by Pain Clinic F, which was based in Maryville. Purdue had knowledge of facts indicative of abuse or diversion long before Purdue decided to place some of Pain Clinic F's providers in cease calling status.

839. Dr. Y and Dr. B were providers associated with Pain Clinic F.[1088] Purdue placed Dr. B, a gynecologist, in cease calling status on December 20, 2010.[1089] As of 2016, Purdue had not placed Dr. Y, also a gynecologist, in cease calling status.[1090] Purdue moved Donna Smith, a nurse practitioner associated with Pain Clinic F,[1091] to cease calling status on June 23, 2011,[1092] and noted that she was "[a]ffiliated with [an] advertising pain clinic."[1093] As of 2016, Purdue had not placed Pain Clinic F in cease calling status.[1094]

840. Purdue had general knowledge of red flags concerning Pain Clinic F as a whole. For example, on October 20, 2010, Sales Representative 16 emailed Purdue's Law Department to notify Purdue that she was removing two clinics from her call list.[1095] One was Breakthrough, addressed above, and the other was the Pain Clinic F.[1096] Notably, Breakthrough and Pain Clinic F were both owned by the same family, Sandy and Randy Kincaid, as Sales Representative 16 pointed out in her email.[1097]

[1088] PTN000039890.
[1089] PTN000031810.
[1090] PTN000031810.
[1091] PTN000036251.
[1092] PTN000031810.
[1093] PTN000036283.
[1094] PTN000031810.
[1095] PTN000042500.
[1096] PTN000042500–01.
[1097] PTN000042500–01.

841. On October 20, 2010, Sales Representative 16 also noted that Donna Smith, a nurse practitioner associated with Pain Clinic F, had also worked at Breakthrough.[1098] Purdue sales representatives continued to call on providers at Pain Clinic F after October 20, 2010 for the purpose of promoting OxyContin.[1099] For example, Sales Representative 6 called on Dr. Y on March 6, 2015 and left OxyContin promotional materials.[1100]

842. On December 15, 2010, Sales Representative 16 reported that during a pharmacy visit, a pharmacist "asked if [she] knew anything about [Pain Clinic F]" and "said that it just doesn't make sense to him that a gynecologist would run a pain clinic."[1101]

843. This concern was reiterated by another pharmacist that Sales Representative 16 called on who said, "he just doesn't understand why some Dr's are into pain. [He] gave two examples: [he] said like Dr [B], who is a Gynecologist at [Pain Clinic F.]"[1102] In an email reporting this information to her manager at Purdue, District Manager 3, Sales Representative 16 also noted that "Dr [B] is already assigned to region zero. She is the Director for [Pain Clinic F] in Maryville."[1103]

844. On April 8, 2011, Sales Representative 16 reported to Purdue that:

> I observed the *waiting room was full of patients who appeared to be in their 20's and 30's. There was also an armed guard sitting at the office entrance near the waiting room. I reported the above information to [Purdue's Law Department], as well as, re-capping the history of the [Pain Clinic F].*[1104]

[1098] PTN000042500.
[1099] PTN000031807 ID145201 (3/6/2015).
[1100] PTN000031807 ID145201 (3/6/2015).
[1101] PTN000039571.
[1102] PTN000031807.
[1103] PTN000043039.
[1104] PTN000036251 (emphasis added).

845. Her accompanying call note states:

> *Donna [Smith, NP] called me on the cell phone and asked if I was going to bring her savings cards or what? Donna has called me previously asking if I was her rep and if I could bring her some Oxycontin information ans savings cards. In the past I have told her that I am not her rep and to call the company. I asked Donna if she called the company. Donna said that she did and they told her that I was her rep and gave her [District Manager 3]'s name and number too.* I reiterated that I am not her rep, *but that I was near her office and would drop by some information and savings cards.*

846. In addition to the above red flags, Purdue knew shortly after April 2011 that at least 25% of Nurse Practitioner Smith's patients paid in cash,[1105] yet Purdue still did not place her in cease calling status until two months later on June 23, 2011.[1106]

847. Purdue sales representatives continued to call on providers at Pain Clinic F over the next few years. On December 9, 2015, District Manager 3 submitted the following ROC:

> *I had just come from [Pain Clinic F] earlier in the day.* I asked [the pharmacist] if he knows the clinic since it is so close to the pharmacy. *He stated that he does not fill from that clinic. His managing pharmacist told him not bc it is "sketchy prescriptions and the HCPs have odd specialties for a pain clinic (OBYGYN, Urology, etc).".* He did not specify any particular product. The HCPs that are currently there are Dr. [B] and Dr. [Y].[1107]

848. Nurse Practitioner Donna Smith was disciplined by the Tennessee Board of Nursing on August 14, 2015 and, among other things, the Board found the following:

> 3. Respondent was the second highest prescriber of opioids in Tennessee in 2013 and the highest prescriber of opioids in Tennessee in 2014.
>
> ...
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> 5. Between January 2010 and October 2014, while employed as a nurse practitioner at [Pain Clinic F] in Maryville, Tennessee, Respondent provided treatment for chronic pain to numerous patients which included

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[1105] PTN000036262–67.
[1106] PTN000031810.
[1107] PTN000039890 (emphasis added).

> prescribing large doses of narcotics and other controlled substances in amounts and/or for durations not medically necessary, and without documenting sufficient justification for such prescribing in the patients' charts.
>
> 6. Respondent prescribed controlled substances and other medication without documenting a written treatment plan with regard to the use of controlled substances and other medications.
>
> 7. Respondent failed to adequately counsel patients regarding anomalous urine drug screens, and failed to inform patients of the possible harmful effects of certain medication combinations, and/or amounts.
>
> Respondent provided few modalities of treatment other than the prescription of controlled substances.[1108]

849. Despite reports that the clinic had an armed security guard, had noticeably younger patients, was being run by a gynecologist, and had providers associated with the problematic Breakthrough clinic, Purdue never placed Pain Clinic F in cease calling status. Purdue also never placed Dr. Y in cease calling status and failed to timely place Donna Smith in cease calling status despite the red flags identified above.

Alan Pecorella, PA
Cease Calling Status Date: August 28, 2013

850. Alan Pecorella was a physician assistant based in Knoxville who prescribed significant amounts of OxyContin, especially in 2011.[1109] Purdue regularly called on Mr. Pecorella, invited him to speaker programs,[1110] and knew that he worked at Pain Clinic A.[1111]

851. Purdue reviewed Mr. Pecorella's file and decided to keep him in continue calling status on July 18, 2013 in spite of a ROC submitted by Sales Representative 16 notifying the

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[1108] https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1702_11729_081415.
[1109] PTN000031465 (listing 287.85 prescriptions for 2011).
[1110] PTN000030156.
[1111] PTN000031807 ID106923 (9/26/2013).

company that Physician Assistant Pecorella's office had young patients in the waiting room and the parking lot had several cars from distant counties.[1112]

852. Purdue later placed Mr. Pecorella in cease calling status on August 28, 2013 following a ROC that Sales Representative 16 submitted that described how a patient was being coached in the waiting room on how to fill out forms to obtain controlled substances.[1113]

853. The Tennessee Board of Medical Examiners later revoked Mr. Pecorella's license in 2014 for two years for violations concerning controlled substances including a previous guilty plea for possession of a controlled substance.[1114]

854. During the time that Mr. Pecorella was in continue calling status, Purdue had knowledge of facts indicative of abuse or diversion. On May 14, 2013, Sales Representative 16 entered a call note from a sales call with Mr. Pecorella that stated, among other things:

> *Al discussed that these patients try to tell Him what to prescribe.* Al discussed that he tells the patients what he is willing to prescribe for them based on their MRI results, diagnosis and other factors.[1115]

855. On the same day, Sales Representative 16 submitted a ROC that stated:

> When I went into the office today, I noticed that the waiting room was half full. *I also noticed that with the exception of two elderly people most of the patients today appeared to be relatively young. I would guess that most of the patients were 30-40. When I left the office, I looked at the license plates on the vehicles in the parking lot. Several were from other counties, including: Union, Roane, Morgan and Anderson. Also several cars had people waiting in them.*[1116]

[1112] PTN000038344–46.
[1113] PTN000031810; PTN000038338.
[1114] https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/3628_2010_111914.
[1115] PTN00031807 ID100004 (5/14/2013) (emphasis added).
[1116] PTN000038327 (emphasis added).

856. Purdue had knowledge of this suspicious conduct, yet still decided to keep Mr. Pecorella in continue calling status on June 7, 2013.[1117]

857. On July 9, 2013, Sales Representative 16 submitted a ROC to Purdue concerning Mr. Pecorella with the Drug Product Name listed as oxycodone that stated:

> While waiting in the waiting room today I observed the following: 1. *A patient who was about 40 had a younger woman with her who appeared to be coaching the patient on how to fill out her forms. The patient appeared to be quite nervous. The woman she was with also appeared to be on edge, wanting the patient to do everything correctly. At one point the woman went out the car and brought back In a Manila envelope and told the patient she will need this.* 2. There is a sign in the reception window advertising L&R Imaging in Tucker, Georgia. The advertisement says that they do MRI's for $270 cash. They also accept MasterCard and Visa. When I got out the car, I googled L&R Imaging and noted that they also have a facility in Pompano Beach Florida.[1118]

858. After receiving credible information that Mr. Pecorella's patients were noticeably younger, were from distant counties, and other red flags, Purdue affirmatively decided to keep him in continue calling status. Even when Purdue received another report that patients were being coached in Mr. Pecorella's waiting room about how to fill out forms to obtain controlled substances, it took 9 days for Purdue to open a file and 48 days for Purdue to decide to finally place Mr. Pecorella in cease calling status.[1119]

Dr. Z
Cease Calling Status Date: N/A

859. Dr. Z was a family doctor in Lawrenceburg who prescribed OxyContin from 2007 to 2014. Purdue sales representatives continued to call on him after Purdue had facts indicative of abuse or diversion.

[1117] PTN000031810.
[1118] PTN000038338 (emphasis added).
[1119] PTN000031810.

860. From 2003 to August 2017, Dr. Z prescribed over twice as many OxyContin doses over 40 mg than under 40 mg. In 2010, Dr. Z prescribed 7,033 OxyContin tablets that were 40 mg or higher compared to 1,790 OxyContin prescriptions that were less than 40 mg. [1120]

861. Sales Representative 16 reported on October 28, 2009 that a nurse:

> *shared with me that she was concerned there may be a drug ring in Lawrenceburg,* TN Patsy found out at a healthy 28 year old female patient was seeing Dr. [Z] *and receiving 80mg Oxycontin 120 pills a month Dr. [Z] and 10 days later Dr. [Z] refilled another 120 pills for 80mg Oxycontin for this 28 year old patient and 6 days later received another 120 pills of 80 oxycontin for the same 28 year old patient, [Nurse] said the 28 year old female as taking some, selling some and giving some to Dr. [Z]. [Nurse] stated that the 28 year old patient has been [arrested] but has not heard if anything has happened to Dr. [Z] yet.*[1121]

862. On November 2, 2009, Purdue's Law Department instructed sales representatives to continue calling on Dr. Z.

863. Despite the ROC notifying Purdue that Dr. Z may be involved in a drug ring and prescribed unusually high quantities of high dose OxyContin, Purdue never placed him in cease calling status.[1122] Purdue sales representatives continued to call on Dr. Z at least through 2017.[1123]

Dr. HH
Cease Calling Status Date: N/A

864. Dr. HH was an anesthesiologist in Antioch who prescribed large quantities of OxyContin and other opioids. Purdue sales representatives called on him after Purdue had facts indicative of abuse or diversion.

[1120] PWG003984543.
[1121] PTN000038963–65.
[1122] PTN000031810.
[1123] *See, e.g.*, PTN000047136.

865. Call notes dating back to January 6, 2004 show that Dr. HH previously worked at a pain clinic that had since closed.[1124] Dr. HH worked at several high-volume pain clinics, including Pain Clinic G in Camden and Pain Clinic H in Antioch.

866. Additionally, on March 21, 2013, Sales Representative 13 entered a call note which included Dr. HH's admission to recent recovery of a serious drug addiction:

> Inservice with Dr. [HH], ...; we reviewed clinical data for Butrans, formulary grids and managed care;also spoke with [physician assistant] about the PA's;said they do have a few pain patients who are doing well on Butrans. *Dr.said he is a recovering drug addict of 20 months from Cocaine and Heroin.*[1125]

867. Notably, Purdue sales representatives have called on Dr. HH for well over a decade—including during the period time Dr. HH asserted he was addicted to illegal opiates.

868. Purdue has never placed Dr. HH in cease calling status and continues to be called on by sales representatives. Furthermore, Purdue sales representatives consider him to be a "Key HCP,"[1126] with at least one district manager identifying Dr. HH as a KOL for Purdue.[1127]

869. Elsewhere, Purdue had knowledge of other red flags regarding Dr. HH. On December 12, 2016, Sales Representative 15 entered a call note which read, in part, "[Dr. HH]: discussed weaned off suboxone pts that meet indication, tolerated molecule; *Reiterated Butrans not indicated for addiction*, must meet indication."[1128]

870. Despite knowing that Dr. HH had worked in several problematic pain clinics, being told by Dr. HH himself that he had been addicted to heroin within the last two years, and being

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[1124] PTN000041012.
[1125] PTN000040966 (emphasis added).
[1126] PTN000093607.
[1127] PTN000097421.
[1128] PTN000119294 (emphasis added).

told of suspect uses of opioids, Purdue has continued to make sales calls to Dr. HH at least through the end of 2017.

G. PURDUE IS SUBSTANTIALLY RESPONSIBLE FOR THE OPIOID EPIDEMIC IN TENNESSEE

871. The United States has approximately 4.4% of the world's population, but accounts for the vast majority of opioids consumed globally, including oxycodone, which is the concentrated active ingredient in OxyContin. In 2014, the United States accounted for 81% of the global total for oxycodone.[1129] Within the United States, Tennessee accounts for disproportionately high rates of opioid consumption generally and oxycodone consumption specifically for its population. This is true as well in absolute numbers of oxycodone. As of 2011, there were 21 pills of oxycodone for every Tennessean above the age of 12.[1130]

872. While some progress has been made, in 2015, Tennessee had the third highest prescription rate in the country[1131] and one of the highest amounts of opioids prescribed per person in the country as measured in MMEs according to the CDC.[1132] A substantial portion of Tennessee's high MME level came from OxyContin. Between 2008 and 2017, 6,371,957,981 MMEs of OxyContin were sold in Tennessee[1133] with MME levels attributable to 40 mg or higher OxyContin tablets peaking at 797,153,640 MMEs in 2010.

873. A cause for this imbalance is not that Americans and Tennesseans experience pain at higher rates than their global or national peers or have greater access to healthcare. Rather, one

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[1129] Nora Volkow, M.D., *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, NATIONAL INSTITUTE ON DRUG ABUSE (May 14, 2014) available at: https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse (internal citations omitted).
[1130] *Prescription for Success*, TENNESSEE DEPARTMENT OF MENTAL HEALTH AND SUBSTANCE ABUSE SERVICES, 11 (2014).
[1131] https://www.cdc.gov/drugoverdose/maps/rxstate2016.html.
[1132] https://www.cdc.gov/vitalsigns/opioids/infographic.html.
[1133] PWG003984518-45.

of contributing factors to the severity of the current opioid crisis is "aggressive marketing by pharmaceutical companies" as recognized by the Director to the National Institute on Drug Abuse within the National Institutes of Health in a 2014 report to the United States Senate.[1134]

874. Purdue's aggressive marketing and other conduct has played a substantial role in creating and prolonging the opioid crisis in Tennessee. Purdue's conduct led to addiction, abuse, diversion, and other negative outcomes that have caused the State and its political subdivisions to spend substantial resources to attempt to address.

875. Purdue's OxyContin is the branded opioid that is most associated with the opioid crisis nationally and in Tennessee for good reason. Purdue created the market for a highly potent, extended release single entity opioid consisting of oxycodone that was easily manipulated by misrepresenting OxyContin's potential for addiction and abuse through an unprecedented marketing campaign for a Schedule II narcotic that targeted some of the highest prescribing providers and pharmacies of opioids and OxyContin in Tennessee.

876. In many cases, Purdue had knowledge of signs of abuse or diversion from the Tennessee providers and pharmacies that its sales representatives called upon and yet Purdue ignored these red flags.

877. Purdue's marketing was effective. Purdue's sales calls to providers generated more prescriptions for OxyContin and its other opioid products. Purdue found in internal marketing documents that "TRx Level is Highly Correlated to Call Activity."[1135]

[1134] Nora Volkow, M.D., *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, NATIONAL INSTITUTE ON DRUG ABUSE (May 14, 2014) available at: https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse.
[1135] PWG000324250.

878. Purdue knew that more sales calls to the top prescribers of its opioid products led to more prescriptions. A Purdue consultant found: "For all deciles, increased calls are associated with higher OxyContin TRx growth—a sign of promotional sensitivity" in a marketing document from 2013 titled "OxyContin Growth Opportunities."[1136] Similarly, Purdue had evidence that "[r]eps who make more OxyContin P1s on high-decile prescribers generate more OxyContin growth in their territory."[1137] "P1" denotes first priority or presenting OxyContin first in a sales call.

879. As part of these sales calls, Purdue emphasized "new to brand" starts[1138] and trained its Tennessee sales representatives to "Ensure New [Patient] starts on Oxycontin."[1139]

880. Purdue also fueled the opioid epidemic through its heavy promotion and use of OxyContin savings cards, which operated like a coupon to offset the cost of a prescription for a patient, could be used by cash-paying patients, could be used multiple times,[1140] and were relied on by high-volume prescribers and pain clinics that exhibited strong signs of abuse or diversion of opioids.

881. Purdue used savings cards to generate new patient starts including to opioid-naïve patients.[1141] For example, Purdue found that a $0 co-pay for Butrans prescriptions "[h]elps generate new trials, *effectively acting like a sample*."[1142]

[1136] PWG000447858 (referencing both a final report and working draft).
[1137] PWG000447879.
[1138] PWG0004285342.
[1139] PWG0004285342.
[1140] PWG000004105.
[1141] PWG000195230.
[1142] PWG000001611.

882. Purdue determined with OxyContin that "[w]hen an HCP uses a Savings Card with a new patient there is an 8.3% total prescription growth compared with HCPs that do not utilize a savings card. Also there is a higher persistency of new patients at 60 days when savings cards are used."[1143]

883. Purdue found "[d]ata proves that HCPs who use savings cards have a lift in prescriptions"[1144] and made increasing utilization of the OxyContin Patient Savings Program a strategic initiative.[1145]

884. Purdue trained its sales representatives to discuss savings cards on every call because the company had evidence that approximately 60% of patients stayed on the Purdue's products more than 90 days if the savings card was redeemed.[1146] In a 2012 sales training document, Purdue stated:

> [I]t is also important that the OxyContin Patient Savings Card is discussed on every sales call as market research has shown that ~60% more patients stay on therapy >90 days if a savings card is redeemed.[1147]

885. As Purdue knew through data the company collected and tracked, Purdue's savings cards were frequently used to pay at least in part for high quantities of high dose OxyContin prescriptions.[1148] Purdue knew or should have known that these prescriptions were highly unlikely to be consumed by a single patient and were most likely diverted.

[1143] PWG000028274.
[1144] PWG000345971.
[1145] PWG000004094.
[1146] PWG000194960.
[1147] PWG000194964.
[1148] PTN000056673.

886. Purdue's savings cards were used by patients to acquire high quantities of high dose OxyContin that had a significant street value and could be easily diverted.[1149] As one example, a Purdue savings card with a unique patient identifier was used to purchase a 30 day supply of 240 80 mg OxyContin tablets on February 18, 2010, March 22, 2010, April 19, 2010, May 17, 2010, June 17, 2010, and July 13, 2010.[1150] At $1 per milligram,[1151] these prescriptions, which were purchased in part through a Purdue savings card with the same unique patient identifier, would have a street value of *$115,200*.

887. In addition, Purdue worked with distributors to ensure that pharmacies had the maximum supply of OxyContin. Distributors set threshold limits for a pharmacy's opioid supply that are supposed to serve as a protection against abuse or diversion. But as a self-described "strategic imperative," Purdue sought to have distributors create separate threshold limits for oxycodone and OxyContin, instead of one for oxycodone generally, and to create separate threshold limits for oxycodone immediate release 30 mg in order to ensure that pharmacies carried more OxyContin.[1152]

888. Purdue also had a replacement program for pharmacies whose inventories of Purdue opioid products were stolen or robbed that supplemented whatever the pharmacy's insurance did not cover.[1153]

889. Purdue sales representatives made sales calls to and used pharmacies as a source of information regarding problematic prescribers. Purdue also used pharmacies as a source of

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[1149] PTN000056673.
[1150] PTN000056673 ID636 (2/18/2010); PTN000056673 ID1547 (3/22/2010); PTN000056673 ID2868 (4/19/2010); PTN000056673 ID4702 (5/17/2010); PTN000056673 ID6922 (6/17/2010); and PTN000056673 ID8730 (7/13/2010).
[1151] https://www.justice.gov/archive/ndic/pubs10/10550/10550p.pdf.
[1152] PWG000212739.
[1153] ST000446.

information to track down high-prescribing doctors as well as to identify new prescribers to call on. For example, on February 16, 2012, Sales Representative 5 called on a Springfield pharmacy where the pharmacist told him the location where Dr. Rhodes had relocated. His district manager congratulated him on finding the new practice.[1154]

890. Purdue ignored red flags for abuse or diversion at Tennessee pharmacies and continued to push OxyContin. For example, Sales Representative 3 was told on July 11, 2013 that one of Pharmacy E's distributors had stopped shipping it controlled substances[1155] and yet continued to call on Pharmacy E.[1156]

891. Similarly, on August 16, 2013, Sales Representative 6 made a sales call to a pharmacist at Pharmacy D, who informed Sales Representative 6 that the pharmacy's quantities of oxycodone were restricted. Sales Representative 6 documented his interaction as follows:

> Met with … the pharmacist. Reviewed the OxyContin pharmacy guide and *discussed the promotional focus around conversions from oxycodone and Percocet. He did confirm that that would help them out because their quantities of oxycodone are so restricted.* I also mentioned the seven dosing strengths and he said they are moving some of the 30 mg but not the 15 mg …[1157]

892. Purdue also made sales calls to pharmacies that it knew from savings card data to dispense both significant quantities of and high percentages of high dose OxyContin. For example, between 2009 and 2016, the average number of OxyContin pills dispensed for each prescription that was paid for in part through a savings card in Tennessee was 62.[1158] At Pharmacy B, that

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[1154] PTN000035268.
[1155] PTN000119294 ID135216 (7/11/2013).
[1156] PTN000119294 ID135706 (7/17/2013); PTN000119294 ID140094 (8/29/2013).
[1157] PTN000119294 ID138805 (8/16/2013) (emphasis added).
[1158] PTN000056673.

number was 93.[1159] In addition, Purdue knew that 86% of OxyContin prescriptions paid for in part through a savings card and filled by Pharmacy B were for high doses (greater than or equal to 40 mg).[1160] Purdue also knew that *38% of all OxyContin* purchased in part through a savings card at Pharmacy B were for 80 mg tablets.[1161] Purdue also knew that for all Tennessee pharmacies that filled an OxyContin prescription and accepted a savings card between December 31, 2009 and August 17, 2016, 50% were high dose (greater than or equal to 40 mg) and 16% were for 80 mg tablets.[1162]

893. Purdue's marketing efforts worked in Tennessee. In Morristown, a city of 29,137 according to the 2010 census,[1163] Purdue sold 100.6 OxyContin tablets per person from 2008 to 2017 compared with 9.1 OxyContin tablets per person in Memphis and 16.5 OxyContin tablets per person in Nashville over the same period.[1164] In Knoxville, a city of 178,874 according to the 2010 census,[1165] Purdue sold *96.3* OxyContin tablets per person from 2008 to 2017.[1166]

894. Purdue's marketing worked particularly well for high dose OxyContin. As shown below, the majority of OxyContin tablets sold in Tennessee from 2008 to 2017 were high dose tablets of 40 mg and above. Out of the 104,340,372 total OxyContin tablets prescribed in

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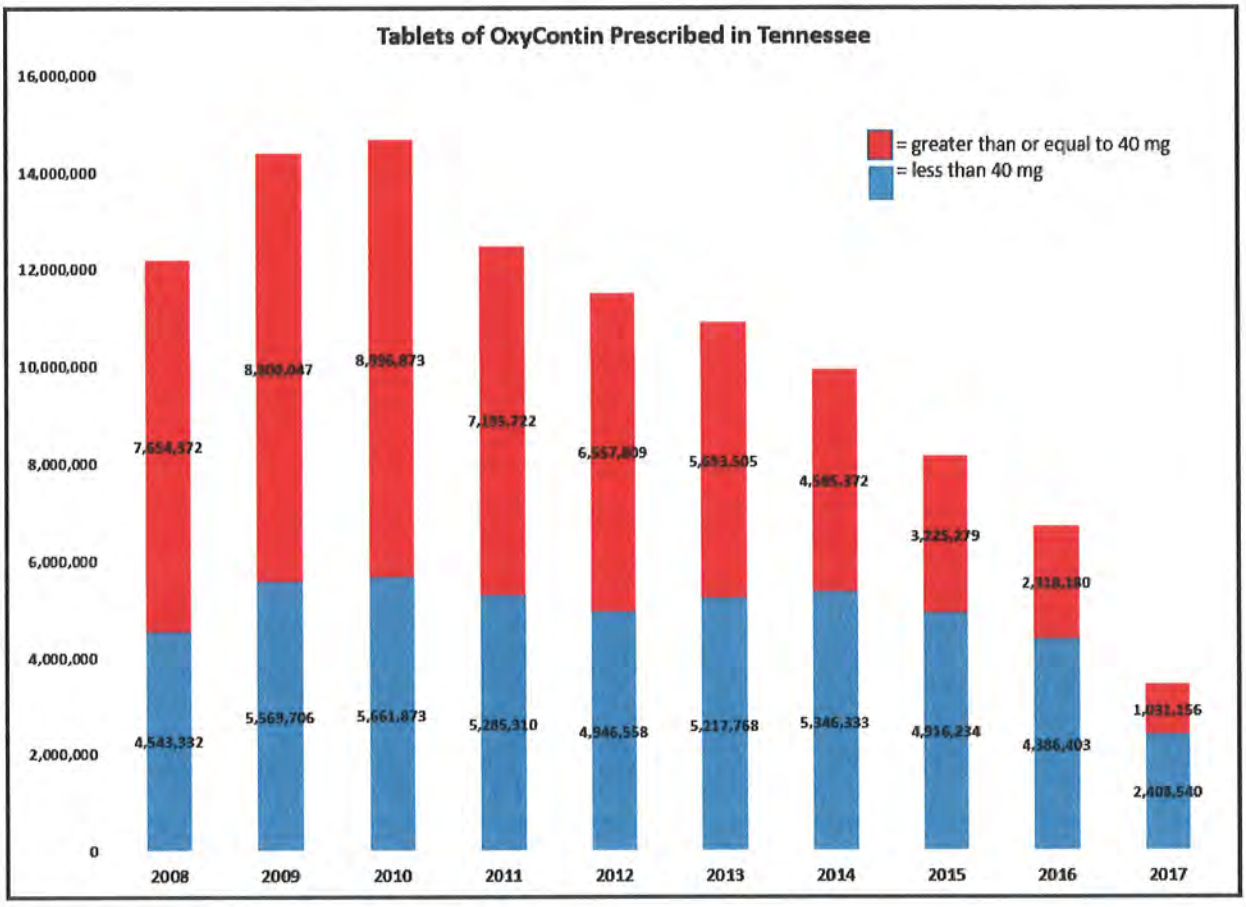
[1159] PTN000056673.
[1160] PTN000056673.
[1161] PTN000056673.
[1162] PTN000056673.
[1163] https://www.census.gov/quickfacts/fact/table/collegedalecitytennessee,oakridgecitytennessee,maryvillecitytennessee,morristowncitytennessee,knoxvillecitytennessee,nashvilledavidsonbalancetennessee/PST045217.
[1164] PWG003984543.
[1165] https://www.census.gov/quickfacts/fact/table/collegedalecitytennessee,oakridgecitytennessee,maryvillecitytennessee,morristowncitytennessee,knoxvillecitytennessee,nashvilledavidsonbalancetennessee/PST045217.
[1166] PWG003984543.

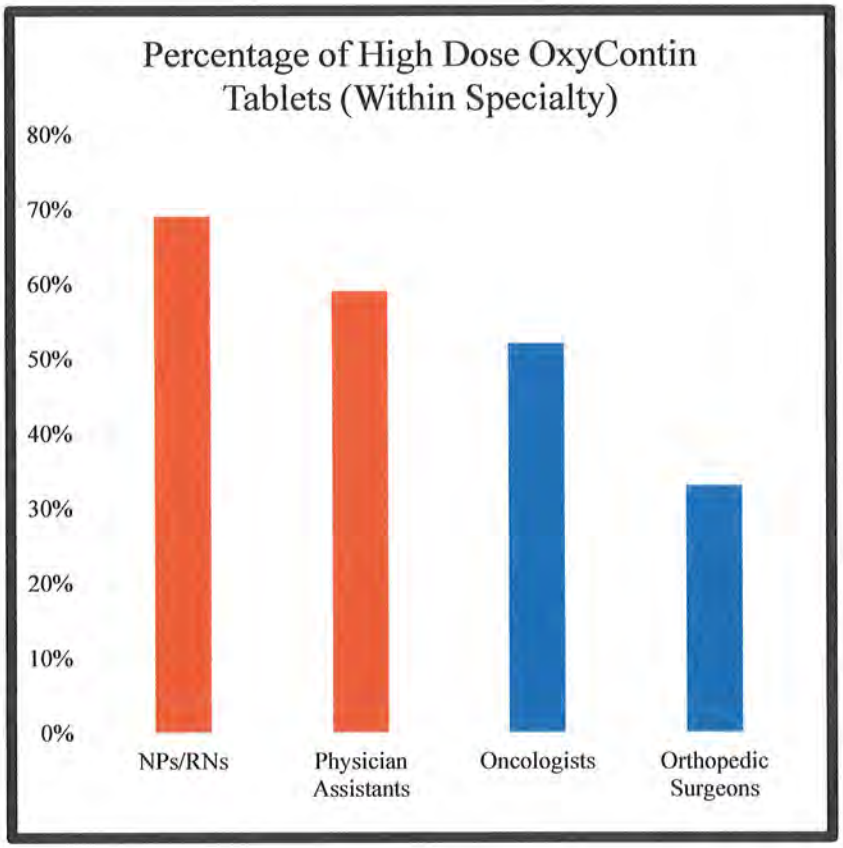
Tennessee from 2008 to 2017, *53.7%* of them were 40 mg or higher,[1167] which if taken twice a day exceeds the daily amount of opioids the CDC warns against *by over 33%.*[1168]



895. From the approximately 1,471,006 prescriptions for OxyContin in Tennessee from 2008 to 2017, *48.1%* of these prescriptions were for doses of OxyContin 40 mg or higher,[1169] which if taken twice a day exceed the MME level the CDC warns against using *by over 33%.*[1170]

[1167] PWG003984543.
[1168] https://tenncare.magellanhealth.com/static/docs/Program_Information/TennCare_MME_Conversion_Chart.pdf; https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.
[1169] PWG003984537.
[1170] https://tenncare.magellanhealth.com/static/docs/Program_Information/TennCare_MME_Conversion_Chart.pdf; https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.

896. Moreover, Purdue's joint marketing efforts to focus on high doses of OxyContin as well as nurse practitioners and physician assistants worked. As shown by the chart below, from January 2007 to August 2017, 69% of the OxyContin tablets prescribed by nurse practitioners or registered nurses in Tennessee were 40 mg or higher. Similarly, during the same period, 59% of the OxyContin tablets prescribed by physician assistants in Tennessee were 40 mg or higher. In comparison, 52% of the OxyContin tablets oncologists prescribed in Tennessee were 40 mg or higher and 33% of the OxyContin tablets orthopedic surgeons prescribed in Tennessee were 40 mg or higher during the same time period.[1171]



[1171] PWG003984543.

897. This large number of OxyContin prescriptions especially at high doses has equated to a substantial number of residents who have become addicted in Tennessee. A 2015 meta-analysis of 38 studies evaluating opioid misuse, abuse, and addiction in chronic pain patients found rates of addiction averaging between 8–12%[1172] though the actual percentage is most likely higher because of those misclassified as physically tolerant.

898. Most people with opioid addiction started with prescription painkillers. According to data from the Substance Abuse and Mental Health Services Administration, it is estimated that of the 4,850,000 adults in Tennessee, 221,000 (or 4.56%) have used prescription opioids for non-medical purposes. Of these, it is estimated that, as of 2014, at least 69,100 were addicted to opioids and required treatment for opioid abuse and 151,900 had risky prescription opioid use.[1173]

899. Within this subgroup, a substantial portion of Tennesseans were addicted to or because of OxyContin. OxyContin, which is highly concentrated oxycodone, has been consistently popular among those suffering from opioid use disorder or opioid abusers.

900. A study of 3,520 opioid-dependent individuals conducted by clinical investigators from Washington University in St. Louis and others found that oxycodone and hydrocodone are "by far" the most popular drugs of choice among prescription opioid abusers.[1174] Within that subset, oxycodone was the choice of significantly more users (44.7%) than hydrocodone (29.4%) because the quality of the high was viewed to be much better by oxycodone users (54%) than

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[1172] Kevin E. Vowles, Rates of Opioid Misuse, Abuse, and Addiction in Chronic Pain: A Systematic Review and Data Synthesis, PAIN, 569, 156:4 (April 2015).

[1173] *Prescription for Success*, TENNESSEE DEPARTMENT OF MENTAL HEALTH AND SUBSTANCE ABUSE SERVICES, 4 (2014).

[1174] Theodore Cicero, PhD, *Factors Influencing the Selection of Hydrocodone and Oxycodone as Primary Opioids in Substance Abusers Seeking Treatment in the United States*, PAIN, 154:12 (2013) available at: http://cicero.wustl.edu/skip/publications/documents/Factorsinfluencingtheselectionofhydrocodoneandoxycodoneasprimaryopioidsinsubstanceabuserssee.pdf.

hydrocodone users (20%).[1175] The study found that hydrocodone was less attractive than oxycodone because of hydrocodone's frequent combination with other products like acetaminophen.[1176]

901. Oxycodone's popularity over other opioids is supported elsewhere in the literature. For example, another study found that oxycodone scored most favorably among patients dependent on heroin compared with fentanyl, buprenorphine, and morphine.[1177]

902. Given this preference for oxycodone, it is no surprise that OxyContin, which offered concentrated oxycodone that could be easily manipulated to access, was popular and a substantial contributor to the opioid epidemic in Tennessee.

903. OxyContin's addictive qualities and easy manipulation led a subset of addicts to turn to heroin, which was cheaper, when the old formulation of OxyContin was removed from the market on August 5, 2010, and replaced with the reformulated version beginning August 9, 2010.

904. Highly credible statistical evidence shows that the abrupt growth in the heroin death rate, which the CDC found to have increased by more than five times between 2010 and 2016,[1178] was caused by the reformulated OxyContin.

905. A publication by the National Bureau of Economic Research reached this conclusion by analyzing time-series evidence that dated the changes in the heroin and opioid markets to the month in which reformulation occurred, by analyzing the availability of heroin in

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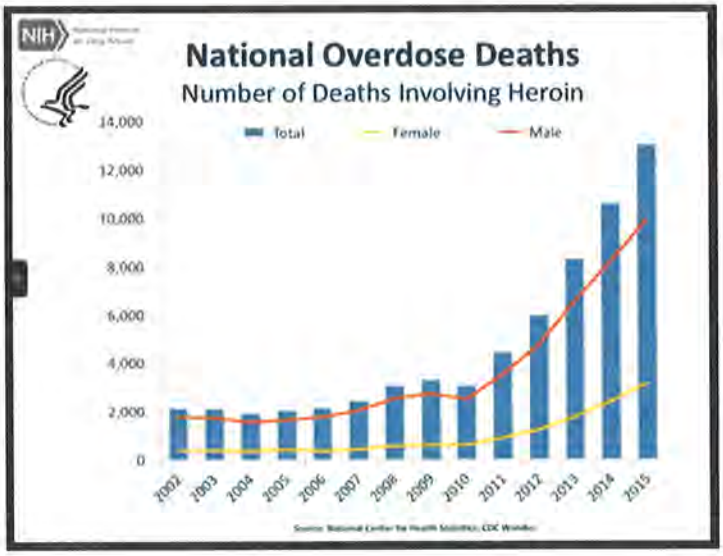
[1175] Theodore Cicero, PhD, *Factors Influencing the Selection of Hydrocodone and OxyCodone as Primary Opioids in Substance Abusers Seeking Treatment in the United States*, PAIN, 154:12 (2013).
[1176] Theodore Cicero, PhD, *Factors Influencing the Selection of Hydrocodone and OxyCodone as Primary Opioids in Substance Abusers Seeking Treatment in the United States*, PAIN, 154:12 (2013).
[1177] Comer, S.D. *Relative Abuse Liability of Prescription Opioids Compared to Heroin in Morphine-maintained Heroin Abusers*. NEUROPSYCHOPHARMACOLOGY, 33(5):1179-1191 (2008)) (available at https://www.nap.edu/read/24781/chapter/8#190) .
[1178] *Heroin Overdose Data*, CENTERS FOR DISEASE CONTROL AND PREVENTION, available at https://www.cdc.gov/drugoverdose/data/heroin.html.

local markets, and by accounting for alternative theories.[1179] The study also found that outcomes such as deaths, poisonings, emergency room visits, and enrollments in treatment programs from heroin abuse have all increased since August 2010.[1180]

906. A similar working paper by the Rand Corporation in January 2017 stated "[o]ur results imply that a substantial share of the dramatic increase in heroin deaths since 2010 can be attributed to the reformulation of OxyContin." [1181]

907. This conclusion is consistent with national data showing a spike in the number of overdose deaths involving heroin showing a four-fold increase from 2010 as shown below.[1182]



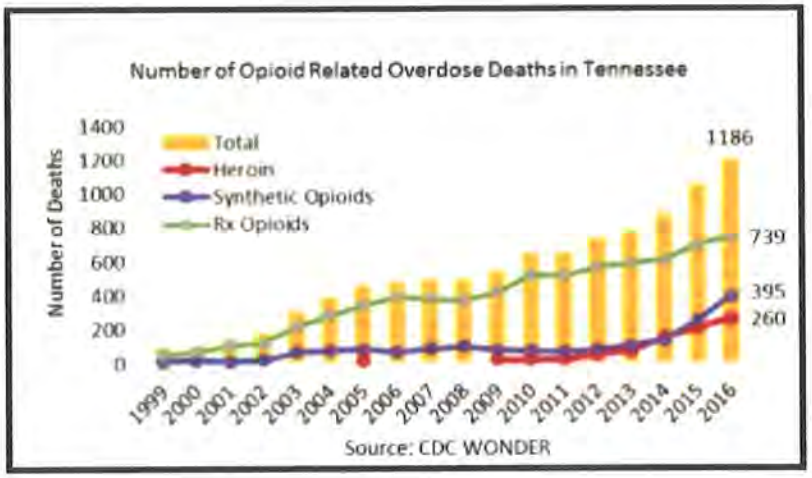
[1179] William Evans, *How the Reformulation of OxyContin Ignited the Heroin Epidemic*, NATIONAL BUREAU OF ECONOMIC RESEARCH 6 (April 2018), available at: https://www3.nd.edu/~elieber/research/ELP.pdf (hereinafter NBER).

[1180] NBER (citing Paul Coplan, *Changes in Oxycodone and Heroin Exposures in the National Poison Data System after Introduction of Extended release Oxycodone with Abuse-Deterrent Characteristics*, PHARMACOEPIDEMIOLOGY AND DRUG SAFETY 23(12): 1274-1282 (2013); Theodore Cicero, *Effect of Abuse-Deterrent Formulation of OxyContin*, NEW ENGLAND JOURNAL OF MEDICINE 367(2): 187-189 (2012); Theodore Cicero, *The Changing Face of Heroin Use in the United States: a Retrospective Analysis of the Past 50 Years*," JAMA PSYCHIATRY 71(7):821-826 (2014); Theodore Cicero, *Shifting Patterns of Prescription Opioid and Heroin Abuse in the United States*, NEW ENGLAND JOURNAL OF MEDICINE, 373(18): 1789-1790 (2015); and Wilson Compton, *Relationship between Nonmedical Prescription-Opioid Use and Heroin Use*, NEW ENGLAND JOURNAL OF MEDICINE 374(2): 154-163 (2016)).

[1181] Abby Alpert, *Supply-Side Drug Policy in the Presence of Substitutes: Evidence from the Introduction of Abuse-Deterrent Opioids*, RAND CORPORATION (Jan. 2017).

[1182] https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates.

908. Likewise, the finding is consistent with data from Tennessee where deaths from heroin overdoses have increased *15 times* from 2010 to 2016—rising from 17 deaths in 2010 to at least 260 in 2016.[1183]



909. This statistical evidence concerning heroin overdoses linked to the reformulation of OxyContin serves as a marker for those individuals addicted or otherwise impacted by the prior formulation of OxyContin.

910. The State and its political subdivisions have spent significant public resources on treatment, toxicology reports and autopsies, law enforcement, corrections, intervention programs, drug courts, prosecution, probation, and child welfare related to opioids, OxyContin, and heroin and more funds are needed to address this public health crisis.

911. Opioid use, morbidity, and mortality have increased exponentially nationwide and across Tennessee in the years since Purdue first began aggressively marketing opioids for long-term use.

[1183] *Tennessee Opioid Summary*, NATIONAL INSTITUTE ON DRUG ABUSE, available at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/tennessee-opioid-summary.

912. In 2015, Tennessee had 13,034 nonfatal overdose outpatient visits and 7,092 overdose inpatient stays.[1184] In 2016, 7,636,112 opioids were prescribed in Tennessee. In 2016, there were 1,186 opioid-related overdose deaths in Tennessee-a rate of 18.1 deaths per 100,000 persons—higher than the national rate of 13.3 deaths per 100,000.[1185]

913. SAMHSA has stated that the number of individuals enrolled in substance use treatment in Tennessee has varied between 16,590 in 2011, 19,115 in 2012, 14,149 in 2013, and 22,445 in 2015.[1186]

914. Similarly, SAMHSA has stated that 5,371 Tennesseans in 2011, 6,079 Tennesseans in 2012, 2,422 Tennesseans in 2013, and 4,421 Tennesseans in 2015 were enrolled in an opioid treatment program and received medication-assisted therapy (MAT), excluding those receiving MAT through a private physician.[1187] Similarly, the number of individuals receiving buprenorphine at substance use facilities in Tennessee has climbed from 299 in 2011, 475 in 2012, 488 in 2013, to 1,179 in 2015.[1188]

915. Still, a significant number of Tennesseans remain to be treated. In Tennessee, only about 10.6% of individuals aged 12 or older with illicit drug dependence or abuse received treatment for their illicit drug use within the year prior to being surveyed.[1189]

[1184] https://www.tn.gov/health/health-program-areas/pdo/pdo/data-dashboard.html.

[1185] *Tennessee Opioid Summary*, NATIONAL INSTITUTE ON DRUG ABUSE, available at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/tennessee-opioid-summary.

[1186] *Behavioral Health Barometer Tennessee, Vol. 4*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, 13 available at https://store.samhsa.gov/shin/content//SMA17-BAROUS-16/SMA17-BAROUS-16-TN.pdf (hereinafter *Behavioral Health Barometer Tennessee*).

[1187] *Behavioral Health Barometer Tennessee,* 13.

[1188] *Behavioral Health Barometer Tennessee,* 14.

[1189] K. Edwards, *Opioid Abuse in Tennessee*, TENNESSEE DEPARTMENT OF MENTAL HEALTH & SUBSTANCE ABUSE SERVICES (citing SAMHSA Center for Behavioral Health Statistics and Quality, 2014), p. 1, available at https://www.tn.gov/content/dam/tn/mentalhealth/documents/Opioid_Abuse_in_TN_July_2015.pdf.

916. The opioid epidemic in Tennessee has also had a negative impact on infants, children, the elderly, and families generally.

917. Tennessee is ranked number 6 in the nation for rates of opioid-related hospital admissions among senior citizens. In 2005, 467 out of every 100,000 Tennesseans aged 65 and older spent time hospitalized from opioid related use. By 2015, that rate shot up to 1,055 out of every 100,000 Tennesseans aged 65 and older.[1190]

918. Opioid use and misuse have increased the numbers of infants suffering from neonatal abstinence syndrome (NAS), a withdrawal syndrome that occurs in infants exposed to opioids in utero. The number of NAS cases attributable to prescription opioids has been disproportionately high in Tennessee. A 2015 NAS update prepared by the Tennessee Department of Health shows that "[w]hen categorized into mutually exclusive categories of exposure, 48.5% of cases were exposed to prescription drugs only, 26.8% were exposed only to illicit or diverted drugs, and 23.2% were exposed to a mix of prescription and illicit or diverted drugs."[1191]

919. In Tennessee, the rate of NAS was three times above the national average between 2009 and 2012 and has been more than *10 times* the national average in some areas of East Tennessee.[1192] In 2013 and 2014, Tennessee had NAS rates of 25.5 and 28.5 per 1,000 live births respectively.[1193]

[1190] Anita Wadhwani, *Opioid-related Hospitalizations More than Triple for Tennessee Seniors*, THE TENNESSEAN, available at https://www.tennessean.com/story/news/2017/08/13/opioid-related-hospitalizations-more-than-triple-tennessee-seniors/545556001/ (citing the U.S. Agency for Healthcare Research and Quality).

[1191] A.M. Miller, *Neonatal Abstinence Syndrome Surveillance Annual Report 2015*, TENNESSEE DEPARTMENT OF HEALTH 5 (2015), available at https://www.tn.gov/content/dam/tn/health/documents/nas/NAS_Annual_report_2015_FINAL.pdf.

[1192] Paul Campbell, M.D., PhD, *Neonatal Abstinence Syndrome in East Tennessee: Characteristics and Risk Factors among Mothers and Infants in One Area of Appalachia*, J. HEALTH CARE POOR UNDERSERVED 1293-1408, 28(4) 2017.

[1193] Paul Campbell, M.D., PhD, *Neonatal Abstinence Syndrome in East Tennessee: Characteristics and Risk Factors among Mothers and Infants in One Area of Appalachia*, J. HEALTH CARE POOR UNDERSERVED 1293-1408, 28(4) 2017.

920. Unfair and deceptive marketing of opioids by Purdue also has a significant detrimental impact on children in Tennessee. Adolescent misuse of prescription opioids is particularly devastating because it is the peak period in life when people first misuse opioids. Purdue pushing the overprescribing of opioids has given more young children access to them.

921. Parental substance abuse is a major risk factor for child fatalities, child maltreatment, and involvement with the child welfare system. Children removed from their home as a result of parental substance abuse are likely to remain in foster care longer and have significantly higher rates of adoption than those in foster care for other reasons. A higher rate of adoption indicates that children removed from their homes remain in foster care longer and are less likely to exit from foster care to reunite with biological parents.

922. In February 2018, Purdue stated that it has ceased detailing its opioid products to health care providers. Even if true, this does not affect the State's nuisance abatement action because the company could resume sales calls and other marketing, the effects of Purdue's conduct are long-term, pervasive, and continuous, and substantial equitable costs of abating the nuisance remain.

III. VIOLATIONS OF THE LAW

COUNT I: TENNESSEE CONSUMER PROTECTION ACT
Tenn. Code Ann. § 47-18-104(a) and (b)

923. The Plaintiff, the State of Tennessee, incorporates by reference and re-alleges each and every allegation contained in paragraphs 1–870 of this Complaint.

924. The Defendant's advertising, promotion, and offering of its opioid products, as alleged herein, constitutes "trade," "commerce" and/or a "consumer transaction" as defined in Tenn. Code Ann. § 47-18-103(19) and as those terms have been interpreted by the Tennessee Supreme Court in *Fayne v. Vincent*, 301 S.W.3d 162, 175 (Tenn. 2009) and elsewhere.

925. As used in this Complaint, "unsubstantiated" means not possessing competent and reliable scientific evidence, defined as tests, analyses, research, studies, or other evidence based upon the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results, at the time a claim is made. In the alternative, the State submits that "unsubstantiated" means not possessing substantial evidence, defined as adequate and well-controlled investigations, at the time a claim is made. The State submits that as applied there is no difference between the standards and that, regardless, Purdue's unsubstantiated claims as referenced in this Complaint fail either standard.

926. By engaging in any act or practice that causes or tends to cause a consumer or any other person to believe what is false or that misleads or tends to mislead a consumer or any other person as to a matter of fact, the Defendant has violated Tenn. Code Ann. § 47-18-104(b)(27).

927. By expressly claiming without qualification that OxyContin does not have a dose ceiling or through words or phrases of similar import when this is not the case or when this claim was unsubstantiated at the time made, the Defendant has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), and (b)(27) in each instance.

928. By expressly referencing pseudoaddiction in its marketing or through words or phrases of similar import when this claim was deceptive or unsubstantiated at the time made, the Defendant has violated Tenn. Code Ann. § 47-18-104(a) and (b)(27) in each instance.

929. By expressly or implicitly claiming that an addiction mitigation tool including a patient contract, patient diary, patient self-report, urine drug screen, opioid risk tool, or other tool is more effective than it actually is or when this claim was unsubstantiated at the time made, the Defendant has violated Tenn. Code Ann. § 47-18-104(a) and (b)(27) in each instance.

930. By expressly or implicitly claiming that OxyContin or Butrans did not produce peaks and valleys that led to feelings of euphoria or less effective pain relief or through words or phrases of similar import when this is not the case or when this claim was unsubstantiated at the time made, the Defendant has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), and (b)(27) in each instance.

931. By expressly or implicitly claiming that OxyContin's pre-2010 formulation could not be crushed, liquefied, or abused when this was not the case or when this claim was unsubstantiated at the time made, the Defendant has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), and (b)(27) in each instance.

932. By referring to the abuse-deterrent properties of OxyContin and Hysingla ER's post-2010 formulations and failing to disclose that these properties do not deter or otherwise impact oral ingestion, the most common form of abuse, the Defendant has violated Tenn. Code Ann. § 47-18-104(a) and (b)(27) in each instance.

933. By expressly or implicitly understating the risk of addiction from its opioid products, the Defendant has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), and (b)(27) in each instance.

934. By referring to "seven dosing strengths of OxyContin," using a stair-step graphic for increased titration, or otherwise making claims about higher doses of its opioid products and failing to disclose the increased risk of addiction and other serious risks or side effects from higher doses of its opioid products, the Defendant has violated Tenn. Code Ann. § 47-18-104(a) and (b)(27) in each instance.

935. By promoting its opioids for long-term use and failing to disclose the lack of evidence for long-term use of its opioids, the Defendant has violated Tenn. Code Ann. § 47-18-104(a) and (b)(27) in each instance.

936. By expressly or implicitly claiming without qualification that its opioid products were safer than they actually were or when this claim was unsubstantiated at the time made, the Defendant has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), and (b)(27) in each instance.

937. By expressly or implicitly claiming that OxyContin was safer, more effective, as effective, or superior to Opana, Duragesic, methadone, or Avinza, or through words or phrases of similar import, when this is not the case or when the claim was unsubstantiated at the time made, the Defendant has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(8), and (b)(27) in each instance.

938. By expressly or implicitly claiming that OxyContin was safer, more effective, as effective, or superior to immediate release opioids generally or Dilaudid, hydrocodone, immediate release opioids containing acetaminophen, hydrocodone combinations, Lortab, Vicodin, and Percocet specifically when this is not the case or when the claim was unsubstantiated at the time made, the Defendant has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(8) (except for Dilaudid), and (b)(27) in each instance.

939. By expressly or implicitly claiming that OxyContin was safer, more effective, as effective, or superior to non-opioids when this is not the case or when the claim was unsubstantiated at the time made, the Defendant has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(8), and (b)(27) in each instance.

940. By expressly or implicitly claiming that Butrans was safer, more effective, as effective, or superior to immediate release opioids such as hydrocodone, hydrocodone

combinations, Darvocet, tramadol, and Lortab when this is not the case or when the claim was unsubstantiated at the time made, the Defendant has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(8), and (b)(27) in each instance.

941. By expressly or implicitly claiming that Ryzolt was safer, more effective, as effective, or superior to immediate release opioids generally or Percocet specifically or through words or phrases of similar import when this is not the case or when the claim was unsubstantiated at the time made, the Defendant has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(8), and (b)(27) in each instance.

942. By expressly or implicitly claiming that Ryzolt was safer, more effective, as effective, or superior to opioids including immediate release tramadol generally or Ultram ER specifically or through words or phrases of similar import when this is not the case or when the claim was unsubstantiated at the time made, the Defendant has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(8), and (b)(27) in each instance.

943. By expressly or implicitly claiming that Hysingla ER was safer, more effective, as effective, or superior to immediate release opioids including hydrocodone combinations and those containing acetaminophen or through words or phrases of similar import when this is not the case or when the claim was unsubstantiated at the time made, the Defendant has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(8), and (b)(27) in each instance.

944. By expressly or implicitly representing that its opioid products improve a patient's quality of life, or through words or phrases of similar import when this is not the case or when the claim was unsubstantiated at the time made, the Defendant has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), and (b)(27) in each instance.

945. By expressly or implicitly representing that its opioid products improve a patient's function or through words or phrases of similar import when this is not the case or when the claim was unsubstantiated at the time made, the Defendant has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), and (b)(27) in each instance.

946. By expressly or implicitly representing that its opioid products act as a sleep aid, or through words or phrases of similar import when this is not the case or when the claim was unsubstantiated at the time made, the Defendant has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), and (b)(27) in each instance.

947. By expressly or implicitly misrepresenting the safety of OxyContin or Butrans when taken by the elderly, the Defendant has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), and (b)(27) in each instance.

948. By targeting health care providers who worked in nursing homes or who otherwise had large elderly patient populations for sales calls for OxyContin and Butrans, both of which have an increased risk of respiratory depression in the elderly, the Defendant has violated Tenn. Code Ann. § 47-18-104(a) in each instance.

949. By referring to low-dose starts of OxyContin in elderly patients and failing to disclose that low dose starts most often lead to higher doses of OxyContin where safety risks in the elderly are increased, the Defendant has violated Tenn. Code Ann. § 47-18-104(a) and (b)(27) in each instance.

950. By referring to recommendations or promotional, policy, educational, and other materials from the American Pain Society, the American Pain Foundation, the American Academy of Pain Medicine, or other pain advocacy groups Purdue substantially funded in its marketing

without disclosing this connection, the Defendant has violated Tenn. Code Ann. § 47-18-104(a) and (b)(27) in each instance.

951. By making sales calls to providers and pharmacies after knowing of likely indicators of abuse or diversion, the Defendant has violated Tenn. Code Ann. § 47-18-104(a) and (b)(43)(C) in each instance.

COUNT II: VIOLATIONS OF 2007 AGREED FINAL JUDGMENT

952. The Plaintiff, the State of Tennessee, incorporates by reference and re-alleges each and every allegation contained in paragraphs 444–870 of this Complaint.

953. The Defendant had actual awareness of its violations of the 2007 Judgment as a reasonable person would have known or had reason to know that his or her conduct described above violated the 2007 Judgment.

954. By knowingly engaging in the conduct described above, the Defendant has violated the 2007 Judgment and Tenn. Code Ann. § 47-18-108(c) in each instance.

COUNT III: COMMON LAW NUISANCE

955. The Plaintiff, the State of Tennessee, incorporates by references and re-alleges each and every allegation contained in paragraphs 1–922 of this Complaint.

956. Through the actions described above, Purdue has contributed to and/or assisted in creating and maintaining a condition that has interfered with the operation of the commercial market, interfered with public health, and endangered the lives and health of Tennessee residents.

957. The Defendant had a duty under the TCPA to disseminate non-misleading promotional material, had a duty under the TCPA to disclose material facts, had a duty under the 2007 Judgment to effectively establish, implement, and follow an abuse and diversion detection

program, and had a duty not to indirectly offer or sell an unlawful product and it violated these duties.

958. While the Defendant's degree of care is not relevant in a common law nuisance suit brought by the sovereign State, the Defendant behaved negligently, recklessly, or intentionally as set forth above.

959. Through the actions described above, Purdue has contributed to and/or assisted in creating and maintaining a condition that endangers the life or health of Tennessee residents and that unreasonably interferes with or obstructs rights common to the public.

960. Opioid use, abuse, addiction, and overdose deaths have increased throughout Tennessee. Locations such as the offices of high-prescribing health care providers and the pharmacies at which their patients fill opioid prescriptions have attracted drug dealers and those addicted to opioids.

961. The greater demand for emergency services, law enforcement, addiction treatment, and other social services places an unreasonable burden on governmental resources including the State and its political subdivisions.

962. Expanding the market for prescription opioids by making misrepresentations and omissions to health care providers, especially to general practitioners, nurse practitioners, and physician assistants, as well as targeting providers and pharmacies with practices that had actual abuse or diversion or signs indicative of abuse or diversion, has created an abundance of opioids available for criminal use and fueled a wave of addiction, abuse, injury, and death.

963. Purdue's actions described above were a substantial factor in opioids becoming widely available, used, and all too often abused.

964. But for Purdue's actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted. Purdue's actions have and will continue to injure and harm many residents throughout Tennessee.

965. While tort based standards are not applicable to a public nuisance suit brought by the sovereign State, the public nuisance and associated financial and economic losses were foreseeable to Purdue, who knew or should have known that its unfair and deceptive business practices regarding the safety, purported benefits, and comparative superiority or equivalency of its opioid products, its continued sales targeting of providers and pharmacies with practices that had actual abuse or diversion or signs indicative of abuse or diversion of opioids, and its other conduct described herein were creating a public nuisance.

966. Purdue intended health care providers to prescribe its extended release opioids for long-term use and for patients to fill those prescriptions and to keep filling those prescriptions at higher and higher doses. A reasonable person in Purdue's position would foresee not only an expanded market, but the other likely and foreseeable result of Purdue's conduct—the widespread problems of opioid addiction and abuse, particularly given the easy manipulation of its prior formulation and its popularity among opioid abusers and those addicted.

967. Purdue was on notice and aware of signs both that health care providers were prescribing unreasonably high numbers of opioids and that the broader use of opioids were causing the kinds of harm described in this Complaint.

968. Purdue's business practices generated a new and very profitable circular market with the promotion of opioids—providing both the profitable supply of narcotics to prescribe and sell, as well as causing addiction which fueled the demand to buy more.

969. Purdue acted without express authority of a statute in misrepresenting the safety, comparative superiority or equivalence of its opioids to other products, and benefits of its opioid products, failing to disclose the increased risk of addiction at higher doses, and failing to disclose the lack of substantiation for long-term use of opioids among other conduct.

970. The health and safety of Tennessee residents, including those who use, have used, or will use opioids, as well as those affected by users of opioids, is a matter of great public interest and of legitimate concern to the State. Tennesseans have a right to be free from conduct that endangers their health and safety and that interferes with the commercial marketplace. Purdue's conduct interfered in the enjoyment of these public rights.

971. As part of its nuisance action, the State does not seek any damages attributable to Tenncare, Medicaid, or Medicare.

IV. PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiff, the State of Tennessee, *ex rel.* Herbert H. Slatery III, Attorney General and Reporter, pursuant to the TCPA, the Attorney General's general statutory authority, the Attorney General's authority at common law, and this Court's equitable powers, prays:

1. That this Complaint be filed without cost bond as provided by Tenn. Code Ann. §§ 20-13-101 and 47-18-116;

2. That process issue and be served upon the Defendant requiring it to appear and answer;

3. That this Court adjudge and decree that the Defendant has engaged in the aforementioned acts or practices that violate the TCPA;

4. That pursuant to Tenn. Code Ann. § 47-18-108(a)(1), (a)(4), and (a)(5), this Court permanently enjoin and restrain the Defendant from engaging in the aforementioned acts or practices which violate the TCPA;

5. That the Court find that the Defendant has made the material misrepresentations and omissions set forth above, that the misrepresentations and omissions were widely-disseminated, and that the Defendant's opioid products were purchased;

6. That pursuant to Tenn. Code Ann. § 47-18-108(b)(1), this Court make such orders or render such judgments as may be necessary to restore to any person, as defined in Tenn. Code Ann. § 47-18-103(13), who has suffered any ascertainable loss as defined in Tenn. Code Ann. § 47-18-2102(1) including statutory interest and requiring that the Defendant pay all costs of distributing and administering the same, including through the use of third-party administrator;

7. That this Court make such orders or render such judgments as may be necessary to disgorge the profits and ill-gotten gains the Defendant realized by reason of the alleged violations of the TCPA;

8. That this Court adjudge and decree that the Defendant pays a civil penalty of $1,000.00 to the State for each violation of the TCPA as provided by Tenn. Code Ann. § 47-18-108(b)(3);

9. That apart from any civil penalties referenced above and pursuant to Tenn. Code Ann. § 47-18-125, this Court adjudge and decree that the Defendant pays a civil penalty of $10,000 per violation for any method, act, or practice that violates the TCPA that the Court finds the Defendant knowingly, as defined in Tenn. Code Ann. § 47-18-103(10), used which targeted elderly persons with each violation constituting each misrepresentation or deceptive statement that appeared on a solicitation or advertisement;

10. That this Court enter judgment against the Defendant and in favor of the State for the reasonable costs and expenses of the investigation and prosecution of this action, including attorneys' fees and costs, expert and other witness fees, as provided by Tenn. Code Ann. § 47-18-108(a)(5) and (b)(4), and other state law;

11. That pursuant to Tenn. Code Ann. § 47-18-108(c), this Court adjudge and decree that the Defendant has knowingly violated paragraph 13 of the 2007 Judgment and that the Defendant shall pay the State $2,000 for each violation of the Judgment in addition to any other appropriate relief;

12. That an order be entered that provides for abatement of the public nuisance the Defendant has created, the equitable costs of abating this nuisance, an award to the State for damages in an amount to be determined at trial, and any other relief or remedy allowable under state law;

13. That all costs, including discretionary costs, in this case be taxed against the Defendant;

14. That a jury be empaneled to hear and decide all appropriate matters; and

15. That this Court grant the State such other and further relief as this Court deems just and proper.

Respectfully submitted,

Herbert H Slatery III

HERBERT H. SLATERY III by Paul Ney
Attorney General and Reporter Chief Deputy Attorney General
B.P.R. No. 009077

BRANT HARRELL, B.P.R. No. 24470
Senior Counsel
MARGARET ROWLAND, B.P.R. No. 33513
Assistant Attorney General
CAROLYN U. SMITH, B.P.R. No. 17166
Senior Counsel
Office of the Attorney General of Tennessee
Consumer Protection and Advocate Division
UBS Tower, 20th Floor
315 Deaderick Street
Nashville, TN 37243
(615) 741-3549
(615) 532-2910 (fax)
brant.harrell@ag.tn.gov
margaret.rowland@ag.tn.gov
carolyn.smith@ag.tn.gov

GLOSSARY OF TERMS

AAPM – American Academy of Pain Medicine

ADD – Abuse and Diversion Detection

ADP – abuse deterrent properties

APAP – acetaminophen or N-acetyl-para-aminophenol

APF – American Pain Foundation

APS – American Pain Society

ASA – aspirin or acetylsalicylic acid

ATC – around-the-clock

CII or C2 – controlled substance under Schedule II of the Controlled Substances Act

HCPs – health care providers

KOLs – key opinion leaders

LA – long-acting

NSAIDs – non-steroidal anti-inflammatory drugs

Q12h – once every 12 hours

ROCs – Reports of concern or records of contact

SA – short-acting

SOP – Standard Operating Procedure

SOP 1.7.1 – Section in Purdue's Standard Operating Procedures concerning the ADD program