IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA,	§	
Plaintiff,	§	
vs.	§	**Case No. CJ-2017-816**
	§	**Judge Thad Balkman**
(1) PURDUE PHARMA L.P.;	§	
(2) PURDUE PHARMA, INC.;	§	
(3) THE PURDUE FREDERICK COMPANY;	§	
(4) TEVA PHARMACEUTICALS USA, INC.;	§	**William C. Hetherington**
(5) CEPHALON, INC.;	§	**Special Discovery Master**
(6) JOHNSON & JOHNSON;	§	
(7) JANSSEN PHARMACEUTICALS, INC.;	§	
(8) ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.;	§	
(9) JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.;	§	
(10) ALLERGAN, PLC, f/k/a ACTAVIS PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.;	§	
(11) WATSON LABORATORIES, INC.;	§	
(12) ACTAVIS LLC; and	§	
(13) ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.,	§	
Defendants.	§	

NOTICE OF FILING OF THE STATE'S PROPOSED (1) FINAL JUDGMENT & (2) FINDINGS OF FACT AND CONCLUSIONS OF LAW

PART 2

273. The APS is the group that coined the term "fifth vital sign" and worked with Dr. June Dahl to convince the Joint Commission to "operationalize that slogan by introducing pain standards" as well as the VA system. Trial Tr. (6/13/19 a.m., Kolodny) at 9:2-23. June Dahl had a "direct financial relationship" with Defendants and Purdue and took "credit for convincing the [JCAHO] to introduce the pain standards and to require that pain be treated like it's a vital sign." Trial Tr. (6/13/19 a.m., Kolodny) at 5:20-6:9. Defendants were on the corporate council for the APS from 1994 to 2014. The APS worked with a number of KOLs, including June Dahl, Russell Portenoy, Richard Payne, and Charles Argoff. *See* Trial Tr. (6/13/19 a.m., Kolodny) at 8:16-10:11. The "5th Vital Sign" was trademarked by the APS in 1995. Trial Tr. (6/11/19 p.m., Kolodny) at 71:19-05. Pain is not a vital sign; unlike other objective vital signs, pain is purely subjective. *See, e.g.*, Trial Tr. (6/11/19 p.m., Kolodny) at 72:6-17.

274. Defendants also paid funds to the JCAHO. *See* S-1349.

275. In order to build "a $1 Billion Brand," Defendants' internal marketing materials identified a number of "Growth Drivers" that Defendants used to leverage as opportunities for Duragesic, including the increased awareness of the "under treatment of pain" through things like the JCAHO's "5th Vital Sign." *See* S-2359 at 3-4.

276. The JCAHO has significance influence on healthcare in the U.S., as they are the main accreditation organization of healthcare organizations in the United States, and they worked with Defendants and Purdue to disseminate resources that included the pain as the fifth vital sign slogan. Indeed, Defendants gave their sales representatives JCAHO

"educational materials" for use in their selling operations. *See e.g.*, S-1246 at 2. Defendants paid the Joint Commission $545,244. *See* Trial Tr. (6/13/19 a.m., Kolodny) at 16:22-19:08.

277. The AAPM was a member of the Pain Care Forum and received $573,000 in funding from Defendants. The AAPM existed prior to 1996. Its position on the use of opioids to treat chronic pain changed when they started receiving funding from opioid manufacturers including publishing the Consensus Statement. Defendants were on the AAPM Corporate Council from 1996 to approximately 2013. *See* Trial Tr. (6/13/19 a.m., Kolodny) at 11:08-12:11, 14:19-25. Defendants created their pro-opioid brochure "Finding Relief" (S-1247) in concert with the AAPM and AGS, whose logos appear on the front cover and who are referred to as Defendants' "partners" inside the front cover. *See* S-1247.0001-02. Defendants provided substantial funding to both the AAPM and AGS. *See* S-1349.

278. Lynn Webster, another of Defendants' KOLs and paid speakers, was a former president of the AAPM. Defendants offered excerpts from his videotaped deposition at trial. Their excerpts did not include the fact that Dr. Webster's own clinic was raided by the DEA in 2010 following concerns based on the opioid related deaths of multiple patients. *See* Trial Tr. (6/13/19 a.m., Kolodny) at 12:14-14:18.

279. Dr. Perry Fine was a prominent KOL paid by Defendants. Trial Tr. (6/13/19 a.m., Kolodny) at 50:9. He was a former president of AAPM (like Lynn Webster) and served on the board of the APF. Trial Tr. (6/13/19 a.m., Kolodny) at 50:9-12. He also served on the Advisory Board and was an Associate Editor for the book Responsible Opioid Prescribing: A Physician's Guide, which is discussed below. S-1445. Defendants

paid Dr. Fine substantial amounts of money. S-1350-002. For example, in 2010 alone, the payments to Dr. Fine identified by Defendants exceed $57,800. *Id.*

280. Charles Argoff was another paid KOL who testified *via* video deposition. *See* C-0175. Defendants also paid Dr. Argoff substantial sums from 1998 to 2014. S-1350-0001. In 2014 alone, Defendants paid Dr. Argoff at least $37,288.15. *Id.* Defendants also controlled or wrote the content of certain journal articles that were intended to be published under Dr. Argoff's name and which were intended to increase sales of Defendants' opioids. *See e.g.*, S-0972; Trial Tr. (6/13/19 a.m., Kolodny) at 47:1-50:1. Dr. Argoff testified that that he did not see a problem with a drug company entirely drafting a quote on his behalf with a message benefiting the drug company to be put in a press release and published on the drug company's website. Ct. Ex. 175 at 301:5-15.

281. Defendants' employees also co-authored self-serving studies and articles with their paid KOLs. For example, Bill McCarberg, one of Janssen's Top 15 National KOLs (S-1372 at 22), was also a co-author along with Defendants' expert Bruce Moskovitz on a 2011 article titled, "Analgesic treatment for moderate to severe acute pain in the United States: Patients' Perspectives in the Physicians Partnering Against Pain Survey." This article promoted the demand-generating idea that even in 2011, "moderate to severe acute pain continues to be widely undertreated in outpatient settings in the United States, particularly among older patients." S-0449. Defendants paid Dr. McCarberg substantial sums of money, often exceeding $25,000 in a single year. S-1350 at 3. In 2010, Defendants paid Dr. McCarberg over $36,000. *Id.*

282. Other KOLs that Defendants used to market their drugs, including Dr. Passik, advocated that opioids could be safely and effectively used in pregnant women, falsely claiming babies born with NAS do not experience withdrawal. Trial Tr. (6/26/19 p.m., Commissioner White) at 112:21-113:15, 117:14-120:12, 129:2-13, 130:22-132:7. In 2003, Dr. Passik was participating as a paid KOL on one of Defendants' advisory boards. *See* Trial Tr. (6/28/19 a.m., Moskovitz) at 104:01-105:19; S-4735.

283. Defendants paid $265,000 to the AIPM—a group led by Bob Twillman, who was an influential member of the Pain Care Form. Bob Twillman and the AIPM opposed the CDC's guidelines for opioid prescribing. *See* Trial Tr. (6/13/19 a.m., Kolodny) at 19:24-21:18.

284. Defendants later officially brought Bob Twillman in as one of their own by making him a member of Defendants' "Imagine the Possibilities Pain Coalition," an organization that Defendants controlled and that sought to target veterans and children and the media. *See* S-2389; S-1166; Trial Tr. (6/13/19 a.m., Kolodny) at 22:11-22; Trial Tr. (6/3/19 a.m., J&J: Deem-Eshleman) at 124:14-125:14. The American Chronic Pain Association—another group that Defendants provided funding to—also participated in the IPPC. *See* S-1349; Trial Tr. (6/3/19 a.m., J&J: Deem-Eshleman) at 115:24-116:4. According to one of the IPPC documents: "Each year more and more opioids are produced but we are still talking about the undertreatment of pain. There is a disconnect somewhere." J-3793; Trial Tr. (6/5/19 a.m., J&J: Deem-Eshleman) at 63:21-25. This occurred at the same time as Defendants were utilizing sales representatives and other

marketing tools to promote increased use of opioids. *See* Trial Tr. (6/5/19 a.m., J&J: Deem-Eshleman) at 64:07-65:10.

285. Like the APS and APF, the AIPM has shut down its operations since it stopped receiving funding from opioid manufacturers. *See* Trial Tr. (6/13/19 a.m., Kolodny) at 23:20-24:12.

286. Defendants also funded the Center for Practical Bioethics, a group dedicated to helping opioid manufacturers frame harms resulting from overprescribing as being limited to abuse. *See* Trial Tr. (6/13/19 a.m., Kolodny) at 25:17-26:20. Defendants worked in concert with the founder and director of the Center for Practical Bioethics, Myra Christopher, and other industry participants to create the Pain Action Alliance to Implement a National Strategy ("PAINS"), which Defendants leveraged to improperly inflate demand for opioids to justify oversupply, as explained below. *See* S-1216; Trial Tr. (6/12/19 p.m., Kolodny) at 140:20-147:24.

287. Another notable KOL, whose deposition testimony was played at trial, was Aaron Gilson, Ph.D.[31] Dr. Gilson was an employee of the University of Wisconsin and specifically worked for PPSG—an organization formed by another of Defendants' KOLs, David Joranson in 1996—until December 31, 2017. Ct. Ex. 0044 (Gilson) at 12:13-22, 15:5-23.

[31] Excerpts of the videotaped deposition testimony of Aaron Gilson, Ph.D., taken in Wisconsin on December 20, 2018, were played on June 6, 2019. *See* Trial Tr. (6/7/19 p.m.) at 57:24-58:22. A transcript of the excerpts of the videotaped deposition testimony of Aaron Gilson was marked, provided to and accepted by the Court as Court Exhibit 44 ("Ct. Ex. 0044"). Citations to Dr. Gilson's testimony herein will be to: Ct. Ex. 0044 (Gilson). Dr. Gilson is not a medical doctor, but holds a Ph.D. Ct. Ex. 0044 (Gilson) at 19:24-25.

288. Dr. Gilson served as an advisor and associate editor for the book, Responsible Opioid Prescribing: A Physician's Guide, authored by Defendants' KOL, Scott Fishman. Ct. Ex. 0044 (Gilson) at 36:2-4, 40:15-18; *see also* S-0619 at 4; S-1350; S-1249. This book was "widely disseminated." Ct. Ex. 0044 (Gilson) at 51:9-10, 51:14. Dr. Perry Fine also served as an advisor and editor for the book. The book also was sponsored by a "consortium of organizations" that joined together to sponsor it, including AAPM, APF, American Society for Pain Management Nursing, Center for Practical Bioethics, Cephalon, Endo Pharmaceuticals, the Federation of State Medical Boards, the National Pain Foundation, PPSG, and Purdue. Ct. Ex. 0044 (Gilson) at 70:12-18, 70:20-72:6; S-1455 at 4. Defendants provided substantial funding to the AAPM, APF, American Society for Pain Management Nursing, Center for Practical Bioethics, National Pain Foundation, and PPSG. *See* S-1349.

289. Like Dr. Gilson, many of these organizations that sponsored Responsible Opioid Prescribing: A Physician's Guide were also members of the Pain Care Forum (discussed below). *See* Ct. Ex. 0044 (Gilson) at 39:5-6, 70:12-72:6; S-0619 at 4; S-1455 at 4. Dr. Gilson also served on the Editorial Committee for the Federation of State Medical Boards Research and Education Foundation, another participating member of the Pain Care Forum. Ct. Ex. 0044 (Gilson) at 50:11-22; S-0619 at 4; S-0620 at 2.

290. The sponsors and authors of Responsible Opioid Prescribing: A Physician's Guide intended for it to be used to instruct doctors, as well as policymakers and regulators, about how to prescribe opioids. *See, e.g.*, Ct. Ex. 0044 (Gilson) at 78:23-79:7, 104:7-24, 126:14-127:5; S-1455 at 133-142. Appended to the book was a "Model Policy for the Use

of Controlled Substances for the Treatment of Pain," which the sponsors of the book wanted to be adopted as policy by "as many states as possible." Ct. Ex. 0044 (Gilson) at 126:14-127:5; S-1455 at 133-142.

291. Responsible Opioid Prescribing: A Physician's Guide discussed "pseudoaddiction"—the term coined by David Haddox and Dave Weissman[32]—although that term had no definition in the Diagnostic and Statistical Manual of Mental Disorders ("DSM"). Ct. Ex. 0044 (Gilson) at 70:12-18, 74:11-78:22; S-1455 at 70-71.

292. Defendants' marketing materials promoted and directed doctors to Responsible Opioid Prescribing: A Physician's Guide, without making clear in the marketing materials the significant ties to industry. *See, e.g.*, S-1249. This book includes a table of behaviors related to "pseudoaddiction," identifying behaviors supposedly more or less indicative of addiction. *See* S-2372; Trial Tr. (6/13/19 a.m., Kolodny) at 74:25- 89:11; *see also* S-1455. The book identifies several behaviors as "less" indicative of addiction, including: hoarding opioids and taking pain medicine from someone else. *See* S-2372; Trial Tr. (6/13/19 a.m., Kolodny) at 74:25-89:11; *see also* S-1455. The behaviors that the book identifies as actually indicating addiction include, among other behaviors, doctor shopping and performing sex for drugs. *See* S-2372; Trial Tr. (6/13/19 a.m., Kolodny) at 74:25-89:11; *see also* S-1455. The result was to blur (if not entirely erase) the lines between

[32] Dr. Gilson knew that David Haddox became a Purdue employee, although he was unaware that Mr. Haddox and Mr. Weissman were paid to be speakers in Purdue's Speakers Bureau. Ct. Ex. 0044 (Gilson) at 76:4-20.

proper, conservative use of opioids and the known red flags of misuse, abuse, and addiction.

293. Along with Purdue, Defendants also funded a continuing medical education ("CME") program based on this book. *See* S-2372; Trial Tr. (6/13/19 a.m., Kolodny) at 74:25-89:11. The CME provides supposed training related to "opioids" generally as a class of drug and makes statements about the rarity of addiction in this entire class of drugs. *See* S-2372; Trial Tr. (6/13/19 a.m., Kolodny) at 74:25-89:11. The CME included statements about addiction, dependence and "pseudoaddiction," training that "pseudoaddiction" should be solved by prescribing higher doses of opioids until pain relief is fully achieved. *See* S-2372; Trial Tr. (6/13/19 a.m., Kolodny) at 74:25-89:11. The CME suggests that tolerance is not a problem with chronic opioid therapy. *See* S-2372; Trial Tr. (6/13/19 a.m., Kolodny) at 74:25-89:11. These statements are misleading. *See* Section F.3 *infra.*

294. Dr. Gilson, David Joranson and June Dahl, Ph.D., co-authored an article, titled "*Trends in Medical Use and Abuse of Opioid Analgesics*," that was published in the Journal of the American Medical Association ("JAMA") in 2000, with David Joranson and June Dahl, Ph.D. Ct. Ex. 0044 (Gilson) at 156:5-157:18; S-0624 at 1.[33] Defendants instructed their sales force to use this article in a way that Gilson testified was inaccurate

[33] Dr. Gilson's co-authors of this article also had financial ties to opioid manufacturers, including Defendants. Both Mr. Joranson and Dr. Dahl were listed as KOLs in 'Defendants' internal documents. *See* S-0641 (Defendants' document entitled, "Medical Affairs Analgesia, Medical Science Liaison Report, February 2004"); *see also, e.g.*, Ct. Ex. 0044 (Gilson) at 311:14-312:16, 317:7-13. Mr. Joranson, who formed PPSG in 1996, "received honoraria from Knoll Pharmaceutical, Purdue Pharma, and [Defendants]." Ct. Ex. 0044 (Gilson) at 15:5-23, 156:22-157:2; S-0624 at 1. Dr. Dahl "serve[d] on the Speakers Bureau of Purdue Pharma and [was] a consultant for Knoll Pharmaceuticals." Ct. Ex. 0044 (Gilson) at 157:5-8; S-0624 at 1.

and deceptive in discussions with physicians, as discussed below. *See* Section F.3, *infra*; *see also, e.g.*, S-0629 at 1-2; Ct. Ex. 0044 (Gilson) at 165:7-17, 206:10-208:9.

295. Defendants also funded and used for their marketing purposes the work of PPSG. *See* S-1349; *see also* Ct. Ex. 0044 (Gilson) at 146:13-15, 275:16-21, 328:14-332:2, 335:6-11.

296. Formed by David Joranson in 1996, PPSG's "mission" was "to conduct policy research and to inform healthcare professionals about the content of current policies under which they practice." Ct. Ex. 0044 (Gilson) at 15:5-23. Dr. Gilson worked for the PPSG and testified that Defendants misused materials created by PPSG.

297. Among other similar groups, PPSG was involved with the Federation of State Medical Boards and the Pain Care Forum in efforts to advocate for states to adopt "policies, guidelines, and regulations" surrounding the treatment of pain. Ct. Ex. 0044 (Gilson) at 35:4-9, 36:25-37:6.

298. PPSG considered its achievements from 2000 to 2003 to include "16 States [taking] legislative and regulatory actions to improve their pain policies," many of which "were based on [PPSG's] evaluations, recommendations and technical assistance and were accomplished in collaboration with many governmental and non-governmental groups which use[d] PPSG policy evaluations as a road map." Ct. Ex. 0044 (Gilson) at 223:8-224:9; S-0631 at 1.

299. PPSG's policy evaluations included the release of "state pain policy report cards," which "evaluate[d] and quantifie[d]" the content of state-controlled medical and

pharmacy practices governing pain management and the use of controlled substances. Ct. Ex. 0044 (Gilson) at 239:6-16.

300. One of the states that PPSG's pain policy report cards graded was Oklahoma. Ct. Ex. 0044 (Gilson) at 239:17-19. These PPSG pain policy report cards graded Oklahoma with either a "C" or "C+," indicating that Oklahoma's state policies surrounding the use and availability of opioids to treat pain were ***more restrictive*** than other states. *See* Ct. Ex. 0044 (Gilson) at 273:14-16; Ct. Ex. 0095 (Ponder) at 277:20-278:15 (agreeing that "a low grade of a C plus and down" from the PPSG state pain policy report cards "would represent a policy that does not support opioid use in pain management as much as an A or a B" grade); S-0635 at 18; *see also, e.g.*, S-0634 at 2 (identifying Oklahoma as one of the "Perennial 'C' States" according to PPSG's state pain policy report cards); Ct. Ex. 0044 (Gilson) at 265:18-271:24. The more liberal a state's opioid prescribing regulations, the higher grade the state received from PPSG. *See* Trial Tr. (6/13/19 a.m., Kolodny) at 6:16-8:15.

301. PPSG's state pain policy report cards were intended to be used as "a research product" for "education and for outreach," not as a "tool of industry" and opioid manufacturers, including Defendants, to make money selling opioid drugs. Ct. Ex. 0044 (Gilson) at 264:17-25, 271:21-272:15.

302. Nevertheless, Defendants' internal documents demonstrate that Defendants attempted to "[e]xtract[] value from [PPSG's] state report cards," assign a "commercial value to each state" based on PPSG's pain policy report cards, and use the report cards to analyze the relationship between state regulations and "opioid prescribing" or physicians'

"prescribing behavior" in different states in order to determine where "to focus" Defendants' "efforts" and identify any "'hot spots' to watch." *See, e.g.*, Ct. Ex. 0044 (Gilson) at 271:6-275:21; S-0635 at 1, 17-18; Ct. Ex. 0095 (Ponder) at 277:1-279:22 (agreeing that Defendants commercially valued each state and determine where to focus Defendants' efforts based on the grade each state received in the PPSG report cards). Like Defendants, Purdue similarly used PPSG's pain policy report cards to "generate consumer attention" and publicize "Media Hook[s]" surrounding the undertreatment of chronic pain and the "value of and need for opioid medications" to "consumer audiences" and the public for Purdue's monetary benefit. *See* Ct. Ex. 0044 (Gilson) at 265:18-269:24; S-0634 at 1-2.

303. Dr. Gilson's and PPSG's research, including the state pain policy report cards, were not intended to be used by the pharmaceutical industry for opioid manufacturers' monetary purposes. Ct. Ex. 0044 (Gilson) at 270:18-22. But, opioid manufacturers, specifically Defendants and Purdue, used this research as a tool for that purpose. *See* Ct. Ex. 0044 (Gilson) at 270:18-275:21. PPSG specifically did not intend for its research to be used in the commercial manner that Defendants used it. Ct. Ex. 0044 (Gilson) at 274:6-275:21. No drug company ever informed Dr. Gilson that it was using his reports to "try to achieve commercialization of value" for its drugs based on Dr. Gilson's and PPSG's work. Ct. Ex. 0044 (Gilson) at 278:9-12. Dr. Gilson did not understand "the scope and the magnitude or the complexity of how [] drug companies were using the work that [he] and [his] friends and [his] colleagues around the country were doing." Ct. Ex. 0044 (Gilson) at 334:16-335:16. Opioid manufacturers, including Defendants,

"compromised" this research and "manipulated it for their own commercial purposes." *See* Ct. Ex. 0044 (Gilson) at 328:14-332:2.

304. Defendants, along with Purdue, Cephalon and the APF, also were original members of a group called the Pain Care Forum. Ct. Ex. 49 (Rosen) at 256:23-257:22; *see also, e.g.*, Ct. Ex. 0044 (Gilson) at 146:13-15, 225:24-226:7; S-0620 at 2. Defendants participated in the Pain Care Forum from at least 2005 (when it started) to 2014. Ct. Ex. 0090 (Colligen) at 14:15-18, 19:18-21;[34] *see also, e.g.*, Ct. Ex. 0095 (Ponder) at 70:7-8.

305. In addition to these organizations, other participating members of the Pain Care Forum included Abbott Laboratories, the AAPM, the American Society for Pain Management Nursing, the Center for Practical Bioethics, Endo Pharmaceuticals, the Federation of State Medical Boards, PPSG, and Dr. Gilson. *See, e.g.*, Ct. Ex. 0044 (Gilson) at 35:7-9, 39:5-6, 50:19-22, 70:12-72:16; S-0619 at 4; S-0620 at 2.

306. The Pain Care Forum was an idea to "bring together representatives from all of the [opioid-manufacturing, pharmaceutical] companies" as a "cohesive voice" that Dr.

[34] Excerpts of the videotaped deposition testimony of Bruce Colligen, taken on November 27, 2018, were played on June 19, 2019. *See* Trial Tr. (6/19/19 p.m.) at 6:4-11. A transcript of the excerpts of the videotaped deposition testimony of Bruce Colligen was marked, provided to and accepted by the Court as Court Exhibit 90 ("Ct. Ex. 0090"). Citations to Mr. Colligen's testimony will thus be to: Ct. Ex. 0090. Mr. Colligen has worked for Defendants for almost 23 years. Ct. Ex. 0090 (Colligen) at 7:10-14. He holds the title of Executive Director of State Policy. Ct. Ex. 0090 (Colligen) at 7:15-17. Mr. Colligen was designated to testify on behalf of Defendants, as Defendants' corporate representative, regarding 'Defendants' role or participation in the Pain Care Forum. Ct. Ex. 0090 (Colligen) at 10:10-13.

Kathleen Foley shared with Dr. Richard Sackler at Purdue in 2001. *See* Ct. Ex. 49 (Rosen) at 61:24-63:15[35]; S-1413.

307. Dr. Foley stated: "I'm thinking of an alternative strategy of bringing together all of the members of the pharmaceutical industry, who have analgesic drugs out there and try to come together as a sort of cohesive voice recognizing that your particular drug has been recently identified in the newspapers as a drug issue. I think that there is a tightrope that you need to walk, because you are a drug company and it would be much better if the advocacy came from outside of the drug company and even better without much in the way of support from you. So along those lines, the kinds of things that I am thinking of is that maybe we should call a meeting, bring together representatives from all of the companies, ideally high level representatives, like presidents or major leaders and strategize about the way to play the media issues." Ct. Ex. 49 (Rosen) at 59:18-61:07; 61:09-63:16; 64:02-65:09; S-1413.

308. Dr. Foley added: "This may sound relatively self-serving but it might be a good idea if we could get the pharmaceutical companies together along with Purdue willing to take the lead and agree to funding strategy to the American Association of Medical

[35] Excerpts of the videotaped deposition testimony of Burt Rosen was played on June 7, 2019. *See* Trial Tr. (6/7/19 p.m.) at 38:13-24. A transcript of the excerpts of the videotaped deposition testimony of Burt Rosen was marked, provided to and accepted by the Court as Court Exhibit 49 ("Ct. Ex. 49"). Citations to Mr. Rosen's specific testimony will, thus, be to that transcript: Ct. Ex. 49. Mr. Rosen is an "inside the beltway Washington D.C. lobbyist" and lawyer, who was employed by Purdue as a lobbyist and Vice President of Federal Government Relations. Ct. Ex. 49 (Rosen) at 9:14-23, 13:1-6. Mr. Rosen is the individual who established, and acted as primary moderator for, the Pain Care Forum. Ct. Ex. 49 (Rosen) at 194:10-195:1

Colleges to facilitate the education of medical students in pain management." Ct. Ex. 49 (Rosen) at 67:07-17; S-1413.

309. Dr. Foley's idea ultimately materialized into a group of organizations that identified themselves as the Pain Group and, by approximately 2005, "formalized into the Pain Care Forum"—a self-described collaborative group of pharmaceutical companies and advocates that, by 2005, included "about 30 organizations aligned behind issues relating to access to pain care." Ct. Ex. 49 (Rosen) at 157:15-160:22; 167:03-168:01; S-1421 at 4.

310. The Pain Care Forum is an "organizational collaborative with no single affiliation." Ct. Ex. 0044 (Gilson) at 38:10-16; S-0619 at 4. Pain Care Forum activities included "support[ing] collaborative actions about common issues related to the effects of policy on patient care." Ct. Ex. 0044 (Gilson) at 39:20-24; S-0619 at 4.

311. The Pain Care Forum has been described as an echo chamber. It does not have an actual office, address, designated or registered representative to accept service of process, telephone number, website, or e-mail domain. Ct. Ex. 0090 (Colligen) at 26:20-25, 27:22-24, 28:2-12, 29:24-30:10, 33:20-34:3, 36:7-12, 48:3-6.

312. Nor does the Pain Care Forum have a Chairman or CEO. Ct. Ex. 0090 (Colligen) at 30:11-21.

313. The Pain Care Forum was not regulated by the FDA, DEA or any other governmental organization. Ct. Ex. 0090 (Colligen) at 80:2-4, 85:25-86:1.

314. One of the stated goals of the Pain Care Forum was to "provide a forum to coordinate and focus commitments to action regarding public policy issues that affect the treatment of pain." Ct. Ex. 0049 (Rosen) at 232:07-17; S-1424. The Pain Care Forum was

created in response to increasing scrutiny of opioids as a means of maintaining profitability for Purdue (and other manufacturers) by advocating for pain management through seemingly-neutral third parties and removing barriers to opioids. *See, e.g.*, S-1413, S-1418, S-1421, S-1497.

315. Defendants paid dues to the Pain Care Forum. Ct. Ex. 0090 (Colligen) at 58:11-13. Defendants paid its Pain Care Forum dues out of the advertising budget for Defendants' branded opioid drug, Nucynta, in the year that Defendants brought Nucynta to market. Ct. Ex. 0090 (Colligen) at 64:14-16, 64:18-21, 66:24-67:1, 67:3, 67:5-11.

316. Defendants collaborated with the members of the Pain Care Forum. Ct. Ex. 0090 (Colligen) at 24:6-15. The Pain Care Forum collaborated to the benefit of its members, including Defendants. *See* Trial Tr. (6/12/19 p.m., Kolodny) at 130:19-24.

317. Defendants and others used the Pain Care Forum to preserve the status quo of opioid prescribing and increase prescribing of opioids. Trial Tr. (6/11/19 p.m., Kolodny) at 86:12-24. In a Pain Care Forum Media Committee meeting, the goal of the campaign discussed "was suggested to be delivering a 'zero sum game' message (i.e. zero barriers to patient access)." S-1497; Trial Tr. (6/12/19 p.m., Kolodny) at 96:13-104:20.

318. In a June 13, 2006 document from the Pain Care Forum and APF to Congress, entitled "The Epidemic of Pain in America," the idea of widespread undertreatment of chronic pain was discussed extensively along with other messages similar to those employed by Defendants in direct marketing (e.g. untreated acute pain leads to chronic, dependence and addiction are unrelated). *See* S-2352; Trial Tr. (6/12/19 p.m., Kolodny) at 105:14-125:03.

319. This 2006 document also misleadingly claims: "Appropriate use of opioid medications (like oxycodone) is safe and effective and unlikely to cause addiction in people who are under the care of a doctor and who have no history of substance abuse." S-2352; *see* Trial Tr. (6/12/19 p.m., Kolodny) at 119:14-120:08.

320. The Pain Care Forum was not a passive group; they took action to affect the public's perception of opioids. *See, e.g.*, S-1859; S-2352; Trial Tr. (6/12/19 p.m., Kolodny) at 148:08-153:20.

321. The Pain Care Forum opposed efforts for the Joint Commission to remove pain as a vital sign in 2016. S-1120; *see* Trial Tr. (6/12/19 p.m., Kolodny) at 132:02-134:23.

322. Defendants remained in the Pain Care Forum with Purdue after Purdue pled guilty to the federal felony of criminal misbranding in 2007. Ct. Ex. 0090 (Colligen) at 62:18-63:1, 63:3-63:11, 63:13-15.

323. By no later than 2008, the Pain Care Forum had "become 'a force' to be courted by members of Congress." Ct. Ex. 49 (Rosen) at 271:15-24; S-1429.0001.

324. Internally, Defendants identified the Pain Care Forum as a coalition of organizations that Defendants were "[p]artnering" with. Ct. Ex. 0090 (Colligen) at 122:18-24; S-0303 at 1; *see also, e.g.*, S-1217 (as part of its "Advocacy/Policy Focus," Defendants planned to "[s]upport collaboration with the Pain Care Forum (PCF) members on policy issues and common strategies with key decision makers"); *see* Trial Tr. (6/12/19 p.m., Kolodny) at 68:07-13.

325. In 2011, in the midst of the epidemic, members of the Pain Care Forum, including Defendants, joined together to form a group called the Pain Action Alliance to Implement a National Strategy ("PAINS"). *See* S-1216; Trial Tr. (6/12/19 p.m., Kolodny) at 140:20-147:24.

326. The mission of the PAINS Project was to "advocate for and act collectively to actualize the recommendations set forth in the Institute of Medicine's report," called *Relieving Pain in America.* S-1216.

327. Goals of the PAINS Project included to "[a]ssert collective pressure/influence on governmental agencies to act on the recommendations, educate and engage the public about the IOM report, the benefits of a biopsychosocial model of pain management and their [responsibilities], and advocate for better and broader research." Trial Tr. (6/12/19 p.m., Kolodny) at 146:15-25; S-1216.

328. Examples of materials that Defendants received from the Pain Care Forum included meeting agendas identifying items that would be presented during a Pain Care Forum meeting, such as: (i) "Update on National Pain Policy Act Implementation and meetings with Institute of Medicine, and membership on IOM Committee"; (ii) "Update Class Rems Task Force"; and (iii) "Congressional Reorganization following Elections." Ct. Ex. 0090 (Colligen) at 119:21-120:3, 120:5-8, 120:10-13, 120:19; S-0301 at 1.

329. Defendants' internal documents identified one of Defendants' national advocacy and business plans for its pain franchise to be to "[c]ollaborate with The Pain Care Forum on policy issues and common strategies with key decisionmakers, such as HHS, surgeon general's office, CDC, state and federal legislators and regulators." Ct. Ex.

0090 (Colligen) at 129:19-130:10; S-0304 at 6. Among other things, Defendants' internal presentation identified Defendants' "Key Business Questions" to include:

- "How do we leverage sales & marketing resources to disproportionately grow NUCYNTA ER within a focused, yet strategic customer base (Pain + other HV targets)?"
- "How do we improve access perceptions & remove access barriers?"
- "How will potential legislative / policy events affect overall pain market growth?" and
- "How do we improve NUCYNTA ER'S value proposition?"

S-0304 at 2. This business planning presentation further identified Defendants' pain advocacy strategy and strategic imperatives to include: (i) "Engag[ing] partners to Embrace the IOM Report-National/State implications"; (ii) "Advocat[ing] for and act[ing] collectively to actualize the recommendations"; (iii) "Relieving Pain in America"; and (iv) "Influenc[ing] Agencies that Impact Policy and Quality to Maintain or Improve Access." S-0304 at 3. And, the presentation identified Defendants' advocacy priorities to include, among other things: (i) "Encourag[ing] governmental agencies (both state and federal) to respond to the IOM *Relieving Pain* recommendations"; and (ii) "Engag[ing] the public about the findings and recommendations." S-0304 at 3.

330. Dr. Gilson, a member of the Pain Care Forum for nearly a decade from 2007 through 2016, was not aware of any effort by the Pain Care Form to "act[] jointly to take steps to abate the opioid crisis." Ct. Ex. 0044 (Gilson) at 39:5-6, 404:19-24; S-0619 at 4.

331. Defendants could not identify any instance in which Defendants: (a) went to the Pain Care Forum and expressed any disapproval of the conduct of the Pain Care Forum (Ct. Ex. 0090 (Colligen) at 73:14-18, 73:20-22); or (b) rejected or opposed any specific

conduct by any of Defendants' fellow members of the Pain Care Forum. Ct. Ex. 0090 (Colligen) at 88:16-21.

(3). Using Literature, Research, CME and Other "Education" to Sell Drugs

332. Defendants also misleadingly used seemingly educational materials, including academic literature and research, as well as CME, in a commercial manner to increase the prescribing of opioids.

333. Over the past two decades, there were relatively few CME courses related to pain treatment that were not funded or influenced by opioid manufacturers; whereas free CME courses funded and influenced by the opioid industry were easy to come to by. Trial Tr. (6/6/19 a.m., Mazloomdoost) at 46:12-47:19.

334. Part of Defendants' marketing strategy included medical education activities. *See, e.g.*, S-1358; S-2364; Trial Tr. (6/13/19 a.m., Kolodny) at 52:20-68:18. Medical education activities were one of two "most frequently analyzed promotional activities" (along with sales rep detailing) that Defendants evaluated based on the activity's "return on investment." *See* S-2364; Trial Tr. (6/13/19 a.m., Kolodny) at 52:20-68:18.

335. For example, Defendants' internal documents memorialized strategies designed to "[d]etermine which types of medical education programs have the greatest ROI for each segment." S-2364.

336. Throughout his career, Dr. Portenoy accepted financial support from drug companies, including in the form of direct payments to Dr. Portenoy, honoraria payments

for speaking engagements, and payments to Dr. Portenoy's institutional employer to support research or academic activities. Ct. Ex. 2 (Portenoy) at 46:10-47:5.[36] Dr. Portenoy also received fees from opioid manufacturers for consulting and speaking at continuing medical education events for doctors that were sponsored by drug companies. Ct. Ex. 2 (Portenoy) at 49:16-50:23. Over the course of his career, Dr. Portenoy also received increasing levels of funding from medical education companies—companies that organized speakers for speaker programs sponsored by pharmaceutical companies and paid the speakers with funds provided by pharmaceutical companies. Ct. Ex. 2 (Portenoy) at 50:24-52:12. These companies "only funded activities that supported their interests." S-0879 at ¶22. The "amount of funding provided by drug companies for the purpose of educating clinicians about drug abuse and addiction, and for the purpose of clinical research into the risk of abuse and addiction, was very limited between the 1980s and the 2000s." S-0879 at ¶¶26-27.

337. Drug companies are a major source of research funding, and this type of funding has the ability to influence study proposals. Ct. Ex. 2 (Portenoy) at 62:5-10. In Dr. Portenoy's experience, research grants from drug companies that funded academic studies were provided to help the marketing of the funding company's drugs. Ct. Ex. 2 (Portenoy) at 62:13-24, 67:11-68:1; S-0879 at ¶¶26-27 (opining that "drug company research grants to researchers working in academic centers or health care facilities after a drug is approved

[36] Honorarium fees were paid by drug companies sponsoring an event to the institution holding the event, after which the institution would pay a speaker fee to the speaking physician, like Dr. Portenoy. Ct. Ex. 2 (Portenoy) at 46:25-48:19.

for marketing almost always align with the company's interest in demonstrating the benefits of the drugs they manufacture, with the intention of publishing results that could yield higher sales in the future"). While many of these studies would look like "the work of the academic," in reality, it actually reflected "the influence of the pharmaceutical industry" and could be misleading. Ct. Ex. 2 (Portenoy) at 71:12-72:10. Dr. Portenoy further testified that drug companies pay honoraria fees and grants in a way that elevates specific messages, and messengers, that favor the companies' preferred messaging. Ct. Ex. 2 (Portenoy) at 63:2-5; S-0879 at ¶35. For example, one of Defendants' companies, Ortho-McNeil-Janssen Scientific Affairs paid approximately $40,000 to Dr. Portenoy's employer, Beth Israel Medical Center, for creating materials and providing six lectures related to "practices in opioid prescribing for chronic pain[.]" Ct. Ex. 2 (Portenoy) at 141:22-142:19; *see also* S-0879 at ¶30 (listing other examples of projects that opioid manufacturers paid Dr. Portenoy to participate in).

338. Defendants created a group known as "NPEC" (National Pain Education Council). *See* S-0975; Trial Tr. (5/29/19 p.m., J&J: Deem-Eshleman) at 23:06-28:12. Defendants created this group to provide CME related to pain and opioids. S-0975; S-0582. Defendants created and funded NPEC. *See* S-0975; Trial Tr. (5/29/19 p.m., J&J: Deem-Eshleman) at 23:06-28:12; Ct. Ex. 2 (Portenoy) at 87:25-89:9. Drs. Portenoy and Payne led NPEC. *See* S-0975; Trial Tr. (5/29/19 p.m., J&J: Deem-Eshleman) at 23:06-28:12. The money for NPEC originally came from Defendants' marketing budget. *See* Trial Tr. (5/29/19 p.m., J&J: Deem-Eshleman) at 23:06-28:12.

339. Dr. Portenoy served as a co-chair of NPEC. Ct. Ex. 2 (Portenoy) at 87:25-89:9. In a 2002 marketing and sales memorandum, Defendants identified NPEC as one of Defendants' "Sales Materials/Programs[.]" S-0881 at 3.[37] In this 2002 sales memorandum, Defendants described NPEC as being "funded by an educational grant from Janssen" and providing an "[i]nvitation to participate in a multimedia CME program for physicians and other medical professionals on the appropriate opioid pharmacotherapy for chronic pain management" that "invites medical professionals to visit the www.npecweb.org website." S-0881 at 3. The target audience for Defendants' NPEC initiative included primary care physicians, pain specialists, oncologists, residents, nurses and pharmacists. S-0881 at 3. In Defendants' 2003 Business Plan Summary for Duragesic, Defendants described NPEC as serving "to benefit not only DURAGESIC but also all future Janssen pain products." S-1358 at 10. Internally, Defendants further described its commercial motivation for the NPEC program:

> NPEC and other brand medical education and promotional initiatives will *continue to establish* Janssen as a leader in pain management and fuel the growth of a Janssen Pain Franchise. Along with these initiatives it will also be vital for the sales force to continue to drive share by targeting the right physicians with the refined message.

S-1358 at 13.

340. Dr. Portenoy, the NPEC co-chair, did not know until he was deposed in this case (and was troubled when he learned) that Defendants secretly intended the NPEC to be a platform "as a marketing strategy" to "sell its drugs to doctors[.]" Ct. Ex. 2 (Portenoy) at

[37] S-0881, a 2002 Duragesic sales memorandum, was admitted into evidence with no objection. *See* Trial Tr. (5/30/19 p.m.) at 8:22-9:2.

89:10-92:25. According to Dr. Portenoy, there was supposed to be "a firewall between continuing medical education and marketing," and he had "no understanding" that NPEC would be used by Defendants "as a marketing strategy." Ct. Ex. 2 (Portenoy) at 89:10-92:16. Dr. Portenoy further did not recall Defendants ever sharing with him Defendants' internal survey data that showed speakers bureaus and conferences, like NPEC, helped Defendants sell more drugs. Ct. Ex. 2 (Portenoy) at 92:18-93:22.

341. When Defendants provided funding to Dr. Portenoy for programs or initiatives, like NPEC, that Defendants internally viewed as commercially beneficial for their sales, Dr. Portenoy's presentations dealt with opioids "generally" and were "not drug-specific[.]" Ct. Ex. 2 (Portenoy) at 98:21-100:2; *see also* Ct. Ex. 2 (Portenoy) at 257:14-18.

342. Moreover, the CME materials for Defendants' NPEC program in 2002 disseminated false and misleading statements regarding opioids and pain management. *See, e.g.*, Trial Tr. (6/6/19 a.m., Mazloomdoost) at 48:12-62:24. For example, one of the NPEC primers states: "Patients may be successfully weaned from opioid therapy by gradual downward titration." *See* S-0975 (NPEC primer entitled, *"Appropriate Opioid Pharmacotherapy for Chronic Pain Management: A Multimedia CME Program"*) at 21. This statement, Dr. Mazloomdoost testified, was untrue and misleading because it is actually very difficult to "wean" patients receiving chronic opioid treatment off of their medication. *See* Trial Tr. (6/6/19 a.m., Mazloomdoost) at 61:16-62:12. As a whole, Dr. Mazloomdoost testified that Defendants' NPEC CME was a "miserable" example of "industry bias" that inaccurately presented opioids as the fix-all solution for chronic pain

and misrepresented the risks of tolerance, dependence and addiction that accompany opioid use:

> It's a miserable CME. The only purpose it has is to give physicians this – this sense that pain is undertreated, that opioids are the solution, that there are minimal risks and that there are barriers that the system is putting up for them and they need to overcome those barriers.

See Trial Tr. (6/6/19 a.m., Mazloomdoost) at 47:20-63:8.

343. Medical schools have not traditionally taught pain management skills, leaving most physicians who do not specialize in pain treatment without much education regarding proper pain management therapy. Trial Tr. (6/6/19 a.m., Mazloomdoost) at 53:8-25, 59:6-15.

344. Medical education around the country was influenced by the opioid manufacturing industry, including by Defendants. Trial Tr. (6/6/19 a.m., Mazloomdoost) at 44:7-45:4. Even the most respected institutions of learning were affected by the pro-opioid messaging of Defendants and others in the opioid industry. For example, Dr. Mazloomdoost, who attended Johns Hopkins for medical school and residency, followed by a fellowship at M.D. Anderson, testified, "I know attendings that I had, that I respected, were key opinion leaders influenced by pharmaceutical marketing...." Trial Tr. (6/6/19 a.m., Mazloomdoost) at 44:9-11. While a resident, Dr. Mazloomdoost learned industry-created concepts, like "pseudoaddiction" and was taught to prescribe opioids aggressively. Trial Tr. (6/6/19 a.m., Mazloomdoost) at 44:12-19. He testified:

> As a resident, I didn't know any different. I was just learning the field. But – but having learned what I have learned, having grown or matured in this field, I now recognize how – how much influence there was in that. . . . [I]t was influences from companies like Johnson & Johnson that kind of

> infiltrated and spread like a virus of ideas in everybody's mind and became kind of the – the fabric of how we developed the science.

Trial Tr. (6/6/19 a.m., Mazloomdoost) at 44:19-23.[38]

345. Today, it is difficult to find sound medical education about opioids that is not directly or indirectly influenced by the opioid industry. Trial Tr. (6/6/19 a.m., Mazloomdoost) at 45:19-46:11.

346. Another seemingly educational program, the Risk Evaluation and Management Strategies ("REMS") program was marginalized and manipulated by the opioid industry, including by Defendants. Trial Tr. (6/6/19 a.m., Mazloomdoost) at 63:13-17.

347. A report from a consultant to Defendants in 2004 advised the company that "Although risk management is generally focused on addressing medical and public health concerns and reassuring regulatory agencies such as FDA and DEA, it also offers potential protection against litigation in the event that unintended consequences occur (e.g. litigation brought by the parents of adolescents who might overdose)." J-0862; Trial Tr. (6/28/19 p.m., Moskovitz) at 121:14-123:05.

348. A 2014 paper authored by Defendants' expert, Dr. Moskovitz, describes the shortcomings of the REMS program as follows:

> A component of the REMS provider education is to take prescribers aware of the potential abuse liability of opioids . . . Either the data about opioid misuse and overdose are not being sufficiently disseminated or they are being

[38] For example, while in residency at Johns Hopkins, Dr. Mazloomdoost worked on a study with one of his attending physicians that "used Duragesic, the fentanyl patch, to evaluate outcomes in sleep and activity level and movement." Trial Tr. (6/6/19 a.m., Mazloomdoost) at 45:5-11. The study was funded by Defendants. *Id.*

> ignored. The failure to be impacted by these troubling data on morbidity and mortality indicates that research is needed to understand whether and how these data are perceived by prescribers and how information is being communicated.

Trial Tr. (6/28/19 p.m., Moskovitz) at 69:25-85:01; *see also* Ct. Ex. 141.

349. Despite their stated educational purpose, REMS programs contain bias and influence from the opioid manufacturing industry and tend to encourage attendees to prescribe opioids. Trial Tr. (6/6/19 p.m., Mazloomdoost) at 105:9-13, 110:1-10. This is in part due to the fact that opioid manufacturers, including Defendants, had direct input regarding the content of the opioids REMS programs and they continued to include false and misleading information therein. *Id.*

350. Dr. Mazloomdoost described the REMS programs as the fox guarding the hen house. Trial Tr. (6/6/19 p.m., Mazloomdoost) at 131:12-22. In fact, Dr. Mazloomdoost once agreed to speak at an opioids REMS program so that he could correct some of the canned material and clarify to his colleagues in attendance that there was industry bias in the program. Trial Tr. (6/6/19 p.m., Mazloomdoost) at 109:2-19, 112:4-8.

351. Defendants further participated in the coordination and drafting of several journal articles related to their drugs and pain treatment; a process known as "ghost writing." Defendants' employees would schedule calls, draft outlines, send comments, and send drafts to the named authors of these articles for approval and at different stages. *See* S-0972; Trial Tr. (6/13/19 a.m., Kolodny) at 46:17-52:19.

(4). Influencing Governmental Agencies and Regulatory Boards to Sell Drugs

352. Commissioner White testified that "it seemed like every time a state was going to try to talk about limiting access to opioids, Johnson and Johnson released a swat team to try and go down and ensure that no controls were enacted." Trial Tr. (6/25/19 p.m., Commissioner White) at 70:21-71:4.

353. As part of their overall strategy to reduce barriers to increased opioid prescribing, Defendants' marketing and advocacy plans specifically sought to influence governmental and regulatory agencies and boards, including in Oklahoma, to generate "value" and increase total prescriptions written for opioids. *See, e.g.*, S-1161.

354. For example, Defendants' business plans specifically contemplated "minimizing restrictions" to opioid prescribing by "State Medicaid" in order to grow Defendants' Medicaid sales by millions of dollars. Trial Tr. (6/26/19 p.m., Commissioner White) at 95:24-98:13; S-2352.

355. For another example, after the Oklahoma Board of Pharmacy ("OBP") received reports of diversion of tramadol, Cindy Hamilton-Fain of the OBP requested that tramadol be scheduled as a controlled substance because "it was really impossible to track the numbers" to investigate potential diversion otherwise. *See* Trial Tr. (7/12/19 p.m., Hamilton-Fain) at 15:6-16:9.[39] However, when the matter came before the OBP, Defendants "sent representatives to the [OBP] to argue on [Defendants'] behalf that [tramadol] shouldn't be a controlled substance . . . and it did not become a controlled

[39] Excerpts of the videotaped deposition testimony of Cindy Hamilton-Fain, taken on February 19, 2019 in Little Rock, Arkansas, were read into the record on July 12, 2019. *See* Trial Tr. (7/12/19 p.m.) at 13:5-8. Ms. Hamilton-Fain worked for the OBP for over a decade, beginning around 1998. *See* Trial Tr. (7/12/19 p.m., Hamilton-Fain) at 14:22-15:4.

substance." Trial Tr. (7/12/19 p.m., Hamilton-Fain) at 15:21-16:9; *see also, e.g.*, Trial Tr. (6/25/19 p.m., Commissioner White) at 48:3-49:4 (testifying that Defendants' representatives influenced the OBP "to try to keep tramadol from being in any way restricted"). Until the production of Defendants' confidential documents in this litigation, Commissioner White was unaware of Defendants' internal operations and strategic plans. *See* Trial Tr. (6/25/19 a.m., Commissioner White) at 40:10-17, 45:25-46:11.

356. Again, when Oklahoma Representative David Derby was considering "filing a bill to schedule Tramadol" in the State, Defendants' employee, Mr. Ponder, held a phone conference with Representative Derby and "encourage[d] him" that there were "low levels" of "abuse with Tramadol in the State of Oklahoma." Ct. Ex. 0095 (Ponder) at 301:2-302:5. Scheduling Tramadol, or placing it on the list of scheduled drugs, would have represented a restriction on prescribing Tramadol that would have made it less available and more difficult to be prescribed. Ct. Ex. 0095 (Ponder) at 302:3-18. Internally, Defendants considered this "interaction in Oklahoma" a success. *See* S-0268 at 1; Ct. Ex. 0095 (Ponder) at 301:5-22.

357. According to Defendants' documents, Defendants viewed the efforts to schedule tramadol by agencies within the State of Oklahoma as a "threat." S-0463; *see* Trial Tr. (6/3/19 a.m., J&J: Deem-Eshleman) at 49:07-54:15.

358. Scheduling a drug has the potential effect of making it more difficult to access and making patients less inclined to take it. *See* S-0463; Trial Tr. (6/3/19 a.m., J&J: Deem-Eshleman) at 49:07-54:15.

359. In 2008, in response to Defendants learning that "the Oklahoma Board of Pharmacy is threatening to schedule tramadol again," Defendants' Therapeutic Area Head and expert witness, Dr. Bruce Moskovitz, recommended that Defendants "mobilize" and send a "'swat' team" to Oklahoma to deal with the threat. S-0463; *see* Trial Tr. (6/3/19 a.m., J&J: Deem-Eshleman) at 49:07-54:15.

360. In the same email chain, another one of Defendants' employees, Gary Vorsanger, noted that he and Ted Cicero "were out there several years ago" and had addressed the same issue. S-0463; *see* Trial Tr. (6/3/19 a.m., J&J: Deem-Eshleman) at 49:07-54:15.

361. "According to the National Survey on Drug Use and Health (NSDUH) in 2016, 1.6 million people in the U.S. aged 12 or older misused tramadol products in the past year." S-2384; *see* Trial Tr. (6/12/19 p.m., Kolodny) at 37:20-42:10. "Tramadol is most commonly abused by narcotic addicts, chronic pain patients, and health professionals." S-2384; *see* Trial Tr. (6/12/19 p.m., Kolodny) at 37:20-42:10.

362. At trial, Defendants introduced and read into evidence numerous examples of packets of materials and minutes of meetings of the Oklahoma Drug Utilization Review Board ("DURB"). *See, e.g.*, Trial Tr. (6/25/19 a.m., Commissioner White) at 129:16-136:15; Trial Tr. (6/25/19 p.m., Commissioner White) at 5:8-38:3; J-734, J-823, J-710. The DURB is an advisory board that makes periodic recommendations to the Oklahoma Health Care Authority ("OHCA") regarding Oklahoma's Medicaid or SoonerCare program and its coverage for various drugs. *See, e.g.*, Trial Tr. (6/25/19 a.m., Commissioner White) at 131:13-21, 136:4-11, 92:7-20; Trial Tr. (6/26/19 a.m., Commissioner White) at 46:9-15;

Trial Tr. (6/26/19 p.m., Commissioner White) at 52:22-53:4. One seat on the DURB is filled by a representative of the pharmaceutical industry. *See, e.g.*, Trial Tr. (6/25/19 p.m., Commissioner White) at 9:21-23, 30:25-35:1.

363. Defendants' employees and representatives frequently attended these periodic DURB meetings. *See, e.g.*, Trial Tr. (6/25/19 p.m., Commissioner White) at 9:18-21; Trial Tr. (6/26/19 a.m., Commissioner White) at 16:16-22, 18:22-23, 43:13-15, 51:19-52:2; Trial Tr. (6/26/19 p.m., Commissioner White) at 47:17-48:19; *see also* Ct. Ex. 0095 (Ponder) at 325:14-17 (Defendants' employee, Mr. Ponder, attended 46 DURB meetings). Materials that Defendants used in their marketing, including for example, the Consensus Statement, were included in some of these DURB meeting materials. *See, e.g.*, Trial Tr. (6/25/19 p.m., Commissioner White) at 22:9-24:11, 107:11-108:7, 124:15-125:10; J-2455.

364. If an FDA-approved product is covered and on the Medicare/Medicaid rebate programs, a state's Medicaid program is required to provide coverage for that drug. Trial Tr. (6/26/19 a.m., Commissioner White) at 30:3-11.

365. Regarding the suggestion by Defendants' counsel that Oklahoma's state agencies caused the opioid epidemic in the State, Commissioner White testified that, in her opinion:

> [W]hat was occurring in Oklahoma in 2001 was a host of intense marketing by [Defendants] pushing and pushing and pushing for doctors to prescribe more opioids while it appears that we have some of the State agencies stepping up to try to say, this is a problem, this is a problem. But there's no way we could win a tug-of-war when you drop $30 million into [Defendants' marketing] and that doesn't include your sales force. So if what you're trying to say to me with this yesterday and today, is that somehow [it is] the State's fault when [Defendants] were shooting bullets at the State of Oklahoma, that we didn't invest enough or act fast enough to buy Oklahomans enough

> bulletproof vests, or when you were dropping bombs on the State of Oklahoma that we didn't work fast enough or hard enough to build bomb shelters to save peoples' lives, I find that offensive and I completely disagree with it. . . . I find it incredibly offensive that what you would stand here and suggest is that as [Defendants] unleashed a series of bombs, as I have described to you already, across the United States of America that landed squarely in Oklahoma, that killed over 6,000 Oklahomans, without you telling us that you were going to do this, without you still accepting any responsibility today, that as we have worked as hard as we have worked and we are the only reason, the only reason that lives are being saved in this State, that what you say to us is, You didn't build bomb shelters fast enough, you didn't purchase enough bulletproof vests, you couldn't run from us fast enough. . .

Trial Tr. (6/26/19 p.m., Commissioner White) at 45:13-46:4, 47:17-48:19, 53:20-56:22, 65:17-22.

366. Defendants never asked their Director of State Government Affairs in Oklahoma, Mr. Ponder, to help mobilize a reaction team to the opioid addiction problem in Oklahoma. Ct. Ex. 0095 (Ponder) at 317:3-14. Mr. Ponder was not aware of "anything that [Defendants] had specifically focused or targeted on Oklahoma" to help identify what can be done to fix the opioid problem in the State of Oklahoma. Ct. Ex. 0095 (Ponder) at 383:6-16, 354:21-355:3.

367. No one from Defendants' organizations attended the State of Oklahoma's committees and sessions convened to discuss the opioid crisis. Ct. Ex. 0095 (Ponder) at 317:16-22. Defendants' corporate representative was not aware of any money that Defendants had spent to help abate the opioid crisis in Oklahoma—not even one dollar. *See* Trial Tr. (5/30/19 a.m., J&J: Deem-Eshleman) at 85:04-19

(5). Marketing Directly to Patients to Sell Drugs

368. Another of the key programs that Defendants implemented to help achieve its stated goal of building a billion-dollar brand was direct to patient marketing programs. S-3962; Trial Tr. (5/30/19 p.m., J&J: Deem-Eshleman) at 50:11-52:01.

369. Ms. Deem-Eshleman initially stated Defendants did not ever market directly to patients about opioids. Trial Tr. (5/31/19 p.m., J&J: Deem-Eshleman) at 120:04-08. Internal documents indicate there were "direct to patient" marketing programs for opioids, including the "Making Connections" program for Duragesic. S-3962. In response, Ms. Deem-Eshleman clarified that Defendants did market "direct to patient," but did not promote "direct to consumer." Trial Tr. (5/31/19 p.m., J&J: Deem-Eshleman) at 123:01-124:07.

370. Defendants' "outlook analysis" for its "Pain Franchise" in 2001 revealed that Defendants viewed "DTC" (direct-to-consumer) marketing to be of increasing significance, acknowledged that access to information and connectivity was increasing, consumers and doctors were becoming increasingly Internet savvy, the Internet was a marketing tool, and "e-detailing" was expanding such that it would be "imperative" for the Pain Franchise to, among other things, "leverage DTC opportunity." S-2358; Trial Tr. (5/30/19 a.m., J&J: Deem-Eshleman) at 137:14-139:04.

371. In the Duragesic 2001 Business Plan, dated August 2000, Defendants identified one of its "2001 Business Objectives" was to: "Drive patients to request DURAGESIC® in DTC offerings." S-2357 at 20. The plan further identified as a "Lesson[] Learned" that "DTC will work to drive consumers" due to "[u]nmet needs," "[l]ack of understanding," and a "[h]igh degree of dissatisfaction with current therapies." S-2357 at

17. Defendants' plan described one of Defendants' "Key Strategies" to be: "Generate awareness and call to action among patients/caregivers." S-2357 at 21. The plan identified "[t]actics" to accomplish this strategy, including "DTC Advertising" and "DTP in Office/Pharmacy." S-2357 at 25.

372. In Dr. Portenoy's opinion, "direct-to-patient marketing" should not be done by drug companies that make opioids. Ct. Ex. 2 (Portenoy) at 229:14-20. Dr. Portenoy advised Defendants against carrying out a direct-to-consumer marketing campaign. Ct. Ex. 2 (Portenoy) at 229:21-24; S-0879 at ¶46. Dr. Portenoy testified:

> Patients don't have the knowledge to make a judgment about what the risks are of [opioid] treatment. And if marketing is done that suggests to them that pain relief is a possibility, they're going to focus on that. And they're going to bring that information to their physicians, and they're going to ask for these drugs, or to push their physicians to prescribe these drugs. And then they just have to be hopeful that their physicians have been adequately educated and have the ability to say no to a patient who perhaps assertively or . . . says: Treat me, I have terrible pain. And I think it just increases the risk that inappropriate patients are going to get access to opioids and may suffer consequences, negative consequence[s] as a result of that. . . . In my opinion, with respect to the opioids, the Schedule II opioids—with respect to any opioid, I think the risks of adverse consequences, not just abuse and addiction, but also adverse consequences like falls and cognitive change, particularly in the elderly, are too grave to justify a direct-to-consumer campaign. The risks of a drug like Cialis don't match up to the risk of drugs that are Schedule II opioids. And I think it is true that whether you like direct-to-consumer advertising or not as a general concept, in my opinion, direct-to-consumer advertising for opioids is a mistake.

Ct. Ex. 2 (Portenoy) at 230:9-231:14, 233:14-234:1.

373. In Dr. Portenoy's opinion, it would be "wrong" for a drug company "to go directly to a specific subset of the population, including the elderly, to market the use of opioids for chronic non-cancer pain[.]" Ct. Ex. 2 (Portenoy) at 230:9-15.

374. Along with women, veterans and "high abuse-risk patients (e.g., males under 40)," Defendants specifically targeted elderly people with their marketing. *See, e.g.*, S-1253; S-2375; Trial Tr. (6/11/19 p.m., Kolodny) at 96:01-13, 110:08-111:17.

375. In Dr. Portenoy's opinion, whether branded or unbranded, direct-to-consumer marketing of opioids is simply "bad" and not "the right thing to do." Ct. Ex. 2 (Portenoy) at 234:23-235:5. Direct-to-consumer marketing of opioids can cause illicit drug use problems by teaching individuals how to tell a doctor "the right buzzwords" to obtain a prescription. Ct. Ex. 2 (Portenoy) at 235:10-236:16.

376. Dr. Mazloomdoost testified that he faces push-back from new patients who have heard from former physicians, the media, and even support groups that pain pills are the answer. Trial Tr. (6/6/19 a.m., Mazloomdoost) at 26:16-27:19. He testified, "most of them have just been worn away and have bought into the notion that – that they're powerless against whatever condition they have and that it's the opioids that are the only thing that are getting them through the day." Trial Tr. (6/6/19 a.m., Mazloomdoost) at 27:16-19.

(6). Partnering with Other Opioid Manufacturers to Sell More Opioids

377. In addition to supplying other pharmaceutical companies with the ingredients to make other opioid drugs, Defendants also expressly partnered with other opioid manufacturers to sell more opioid drugs. *See, e.g.*, S-1069.

378. As part of Defendants' "Sales and Marketing Philosophy," Defendants "value[d] partnership[s]" with other drug manufacturers "as an opportunity to create

positive relationships that drive product success." Ct. Ex. 0092 (Mashett) at 301:15-21; S-1073 at 11.[40]

379. In describing themselves as the "Partner of Choice in Pharmaceuticals" in 2002, Defendants touted their "U.S. Marketing and Sales Capabilities" to include, among other things: (i) Defendants' "[p]rofessional and personal relationships with key thought leaders in the field of pain management"; (ii) Defendants' creation of an "interactive patient data base established via the Internet that focuses on patient's pain condition and therapy"; (iii) Defendants' "[e]xperience with Direct to Consumer and Direct to Patient advertising campaigns"; and (iv) Defendants' work "with institutions & advocacy groups," including the American Pain Society. Ct. Ex. 0092 (Mashett) at 302:5-304:11; S-1073 at 10-11.

380. To justify their claim that Defendants were "the Best Partner" in Defendants' 2002 "Partner of Choice in Pharmaceuticals" presentation, Defendants emphasized their: (i) "Well trained field & hospital sales organizations with experience in selling analgesics"; (ii) "Experienced sales organization[s] that have relationships with the targeted audience of high prescribing analgesic prescribers"; (iii) "Knowledgeable marketing team with experience in the analgesic market and established relationships with key opinion leaders"; (iv) "Managed Care & Long-Term Care Account teams with knowledge and experience in the analgesic market"; and (v) "Relationships with key physician specialties that would

[40] S-1073 is a 2002 slideshow presentation, entitled "Johnson & Johnson – Partner of Choice in Pharmaceuticals." *See* S-1073; Ct. Ex. 0092 (Mashett) at 295:5-14. S-1073 was admitted into evidence at trial on June 19, 2019. *See* Trial Tr. (6/19/19 p.m.) at 76:9-77:4.

provide a jump start at launch and a continuous commitment to loyalty." S-1073 at 15-16; *see also* Ct. Ex. 0092 (Mashett) at 326:13-333:18.

381. As of 2002, Defendants described their "Pain & Inflammation Franchise" as a "lifelong franchise" and "priority area for J&J." S-1073 at 16. Defendants also touted their "Dedicated Global Product Team for [the] life cycle of" a given "compound." S-1073 at 16.

382. Defendants' 2002 "Partner of Choice in Pharmaceuticals" presentation likewise described Defendants' action plans for other countries, like Spain and Germany, to include things like: (i) "increase[ing] the education in Pain Management [in Spain] by working from Pain Clinics through specialists to G[eneral] P[ractitioners] (Domino Strategy)"; (ii) "Building a new market" in Spain; (iii) "Creat[ing] broad acceptance on the under treatment of pain (spec. with opioids) with authorities, health insurances, payers, doctor associations, doctors and patients" in Germany; (iv) "Initiat[ing] public discussion on the situation of under treatment of pain in German"; (v) "PR" and "[d]estigmatiz[ing] opioids" in Germany; and (vi) "Intensively train[ing Sales Force] reps to be pain education managers" in Germany. S-1073 at 22-23; *see also, e.g.*, Ct. Ex. 0092 (Mashett) at 339:24-341:1.

383. Defendants entered a co-development and co-promotional agreement for Ultram SR with Purdue in 1997 that was terminated prior to approval of the product. Ct. Ex. 0092 (Mashett) at 280:10-20; S-1069 at 1.[41]

[41] S-1069, a self-explanatory document entitled "Business Dealings with Other Opioid Manufacturers," was prepared by Defendants in connection with the corporate representative

384. Defendants and Purdue entered into a licensing agreement for Ultram ER in 2005, under which Defendants paid a royalty to Purdue for sales of Ultram ER. Ct. Ex. 0092 (Mashett) at 281:15-282:25; S-1069 at 1-2; Trial Tr. (6/12/19 p.m., Kolodny) at 35:22-25. This licensing agreement between Defendants and Purdue lasted until Defendants lost exclusivity on Ultram ER. Ct. Ex. 0092 (Mashett) at 281:15-282:25; S-1069 at 1-2.

385. Defendants entered a supply agreement for generic Duragesic in 2004 with a company called "Sandoz." S-1069 at 3. Under this agreement, Defendants "supplied generic Duragesic to Sandoz, which Sandoz marketed." *Id.* Defendants' expert, Dr. Marais, was unaware that Sandoz generic fentanyl patches were handed out in Oklahoma with Duragesic coupons inside the box. *See* Trial Tr. (7/11/19 a.m., Marais) at 158:23-159:1.

386. Defendants generated sales of Ultram by themselves, as well as through agreements with other companies. Ct. Ex. 0092 (Mashett) at 398:9-399:2; *see also, e.g.*, S-1069.

387. Defendants generated sales of Ultracet by themselves, as well as through agreements with other companies. Ct. Ex. 0092 (Mashett) at 399:3-11; *see also, e.g.*, S-1069.

---

deposition of Frank Mashett on January 30, 2019. *See* S-1069; Ct. Ex. 0092 (Mashett) at 272:13-22. S-1069 was admitted into evidence with no objection. *See* Trial Tr. (6/19/19 p.m.) at 75:12-76:8.

388. Defendants generated sales of Duragesic by themselves, as well as through agreements with other companies. Ct. Ex. 0092 (Mashett) at 399:12-23.

389. Through their subsidiary, Noramco, Defendants supplied other manufacturers with the APIs, tramadol and fentanyl, used in each of Defendants' branded drugs, Ultram and Duragesic. Ct. Ex. 0092 (Mashett) at 399:24-400:2.

390. Through their subsidiary, Noramco, Defendants sold API to both Purdue and Teva. Ct. Ex. 0092 (Mashett) at 399:24-400:7.

391. Defendants had supply and licensing agreements for end-product opioids with both Purdue and Teva. Ct. Ex. 0092 (Mashett) at 400:8-25.

392. It is "reasonable" to interpret Defendants' Code of Conduct as having required Defendants to have gone and sat down with Purdue to find out "what [was] going on" with Purdue following the release of the 2003 GAO Report. Ct. Ex. 0092 (Mashett) at 247:3-255:24.

393. It would have been "incumbent upon" Defendants to ensure that Defendants' business partner, Purdue, "took the corrective actions that were necessary" if Purdue was "doing wrong," and in particular, if Purdue was "doing that wrong with something that" Defendants supplied to Purdue. Ct. Ex. 0092 (Mashett) at 248:4-255:24.

394. Defendants could have gone to Purdue after the 2003 GAO Report was issued and told Purdue that Defendants would no longer supply Purdue with oxycodone. Ct. Ex. 0092 (Mashett) at 242:1-8.

395. However, Defendants identified no discussions that Defendants had with Purdue "to ensure that Purdue would no longer engage in the conduct" described in the 2003 GAO Report. Ct. Ex. 0092 (Mashett) at 255:4-24.

396. The U.S. Department of Justice publicly announced on May 10, 2007, that Purdue and three of its executives had pled guilty to federal crimes related to misbranding of OxyContin. *See* Ct. Ex. 0092 (Mashett) at 260:6-261:19; S-1068 at 1-2. Defendants' corporate representative, Mr. Mashett, was not aware of anything Defendants "did to get with Purdue and try to keep this kind of conduct from not happening" following Purdue's 2007 guilty plea. Ct. Ex. 0092 (Mashett) at 271:13-17, 271:19-20.

397. Defendants did not stop doing business with Purdue in 2007. Ct. Ex. 0092 (Mashett) at 263:25-264:17, 264:18-21.

398. Instead, in 2011, Defendants internally referred to Purdue as Defendants' "[p]artners" for years with whom Defendants had "excellent communications" and sat with at the "same table for most partner meetings." S-1439 at 37.

3. Defendants' Opioid Marketing Was False, Deceptive and Misleading

399. Defendants' opioid marketing, in its multitude of forms, was false, deceptive and misleading. *See, e.g.*, Trial Tr. (6/11/19 a.m., Kolodny) at 69:6-72:23, 85:10-21, 90:21-91:25; Trial Tr. (6/13/19 p.m., Kolodny) at 17:2-23:13; Trial Tr. (6/17/19 a.m., Kolodny) at 109:4-25; Trial Tr. (6/25/19 a.m., Commissioner White) at 66:10-19; Trial Tr. (6/26/19 p.m., Commissioner White) at 112:21-113:15, 117:14-120:12, 129:2-13, 130:22-132:7; Trial Tr. (6/17/19 p.m., Beaman) at 64:20-71:12, 80:18-85:7-20; S-0760; S-0037; S-0038;

S-2481 – S-2492; S-2524; S-2538; S-2515; S-0974; S-0954; S-1247; S-0712; S-4128; S-1249; S-1706; S-2354; S-2372.

400. Internally, Defendants defined the types of marketing and promotion that would constitute false and misleading messaging. S-2376 at 20; Trial Tr. (5/30/19 a.m., J&J: Deem-Eshleman) at 89:19-94-02. In particular, Defendants' internal documents identify at least the following as examples of messaging that qualify as false and misleading marketing or promotion: (i) "broadening of product indication"; (ii) "data taken out of context"; (iii) "minimization of safety issues"; (iv) "omission of material information"; (v) "comparative efficacy or safety claims without substantial evidence (e.g., label-to-label comparisons)"; and (vi) "overstatements of efficacy or safety." S-2376 at 20; Trial Tr. (5/30/19 a.m., J&J: Deem-Eshleman) at 89:19-94:02.

401. Over the last two decades, Defendants have marketed and promoted opioids generally, as well as Defendants' branded opioid drugs, in each of the ways that Defendants internally defined as false and misleading. *See, e.g.*, Trial Tr. (6/13/19 p.m., Kolodny) at 17:2-23:13.

402. On March 5, 1998, shortly after Defendants re-launched Duragesic and broadened its promotion and marketing for chronic non-cancer pain in 1997, the FDA notified Defendants that the FDA found materials Defendants were using to market Duragesic "to be false and misleading" and "in violation" of federal law and regulations. *See* S-4128 at 1; *see also, e.g.*, Trial Tr. (6/28/19 p.m., Moskovitz) at 143:02-146:08.

403. Unlike these examples of specific branded marketing materials that Defendants were supposed to submit to the FDA, Defendant's' unbranded marketing—*i.e.*,

their campaigns, programs, materials and statements promoting "opioids" in general—is not regulated by the FDA or any other federal agency or regulatory body. *See, e.g.*, Trial Tr. (6/11/19 p.m., Kolodny) at 103:17-104:3, 122:4-12. And, of course, unless physically present in the room, no one can regulate what is said in a doctor's office.

404. Specifically, in 1998, the FDA found three different convention posters Defendants used to promote Duragesic to contain marketing messages that were "false and misleading" for numerous reasons. *See* S-4128 at 1.[42]

405. First, the FDA found that Defendants used "misleading comparisons to competitive" drugs in Defendants' Duragesic posters. *See* S-4128 at 1. In particular, two of Defendants' Duragesic posters implied that transdermal fentanyl was superior to sustained-release oral morphine. S-4128 at 1. "However, [such] claims of superiority to other competitive drug products require substantial evidence," which generally consists "of two adequate and well-controlled, head-to-head studies of the drugs" that adequately support the comparative statement. S-4128 at 1. The FDA found the study Defendants had cited as supposed support for its comparative claims did not "constitute substantial evidence." S-4128 at 1.

[42] Neither this letter nor any other communication by, with, to, from or otherwise between Defendants and the FDA are binding, dispositive, preclusive or otherwise conclusive evidence of any fact found or conclusion of law reached by the Court herein. Nor does the Court rely on any such communications for any such purpose. To the contrary, the Court simply finds the FDA communications referenced herein to represent one of the many pieces of evidence that demonstrate, *inter alia*, Defendants' knowledge about the misleading nature of their marketing materials.

406. Second, the FDA found that Defendants selectively presented the results of a study in a Duragesic poster to provide "the misleading impression that the tolerability profile of fentanyl transdermal system is superior to sustained-release morphine." S-4128 at 2. The FDA found that Defendants "failed to present data" from the study showing higher instances of particular side effects and that, in fact, the study showed that "more patients required rescue medication with the use of Duragesic than with the use of sustained-release morphine." S-4128 at 2.

407. Third, the FDA found that all three of Defendants' Duragesic posters promoted an unapproved use for Duragesic by "present[ing] in bold type across the top of the poster that the fentanyl transdermal system is recommended for use in chronic pain," when Duragesic's "approved product labeling states that the drug is 'indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by lesser means...'" S-4128 at 2.

408. The FDA reminded Defendants that this was *not* the first time that the FDA had warned Defendants about promoting unapproved uses of Duragesic, as the FDA previously had sent a letter to Defendants in 1995 "communicat[ing] [the FDA's] concern that the full indication [for Duragesic] should be presented so that sufficient context is provided in which the efficacy and safety claims can be reviewed." S-4128 at 2. In the 1998 letter, the FDA stated it found Defendants' "presentation of the full indication [for Duragesic] near the bottom of the poster in small, inconspicuous type size" to be "misleading and overwhelmed by the more prominent claim of chronic pain at the top of the poster." S-4128 at 2. Therefore, the FDA found that Defendants were "promoting

Duragesic for a much broader use than that recommended in the approved product labeling." S-4128 at 2.

409. Fourth, the FDA informed Defendants that Defendants had made false or misleading statements by asserting that Duragesic "'[s]tops the pain. Not the patient,'" which indicated that "a fentanyl transdermal patch was not associated with impairment of mental or physical abilities." S-4128 at 2. The FDA found these statements conflicted with Duragesic's product labeling, which appropriately contained a precaution that the use of strong opioid analgesics impair the mental or physical abilities required to perform certain tasks. S-4128 at 2. Defendants' statement, the FDA found, "implies that the use of Duragesic is not associated with any impairment of mental or physical abilities" without "data to substantiate such a claim" and was, therefore, "false or misleading." S-4128 at 2-3.

410. Fifth, the FDA found that Defendants' Duragesic posters were "lacking in fair balance or otherwise misleading" because "the risk information on each of these posters is not presented with a prominence and readability comparable to the claims of efficacy." S-4128 at 3. In contrast to Defendants' statements promoting Duragesic's supposed efficacy, which were displayed "in large type size that is easily readable," Defendants relegated "information concerning the risks associated with the use of Duragesic" to a "single line . . . presented in small type size near the bottom of the poster that [wa]s difficult to detect and to read." S-4128 at 3. Based on Defendants' dissemination of these false and misleading messages about Duragesic in these materials, the FDA

required Defendants "to immediately suspend all promotional activities or materials" conveying the information identified in the letter. S-4128 at 3.

411. After 1998, Defendants continued to market opioids by using misleading comparative efficacy claims without substantial evidence, taking data out of context to deliver misleadingly incomplete impressions, promoting unapproved uses, emphasizing the "chronic pain" indications without the limitations and restrictions, and deceptively minimizing risks and safety issues. *See* S-4128; *see also* Section F.2 *supra.*

412. In 2001, Defendants again were advised—this time, by Defendants' own hired scientific advisory board—that many of the primary marketing messages Defendants used to promote opioids in general, and Duragesic specifically, were misleading and should not be disseminated. *See* S-0035.

413. Specifically, in November 2001, experts that Defendants hired advised Defendants to not market opioids, including fentanyl-based Duragesic, using messages related to abuse or with claims about supposedly low abuse potential. *See* S-0035; Trial Tr. (5/30/19 a.m., J&J: Deem-Eshleman) at 94:16-124:21.

414. By the time of this meeting in November 2001, Defendants were aware of increasing reports of overdoses on and abuse of OxyContin. Trial Tr. (5/30/19 a.m., J&J: Deem-Eshleman) at 97:20-25. Defendants' advisors informed Defendants that these overdoses and abuse of this opioid were, at least in part, due to Purdue's aggressive over-marketing of OxyContin to inexperienced primary care physicians. Trial Tr. (5/30/19 a.m., J&J: Deem-Eshleman) at 98:01-05; S-0035. Defendants' advisors informed Defendants that primary care physicians were inexperienced and lacked knowledge and skill in pain

management and opioid prescribing. Trial Tr. (5/30/19 a.m., J&J: Deem-Eshleman) at 99:03-09; S-0035. Defendants' expert advisory board made recommendations to Defendants about marketing opioids based on the experience that was developing with the aggressive promotion of OxyContin. Trial Tr. (5/30/19 a.m., J&J: Deem-Eshleman) at 99:10-13; S-0035.

415. Among other things, Defendants' advisors told Defendants that primary care physicians were not generally knowledgeable about titrating doses of opioids. Trial Tr. (5/30/19 a.m., J&J: Deem-Eshleman) at 105:03-18.

416. Moreover, with a "resounding and unanimous" "NO," Defendants' hired advisors told Defendants to not market opioids, including Duragesic, based on claims that the drug had a low potential for abuse or with an "abuse message" at all. Trial Tr. (5/30/19 a.m., J&J: Deem-Eshleman) at 116:18-22. Defendants' consultants specifically advised Defendants about the problems, including abuse and addiction, that have accompanied widespread use of opioids throughout the history of civilization. S-0035; Trial Tr. (5/30/19 a.m., J&J: Deem-Eshleman) at 123:03-124:21. They specifically advised Defendants that history demonstrates that when the supply of opioids in a civilization rapidly increases, abuse of and addiction to opioids does as well. *See* Trial Tr. (5/30/19 a.m., J&J: Deem-Eshleman) at 116:23-117:17; S-0035 (referencing, for example, the Ancient Greeks and the 19th century opioid addiction epidemic in the U.S.); *see also, e.g.*, Section C *supra*. They specifically advised Defendants that Defendants should not make statements, like "the [Duragesic] patch is less abuseable." S-0035; Trial Tr. (5/39/19 a.m., J&J: Deem-Eshleman) at 118:06-16. They specifically advised Defendants to not rely on DAWN data

to suggest that Duragesic was less prone to abuse. S-0035; S-1703; Trial Tr. (5/30/19 a.m., J&J: Deem-Eshleman) at 119:03-120:18.

417. Defendants' internal records memorialized the specific recommendations that Defendants received from their scientific advisors in 2001, including, for example:

- "**Should the abuse potential of Duragesic be discussed?** 'NO' – resounding and unanimous. It is bad for the L[ong] A[cting] O[pioid] class and bad for patients and prescribers. Drug abusers will figure out how to abuse Duragesic once it is more available. Currently, it may be less abused and there is a dangerous narrow margin between a recreational dose to get high and a lethal dose. As market share goes up, so will abuse. Over-promising on the lack of abuseability is what got OxyContin in trouble. Duragesic should not repeat the same mistake.";
- "Many urine toxicology screens are not sensitive to fentanyl.";
- "If you give Duragesic to patients who have no history of substance abuse, how many will abuse it? We don't know. We need the data."; and
- **"Conclusion: Do not include the abuse message. Do not sell opioids on the abuse issue."** S-0035 (emphasis in original).

S-0035 (emphasis in original).[43]

418. In an email following this meeting, one of Defendants' employee wrote:

> I have grave concerns about the acceptability of the DAWN data, based on absolutely negative response at the Scientific Ad Board. If there had been any shades of gray, I wouldn't be so concerned. While these are pain secialists [sic], their opionions [sic] will carry weight and could compromise any message we send. The docs questioned: 1. The denominator in the DAWN abuse statistics (it could be 291 fentanyl abuse reports out of 291 Duragesic prescriptions: oxycodone in its many formulations may have a huge denominator, so raw mentions are meaningless); (2) The docs saw

[43] At trial, Defendant's' expert, Dr. Moskovitz, acknowledged illustrative ways in which individuals can "abuse" 'Defendants' branded opioid products. For example, individuals can abuse Duragesic by wearing multiple patches. *See* Trial Tr. (6/28/19 p.m., Moskovitz) at 92:23-93:02. And although Defendant's' Nucynta was promoted as tamper resistant, this tamper resistant nature of the pill does not prevent an individual from taking higher doses of the pills or simply swallowing more pills. *See* Trial Tr. (6/28/19 p.m., Moskovitz) at 86:20-87:06.

> DAWN as representative of an entirely different and unrelated population—street drug users as opposed to the patients – a very different group, they contend; (3) They felt that, if Duragesic were as widely distributed (as available) as OxyContin, it would have the same uptake in the abuse community and would lead Janssen down the path to problems followed by Purdue.

S-1703; Trial Tr. (5/30/19 p.m., J&J: Deem-Eshleman) at 81:04-83:04; *see also* Trial Tr. (6/3/19 p.m., J&J: Deem-Eshleman) at 27:17-31:03.[44]

419. In 2001, another of Defendants' consultants, Pinney & Associates, informed Defendants that rates of abuse of prescription drugs were increasing. J-0752; Trial Tr. (6/28/19 p.m., Moskovitz) at 109:08-110:24.

420. After 2001, Defendants defied the advice of its own advisors by continuing to market opioids using the precise messaging their advisors told Defendants to avoid, as Defendants had previously done after receiving a warning letter from the FDA in 1998. *See* S-0035; S-1703.

421. And like Defendants' advisors, the FDA soon found Defendants' use of these very same messages to be false and misleading as well. *See* S-0038.

422. In 2004, the FDA sent Defendants a letter stating that a professional file card that Defendants used to promote Duragesic ("Duragesic file card") contained "false or misleading claims about the abuse potential and other risks of [Duragesic], and include[d] unsubstantiated effectiveness claims for Duragesic." S-0038 at 1. The FDA found that the Duragesic file card misbranded the drug by "suggesting that Duragesic has a lower

[44] This internal memorandum, drafted as a result of 'Defendants' 2001 Scientific Advisory Board meeting, was kept confidential from Oklahoma and others. *See* Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 20:13-24; Trial Tr. (6/3/19 a.m., J&J: Deem-Eshleman) at 103:09-25.

potential for abuse compared to other opioid products," and that "the file card could encourage the unsafe use of the drug, potentially resulting in serious or life-threatening hypoventilation." S-0038 at 1.

423. This 2004 FDA letter addressed, among other things, Defendants' "prominent claim" in the Duragesic file card: "'Low reported rate of mention in DAWN data' along with Drug Abuse Warning Network (DAWN) data comparing the number of mentions for fentanyl/combinations (710 mentions) to other listed opioid products" with higher mentions to suggest that "Duragesic is less abused than other opioid drugs." S-0038 at 2; *compare with* S-0035 (advising Defendants, in 2001: "**Do not include the abuse message. Do not sell opioids on the abuse issue.**" (emphasis in original)).

424. Echoing the advice of Defendants' advisors in 2001, in 2004, the FDA found Defendants' suggestion that Duragesic was "less abused than other opioid drugs" was "false or misleading" because: (i) the FDA was "not aware of substantial evidence or substantial clinical experience to support this comparative claim"; (ii) "DAWN data cannot provide the basis for a valid comparison" among opioid products; and (iii) "DAWN is not a clinical database" but, rather, a "national public health surveillance system that monitors drug-related emergency department visits and deaths." S-0038 at 2; *see also* S-0035; S-1703.

425. Again echoing the advice Defendants received from their advisory board in 2001, the FDA further found Defendants' suggestion of low abuse of Duragesic was "false or misleading" because "Duragesic is not as widely prescribed as other opioid products," and, thus, "the relatively lower number of mentions could be attributed to the lower

frequency of use, and not to a lower incidence of abuse." S-0038 at 2; *see also* S-0035; S-1703. Yet, Defendants' Duragesic "file card fail[ed] to disclose this information." S-0038 at 2. The FDA specifically found that a footnote containing information from the Drug Abuse and Dependence section of the Duragesic package insert was "not sufficient to make the claim truthful and non-misleading." S-0038 at 2.

426. The Duragesic file card further stated: "Demonstrated effectiveness in chronic back pain with additional patient benefits" and referenced the Simpson Study. S-0038 at 2. The FDA informed Defendants that the Simpson Study was "inadequate to support this claim because [the study] was an open-label, single-arm trial with no control group," and the FDA was "not aware of substantial evidence or substantial clinical experience to support this claim." S-0038 at 2.

427. The Duragesic file card also used the Simpson Study as supposed support for Defendants' claims that: (i) "86% of patients experienced overall benefit in a clinical study based on: pain control, disability in ADLs, quality of sleep"; (ii) "All patients who experienced overall benefit from Duragesic would recommend it to others with chronic low back pain"; (iii) "Significantly reduced nighttime awakenings"; and (iv) "Significant improvement in disability scores as measured by the Oswestry /Disability Questionnaire and Pain Disability Index." S-0038 at 2-3. The FDA informed Defendants that the "uncontrolled" Simpson Study was "inadequate to support such claims," and the FDA was "not aware of substantial evidence or clinical experience to support these claims." S-0038 at 2-3.

428. Defendants' Duragesic file card also included the claims: (i) "Long-term effects: 12 month open-label study"; (ii) "Significant improvement in physical functioning summary score"; and (iii) "Significant improvement in social functioning"—all of which Defendants supposedly supported by citing the Milligan Study. S-0038 at 3. The FDA, again, informed Defendants that "this open-label, uncontrolled study is not adequate in design to show an analgesic effect." S-0038 at 3. Data from the Milligan Study was "not substantial evidence or substantial clinical experience to support [Defendants'] outcomes claims," and the FDA was not aware of "substantial evidence or substantial clinical experience to support these claims." S-0038 at 3.

429. Defendants' Duragesic file card also included the claims: (i) "Improved patient outcomes: Open-label, crossover comparison study"; (ii) "Significant improvement in physical functioning summary score"; and (iii) "Significant improvement in social functioning," along with "figures comparing data for Duragesic and sustained release oral morphine." S-0038. As supposed support for these claims, Defendants cited an "open-label" study, the Allan Study.[45] S-0038 at 3. The FDA found that the Allan Study was insufficient to support the cited claims because an "open-label study cannot minimize bias in the reporting of subjective response in the SF-36, a general healthcare questionnaire," and the FDA was "not aware of substantial evidence or substantial clinical experience to support these claims." S-0038 at 3.

[45] The Simpson, Milligan, and Allan Studies are discussed in more detail below.

430. Defendants' Duragesic file card also "prominently present[ed]" the claims: (i) "1,360 loaves...and counting"; (ii) "Work, uninterrupted"; (iii) "Life, uninterrupted"; (iv) "Game, uninterrupted"; (v) "Chronic pain relief that supports functionality" (vi) "Helps patients think less about their pain"; and (vii) "Improvements in physical and social functioning." S-0038 at 3. The FDA found these "outcome claims [] misleading because they imply that patients will experience improved social or physical functioning or improved work productivity when using Duragesic" without any "references to support these outcome claims." S-0038 at 3. The FDA was "not aware of substantial evidence or substantial clinical experience to support these claims." S-0038 at 3.

431. The FDA concluded that Defendants' Duragesic file card made "false or misleading safety claims and unsubstantiated effectiveness claims for Duragesic" and "thus misbrand[ed] Duragesic in violation of the Act (21 U.S.C. § 352(a))." S-0038 at 3. The FDA requested that Defendants "immediately cease the dissemination of promotional materials for Duragesic the same as or similar to those described" in this 2004 letter. S-0038 at 3. The FDA further mentioned that the "violations discussed" in the letter did not "necessarily constitute an exhaustive list" and it was Defendants' responsibility to "ensure that [its] promotional materials for Duragesic comply with each applicable requirement of the Act and FDA implementing regulations." S-0038 at 4.

432. Many other promotional materials that Defendants used in Oklahoma contained the same false and misleading messaging as the file card. The file card was not the only piece of marketing that contained these materials. Evidence was presented of a variety of visual aids distributed in Oklahoma and utilized by sales representatives

containing identical false and misleading messages. *See, e.g.*, S-2524; S-2538; *see also* Section F.4 *infra*; S-2481 – S-2492.

433. Once again, Defendants proceeded to ignore the FDA (as well as Defendants' advisors) by continuing after 2004 to market opioids in Oklahoma in false and misleading ways. *See e.g.*, Section F.2 *supra*; Section F.4 *infra*.

a. Defendants Misleadingly Broadened Product Indications by Aggressively Marketing Opioids to Treat Chronic Non-Cancer Pain

434. Marketing a drug in a way that is broader than the drug's indication is, according to both Defendants and their expert, an example of "false and misleading" promotion. *See* S-2376 at 20; S-4128; Trial Tr. (6/28/19 p.m., Moskovitz) at 146:04-08.

435. Defendants promoted opioids generally, as well as Defendants' specific branded opioids, in a manner that broadened the indications of these products, and was misleading because it failed to convey important limitations on the original indications. *See, e.g.*, Trial Tr. (6/13/19 p.m., Kolodny) at 17:14-22.

436. Defendants' branded opioids carry FDA-approved labels, or package inserts. *See* J-2762 – 2787; *see also* Trial Tr. (6/4/19 a.m., J&J: Deem-Eshleman) at 53:10-77:11.

437. Defendants did not pay their "sales force to just go to doctors and hold up a package insert" or drug label. Ct. Ex. 0092 (Mashett) at 322:22-323:11. No sales representative was "likely to go in" to a physician's office "and just read the package insert." Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 61:12-18.

438. Similarly, beyond direct sales visits to physicians, Defendants did not focus on the package inserts for any of Defendants' branded drugs in their many other forms of

marketing and messaging; rather, the package insert was an afterthought at most that was often relegated, for example, to the last slide of a CME presentation and usually in tiny print. *See* Trial Tr. (6/6/19 p.m., Mazloomdoost) at 99:8-16.

439. The original Duragesic New Drug Application ("NDA") includes background information that states: "Duragesic is an extended-release transdermal system which was developed to deliver a narcotic analgesic at a nearly constant rate for use as a supplemental analgesic in postoperative and cancer pain. It was not intended for noncancer chronic pain." J-2843; Trial Tr. (6/28/19 p.m., Moskovitz) at 104:12-19. The distinction between cancer and non-cancer pain is important because the severe risks associated with long-term opioid use are only outweighed in limited circumstances, such as palliative, end-of-life and severe cancer pain scenarios—a fact that had been well-understood and established for a century prior to the time that Defendants set out to expand long-term opioid use in the chronic, non-cancer pain market. *See* Section C, *supra*.

440. The Duragesic label at times, used "malignancy" as an example of the type of "chronic pain" described. *See* J-2768; Trial Tr. (6/5/19 a.m., J&J: Deem-Eshleman) at 85:16-25.

441. The "restrictions" provided in the Duragesic label for its indicated use are always "critical" information to convey to doctors and patients. Trial Tr. (6/28/19 p.m., Moskovitz) at 105:15-106:18.

442. The label for Duragesic in 2003 identifies it as a Schedule II narcotic with the highest potential for abuse. J-2769; Trial Tr. (6/5/19 a.m., J&J: Deem-Eshleman) at 87:20-88:09. A Schedule II narcotic, by definition, has the highest potential for abuse. *See,*

e.g., Trial Tr. (6/28/19 p.m., Moskovitz) at 93:03-07. Defendants acknowledge Duragesic is readily abusable by applying multiple patches, chewing them, and other means. *See* Trial Tr. (6/28/19 p.m., Moskovitz) at 91:06-93:13. Call notes demonstrate that Defendants' sales representatives in Oklahoma repeatedly described Duragesic as a drug with low abuse potential. Trial Tr. (6/5/19 am.) at 88:12-25; *see also* S-2481 – S-2492; Section F.4 *infra.* (collecting some of the many examples of such statements by Defendants' sales representatives to Oklahoma physicians of the thousands in evidence).

443. Moreover, Defendants marketed and promoted the concept of "pseudoaddiction"—a concept Dr. Kolodny testified was "exceptionally dangerous" and Dr. Mazloomdoost testified was "like a license to kill, literally." *See, e.g.*, S-0954; S-0760; S-2354; Trial Tr. (6/11/19 a.m., Kolodny) at 87:03-88:06; Trial Tr. (6/6/19 a.m., Mazloomdoost) at 35:21-36:5. This marketing went beyond the labels of Defendants' branded drugs. For example, the Duragesic label in 2014 stated: "Preoccupation with achieving pain relief can be appropriate behavior in a patient with poor pain control." J-2774 at 26; *see also* J-0410 at 34. The labels, however, do not use the term "pseudoaddiction" which can downplay the significance of addiction as it essentially means "fake addiction." *See* J-2774 at 26; Trial Tr. (6/11/19 a.m., Kolodny) at 87:03-88:06. Nor do the labels include the types of description and language used by Defendants and their partners and advocacy groups to promote this concept. For example, the Prescribe Responsibly website defined Pseudoaddiction as "a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically, when the pain is treated appropriately, the inappropriate behavior ceases." S-0954 at 3.

Similarly, a Duragesic Press Kit described pseudoaddiction as: "a term used to describe patient behavior that can occur when pain is under-treated. Patients with unrelieved pain may become focused on obtaining medications and may seem to inappropriately seek drugs. Pseudoaddiction differs from true addiction because the behavior ends when pain is effectively treated." S-0760 at 2. The labels do not include such language and do not use the term "pseudoaddiction." *See, e.g.*, J-2774 at 26; J-0410 at 34. The concept of pseudoaddiction was used to tell doctors to not be cautious when signs of addiction present themselves but, instead give patients more opioids. *See* Trial Tr. (6/11/19 a.m., Kolodny) at 87:03-88:06. Therefore, Defendants' statements regarding pseudoaddiction and use of the concept goes beyond their drugs' labels.

444. The Duragesic label in 2003 identifies fentanyl as similar to oxycodone. J-2769; Trial Tr. (6/5/19 a.m., J&J: Deem-Eshleman) at 91:13-25. According to call notes, Defendants' sales representatives in Oklahoma repeatedly differentiated Duragesic from OxyContin. Trial Tr. (6/5/19 a.m., J&J: Deem-Eshleman) at 92:01-08.

445. Defendants' corporate representative was unaware of any time that sales representatives told doctors that opioids are not the only solution to treating pain. Trial Tr. (6/5/19 a.m., J&J: Deem-Eshleman) at 63:13-20; *see also* J-3793.

446. The warning letter that the FDA sent to Defendants in 1998 specifically advised Defendants that their promotional material for Duragesic was false and misleading because it emphasized the "chronic pain" aspects of the indication without the accompanying restrictions in the full indication, including that Duragesic was only indicated for "the management of chronic pain in patients who require continuous opioid

analgesia for pain that cannot be managed by lesser means." S-4128 at 2; Trial Tr. (6/28/19 p.m., Moskovitz) at 143:02-146:08.

447. The year before, in 1997, Defendants had re-launched Duragesic for chronic non-cancer pain. *See, e.g.*, S-2355. Defendants' marketing continued to focus on the chronic, non-cancer market for opioids, including Duragesic, as the "growth opportunity" and "key business strategy" for its pain franchise for the next two decades. *See, e.g.*, S-2357; S-2358; S-1358 at 3 (describing growth of Duragesic to "primarily result from increasing acceptance of opioid therapy for the management of chronic non-malignant and malignant pain as well as the increasing acceptance that DURAGESIC can be used as a first line agent"); S-510 ("Strategic Focus" to "Expand DURAGESIC Use in Non-Malignant Pain" and "objective is to convince physicians that DURAGESIC is effective and safe to use in moderate to severe chronic pain such as back pain and degenerative joint disease like osteoarthritis").

448. Similar restrictions in Duragesic's labels that Defendants ignored or minimized in their marketing included, for example: (i) "Duragesic is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by lesser means such as acetaminophen-opioid combinations, non-steroidal analgesics, or PRN dosing with short-acting opioids." J-2765 (1994 Duragesic label); and (ii) "Duragesic is indicated for management of persistent, moderate to severe chronic pain that: requires continuous, around-the-clock opioid administration for an extended period of time, and cannot be managed by other means such as non-steroidal

analgesics, opioid combination products, or immediate-release opioids." J-2769 (2003 Duragesic label).

449. Pain expert, Dr. Mazloomdoost, testified that the way in which Defendants disseminated their messaging surrounding the undertreatment of pain in order to increase opioid prescribing was a "nefarious marketing gimmick." *See* Trial Tr. (6/6/19 a.m., Mazloomdoost) at 55:6-13. While pain may, in fact, be somewhat undertreated, overreliance on opioids exacerbates this undertreatment by "ignoring the underlying fundamental causes of pain." *See* Trial Tr. (6/6/19 a.m., Mazloomdoost) at 55:6-13. For this reason, Defendants' promotion of opioids as safe and effective for all kinds of "chronic pain," while downplaying or omitting limitations on the indication, was misleading because it concealed the fact that opioids can make chronic pain worse, not better.

450. "Pain is not a disease, it's a symptom. It's a symptom of many, many, many different types of diseases. It's the fundamental way by which our body communicates changes" occurring in the body. Trial Tr. (6/5/19 a.m., Mazloomdoost) at 137:13-15.[46]

451. "With opioids, when you take the opioid you get a reduction in pain, but concurrently, there are changes taking place where your body is adapting to that opioid. . . such that when the medicine starts to wear off you're not going back to your starting point,

[46] Dr. Danesh Mazloomdoost, M.D., is a Johns Hopkins trained anesthesiologist and pain specialist who testified as an expert witness for the State about proper pain treatment, how opioids work, and the proper role of opioids in pain management. Trial Tr. (6/5/19 a.m., Mazloomdoost) at 110:5-111:10. Dr. Mazloomdoost graduated from Case Western Reserve University with a degree in healthcare economics and business management and, thereafter, completed medical school and a residency in anesthesiology at Johns Hopkins. Trial Tr. (6/5/19 a.m., Mazloomdoost) at 110:24-111:16. After residency, Dr. Mazloomdoost completed a pain management fellowship at M.D. Anderson in Houston where he treated pain in cancer patients. *Id.* at 11:17-112:8; 113:23-114:9.

you're actually going to a more sensitive point of pain." Trial Tr. (6/5/19 a.m., Mazloomdoost) at 144:12-17. The "pain that your body experiences in the absence of that same level of opioid exposure" is called "rebound pain" or "withdrawal pain." Trial Tr. (6/5/19 a.m., Mazloomdoost) at 145:13-16.

452. The human brain naturally produces opioids called endorphins, which help to regulate pain signals in the brain. Trial Tr. (6/6/19 a.m., Mazloomdoost) at 10:12-19. As Dr. Mazloomdoost explained, "if you get a paper cut and you ignore it" then "you don't feel it anymore because the endorphins or the natural opioids trigger this node in the brain and this node in the spinal cord to say, ok, we got the message." Trial Tr. (6/6/19 a.m., Mazloomdoost) at 10:20-15.

453. However, introducing opioids medications into the body alters this natural process. "When you introduce external sources of opioids, they hijack both of those systems...in a way that your brain can no longer regulate because it's getting the source from the outside. And because the [opioid] levels are so much higher than what your brain can ever produce, it essentially shuts down your brain's ability to regulate pain." Trial Tr. (6/6/19 a.m., Mazloomdoost) at 11:3-8.

454. Opioid medications can actually change the brain's receptors such that they "become less responsive to the presence of the endorphins or the natural opioids and you need higher and higher concentrations in order to get the same affect." Trial Tr. (6/6/19 a.m., Mazloomdoost) at 12:14-20.

455. Dr. Mazloomdoost explained that "the exposure of opioids reduces the pain when [you] take it, but it also increases your sensitivity of pain so that the moment the pain

medicine is gone, you're rebounding and you have a higher perception of that pain. Your threshold is now lower than it was." Trial Tr. (6/6/19 a.m., Mazloomdoost) at 15:20-25. This change in the pain threshold appears to be different, though related, to the concept of "hyperalgesia," which Dr. Moskovitz described as a rare condition wherein opioid exposure does not initially reduce pain but actually makes the pain worse. *See* Trial Tr. (6/27/19 a.m., Moskovitz) at 16:1-7. Rebound or withdrawal pain—which occurs, for example, when a patient misses a dose—is different and far more common; however, some healthcare providers may use the term "hyperalgesia" more generally to describe the occurrence of rebound pain. Trial Tr. (6/6/19 a.m., Mazloomdoost) at 16:1-7. This between-dose spike in pain may also be perceived as what is called "breakthrough" pain. Trial Tr. (6/6/19 a.m., Mazloomdoost) at 18:2-12.

456. As a result of chronic opioid therapy, many pain patients end up worse off than before and have to deal with two problems instead of one: "One [problem] is the physical damage that's causing pain, that's been neglected and mistreated for literally years, and then now the second is the chemical dependency that's developed, the – the changes that have developed in the brain that complicate my management of that original problem." Trial Tr. (6/6/19 a.m., Mazloomdoost) at 26:10-15.

457. Opioids actually discourage and hinder the body's natural healing process by masking pain and pain signals, which causes patients to further damage the affected tissue. Trial Tr. (6/6/19 a.m., Mazloomdoost) at 78:22-79:13. Opioids do not cure the underlying cause of pain. *See, e.g.*, Trial Tr. (6/28/19 p.m., Schick) at 204:17-24, 205:1-8.

458. By further example, Defendants' branded marketing for Duragesic included numerous claims about the benefits and efficacy of long-term use that are not contained within the label, including claims that it improved social and physical functioning. Such claims are not contained within the FDA-approved label. *See* J-2765, J-2769; *see also, e.g.*, S-0038. Such claims related to long-term benefits and improved functioning were never supported by credible evidence, and indeed such uses come with significant risks. Section F.3.b *infra.*

459. By marketing opioids generally as a class of drugs, and Defendants' branded opioids specifically, for the long-term treatment of chronic non-cancer pain in a false and misleading way, Defendants broadened the product indications for opioids.

b. Defendants Deceptively Minimized the Risks and Overstated the Efficacy of Opioids

460. In their marketing, Defendants repeatedly made false, misleading and deceptive statements that minimized the risks and overstated the efficacy of using opioids generally, as well as Defendants' own branded opioids for decades. *See, e.g.*, Trial Tr. (6/13/19 p.m., Kolodny) at 17:2-19:8.

461. For example, Defendants' marketing disseminated false and misleading messages regarding the supposedly "low potential for abuse" and low risk of addiction when using opioids. *See, e.g.*, S-1227; Trial Tr. (6/12/19 p.m., Kolodny) at 79:4-81:16; S-1249; Trial Tr. (6/12/19 p.m., Kolodny) at 81:24-86:18; S-1710; Trial Tr. (6/13/19 a.m., Kolodny) at 69:16-72:20; Trial Tr. (5/31/19 a.m., Deem-Eshleman) at 21:03-133:15; Trial Tr. (5/31/19 p.m., Deem-Eshleman) at 5:06-93:02; Trial Tr. (6/3/19 a.m., Deem-Eshleman)

at 40:13-48:16; S-2481 – S-2492; Trial Tr. (6/25/19 a.m., Commissioner White) at 66:10-19.

462. As part of an FDA media response document, Defendants wrote that "chronic pain patients treated appropriately with opioids by physicians rarely become addicted." S-0037; Trial Tr. (5/30/19 p.m., J&J: Deem-Eshleman) at 102:02-110:03. As part of the same document, Defendants referenced information from the APF, a group to which Defendants provided funding and would later refer to as its "go to" partner. S-0037; Trial Tr. (5/30/19 p.m., J&J: Deem-Eshleman) at 102:02-110:03; *see also* S-1191. Portions of the document do not discuss Duragesic or any other of Defendants' specific products and, instead, discuss "opioids" generally as a class of drug in a manner known as "unbranded marketing." S-0037; Trial Tr. (5/30/19 p.m., J&J: Deem-Eshleman) at 102:02-110:03.

463. Defendants did not have a credible basis for its claims that the risk of addiction in chronic pain patients is low. Ms. Deem-Eshleman, speaking on behalf of Defendants, testified that she does not know the rate of iatrogenic addiction for patients receiving opioids from primary care doctors and taking them as ordered by that doctor, and she is not aware of anyone knowing that information. Trial Tr. (5/30/19 a.m., J&J: Deem-Eshleman) at 110:14-112:05. No one knew that rate in 1997, and no one knows it today. Trial Tr. (5/30/19 a.m., J&J: Deem-Eshleman) at 112:09-12. And, Defendants' corporate representative was not aware of any high-quality studies or evidence that show

otherwise. Trial Tr. (5/30/19 a.m., J&J: Deem-Eshleman) at 112:13-18.[47] Defendants' statements about the rate of addiction to their branded drugs, or opioids generally, omitted these critically important facts.

464. In 1996, the data regarding iatrogenic addiction from using opioids for chronic noncancer pain were limited. Ct. Ex. 2 (Portenoy) at 175:6-12. As of 1996, controlled clinical trials of long-term opioid therapy were needed. Ct. Ex. 2 (Portenoy) at 175:13-18.

465. However, even as of January 2019, "definitive data about" the "risk" of iatrogenic addiction still do not "exist." Ct. Ex. 2 (Portenoy) at 176:25-177:2, 177:19-178:24.[48]

466. Defendants' scientific advisors recommended gathering more data about the long-term risks of opioid use in 2001. *See* Trial Tr. (6/3/19 p.m., J&J: Deem-Eshleman) at 70:05-72:08. Defendants do not have such high-quality data to this day. *See* Trial Tr. (6/3/19 p.m., J&J: Deem-Eshleman) at 71:22-72:08.

467. No high-quality studies have been performed to determine the percentage of patients that will become addicted to opioids through long-term medical use. *See, e.g.*, Trial

[47] 'Defendants' counsel affirmatively confirmed during questioning of Ms. Kimberly Deem-Eshleman that "there is no single rate" of iatrogenic addiction to opioids when taken under a doctor's supervision. Trial Tr. (5/30/19 a.m., J&J: Deem-Eshleman) at 108:21-109:05.

[48] Defendants presented some evidence regarding a "cumulative review of iatrogenic addiction," *see* J-0406, but this review relied only on certain cases of addiction reported to Defendants and Defendants are aware that cases of addiction often go unreported. *See* J-0406; Trial Tr. (6/28/19 p.m., Moskovitz) at 9:13-11:24. Moreover, this review plainly advises that: (i) "it is important to stress the limitations of reporting rates for evaluation of adverse events" (J-0406; Trial Tr. (6/28/19 p.m., Moskovitz) at 12:11-21); and (ii) "caution should be taken in the interpretation of the reporting rate of spontaneous reports." J-0406; Trial Tr. (6/28/19 p.m., Moskovitz) at 12:11-13:01.

Tr. (6/11/19 a.m., Kolodny) at 90:21-91:19; *see also, e.g.*, Ct. Ex. 2 (Portenoy Testimony) at 177:19-179:16. According to Dr. Portenoy, pharmaceutical companies only funded research studies that "align[ed] with the company's interest in demonstrating the benefits of the drug they manufacture[d], with the intention or publishing results that could yield higher sales in the future." S-0879 at ¶¶26-27. The studies that have been performed look at patients already on opioids, and many show a "very high rate, a very high prevalence of opioid use disorder in patients on long-term opioids for chronic pain." Trial Tr. (6/11/19 a.m., Kolodny) at 90:21-91:19. Many of the studies Defendants pointed to in order to feign support for their statements were not even studies in which the patients were assessed for their risk of addiction. *See, e.g*, Trial Tr. (6/11/19 p.m., Kolodny) at 89:5-90:7. These studies were "not really studies that were performed in which individuals who were exposed to opioids long-term were evaluated for the development of addiction." *See, e.g.*, Trial Tr. (6/11/19 p.m., Kolodny) at 162:20-163:9; *see also, e.g.*, S-0760; S-1710; S-1364; Trial Tr. (6/13/19 a.m., Kolodny) at 71:16-72:16. As Dr. Kolodny testified:

> The studies that have come up with a low incidence rate of addiction, these are not really studies that were performed in which individuals who were exposed to opioids long-term were evaluated for the development of addiction. Many of the very low estimates come from papers that are systematic reviews where they compile data from multiple clinical trials that were never performed to determine risk of addiction. Many were industry sponsored efficacy trials, which they combined data, and if the efficacy trial didn't report that anybody got addicted, they would call that zero. And so studies to determine the risk of iatrogenic addiction that have come up with a low incidence rate, I don't believe have been performed.

Trial Tr. (6/11/19 p.m., Kolodny) at 162:22-163:9.

468. Nor do any studies show that opioids are rarely addictive when taken long-term for chronic pain. *See, e.g.*, Trial Tr. (6/11/19 p.m., Kolodny) at 104:22-105:25.

469. Defendants attempted to have several witnesses read from various studies to assert that certain articles and studies supported their marketing statements about the low risk of addiction. To do so, Defendants offered testimony from Dr. Bruce Moskovitz, Dr. Tim Fong and Dr. De La Garza who read excerpts related to alleged "scientific support" for statements regarding the risks and benefits of opioids. *See, e.g.*, Trial Tr. (6/28/19 a.m., Moskovitz) at 55:25-76:12; Trial Tr. (7/1/19 a.m., Fong) at 96:05-97:05; Trial Tr. (7/9/19 a.m., De La Garza) at 56:17-128:08; Trial Tr. (7/9/19 p.m., De La Garza) at 5:08-177:21. None of these reports or articles change the fact that Defendants admitted at trial that they never did, and never had, a prospective study that determined the rate of iatrogenic addiction for any person taking an opioid under a doctor's care. *See* Trial Tr. (5/30/19 a.m., Deem-Eshleman) at 112:09-18. Defendants' top KOL, Dr. Portenoy, wrote in a paper in 1986—a paper Defendants relied upon—that expanding the use of opioids for treatment in chronic non-cancer pain must be done cautiously, and that high-quality clinical studies of the prospective rate of iatrogenic addiction must be done first. *See* Trial Tr. (6/17/19 p.m., Kolodny) at 15:13-19:6. However, Dr. Portenoy testified that Defendants never conducted those studies and, as such, any statements by Defendants regarding the rate of addiction did not contain the proper context needed to make them accurate. *See* Trial Tr. (6/17/19 p.m., Kolodny) at 15:13-19:6; Ct. Ex. 2 (Portenoy) at 176:25-177:2, 177:19-178:24 ("definitive data about" the "risk" of iatrogenic addiction still do not "exist."). Therefore, this is not an issue of a disagreement over the science. No study can change the

fact that any statement Defendants made about the specific rate of addiction was not only false but omitted this highly material piece of information: Defendants did not conduct the necessary studies needed to determine the actual risk of addiction.

470. Moreover, Defendants' marketing differs from the actual underlying studies on which they relied at trial. Defendants still omitted material information from their actual marketing materials, minimized safety concerns, and took data out of context. This is similar to Defendants' false marketing regarding the Simpson, Milligan and Allan Studies (discussed below). And, this is in line with Drs. Portenoy and Kolodny's descriptions of Defendants' marketing. *See* Ct. Ex. 2 (Portenoy) at 164:25-169:05, 268:17-271:24; Trial Tr. (6/11/19 a.m., Kolodny) at 69:16-72:23; Trial Tr. (6/13/19 a.m., Kolodny) at 73:18-74:01. Second, the "studies" on which Defendants relied are not "high quality" studies that support the marketing statements made by Defendants. Third, Defendants at times relied on studies and articles at trial that did not actually exist at the time of their marketing statements and, therefore, could not have been the basis for such statements. None of the studies or articles discussed change that Defendants' corporate representative admitted that no one knows the real risk of iatrogenic addiction for long-term use of opioids. *See* Trial Tr. (5/30/19 a.m., Deem-Eshleman) at 112:09-18; *see also* Trial Tr. (6/11/19 p.m., Kolodny) at 104:22-105:25 (No studies show that opioids are rarely addictive when taken long-term for chronic pain.); Ct. Ex. 2 (Portenoy) at 176:25-177:2, 177:19-178:24 ("definitive data about" the "risk" of iatrogenic addiction still do not "exist."). Moreover, Defendants' false and misleading marketing statements were not limited to their statements about the risk of addiction.

471. When considered together with all the documents and testimony about the risk of addiction associated with opioids, I find Defendants' arguments and evidence based upon these studies unpersuasive as set forth below.

472. First, Defendants' marketing differs from the actual underlying studies on which they relied at trial by omitting information and taking data out of context. Dr. Moskovitz relied on several materials to support the marketing statements in Defendants' marketing. *See, e.g.*, Trial Tr. (6/28/19 a.m., Moskovitz) at 64:02-76:12; J-0406; J-0400; J-0398; J-3606. Included among these materials was J-0406, an internal company report regarding iatrogenic addiction related to Duragesic. *See* J-0406. That report however, did not speak to the risk or reports of addiction related to any opioids other than Duragesic and, as discussed extensively herein, Defendants marketed the safety of all opioids broadly. *See* J-0406; Trial Tr. (6/28/19 a.m., Moskovitz) at 118:05-119:01. Moreover, that report relied on information being reported to Defendants about incidents of addiction, rather than the company affirmatively studying and testing for addiction. *See* Trial Tr. (6/28/19 p.m., Moskovitz) at 9:13-11:05. As a result, that internal report specifically says that its results are of limited value and must be used cautiously because "reporting rates do not reflect occurrence rates." *See* J-0406 at 8. As Dr. Moskovitz acknowledged, addicted patients may not know they are addicted and may try to hide their addiction (and doctors obviously may never report cases of addiction to Defendants). *See* Trial Tr. (6/28/19 p.m., Moskovitz) at 10:13-11:20. The Court notes that during opening statement, Defendants presented a slide with the conclusions of this report but chose not to include any of the qualifications or limitations that the report specifically advised should be included

whenever discussing the results. None of Defendants' marketing presented at trial related to Duragesic, to the extent it was based on this report, included the limiting or qualifying information related to this report and this report provides no basis for any unbranded marketing. Therefore, to the extent Defendants were relying on this internal report for any marketing statements, they omitted material information and took data out of context, and this report neither supports the broad marketing statements admitted into the evidence nor undermines the evidence of the misleading nature of such statements.

473. Dr. Moskovitz also relied on a publication by Treadwell et al. in the *Cochrane Review*. *See* J-0400; Trial Tr. (6/28/19 a.m., Moskovitz) at 67:19-72:17. The plain language summary of the review states, among other things: "the evidence supporting these conclusions is weak, and longer-term studies are needed to identify the patients who are most likely to benefit from treatment." J-0400; Trial Tr. (6/28/19 a.m., Moskovitz) 72:06-10. Further, Defendants received a report internally that addressed the *Cochrane Review* Treadwell article, which stated:

- "The Cochrane review may misrepresent the risk of opioid abuse and misuse"; and
- "The summary stated that the risk of developing addiction or abuse is considered very small. Some practitioners may have the idea that there is no risk when in reality there is a significant risk and a considerable societal concern."

S-1597; Trial Tr. (6/28/19 p.m., Moskovitz) at 18:18-26:17. This is the type of material information that was not included in Defendants' marketing materials. *See, e.g.*, S-1247; Trial Tr. (6/28/19 p.m., Moskovitz) at 27:01-16. Therefore, to the extent Defendants were relying on this *Cochrane Review* article for any marketing statements, they omitted material information and took data out of context, and this article neither supports the broad

marketing statements admitted into the evidence nor undermines the evidence of the misleading nature of such statements.

474. Dr. Moskovitz also relied on an article by Dr. Fishbain et al. entitled "The percentage of chronic nonmalignant pain patients exposed to chronic opioid analgesic therapy." J-0398; Trial Tr. (6/28/19 a.m., Moskovitz) at 72:25-76:12. The Fishbain paper did not rely on the standard medical criteria for diagnosing addiction and included studies that were not studying addiction. *See* Trial Tr. (6/28/19 p.m., Moskovitz) at 29:17-30:04; Trial Tr. (6/13/19 a.m., Kolodny) at 71:16-72:16; Trial Tr. (6/11/19 a.m., Kolodny) at 90:21-91:19; Trial Tr. (6/11/19 p.m., Kolodny) at 89:05-90:07.

475. Defendants also attempted to rehabilitate Dr. Fong by having him testify as to the Fishbain article. However, Dr. Fong admitted he had not read that particular article until the time of this deposition in the case in April. *See* Trial Tr. (7/1/19 p.m., Fong) at 96:19-97:12. Indeed, he testified that one of the Defendants' attorneys went and met with him during trial, on or about June 14, 2019, to discuss these studies with him after it was revealed, in open court, that Dr. Fong had made public statements that the real risk of addiction was as high as 1 in 4. *See* Trial Tr. (7/1/19 p.m., Fong) at 42:09-13, 58:08-60:23. Further, his testimony did not change the inadequacies of that article as a basis for Defendants' marketing statements. As with other studies, Defendants did not provide any of the specific limitations or criteria related to the study in its marketing. *See, e.g.*, S-1247. Therefore, to the extent Defendants were relying on the Fishbain paper for any marketing statements, they omitted material information and took data out of context, and this paper

neither supports the broad marketing statements admitted into the evidence nor undermines the evidence of the misleading nature of such statements.

476. Dr. Moskovitz also relied on an article by Dr. Edlund et al. published in the *Clinical Journal of Pain.* J-3938; Trial Tr. (6/28/19 a.m., Moskovitz) at 78:25-96:09. The study includes numerous statements that support the State's claims: "Increases in use of opioid therapy for chronic noncancer pain have been parallel by increased rates of opioid use disorders, suggesting increases in use and abuse are linked." J-3938; Trial Tr. (6/28/19 p.m., Moskovitz) at 36:10-25, 47:05-10. The study further states: "It is important to note that a recent meta-analysis of the efficacy of opioids for chronic back pain concluded that 'our review, however, found that the evidence in favor of opioids is not always consistent, and when supportive, only supports this treatment for short periods (for example<4 months).'" J-3938; Trial Tr. (6/28/19 p.m., Moskovitz) at 48:19-49:18.

477. The study also states that because of the varying rates in opioid use disorders it is "almost meaningless to talk of a single rate." J-3938; Trial Tr. (6/28/19 p.m., Moskovitz) at 50:05-12; *see also* Trial Tr. (6/28/19 p.m., Moskovitz) at 52:07-14. Contrary to that statement, Defendants repeatedly made false statements about a single rate for all opioids. Therefore, to the extent Defendants were relying on the Edlund paper for any marketing statements, they omitted material information and took data out of context, and this paper neither supports the broad marketing statements admitted into the evidence nor undermines the evidence of the misleading nature of such statements.

478. Dr. Moskovitz also attempted to rely on a website from the FDA entitled "A Guide to Safe Use of Pain Medicine." *See* Trial Tr. (6/28/19 a.m., Moskovitz) at 62:17-

63:24; J-3606. However, the FDA website was not limited to the use of opioids in chronic pain and the statements about the rarity of addiction were not isolated to such use like the *Finding Relief* brochure. *See* J-3606; Trial Tr. (6/28/19 a.m.) at 115:17-117:15. The FDA website describes "Pain relief treatments" related to "all sorts of physical pain—including that brought on by chronic conditions, sudden trauma, and cancer." J-3606. The FDA website does not limit its statements about the "rarity" of addiction to use for chronic pain as Defendants' marketing often did. J-3606. Therefore, to the extent Defendants were relying on the Edlund paper for any marketing statements, they omitted material information and took data out of context, and this paper neither supports the broad marketing statements admitted into the evidence nor undermines the evidence of the misleading nature of such statements.

479. Any reliance by Defendants upon the 1980 Porter and Jick letter to the editor to suggest that their reliance upon that letter for statements regarding the low risk of addiction was appropriate are unpersuasive. Indeed, the evidence at trial demonstrated that Dr. Herschel Jick himself never intended the letter to support a statement about the risk of addiction for taking opioids long term for chronic pain. *See* S-1024; Trial Tr. (7/9/19 p.m., De La Garza) at 147:09-149:06; Trial Tr. (6/28/19 p.m.) at 55:11-13, 55:21-23 (The "Porter and Jick" letter does not have anything to do with chronic pain.). To the contrary, this letter to the editor was limited to a single context—an evaluation of patients in a hospital setting, for a short time, under a doctor's care. *See* Trial Tr. (6/28/19 p.m., Moskovitz) at 55:11-13, 55:21-23. That is why, for example, the White House Commission cited the pharmaceutical industry's reliance upon this letter as support for statements regarding the

low risk of addiction as a root cause of the opioid crisis. *See* S-1574 at 20. Thus, this letter to the editor could not support any statement regarding the long term risk of addiction for a patient taking opioids. *See* Trial Tr. (6/28/19 p.m., Moskovitz) at 55:11-13, 55:21-23. ("Q: And you know that Porter and Jick did not have anything to do with chronic pain, did it? A: That's correct.").

480. Second, regarding all such studies, the State offered substantial evidence as to why they do not actually support Defendants' broad marketing statements. Dr. Kolodny testified:

> The studies that have come up with a low incidence rate of addiction, these are not really studies that were performed in which individuals who were exposed to opioids long-term were evaluated for the development of addiction. Many of the very low estimates come from papers that are systematic reviews where they compile data from multiple clinical trials that were never performed to determine risk of addiction. Many were industry sponsored efficacy trials, which they combined data, and if the efficacy trial didn't report that anybody got addicted, they would call that zero. And so studies to determine the risk of iatrogenic addiction that have come up with a low incidence rate, I don't believe have been performed.

Trial Tr. (6/11/19 p.m., Kolodny) at 162:20-163:09; *see also* Trial Tr. (6/11/19 p.m., Kolodny) at 89:05-90:07 (Many of the "studies" relied on for low risk of addiction were not studies in which the patients were assessed for their risk of addiction). Dr. Portenoy also testified: "definitive data about" the "risk" of iatrogenic addiction still do not "exist." Ct. Ex. 2 (Portenoy) at 176:25-177:2, 177:19-178:24. Dr. Moskovitz also recognized in his own 2014 paper: "Although opioids are considered appropriate for acute and cancer-related pain, their benefits and risks are less well understood and more controversial in the

context of extended use for CNCP patients." Trial Tr. (6/28/19 p.m., Moskovitz) at 69:25-85:01; *see also* Ct. Ex. 141.

481. Having considered all the evidence surrounding the alleged scientific support for Defendants' marketing claims, I find the studies and articles presented by Defendants at trial as "scientific support" do not provide evidence that Defendants' statements regarding the risk and rate of addiction were not false and misleading and did not omit material information. In fact, the studies themselves demonstrate the misleading nature of Defendants' marketing because the marketing does not include a description of the numerous qualifications, limitations, parameters, and deficiencies of the studies.

482. Finally, to the extent that Defendants offered these studies as a foundation for specific pieces of marketing, the following facts are pertinent:

- Duragesic Report (J-0406): This report is signed September 2006 and, therefore, could not be the basis of any marketing or statements related to the risk of addiction made by Defendant' prior to that date.

- Fishbain (J-0398): This paper was published in 2008 and, therefore, could not be the basis of any marketing or statements related to the risk of addiction made by Defendants prior to that date.

- Treadwell (*Cochrane Review*) (J-0400): This paper was published in 2010 and, therefore, could not be the basis of any marketing or statements related to the risk of addiction made by Defendants prior to that date.

- Edlund (J-3938): This study was published in 2014 and, therefore, could not be the basis for any statements in any marketing published prior to that time.

For the reasons described above, these studies and articles do not provide after-the-fact justification for any of Defendants' misleading marketing.

483. Notably, today, Defendants market Tylenol, one of Defendants' non-opioid products, on the basis that, unlike opioids, Tylenol is not "habit forming:"

S-4130. Defendants' marketing now says the opposite of what it said for two decades.

484. Defendants' statements that patients taking prescription opioids under a doctor's care for a longer period of time have a low chance of becoming addicted were not supported by high-quality evidence. *See, e.g.*, Trial Tr. (6/11/19 a.m., Kolodny) at 91:20-25; Trial Tr. (6/17/19 p.m., Beaman) at 121:9-19. Because no one knows the rate of addiction for long-term opioid therapy, Defendants' marketing was false and misleading when it downplayed the risk or pointed to supposedly "low risk" papers that are not high-quality evidence. *See, e.g.*, Trial Tr. (6/13/19 a.m., Kolodny) at 73:18-74:01. And at a minimum, Defendants had an obligation to disclose (and not omit) these highly material facts to all doctors and all patients whenever the issue of addiction was discussed.

485. Defendants did just the opposite. For example, Defendants trained their sales force to "avoid the addiction ditch" when selling opioids to physicians and use Dr. Portenoy's studies to show there was only a 2.6% risk of addiction. *See* S-1364. Dr.

Portenoy testified, however, that from 1996 through 2019, data "in the literature" has never been "precise enough" to "inform medical practice" in a way that would support the use of a specific "number" to say that patients with certain characteristics have a specific rate of addiction or to "describe" the risk of addiction from using opioids with any certainty. Ct. Ex. 2 (Portenoy) at 177:19-179:1. Dr. Portenoy's study, which Defendants used to train their sales representatives to minimize the risk of addiction, did not even assess patients who had been on long-term opioids for their risk of addiction. *See* Trial Tr. (6/11/19 p.m., Kolodny) at 89:5-90:7.

486. As of 2019, Dr. Portenoy could not "say with any certainty what percentage of patients treated with long-term opioids will develop the disease of addiction[.]" Ct. Ex. 2 (Portenoy) at 179:3-16. For example, Dr. Portenoy testified that "saying that the risk of addiction is less than 1 percent when taking an opioid for chronic pain" is "inaccurate" and does not provide the types of data or warnings that are necessary. Ct. Ex. 2 (Portenoy) at 181:24-182:8. Seeing or hearing such statements might cause physicians to become more likely to prescribe opioids in inappropriate situations or to not see warning signs associated with someone who might be addicted to opioids. Ct. Ex. 2 (Portenoy) at 182:9-183:2.

487. Another one of Defendants' KOLs, Dr. Gilson, similarly did not know, and was unaware of any "evidence" that could support a statement identifying, the addiction rate of a person taking an opioid for chronic pain treatment under the care of a primary care physician in 1996, 1997, or any year thereafter through the date of his deposition in December 2018. *See* Ct. Ex. 0044 (Gilson) at 56:8-61:25.

488. One of Defendants' experts, Dr. Timothy Fong, testified that, to his knowledge, reliable scientific data regarding *de novo* iatrogenic addiction from opioid exposure has never been produced. *See* Trial Tr. (7/1/19 p.m., Fong) at 35:17-21.

489. It is widely known by Defendants and in the medical community that the prevalence of opioid use disorder in patients who are on opioids long term can be as high as 25% or even higher at times. *See, e.g.*, Trial Tr. (6/13/19 a.m., Kolodny) at 117:24-118:09.

490. In a presentation Dr. Fong gave in 2016, prior to testifying at trial, he cited the same statistic: "About one in four who actually receive a prescription for opioids at some point in their career will develop an addiction to that. That's really powerful. So, in other words, every one out of four patients that get opiates at some point are going to develop an addiction. That's really, really potent stuff." Ct. Ex. 0073 at 3:21-4:2. In particular, Dr. Fong's presentation presented data to support the statements that (i) 1 in 4 people who receive prescription opioids long term for non-cancer pain in primary care settings struggles with substance use disorder, (ii) 80% of heroin initiates used prescription opiates previously, and (iii) 1 in 15 people who take non-medical prescription pain relievers will try heroin within 10 years:

Signs of the Opioid Epidemic: More Deaths

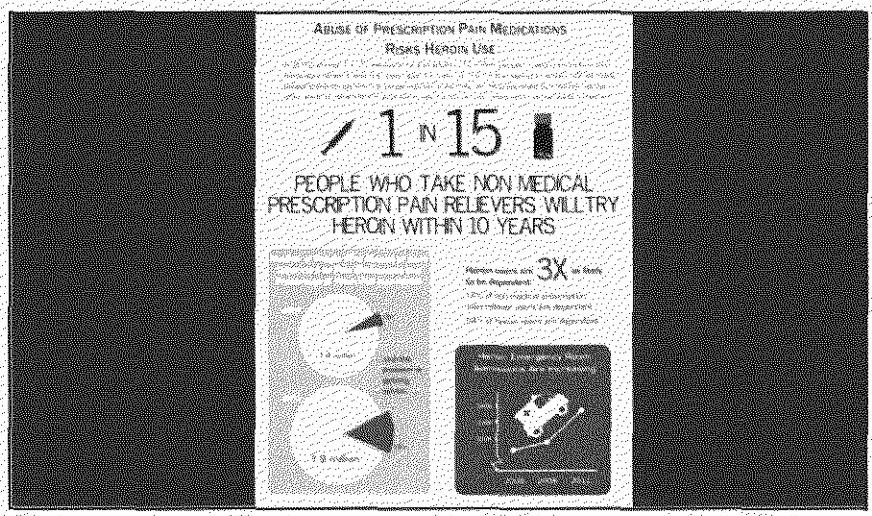
- Since 1999, the rate of overdose deaths involving opioids (prescription opioids and heroin have quadrupled
- More deaths than MVAs
- > 30,000 per year
- ~78 opioid overdoses per day
- ~4500 deaths in California / year

Signs of the Opioid Epidemic: Increased Heroin Use

- Past month heroin use, past year heroin use, and heroin addiction have all since increased among 18-25 year olds since 2000
- More heroin available on the street
- 80% of heroin initiates used prescription opiates previously

Signs of the Opioid Epidemic: Rise of Prescription Opioids

- 2014, ~2 million Americans were *dependent on prescription opioids*.
- 1 in 4 people who receive prescription opioids long term for non-cancer pain in primary care settings struggles SUD
- Daily, >1,000 people are treated in emergency departments for misusing prescription opioids



Ct. Ex. 0060 at 11-13, 15.

491. One study, Dr. Moskovitz acknowledged, has concluded that "current opioid dependence might be as high as 26 percent." S-0467; Trial Tr. (6/28/19 p.m., Moskovitz) at 63:17-20. According to a witness called by Defendants, Dr. Muchmore, there is a 100% certainty of a patient getting addicted to opioids if on the drug long enough at a dose significant enough to treat moderate to severe pain. *See* Trial Tr. (7/3/19 a.m., Muchmore) at 65:19-66:4 (further testifying it would be ridiculous for anyone to tell a doctor that a patient would not become addicted to opioids).

492. Throughout this time period, however, Defendants marketed opioids in general and its own branded opioids with a very low risk of addiction, including in Oklahoma as shown below. *See, e.g.*, S-0760; S-1364; S-0974; *see also* Section F.4 *infra.* (collecting some of the many examples of such statements by Defendants' sales representatives to Oklahoma physicians out of the thousands in evidence).

493. Defendants' marketing further omitted material information regarding the safety and efficacy of both opioids generally and Defendants' own branded opioid drugs. *See, e.g.*, Trial Tr. (6/13/19 p.m., Kolodny) at 18:7-17.

494. For one specific example, Defendants' unbranded *Finding Relief* brochure did not state that "fentanyl is highly addictive." S-1247; Trial Tr. (6/28/19 a.m., Moskovitz) at 113:03-20. In an internal email, however, Defendants' then-employee and expert witness at trial, Dr. Bruce Moskovitz, stated: "Fentanyl is a highly addictive opioid; there should be no data presented to suggest otherwise." S-1769; Trial Tr. (6/28/19 a.m., Moskovitz) at 113:22-114:04.[49] Another statement in the *Finding Relief* brochure—"Many studies show that opioids are rarely addictive when used properly for the management of chronic pain"—is, likewise, false and misleading. Based on the evidence reviewed, there is a lack of data on this issue and the studies that do cite low numbers do not "show" that opioids are rarely addictive because the quality of the studies is low. *See, e.g.*, Trial Tr. (6/13/19 a.m., Kolodny) at 71:16-72:16; Trial Tr. (6/11/19 a.m., Kolodny) at 90:21-91:19. This statement omits material information about the risk of addiction to opioids of which Defendants were aware.

[49] Dr. Bruce Moskovitz is one of Defendants' former employees, who testified as an expert witness for Defendants at trial. Trial Tr. (6/27/19 a.m., Moskovitz) at 23:08-11, 25:15-16. Dr. Moskovitz is a board-certified physician in internal medicine and began working in the pharmaceutical industry after completing his residency. Trial Tr. (6/27/19 a.m., Moskovitz) at 10:07-11:15. He does not treat patients for chronic noncancer pain, has never treated a patient for opioid addiction, and has never diagnosed a patient with opioid use disorder. Trial Tr. (6/28/19 p.m., Moskovitz) at 40:20-41:02.

495. As to the *Finding Relief* brochure specifically, Dr. Moskovitz did not explain why the "advantages" and "disadvantages" of other non-opioid pain treatments, such as NSAIDs, were emphasized in a different way than the opioid advantages and disadvantages. *See* Trial Tr. (6/28/19 a.m., Moskovitz) at 57:24-58:15. Regarding the opioid "myths" and "facts" section of the brochure, Dr. Moskovitz testified that it is correct to call certain items "myths" because it "doesn't happen in all individuals." *See* Trial Tr. (6/28/19 a.m., Moskovitz) at 59:08-19. The brochure states that it is a "myth" that "opioid medications are always addictive." S-1247. Dr. Moskovitz testified that it is accurate to call this a myth. *See* Trial Tr. (6/28/19 a.m., Moskovitz) at 59:08-19. But, Defendants acknowledge that all Schedule II opioids always carry a risk of addiction. *See, e.g., See* Trial Tr. (6/27/19 p.m., Moskovitz) at 129:13-23. Further, the brochure does not include information about the range of risk about which Dr. Moskovitz testified, nor the limitations of any of the "many studies" on which the brochure was relying. *See* S-1247; Trial Tr. (6/28/19 p.m., Moskovitz) at 29:23-31:17. Finally, the brochure is unbranded and discusses "opioids" as a class of drugs. S-1247. Opioids are not all the same. Trial Tr. (6/27/19 a.m., Moskovitz) at 54:10-11; *see also* Trial Tr. (6/28/19 a.m., Moskovitz) at 108:02-14. Similar to Dr. Portenoy's description of Defendants' marketing, the brochure distills the information that appears helpful to Defendants' business interest of selling opioids and does not include the negative or limiting information that Defendants' witnesses agree is important information. *See* S-1247; Trial Tr. (6/28/19 p.m., Moskovitz) at 29:23-30:16, 48:05-15, 50:15-22, 72:07-13, 73:03-75:01. Therefore, the *Finding Relief* brochure was misleading.

496. More universally, Defendants used "positive statements" that Dr. Portenoy made about opioids in his research "to portray opioid treatment as safe and effective[.]" Ct. Ex. 2 (Portenoy) at 66:3-8. These companies used Dr. Portenoy's statements about opioids "without also using [his] accompanying discussion of the risk[s]" about these drugs included in Dr. Portenoy's papers and publications. Ct. Ex. 2 (Portenoy) at 66:10-16.

497. Defendants' representations of medical literature were false and misleading because Defendants cherry-picked favorable aspects of scientific research, while failing to include the warnings and qualifications included in the full works. When drug companies, including Defendants, used Dr. Portenoy's work, they did not fully cite to the warnings and qualifications that Dr. Portenoy gave about the risks associated with the use of opioids in the chronic pain space, including tolerance, addiction, physical dependence, and the risk of abuse, misuse and diversion. Ct. Ex. 2 (Portenoy) at 164:2-166:18. Dr. Portenoy believed "that drug companies used [his] work to provide content and expert support for a strongly positive message about opioids, and in much of the material produced by drug companies, the content lacked context and warnings, and in so doing, presented a message that lacked balance. The effect was to promote opioid therapy to prescribers." S-0879 at ¶41.

498. From the "very first guideline" that Dr. Portenoy published in 1986, he "said that opioids should only be considered after all other reasonable approaches for pain control have not worked." Ct Ex. 2 at 165:13-17. Dr. Portenoy emphasized the "need to understand that risk was irreducible" in using opioids, necessitating the importance of careful patient selection and monitoring. Ct. Ex. 2 (Portenoy) at 207:5-208:7. Dr. Portenoy further always framed the potential benefits of the use of opioids "in the context that said, . . . these drugs

could be abused, . . . these drugs could lead to addiction, and that's why they shouldn't be first used, and that's why they should only be used in carefully selected patients, and that's why they should be monitored in a specific way." Ct. Ex. 2 (Portenoy) at 166:7-13.

499. However, "that context and those messages about risk were neglected, de-emphasized, and the pharmaceutical industry, for understandable reasons, would take the positives, distill out the positives for their messaging." Ct. Ex. 2 (Portenoy) at 166:14-18. The "opioid manufacturers essentially distilled out the positive messages and failed to mention or failed to emphasize appropriately the risks and the context that was included in papers like the very first one that [Dr. Portenoy] wrote." Ct. Ex. 2 (Portenoy) at 165:18-23; *see also* Ct. Ex. 2 (Portenoy) at 179:17-24. The way in which drug companies used Dr. Portenoy's statements and research without providing the background, analysis and cautions Dr. Portenoy included in his work "lacked balance," troubled Dr. Portenoy, and were misleading. Ct. Ex. 2 (Portenoy) at 179:15-180:19, 205:19-23, 207:5-212:22; *see also* S-0879 at ¶36.

500. The "purpose" of only distilling out the positives from Dr. Portenoy's research, in his opinion, "was to improve the sales of their drug[s]" and "to the extent that physicians were given a sense of assurance that the risks were not significant, the drug would do better in the marketplace." Ct. Ex. 2 (Portenoy) at 166:20-167:3; *see also* S-0879 at ¶49.

501. In Dr. Portenoy's experience, the "overarching consideration" in the way in which the opioid "pharmaceutical industry decided to market its products" was "to speak about the benefits [of opioids] that people like [Dr. Portenoy] were writing about without

providing the context related to risk and the caution in selecting the right patient, because the message was more likely to lead to marketing advantage if they did not include the negatives." Ct. Ex. 2 (Portenoy) at 167:4-12; *see also* S-0879 at ¶49.

502. Defendants further misleadingly used definitions of "physical dependence," "tolerance," "addiction," and "pseudoaddiction" to create the impression that doctors and patients should not be concerned about the risk of addiction to opioids. In particular, they presented "physical dependence" "as totally benign" and "something that's going to happen to everybody that takes opioids." *See, e.g.*, Trial Tr. (6/11/19 a.m., Kolodny) at 69:16-72:23. "Whereas addiction, or sometimes it's referred to as psychological dependence, is described in these materials that are designed to promote more prescribing – addiction is described as rare and something that is serious, but is unlikely to happen in patients who are prescribed opioids." Trial Tr. (6/11/19 a.m., Kolodny) at 69:16-72:23. But, in truth, there is not "a bright line between so-called physical dependence and addiction." Trial Tr. (6/11/19 a.m., Kolodny) at 69:16-72:23. As Dr. Kolodny testified:

> Physical dependence is not even the right term because there are psychological symptoms. The correct term is physiological dependence. Physiological dependence and addiction are closely related and the reason that opioids are so highly addictive is because of the physiological dependence, the fact that you feel so awful when you try and stop. That's one of the main reasons people keep using. The reason that opioid manufacturers in their educational materials for prescribers, the reason that they emphasized the distinction is because doctors are very worried about addiction.

Id. Defendants, however, effectively used this misleading distinction to "convince doctors that opioids are not really addictive [by] rely[ing] on sort of this half-truth that physiological dependence and addiction are not the same thing. And so that was – what

they told doctors is you've been making this mistake of thinking about addiction as this physical dependence and you were all wrong about it." *Id.*; *see also, e.g.*, S-0760.

503. Defendants, on their own and through third parties, exaggerated the distinction between physiological dependence and addiction by presenting it as a bright line where physical dependence was not a concern. This marketing worked and led to overprescribing of opioids. *See* Trial Tr. (6/11/19 p.m., Kolodny) at 160:08-20; S-0760; S-0954. For example, Defendants actively promoted, ratified and repeated the Consensus Statement and cited it as support for these and other statements. *See, e.g.*, S-0760; S-0900. The Consensus Statement perpetuates this misleading half-truth by stating: "It was previously thought that the development of analgesic tolerance limited the ability to use opioids efficaciously on a long-term basis for pain management. Tolerance, or decreasing pain relief with the same dosage over time, has not proven to be a prevalent limitation to long-term opioid use. Experience with treating cancer pain has shown that what initially appears to be tolerance is usually progression of the disease. Furthermore, for most opioids, there does not appear to be an arbitrary upper dosage limit, as was previously thought." S-0900. This statement is false and misleading because it downplays the risk of tolerance associated with opioids without any support and downplays the risk of taking high dose opioids. *See, e.g.*, Trial Tr. (6/11/19 p.m., Kolodny) at 31:09-33:11. The Consensus Statement also states that: "Studies indicate that de novo development of addiction when opioids are used for the relief of pain is low." S-0900. This statement is false and misleading as there were no studies that could demonstrate at this time that there was a low rate of addiction for chronic pain use, and omits material information related to

the limitations of the studies that did exist. *See, e.g.*, Trial Tr. (6/11/19 p.m., Kolodny) at 29:06-17. The Consensus Statement further states: "Fear of inducing respiratory depression is often cited as a factor that limits the use of opioids in pain management. It is not accepted by practitioners of the specialty of pain medicine that respiratory depression induced by opioids tends to be a short-lived phenomenon, generally occurs only in the opioid-naïve patient, and is antagonized by pain. Therefore, withholding the appropriate use of opioids from a patient who is experiencing pain on the basis of respiratory concerns is unwarranted." S-0900. This statement is false and misleading as opioids do carry a risk of respiratory depression and the presence of pain (i.e. "antagonized by pain") does not reduce the risk of respiratory depression. This statement thereby downplays the risk of respiratory depression associated with opioids. *See, e.g.*, Trial Tr. (6/11/19 p.m., Kolodny) at 30:08-31:08.

504. Defendants repeatedly and misleadingly promoted, ratified and disseminated the concept of "pseudoaddiction" in their unbranded and branded marketing, including to primary care physicians. *See, e.g.*, S-0760; S-0954; S-1239; S-1249; S-2372; Trial Tr. (6/11/19 p.m., Kolodny) at 87:3-88:6, 139:1-147:25; Trial Tr. (6/13/19 a.m., Kolodny) at 74:25-89:11; Trial Tr. (6/3/19 a.m., J&J: Deem-Eshleman) at 79:01-09.

505. Defendants did so while knowing primary care physicians were not trained in addiction or opioid prescribing. *See, e.g.*, Trial Tr. (5/30/19 a.m., J&J: Deem-Eshleman) at 99:03-09; S-0035. And Defendants did so with sales representatives who were not trained in addiction either. *See, e.g.*, Trial Tr. (5/31/19 p.m., J&J: Deem-Eshleman) at 133:2-15; *see also, e.g.*, Trial Tr. (7/2/19 p.m., Diesselhorst) at 53:1-2.

506. Instructing primary care physicians to give higher doses of opioids to patients that appeared to be addicted is dangerous. Ct. Ex. 2 (Portenoy) at 217:15-19. It is also misleading because it suggests that there is support for the premise that doctors should respond to patients who appear addicted by increasing their dosage.

507. Instead, primary care physicians should have been taught to carefully assess patients with aberrant drug-taking behaviors for the possibility of addiction and to potentially refer the patient to an addiction specialist. Ct. Ex. 2 (Portenoy) at 217:21-218:5.

508. Defendants' promotion of opioids to primary care physicians was "not education," and crossed a dangerous line. *See, e.g.*, S-0879 at ¶46.

509. Giving higher doses of opioids to patients with the disease of opioid addiction is dangerous. Ct. Ex. 2 (Portenoy) at 218:8-13. For example, patients with opioid addiction can more easily die from respiratory depression if given higher doses of opioids. Ct. Ex. 2 (Portenoy) at 218:14-18. Moreover, as Defendants' expert admitted, the longer a person is on opioids, the greater the risk that person will experience an opioid use disorder. *See* J-3938; Trial Tr. (6/28/19 p.m., Moskovitz) at 34:22-35:05; *see also, e.g.*, Trial Tr. (7/8/19 p.m., Halford) at 61:22-62:2, 62:17-63:3) (testifying that higher doses of opioids carry greater risks, including the risk of addiction, respiratory failure and overdose death); Trial Tr. (5/28/19 p.m., Rojas) at 93:16-18. Yet, Defendants persistently and misleadingly marketed opioids with misleading messages to convince physicians to keep patients on long-term therapy for chronic pain for longer periods of time. *See, e.g.*, S-2359; S-3960; S-3961; S-3962; Trial Tr. (5/30/19 p.m., J&J: Deem-Eshleman) at 51:17-52:01.

510. Dr. Portenoy testified that Defendants' dissemination of the concept of pseudoaddiction, without attaching clear messaging about the appropriate response to aberrant behaviors, led prescribers to continue opioid therapy or even raise dosages of opioids they had prescribed to patients when the dosage should have been tapered down or stopped. Ct. Ex. 2 (Portenoy) at 218:19-219:8. This coined term "should not have been used" to describe serious "behaviors, such as 'doctor shopping.'" S-0879 at ¶44. It should never have been "used to avoid the diagnoses of 'abuse' or 'addiction' when these are appropriate, and should never immediately justify higher doses of an opioid as a solution" to "the reality that unrelieved pain can promote aberrant behaviors[.]" S-0879 at ¶44; *see also, e.g.*, Trial Tr. (7/1/19 p.m., Fong) at 156:21-157:4 ("You wouldn't want just a doctor who isn't [] adequately trained to make determinations on pseudoaddiction or addiction in the —in patients").

511. Dr. Mazloomdoost testified that the concept of "pseudoaddiction" was "one of the most egregious statements in [the pain treatment] field because it is rationalizing what every one of us knows in our gut is – is problematic behavior." Trial Tr. (6/6/19 a.m., Mazloomdoost) at 35:21-23. He opined that "labeling somebody as pseudoaddiction is like a license to kill, literally. Because they will just continue to escalate [the dose] and you're egging on that addictive behavior rather than bringing attention to it and nipping it in the bud and addressing it." Trial Tr. (6/6/19 a.m., Mazloomdoost) at 36:1-5.

512. Defendants' marketing made comparative efficacy claims about opioids generally, as well as Defendants' own branded opioids, without substantial evidence. *See, e.g.*, Trial Tr. (6/13/19 p.m., Kolodny) at 18:18-19:4.

513. Defendants' consultants specifically advised Defendants that "[o]ver-promising on the lack of abuseability is what got OxyContin in trouble. Duragesic should not repeat the same mistake." S-0035.

514. Instead of heeding this advice, Defendants "saw a marketing opportunity in the bad press that Purdue Pharma was getting on OxyContin." Trial Tr. (6/11/19 a.m., Kolodny) at 85:10-21.

515. Defendants repeatedly made comparative efficacy and safety claims about opioids in general and Defendants' branded opioids in particular, to Oklahoma physicians. *See, e.g.*, Trial Tr. (6/11/19 a.m., Kolodny) at 85:22-86:3; *see also* S-2481 – S-2492; Section F.4, *infra* (collecting some examples of the many such statements documented in Defendants' Oklahoma call notes).

516. In their marketing, Defendants made misleading overstatements as to the efficacy of opioids generally, as well as Defendants' own branded opioids. *See, e.g.*, Trial Tr. (6/13/19 p.m., Kolodny) at 18:24-19:8; S-510; S-2365; S-1246 (the "objective" of Defendants' sales force was to "convince" physicians that "DURAGESIC is effective and safe to use in areas such as chronic back pain, degenerative joint disease, and osteoarthritis").

517. Reliable evidence demonstrating the efficacy of chronic opioid therapy to treat chronic, non-cancer pain has always been scarce, if not non-existent. Trial Tr. (6/6/19 a.m., Mazloomdoost) at 134:19-20 ("there's really never been any evidence demonstrating efficacy of long-acting opioids for long-term pain."); Trial Tr. (6/6/19 p.m., Mazloomdoost) at 12:15-16 ("there was never any evidence suggesting long-term, long-

acting opioids were effective for chronic pain."); Trial Tr. (6/17/19 p.m., Beaman) at 63:1-13 ("for chronic opioid therapy for noncancer pain, there's really no long-term studies that show that this works").

518. No adequate and well-controlled trials for Duragesic long-term opioid therapy show or ever showed improved function or quality of life. *See, e.g.*, Trial Tr. (6/11/19 p.m., Kolodny) at 104:4-21. Strong opioids, like fentanyl, should never be used in the first instance for moderate pain. Ct. Ex. 2 (Portenoy) at 184:17-19.

519. In a paper published in 2014, Defendants' expert, Dr. Moskovitz, wrote:

> The use of long-term opioid therapy (LOT) for the management of chronic noncancer pain (CNCP) has risen dramatically since the mid-1990s. Although opioids are considered appropriate for acute and cancer-related pain, their benefits and risks are less well understood and more controversial in the context of extended use for CNCP patients.

Trial Tr. (6/28/19 p.m.) at 69:25-85:01; *see also* Ct. Ex. 141.

520. Defendants also researched messaging about and marketed to doctors specifically to keep patients on Duragesic for longer periods of time. *See, e.g.*, S-3960; S-3961; S-3962; S-2359. Due to their risks and lack of demonstrated benefits long-term, it is misleading and improper to market opioids as appropriate for an undetermined or indeterminate amount of time, rather than at the lowest possible dose for the shortest period of time; an opioid is not a medication to start with and stay with. Trial Tr. (6/11/19 p.m., Kolodny) at 58:12-59:02.

521. Despite Defendants' marketing that Duragesic delivered a steady dose of fentanyl to eliminate patients' pain occurring in "peaks and valleys," the package insert for Duragesic contained a chart demonstrating the opposite. *See* J-2769 at 6 (package insert);

Trial Tr. (6/6/19 a.m., Mazloomdoost) at 53:8-25, 65:20-67:17. While it may be true that the fentanyl infusion from a Duragesic patch is fairly even over a single day, that does not remain the case over multiple days because of how the body stores and metabolizes the fentanyl. Trial Tr. (6/6/19 a.m., Mazloomdoost) at 66:11-15. However, Defendants used different charts in their marketing materials that optically demonstrated a steady flow of medication over the course of several days, instead of using the chart in the package insert. Trial Tr. (6/6/19 a.m., Mazloomdoost) at 66:9-11 ("Q. Was this [the package insert] the graph that Johnson & Johnson used in their marketing materials? A. No, it wasn't.").

522. Defendants further took and used data out of context in a misleading manner that minimized the risks and overstated the efficacy of opioids generally, as well as Defendants' own branded opioids. *See, e.g.*, Trial Tr. (6/13/19 p.m., Kolodny) at 17:23-18:6.

523. For one example, Defendants misleadingly used DAWN data to convince physicians that there was a low risk of addiction and abuse when using opioids, and to claim that Duragesic was less prone to abuse than other opioids. *See* Section F.4, *infra*.

524. Defendants' consultants advised Defendants not to "sell opioids on the abuse issue." S-0035. The advisory board specifically rejected "the DAWN data and abuse statistics" as support for any claims about Duragesic or its potential for abuse. *See* S-0035.

525. Defendants' employees acknowledged that DAWN data could not be used to support any valid statistics about "abuse" of Duragesic. *See, e.g.*, S-1703.

526. The FDA specifically advised Defendants that it was false and misleading to use DAWN data in the manner that Defendants did—as supposed support for claims that Duragesic had a low potential for abuse or addiction. *See* S-0038.

527. DAWN data comes from hospital emergency room visits. *See* Trial Tr. (6/11/19 a.m., Kolodny) at 69:3-69:11; *see also, e.g.*, S-0038 at 2. Synthetic opioids (e.g., fentanyl, tramadol and tapentadol) "do not show up on routine testing, and that would include testing performed in hospital emergency rooms." Trial Tr. (6/11/19 a.m., Kolodny) at 68:13-69:02; *see also, e.g.*, S-1703. Therefore, DAWN data underestimates the rate of emergency room visits due to fentanyl. Trial Tr. (6/11/19 a.m., Kolodny) at 68:13-69:11.

528. As Defendants' advisors and employees pointed out, DAWN data lacked a denominator that would offer any meaningful way to determine a rate of addiction or abuse or to otherwise compare to other opioids. *See, e.g.*, S-0035; S-1703; *see also* S-0038. Thus, Defendants' repeated use of DAWN data to claim Duragesic had a low abuse potential and to make comparative claims about the abuse potential of Duragesic vs. OxyContin were deceptive and misleading. *See, e.g.*, S-0035 ("Need to know the denominators of the numbers. What percent of prescriptions of each drug is abused? There are many more oxycodone prescriptions than Duragesic prescriptions. Many urine toxicology screens are not sensitive to fentanyl."); *see also, e.g.*, S-1769; S-2358; Trial Tr. (6/11/19 p.m., Kolodny) at 166:11-170:22.

529. Defendants misleadingly used DAWN data in other ways as well. For example, in a presentation entitled "Optimizing Chronic Pain Management with Duragesic," Defendants included information related to DAWN data and references to

Porter and Jick. S-1706; Trial Tr. (6/12/19 p.m., Kolodny) at 06:23-18:01. The statistics related to DAWN showed a percentage change in fentanyl from 2000 to 2001 only, instead of 1994-2001. S-1706; Trial Tr. (6/12/19 p.m., Kolodny) at 06:23-18:01. Showing a percentage change from 1994-2001, however, would have resulted in showing a more than 2,000% increase for fentanyl. S-1706; Trial Tr. (6/12/19 p.m., Kolodny) at 06:23-18:01.

530. Defendants' marketing materials repeatedly used the Porter and Jick letter to support misleading claims about the risk of addiction when using opioids. *See, e.g.*, S-1706; S-1710; S-1364; Trial Tr. (6/13/19 a.m., Kolodny) at 69:16-72:20.

531. The Porter and Jick letter had "had many limitations[.]" Ct. Ex. 2 (Portenoy) at 225:5-7; S-0879 at ¶43. It was about treatment of patients in a hospital setting under the supervision of a doctor, "which is very different than management of pain in the community[.]" Ct. Ex. 2 (Portenoy) at 225:10-16; S-0879 at ¶43. The Porter and Jick letter had nothing to do with chronic pain. Trial Tr. (6/28/19 p.m., Moskovitz) at 55:11-13, 55:21-23. It was a one-paragraph letter to the editor related to "chart reviews of patients who had been given morphine or demerol or some other opioid while in a hospital bed, and they only found four charts out of 11,882 patients who suddenly appeared drug-seeking after getting a dose of morphine or demerol." It did not study the risk of iatrogenic addiction for short-term outpatient use or long-term outpatient use of opioids. Trial Tr. (6/11/19 p.m., Kolodny) at 172:01-12. The U.S. Commission on Combatting Drug Addiction and the Opioid Crisis credits the "unsubstantiated claims" that pharmaceutical manufacturers made based on the Porter and Jick letter, as well as other frequently cited

sources, with "erod[ing] the historical evidence . . . of iatrogenic addiction and aversion to opioids[.]" *See* S-1574 at 20.

532. The letter lacked sophisticated statistical analysis and could not be used to support conclusions about the probability of future outcomes. Ct. Ex. 2 (Portenoy) at 225:17-226:1. It was not about rates of addiction for people using opioids for long term treatment of chronic pain. Ct. Ex. 2 (Portenoy) at 226:8-11. The Porter and Jick letter only attempted to provide an answer to the question: "What is the incidence of addiction after inpatient exposure to an opioid in a hospital setting?" Ct. Ex. 2 (Portenoy) at 226:12-18. However, the "management of pain in a hospital setting under constant supervision is quite different than a primary care physician using opioids to treat non-cancer chronic pain" in the outpatient setting of the physician's office. Ct. Ex. 2 (Portenoy) at 226:19-24. The findings expressed in the Porter and Jick letter simply "were not relevant to" the "incidence of addiction in a specific patient population during opioid treatment that continues for months and years[.]" Ct. Ex. 2 (Portenoy) at 226:25-227:5.

533. It "would be misleading" for someone to use the Porter and Jick letter to say that a patient had a "less than 1 percent" chance, or really no "risk at all," of becoming addicted to opioids if the patient used opioids for non-cancer chronic pain treatment. Ct. Ex. 2 (Portenoy) at 227:7-15. The "statistic from the Porter & Jick letter—an addiction rate of <1% following short-term inpatient opioid exposure—should not have been used by the pharmaceutical industry to indicate the addiction rate associated with chronic pain treatment." S-0879 at ¶43. It likewise would "be misleading for any drug company to rely

on Porter and Jick" as "high quality evidence" that supported a "low risk factor for using opioids to treat" non-cancer chronic pain. Ct. Ex. 2 (Portenoy) at 227:17-22.

534. The Porter and Jick letter did not support "the notion that using opioids for non-cancer chronic pain is safe and effective[.]" Ct. Ex. 2 (Portenoy) at 227:25-228:10. Porter and Jick did not support "the idea that there is a less than one percent risk of addiction when taking opioids for non-cancer chronic pain therapy without disclosing the limitations of that letter[.]" Ct. Ex. 2 (Portenoy) at 227:21-228:6. A statement to the contrary "would be misleading." Ct. Ex. 2 (Portenoy) at 227:21-228:9. And, "the inclusion of data from studies (particularly the Porter & Jick letter) that reflected clinical scenarios so removed from the scenario of interest (long-term treatment of chronic pain patients) should not have been used to support the conclusion that opioid risk is very low." S-0879 at ¶43

535. Defendants' marketing materials also persistently used the Milligan, Allan and Simpson Studies in deceptive ways to downplay the risk of addiction and overstate the efficacy of opioids. Defendants' Oklahoma call notes documented at least the following amount of times that Defendants' sales representatives used these studies in sales visits to Oklahoma doctors: (i) Allan Study: 369 times between 2002 and 2004; (ii) Simpson Study: 392 times between 1998 and 2004; and (iii) Milligan Study: 266 times between 2002 and 2004:

J&J Studies – Total Mentions in Oklahoma

STUDY	TOTAL	YEARS
Allen	369	2002-2004
Simpson	392	1998-2004
Milligan	266	2002-2004

J&J – Visual Aids Distributed in Oklahoma

DATES	TOTAL
June 02 – Dec 02	726
2003	1,683
2004	754

Ct. Ex. 223 (illustrating data from S-2481 – S-2492).

536. Based on their prescriber data mining and other research efforts, Defendants identified patient functionality benefits as one of the primary marketing messages that increased prescriptions written for Defendants' drugs. *See, e.g.*, S-1358; S-1246. For example, as part of the 2003 Business Plan Summary for Duragesic, Defendants stated: "For the first time in the pain category, the DURAGESIC promotional efforts will focus the core message on improvements in physical and social functioning as a key benefit. The brand will continue to leverage it's competitive advantage of 72 hours." S-1358. Additionally, the "Life, Uninterrupted" marketing campaign was directed towards patient functionality benefits and, according to Defendants, "was credible and compelling enough to cause [physicians] to prescribe DURAGESIC as a 1st choice for chronic pain." S-1246.

537. Defendants instructed their sales force to use the Milligan Study to sell this functionality message to physicians. *See, e.g.*, S-2522. For example, in certain printed advertisements and promotional materials, Defendants used the Milligan Study as a basis for claiming that Duragesic provided "significant improvement in physical functioning summary score" and "significant improvement in social functioning," along with figures illustrating these claims. *See, e.g.*, S-2524; S-2538; S-0038. Defendants provided their sales force with these printed advertisements and promotional materials, and the sales force also specifically used the "Milligan Study" and its results when calling on health care professionals in Oklahoma. *See, e.g.*, Section F.4 *infra* (collecting examples). Defendants sales representatives memorialized using the Milligan Study in Oklahoma sales calls at least 250 times between 2002 and 2004, and distributed thousands of promotional items containing representations based on this study. *See* S-2481 – S-2492; *see also* Ct. Ex. 223 (illustrating data).

538. The Milligan Study, however, does not support such marketing claims. The Milligan Study, which was funded by Defendants, is "not substantial evidence" and does not provide "substantial clinical experience to support such outcomes claims." *See, e.g.*, S-0038. In 2007, one of Defendants' employees reviewed the Milligan Study and concluded: "Milligan et al is loaded with inconsistencies, errors, and omissions of data, which calls into question the integrity of the results." *See* S-2511. Nothing had changed about the study or its data in 2007 from the hundreds of times in which Defendants' sales representatives used it in Oklahoma in prior years between 2001 and 2004. In other words, the deficiencies noted and described by Defendants' employee in 2007, as well as the FDA in 2004, always

existed. However, those deficiencies and issues were not conveyed to health care professionals in Oklahoma. *See, e.g.*, S-2524; S-2538; S-0038; Section F.4 *infra.* Defendants used the study to deliver marketing messages it did not support and without identifying the deficiencies and limiting factors of the study.[50] Defendants, therefore, took data out of context, minimized safety issues and overstated the efficacy of Duragesic as it pertains to functional benefits.

539. Defendants also misleadingly utilized the Allan Study in the State of Oklahoma hundreds of times and in various ways.

540. Similar to the Milligan Study, Defendants used the Allan Study to make unsubstantiated functionality claims about the supposed benefits of using Duragesic. Defendants trained and instructed their sales force to use the Allan Study to sell this message. *See, e.g.*, S-2516. Defendants used the Allan Study along with the Milligan Study as a basis for claiming that Duragesic provided "significant improvement in physical functioning summary score" and "significant improvement in social functioning" along with figures comparing Duragesic to sustained release oral morphine. *See, e.g.*, S-2524; S-2538; S-0038. Defendants trained their sales force to use these printed advertisements and promotional materials to sell these messages to physicians, and the sales force also specifically used the Allan Study and its results with health care professionals in Oklahoma

[50] An expert witness who testified on behalf of Defendants related to this study, Dr. Richard De La Garza, was unfamiliar with the deficiencies and issues Defendants' own employees had identified. *See* Trial Tr. (7/9/19 p.m., De La Garza) at 114:20-115:11, 118:15-119:14. This unfamiliarity was a reoccurring refrain with Defendants' expert witnesses—Defendants did not give many of the critical documents to their own witnesses before they testified, thus undermining the reliability of their testimony.

time and again. *See, e.g.*, Section F.4 *infra*. Defendants' sales representatives recorded using the Allan Study in Oklahoma sales calls at least 350 times between 2002 and 2004, and distributed thousands of promotional items containing representations based on this study. *See* S-2481-2492; *see also* Ct. Ex. 223 (illustrating data).

541. The Allan Study, however, does not support the overstated efficacy claims for which Defendants repeatedly used it in Defendants' marketing. The Allan Study, which Defendants funded, contains bias associated with how the results were reported and is "not sufficient to support the cited claims." *See, e.g.*, S-0038. These limitations were not conveyed to health care professionals in Oklahoma. *See, e.g.*, S-2524; S-2538; S-0038; Section F.4 *infra*. Defendants repeatedly used the Allan Study to deliver marketing messages it did not support and without including the limiting information, biases and insufficiencies. Like the Milligan Study, certain of Defendants' witnesses testified this study was appropriate because it was peer-reviewed. However, as to all of these studies, it is how Defendants *used* the study to deliver unfounded marketing messages about its drugs (and the omission of any discussion of their flaws, weaknesses and shortcomings, all of which were known to Defendants—the funders of each study) that the Court finds to be factually misleading, not the study itself. Therefore, Defendants took data out of context, minimized safety issues and overstated the efficacy of Duragesic as it pertains to functional benefits.

542. Defendants also misleadingly utilized the Simpson Study in the State of Oklahoma hundreds of times and in a variety of ways. Defendants identified chronic back pain as a significant market opportunity to expand sales (sometimes internally referred to

as "CBP" or "CLBP"). *See, e.g.*, S-2358; S-2357; S-2359; S-1358; S-1246. For example, in the 2001 Pain Franchise Plan, Defendants identified "Chronic Back Pain" as a "Significant Market Opportunity" in one of its SWOT analyses. *See* S-2358. Additionally, in the 2001 Business Plan for Duragesic, Defendants stated one of their "strategic objective[s]" was to "position DURAGESIC as preferred long-acting opioid for chronic low back pain." *See* S-2357.

543. This goal continued for years. For example, as part of the 2003 Business Plan Summary for Duragesic, Defendants identified a "Key Business Strategy" as "Expand DURAGESIC use in chronic non-malignant pain (back, OA)." *See* S-1358; *see also* S-2359. Additionally, Defendants instructed their sales force that a "Strategic Focus" was to "Expand DURAGESIC Use in Non-malignant Pain" and specifically made the intention behind these marketing plans clear: "Our objective is to convince [physicians] that DURAGESIC is effective and safe to use in areas such as chronic back pain, degenerative joint disease, and osteoarthritis." *See* S-1246.

544. However, in both 2001 and 2003, Defendants' same business plans acknowledged they had "limited clinical data" or "limited evidence based on scientific data" related to the pain franchise and Duragesic specifically. *See* S-2358; S-2359. Internally, Defendants identified this lack of data to support their promotional statements as a "weakness[]" and "inhibitor[]." *See* S-2358; S-2359; *see also* Trial Tr. (6/11/19 a.m., Kolodny) at 90:08-20 ("So they had limited clinical data. They recognize that as a weakness."). Nevertheless, Defendants used the Simpson Study to make claims about the benefits of using Duragesic for chronic back pain and other benefits.

545. Defendants trained their sales force with the Simpson Study and provided the sales force with promotional materials that cited the Simpson Study as support for Defendants' marketing messages. *See, e.g.*, S-2524; S-2538; S-0038. Defendants used the Simpson Study to make representations that touted the supposed "efficacy" and "effectiveness" benefits of Duragesic for patients. For example, in certain printed advertisements and promotional materials, Defendants used the Simpson Study as a basis for claiming that Duragesic had: (i) "Demonstrated effectiveness in chronic back pain with additional patient benefits"; (ii) "all patients who experienced overall benefit from DURAGESIC would recommend it to others with chronic low back pain"; and (iii) "significantly reduced nighttime awakenings." *See, e.g.*, S-2524; S-2538; S-0038. Defendants provided their sales force with these printed advertisements and promotional materials, and trained the sales force to specifically use the Simpson Study in delivering these messages to health care professionals in Oklahoma. *See, e.g.*, Section F.4 *infra*. Defendants' sales representatives documented using the Simpson Study in Oklahoma sales calls at least 392 times between 1998 and 2004, and distributed thousands of promotional items containing representations based on this study. *See* S-2481 – S-2492; *see also* Ct. Ex. 223 (illustrating data).

546. The Simpson Study, however, does not support such marketing claims. The Simpson Study, which Defendants funded, is "inadequate to support" claims related to demonstrated effectiveness in chronic back pain. *See, e.g.*, S-0038. The FDA specifically advised Defendants that the Simpson Study did not support statements about the efficacy of Duragesic for chronic pain. *See* S-0038. Similarly, the Simpson Study is in inadequate

to support the other efficacy claims regarding back pain and improved sleep that Defendants made. *See, e.g.*, S-0038. However, in delivering their marketing and sales messages, Defendants did not convey these deficiencies and issues with the Simpson Study to health care professionals in Oklahoma. *See, e.g.*, S-2524; S-2538; S-0038; Section F.4 *infra*. Defendants used the Allan Study to deliver marketing messages it did not support and, therefore, took data out of context, minimized safety issues and overstated the efficacy of Duragesic as it pertains to functional benefits.[51]

547. Defendants trained their sales force to use these studies in all of the misleading manners discussed above. *See, e.g.*, S-2522; S-2516; S-2514; S-2515; S-2538; S-2525; S-2517; S-2521; S-2523; S-1769; S-2510; S-2511; Trial Tr. (5/30/19 p.m., J&J: Deem-Eshleman) at 53:2-19, 91:23-94:11, 116:4-152:25. And, that is exactly what Defendants' sales force dutifully and repeatedly did in Oklahoma. *See, e.g.*, S-2481 – S-2492; *see also* Section F.4 *infra* (providing some specific examples).

548. For another example, Defendants used an article authored by another of its KOLs, Dr. Gilson, in a misleading way.

549. On June 12, 2000, Defendants' medical services, product management and sales training team sent a sales bulletin to several of Defendants' employees, including Defendants' sales forces, that encouraged Defendants' employees to use the article, *Trends in Medical Use and Abuse of Opioid Analgesics*, authored by Dr. Gilson, David Joranson

[51] Again, certain of Defendants' witnesses testified that their use of this study was appropriate because the Allan Study was peer-reviewed. But, it was the manner in which Defendants *used* the study out of context and to support overstatements about the efficacy of Defendants' drugs that was misleading, not the study itself in a vacuum.

and Dr. Dahl, in discussing the "potential for abuse or misuse" of opioids "in the context of pain management" with physicians. *See* S-0629 at 1-2; *see also, e.g.*, Ct. Ex. 0044 (Gilson) at 203:6-204:3; *see also* Trial Tr. (5/30/19 p.m., J&J: Deem-Eshleman) at 84:07-91:02, 94:25-101:12. The article was not about Duragesic. S-0629; *see also* Trial Tr. (5/30/19 p.m., J&J: Deem-Eshleman) at 84:07-91:02.

550. Defendants provided their medical science liaisons with information for doctors with certain questions that included the same Joranson and Gilson article Defendants provided to their sales force. S-0740; Trial Tr. (5/30/19 p.m., J&J: Deem-Eshleman) at 94:25-101:12.

551. This article, which was published in April 2000, analyzed "the medical use and abuse" of certain opioids, including morphine, fentanyl, oxycodone, and hydromorphone, "based on data from 1990 to 1996" from the Drug Abuse Warning Network ("DAWN"). Ct. Ex. 0044 (Gilson) at 156:5-10, 157:16-18, 158:21-159:1, 160:9-17; S-0624 at 1. Based only on this 1990-1996 data, Dr. Gilson's article concluded that: "The trend of increasing medical use of opioid analgesics to treat pain does not appear to contribute to increases in the health consequences of opioid analgesic abuse." Ct. Ex. 0044 (Gilson) at 157:19-159:1; S-0624 at 1-2.

552. However, by the time the article was published in 2000, there was evidence that abuse and diversion of prescribed opioids was increasing and had increased between 1996 and 2000. Ct. Ex. 0044 (Gilson) at 164:6-10, 165:18-25. By 2000, it had been widely observed that increased prescribing of opioids led to "increased availability and increased abuse" of opioids as well. *See* Ct. Ex. 0044 (Gilson) at 178:21-179:8. Dr. Gilson, one of

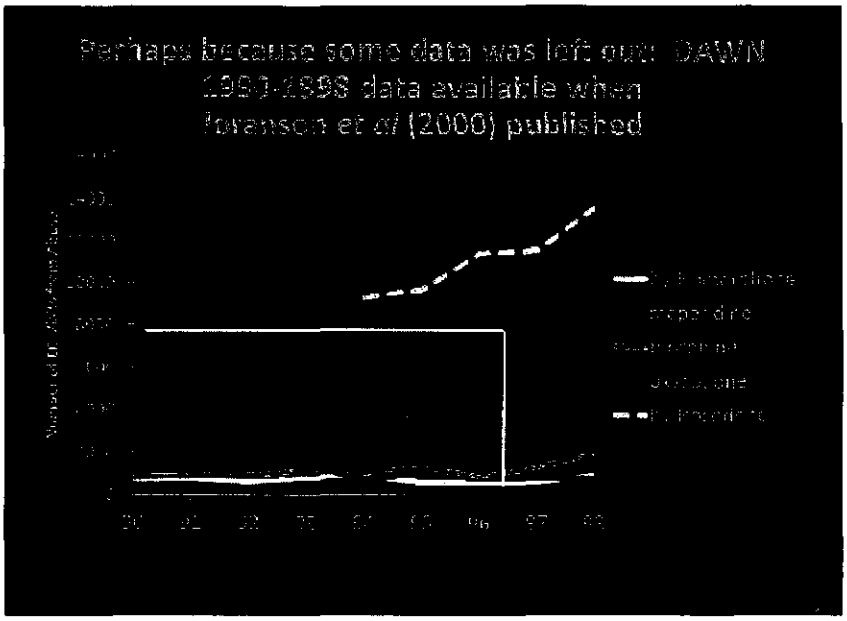
the authors of the *Trends in Medical Use and Abuse of Opioid Analgesics* paper, testified that it would have been deceptive for an opioid manufacturer to use his paper to suggest that abuse and diversion of opioids was not increasing because "there was evidence to the contrary." Ct. Ex. 0044 (Gilson) at 165:7-25.

553. Nevertheless, Defendants' June 12, 2000 bulletin advised Defendants' sales forces to use Dr. Gilson's paper in discussions with physicians about the potential for abuse or misuse of opioids, instructing Defendants' sales forces that:

> The authors [of *Trends in Medical Use and Abuse of Opioid Analgesics*] found that the **present** trend of increasing medical use of opioid analgesics to treat pain does not appear to contribute to opioid analgesic abuse. . . . The authors write that the **present** trend of increasing medical use of opioid analgesics to treat pain does not appear to be contributing to increases in the health consequences of opioid analgesic abuse.

S-0629 at 1 (emphasis added); *see also* Ct. Ex. 0044 (Gilson) at 204:3-17.

554. Defendants' use of the term "present trend" in its 2000 sales bulletin was an "inaccurate representation" that was not supported by the "four-year-old data" analyzed in Dr. Gilson's paper. Ct. Ex. 0044 (Gilson) at 205:24-208:9. This is further confirmed by Dr. Len Paulozzi, an epidemiologist with the CDC, who analyzed Dr. Gilson's paper and the data on which he relied. *See, e.g.*, S-0627. Dr. Paulozzi explained the paper and data could not be indicative of the "present trends" of opioid abuse and prescribing in the year 2000 or later, because it was missing information related to years 1997-2000 and data related to hydrocodone:



S-0627 at 4.

555. After hearing that their article was being disseminated by drug manufacturers for the purpose of trying to show that abuse and diversion of opioids was not actually increasing along with prescriptions of opioids, Dr. Gilson and his co-authors wrote an additional paper. Ct. Ex. 0044 (Gilson) at 166:1-167:6. This second paper, titled "*A Reassessment of Trends in the Medical Use and Abuse of Opioid Analgesics and Implications for Diversion Control: 1997-2002*," was based on national data available for the years 1997 through 2002 and published in August 2004. *See* Ct. Ex. 0044 at 166:23-174:1; *see also* S-0625 at 1. As reported in this paper, the national post-1996 data demonstrated that abuse and diversion of opioids had increased with the increase in opioid prescriptions from 1996 forward. *See* Ct. Ex. 0044 at 167:11-174:12, S-0625 at 1, 9. Defendants' June 12, 2000 sales training bulletin, likewise, did not advise Defendants'

sales forces about the data that existed between 1996 and 2000 showing increases in emergency department visits due to opioids. *See* Ct. Ex. 0044 at 205:12-18; S-0629 at 1-2.

556. Dr. Gilson testified that pharmaceutical companies, including Defendants, compromised the integrity of his work by using the work "outside of its intent." *See* Ct. Ex. 0044 at 328:14-332:2. It "disappointed" Dr. Gilson to learn that Defendants used his research "out of context to tell its field [sales] force how to go to talk to doctors" and that Defendants "manipulated" his research for Defendants' "own commercial purposes." Ct. Ex. 0044 at 327:25-329:5.

557. Despite the fact that the author of this study himself testified it was deceptive to rely upon this study in 2000 as if it were representative of present trends at that time, Defendants relied on that paper as late as 2004 in a letter responding to the FDA. *See* J-861. Indeed, at trial, in an attempt to justify their misleading marketing, Defendants once again relied upon this letter and its citation to Dr. Gilson's article. *See, e.g.*, Trial Tr. (6/5/19 a.m., J&J: Deem-Eshleman) at 97:22-99:14.

558. By 2008, when Dr. Paulozzi published his paper, it had become well-documented, well-demonstrated and well-established that opioid overdose deaths had increased in parallel with increased opioid prescribing. *See, e.g.*, Trial Tr. (6/11/19 p.m., Kolodny) at 136:11-17. However, during the 2007-2008 timeframe, when the public knowledge of the negative health effects and public health problems from opioids were growing, Defendants were ramping up opioid production by releasing a new opioid, continuing an unbranded marketing campaign about the undertreatment of pain for which opioids were the appropriate treatment, and increasing sales calls in Oklahoma. *See, e.g.*,

Trial Tr. (6/11/19 a.m., Kolodny) at 86:04-20; Trial Tr. (5/31/19 p.m., Deem-Eshleman) at 32:10-16; S-0223; S-1364; S-1239; Ct. Ex. 10. And, Defendants continued as the years passed and the public health consequences continued to climb. For example, the publication directed at nurses in pain management that Defendants disseminated in 2011 (S-2354) downplayed the risk of addiction, instead of providing tools and education on cautious prescribing and how to identify addiction. Trial Tr. (6/11/19 p.m., Kolodny) at 158:05-23.

4. Defendants Repeatedly Disseminated Their False, Deceptive and Misleading Marketing Messages in Oklahoma

559. Defendants' marketing strategies in Oklahoma were the same as or similar to their national strategies. *See, e.g.*, Trial Tr. (6/11/19 a.m., Kolodny) at 93:17-94:03. Defendants sold "opioids in Oklahoma just like it did in every other state in this country." Ct. Ex. 0092 (Mashett) at 401:4-16.

560. Defendants disseminated the marketing messages discussed at length above to physicians in Oklahoma repeatedly over the last two decades. These messages were intended to influence Oklahoma doctors to prescribe more opioids and to do so for longer durations. These sales representatives were instructed to be aggressive in pushing doctors to use opioids. And they were incentivized with cash, bonuses and even prizes—all of which were based upon one thing: total prescriptions filled. *See* Section F.2, *supra*.

561. In addition to executing all of the many other aspects of its national marketing campaigns to influence prescribing in Oklahoma, Defendants' sales representatives specifically called on Oklahoma medical professionals as many as 150,000

times to sell opioids over the past two decades. *See* S-2481 through S-2492. The State introduced into evidence 35 boxes of call notes from such sales calls and visits in Oklahoma. *See* S-2481 through S-2492.

562. At trial, Defendants did not call any Oklahoma sales representative to try and refute, rebut or otherwise contest the statements memorialized in these hundreds of thousands of Oklahoma sales visit and call notes.

563. A mere sampling of these voluminous records confirm that Oklahoma sales representatives consistently delivered the false, deceptive and misleading messages discussed above to the Oklahoma medical community.

564. For example, Defendants' sales representatives repeatedly delivered sales messages to Oklahoma doctors that minimized the risk of abuse and addiction of opioids. *See, e.g.*, Trial Tr. (6/13/19 a.m., Kolodny) at 98:07-105:15; Trial Tr. (5/31/19 a.m., Deem-Eshleman) at 21:03-133:15; Trial Tr. (5/31/19 p.m., Deem-Eshleman) at 5:06-93:02; Trial Tr. (6/3/19 a.m., Deem-Eshleman) at 40:13-48:16; Trial Tr. (6/25/19 a.m., Commissioner White) at 66:10-19; *see also, e.g.*, Ct. Ex. 0017 (collection of call notes (excerpted from S-2482 through S-2492) showing Defendants' sales representatives delivering "low abuse potential" message to Oklahoma doctors);[52] Trial Tr. (7/12/19 p.m., Hamilton-Fain) at 13:13-22 (describing sales representatives telling Oklahoma doctors "if it's prescribed for

[52] At various stages in trial, the Court allowed excerpts from Defendants' voluminous call note exhibits (the 35 boxes of documents admitted into evidence as S-2482 through S-2492) to be used in questioning witnesses and published in excerpted and summary format. In these instances, the Court accepted the summary display of the call notes excerpted from exhibits S-2482 through S-2492 as a Court Exhibit. For example, Court Exhibit 17 contains a collection of certain excerpted call notes that were admitted into evidence as S-2482 through S-2492.

legitimate pain, . . . you won't be addicted"); *compare with* S-0035 (Defendants' scientific advisors instructing Defendants in 2001: "**Should the abuse potential of Duragesic be discussed?** 'NO' – resounding and unanimous. . . . **Conclusion: Do not include the abuse message. Do not sell opioids on the abuse issue.**" (emphasis in original).

565. In one example, the call note memorialized one of Defendants' sales representatives' attempt to dissuade Oklahoma nurses that Duragesic patches could be abused by referring to supposedly more problematic abuses with other drugs and making comparative abuse claims. *See* Trial Tr. (6/13/19 a.m., Kolodny) at 98:07-99:09. Downplaying the risks associated with Duragesic through such comparative claims without substantial evidence was deceptive and misleading, as explained above. *See, e.g.*, Trial Tr. (6/13/19 a.m., Kolodny) at 98:07-99:09.

566. In another Oklahoma call note, one of Defendants' sales representatives recorded that the representative needed to "push [the targeted Oklahoma physician] to use more Duragesic." *See* Trial Tr. (6/13/19 a.m., Kolodny) at 105:3-11. Pushing a doctor to prescribe more of an opioid is never appropriate. *See, e.g.*, Trial Tr. (6/13/19 a.m., Kolodny) at 105:03-15.

567. Defendants' sales representatives recurrently emphasized DAWN data to overcome Oklahoma doctors' fears of abuse and/or addiction. *See, e.g.*, Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 52:06-20; *see also* S-2481-2492; Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 21:03-133:15; Trial Tr. (5/31/19 p.m., J&J: Deem-Eshleman) at 5:06-93:02; Trial Tr. (6/3/19 a.m., J&J: Deem-Eshleman) at 40:13-48:16; *See* Trial Tr. (6/11/19 a.m., Kolodny) at 85:22-86:03.

568. For example, one call note in Oklahoma discussed a doctor who was concerned about addiction and Defendants' representative showed the doctor "DAWN data and told him that was one of the benefits of Duragesic, the low abuse potential." Trial Tr. (6/13/19 a.m., Kolodny) at 102:03-21. This is an example of Defendants' misleading marketing in Oklahoma, in light of the true abuse potential of Duragesic and the addictive nature of fentanyl. *See, e.g.*, Trial Tr. (6/13/19 a.m., Kolodny) at 102:03-21. Dr. Kolodny testified at length regarding how Defendants used DAWN data in this misleading way. Trial Tr. (6/11/19 p.m., Kolodny) at 166:11-170:22; Trial Tr. (6/13/19 a.m., Kolodny) at 104:10-105:02; *see also* Trial Tr. (6/13/19 a.m., Kolodny) at 105:16-24, 107:01-24. Moreover, Defendants' internal emails acknowledge that fentanyl is "highly addictive" and all Schedule II drugs have the highest potential for abuse. *See* S-1769.

569. Defendants' sales representatives also used the Milligan, Allan, and Simpson Studies hundreds of times in call notes for Oklahoma doctors, in ways later described as false and misleading by the FDA. *See, e.g.*, Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 21:03-133:15; S-0038; *see also* S-2481 – S-2492. Defendants used these studies as support for messaging related to improved functioning, as well as efficacy for certain conditions such as low back pain. *See, e.g.*, S-0038; Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 21:03-133:15; Trial Tr. (5/31/19 p.m., J&J: Deem-Eshleman) 5:06-93:02; Trial Tr. (6/3/19 a.m., J&J: Deem-Eshleman) at 40:13-48:16. Defendants' sales representatives used the Simpson Study in particular to claim to address doctor concerns about chronic pain patients having sleeping problems and promote the use of Duragesic. *See, e.g.*, Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 73:14-74:06.

570. Defendants' sales representatives further emphasized the use of coupons or vouchers for Duragesic with doctors in Oklahoma. *See, e.g.*, Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 44:21-45:08; *see also* Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 21:03-133:15; S-0038; S-2481-2492.

571. For example, one call note in Oklahoma discussed providing free Sonic drinks in exchange for use of Duragesic coupons. *See* Trial Tr. (6/13/19 a.m., Kolodny) at 101:18-102:02. Dr. Kolodny opined that this is especially concerning given the addictive nature of the drug and the timing of the call note (2004) when the country was already in an opioid epidemic. *See* Trial Tr. (6/13/19 a.m., Kolodny) at 101:18-102:02.

572. Defendants' sales representatives carried out a "spring break blitz" campaign in Oklahoma in which they inappropriately sought to convince physicians to prescribe opioids for "sprains and strains." *See, e.g.*, Trial Tr. (6/13/19 a.m., Kolodny) at 104:6-9; *see also* S-2481 – S-2492. Dr. Halford, a witness called by Defendants, testified that prescribing tramadol for minor sprains and strains is not appropriate. *See, e.g.*, Trial Tr. (7/8/19 p.m., Halford) at 71:21-72:73.

573. The table below collects a small sample of the many examples of such call notes in Oklahoma, as memorialized by Defendants' sales representatives. *See also* S-2481 through S-2492 (thousands of Oklahoma call notes from Defendants' sales representatives). While the Court cannot append 35 boxes of more than 100,000 call notes to these findings, the examples below sufficiently demonstrate that Defendants disseminated their deceptive marketing messages in Oklahoma pervasively, aggressively and over more than a decade:

Defendants' Sales Representative	Date and Location of Call/Visit	Text of Call Note (Record Cite)
Eric Thornhill	August 21, 2002 Ada, OK	"Dur- went over Milligan data. Reinforces patient preference. Said she would try some nonmalignant pain patients. Aci - Went over formulary issues" (Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 22:3-24:25; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Holly Abraham	September 19, 2002 Oklahoma City, OK	"discussed milligan study and asked if this follows close to what his patients feel about dur. talked about functionality. no reason why he would not rx dur. asked if he had any patients on shortactings around the clock, could think of a few. follow up with him to see if he has converted them. invited to program." (Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 25:5-30:10; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Michael Hull	January 10, 2003 Lawton, OK	"Discussed with Dr Ndekwe that chronic low back pain pat are perfect candidate for Dur. Stated that Dur will increase functionality and went over Milligan study. Dr said he would try Dur more with these pat and went on to add that he has had good success with fibromyalgia pat on Dur." (Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 30:11-31:2; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Michael Hull	January 15, 2003 Ardmore, OK	"Dr gave me more time than normal. brought donuts -- big hit. Discussed with Dr that Pain specialist are seeing wonderful results with CLBP being [sic] switched from round the clock SAO to Dur. Discussed seeing an increase in functionality. Went over Milligan page in visual aide and Dr stated he had a couple of pat he should try to switch over. Dr said he would revaluate their

		chart and have them come in to visit about Dur." (Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 31:3-32:2; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Kelly VanBurkleo	April 3, 2003 Tulsa, OK	"Discussed patient with chronic low back pain that she will have to manage for a long period of time. Showed Milligan study to show that pat. prefer it 12 months out because of better pain control as well as these patients had improved function one year out and how that impacts a pat. qual. of life. Asked her to use vouchers to move a patient from lortab to dur. Quick message on fast message and form. status." (Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 32:3-34:3; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	October 6, 2003 Tulsa, OK	"Milligan. Continues to say he has no probs with Dur. Then why so much Oxy??? Also shared DAWN. REally stressed the inc. functionality and low abuse potential. Sd he likes Ultracret. 2 reasons. Gave he and Jane the NPEC info. and gave Jane other websites for her talk." (Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 37:3-39:5; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Kelly VanBurkleo	July 8, 2002 Broken Arrow, OK	"Dur: Only uses long acting opioids in older, 75 yer old patients, in chronic pain. Younger patients needing long acting he refers out to specialists. Showed Allan Study to show how well younger patients with chronic pain do with Dur. Has no problem using long acting opioids in nursing homes." (Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 41:19-22; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Kelly VanBurkleo	February 11, 2003 Tulsa, OK	"Lunch. Invited to Ad Board meeting. Discussed pain control and improving

		function. He sd [sic] that is the whole goal of pain management- to improve function. Had to hold him down to show him the Allan study. He thinks some patients like taking pills because it gives them control over pain." (Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 47:18-49:16; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Holly Abraham	July 29, 2003 Oklahoma City, OK	"HE USES OXY AND MS CONTIN, WENT OVER ALLAN STUDY TO SHOW THAT DUR OFFERS PT BETTER FUNCTIONLITY AS WELL AS PAIN CONTROL. TOLD ME ABOUT PAIN CONFERENCE HE ATTENDED AND SPEAKER SAID PT ARE PUTTING DUR IN MOUTH TO GET HIGH. ASKED IF THEY MENTIONED ABUSE OF OTHER PAIN MEDS, SAID YES. WENT OVER DAWN DATA.HIT ON ACX." (Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 51:7-52:21; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	November 18, 2003 Tulsa, OK	"Showed him Allan. He said he just had a male pt that AM who has 'real cp' and has been on meth for 12 years. Sd through the years he's watched him slowly 'switch off' and does think his mental health has been affected. Sd he 'couldn't tolerate Dur' and tried to get him on it a few years ago. I asked to try it again. Since he's been on cp meds for so long, he should do well on it. Aci-fast and mc. He's rxing a lot now." (Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 55:5-56:5; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Michael Hull	February 3, 2004 Clinton, OK	"Lunch - discussed use of dur instead of oral med's. Discussed allen study and showed how pat on dur will see significant improvement in physical functioning, such as qual of sleep. Dr asked for me to bring

		speaker into office during [sic] lunch. Dr converted pat from oxy to dur while I was in office. Use of voucher for pat to try. Discussed pat asst. program. Ult - ub4 schedule med. Compare to hydrocodone." (Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 56:6-57:13; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	April 1, 2004 Okmulgee, OK	"Asked him what would keep him from rxing Dur? Sd if we take that out of it, then Dur is best choice. Showed him Allan and talked about 'younger' pt and inc. funtionality. Compared it to Oxy cost-wise and stressed that Dur was less in higher doses and comparable in low doses. Ult-'other end of pain' 3 reasons." (Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 57:14-58:16; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Eric Thornhill	February 4, 2004 Oklahoma City, OK	"dur-clbp pt waking at night to take b-through med-has neuropathic associated pain. after showing him simpson, he asked if there had been longer studies. we went through milligan in which he was very impressed, especially with the sf-36 scores. he find that test very valuable in a study. he said he would use dur before going to another lao with function as his primary goal. ult-ub4" (Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 70:14-71:18; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	May 18, 2004 Tulsa, OK	"Simpson. Referred to prev abuse story. I emphasized for every Dur story, there are probably 100 Oxy/Lortab stories. 'Oh I know it'. Told us about pt who died and was taking Avz and 'freaked the rep out'. He says he mainly uses Dur and Avz. Ult-gave him hour glass and he confirmed he used it himself. 3 reasons to Ub4."

		(Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 71:19-73:1; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	July 29, 2004 Tulsa, OK	"Coffee mug, Simpson, sleep. Mentioned a fibro pt of Dr. B's who sd Dur doesn't work. Sd he doesn't believe her. Thinks she wants pill. Sd he wants her to have Dur b/c it's 'non-addictive'. I showed him DAWN and sd pts could get tolerant to it and physically dep on it, but bc it doesn't give a euphoric feelings, it does have less potential for abuse and diversion. He agreed. Ult-oa pt with flare, Smith study/ They still have bags of Ult in closet." (Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 74:22-76:17; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	December 19, 2002 Tulsa, OK	"Asked about abuse potential with Dur. Showed him DAWN data in vis aid. Also discussed titration and conversion." (Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 79:13-21; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Eric Thornhill	September 16, 2003 Ada, OK	"dur-asked for him to write dur over oxy for better pain control and vitality in clbp pts. we looked at the vis aid. he agreed aci-he said that healthchoice was the primary plan in his office. follow up that for those pts, they will have to pay a slightly higher copay, but it will virtually be nullified considering aci can be taken prn where nex has to be taken qd." (Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 88:17-88:25, 90:12-24; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	July 8, 2003 Tulsa, OK	"Left 3 vouchers. Was very glad to get them, never had them before. Sd he uses mainly DUR and Oxy when rxing lao. Sd one thing he likes about Dur is low abuse potential. Showed him DAWN data in vis aid. Also sd he likes 72 hour dosing and how long it

		works. Sd his main pt pain pop is worker's comp, so he's suspicious when they say Dur isn't working. Gave him file card and covered titration and conversion. Lunch in a couple of weeks. Bring dosing wall chart." (Trial Tr. (5/31/19 a.m., J&J: Deem-Eshleman) at 87:15-88:16; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Eric Thornhill	March 11, 2004 Oklahoma City, OK	"dur-dr. Kessler spoke. objections that came up lie around abuse, aberrant behavior, and overall efficacy. dr kessler positioned dur as a first line treatment after sao for several reasons. It gives him the opportunity to address pts outside problems besides medication issues they frequently have when on pills. second, it is the best defense against abuse potential. finally, it is 72 hrs. if pts want a long acting, then why wouldn't they want the longest acting. ult-addressed toward the fibromyalgia pt due to formulation of ssri and opioid." (Trial Tr. (5/31/19 p.m., J&J: Deem-Eshleman) at 6:21-8:2 Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Holly Abraham	March 24, 2004 Oklahoma City, OK	"CLOSED FOR PT WITH CLBP DUE TO INJURY ON SA ATC NOT SLEEPING THROUGHT THE NIGHT TO BE MOVED TO DUR FOR 72 HOURS OF PAIN CONTROL. TOLD ME THAT PT CHEWED THE PATCH AND GOT SICK. REINFORCED THAT DUR IS LESS ABUSABLE THEN THE OTHER LA ON THE MARKET. HIT ON ULTRACET FOR ACUTE PAIN" (Trial Tr. (5/31/19 p.m., J&J: Deem-Eshleman) at 11:10-13:9; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Holly Abraham	April 8, 2004 Enid, OK	"ASKED WHEN HE MOVES PT WITH CLBP DUE TO INJURY IN SA ATC NOT SLEEPING THROUGH THE NIGHT TO A

		LA. SAID WHEN THEY ARE ON TO MANY LORATAB. WENT OVER WHY HE SHOULD MOVE PT TO DUR FROM THE SA. WENT OVER STEADY STATE GRAPH. TOLD ME THAT DUR CAN BE ABUSED. WENT OVER DAWN DATA AND WHY IT IS LESS ABUSED THEN ORALS. HE BROUGHT UP COST. WENT OVER COST. HIT ON ULTRACET. HE SAID IT WAS HIS FAVORITE." (Trial Tr. (5/31/19 p.m., J&J: Deem-Eshleman) at 16:15-17:1; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Holly Abraham	June 28, 2004 Oklahoma City, OK	"GOOD HIT ON DUR. WENT OVER BENEFITS OF DUR AND WHY HE SHOULD CONTINUE TO RX DUR FIRST LINE. ASKED ME TO GET HIM A PAIN CONTRACT FROM A PAIN SPECIALIST BC HE WANTS TO PROTECT HIMSELF. WENT OVER DAWN DATA TO REINFORCE DUR BEING LEAST ABUSED LA. HIT ON ULTRACET FOR ACUTE PAIN PT WITH KNEE PAIN." (Trial Tr. (5/31/19 p.m., J&J: Deem-Eshleman) at 17:13-18:1; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Mark Medina	July 15, 2004 Lawton, OK	"Lunch- siad [sic] that he was seeing a lot of dem pat. and is using a lot of rem. asked for cont use of rem before air and how there [sic] data showes [sic] very min gains compared to rem. RIS-reminded him of the wealth of data that ris has compared to serq. I also gave cost savings. DUR- said the he got a new pat. on dur that has low back pain. Shared that he worries about abuse a lot. I reminde[d] him of the low abuse rate with Dur (dawn data)" (Trial Tr. (5/31/19 p.m., J&J: Deem-Eshleman) at 17:13-18:1; Ct. Ex. 17 (excerpts from S-2481 – S-2492))

Eric Thornhill	August 20, 2004 Midwest City, OK	"dur-continue to position dur 1st line primarily due to abuse potential. works well with pharmacist across the street with daw and pull through on ult so he says ult-ub4" (Trial Tr. (5/31/19 p.m., J&J: Deem-Eshleman) at 19:15-24; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	September 30, 2004 Tulsa, OK	"Ult- showed him Fricke. Dr. brought up Vioxx issue. Did say that he thought it was "bull". Dur- mentioned staff's bro who licked the gel and had to be intubated. Reminded him that it's very rare and many more incidents of abuse with orals. Agreed." (Trial Tr. (5/31/19 p.m., J&J: Deem-Eshleman) at 21:1-24:17; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Kelly Elfstrom	October 7, 2002 Roland, OK	"DUR: said he refuses to use it in a 40 year old because does not want them addicted that young. showed simpson. did not alter his opinion. would only do so if pain specialist recommended. said he uses dur for older/malignant pain. nc: go with the older/malignant pat. talk about functionality. Vouchers? aci: said he prefers nexium. told about warrington data and showed fast. said he had just switched a pat from nex to aci. CLOSE FOR nexium pat. spx: left samples. nc: ask if has used the samples? sell and CLOSE against lamisi!!" (Trial Tr. (5/31/19 p.m. &J: Deem-Eshleman) at 63:25-66:1; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	July 29, 2004 Tulsa, OK	"Coffee mug, Simposon, sleep. Mentioned a fibro pt of Dr. B's who sd Dur doesn't work. Sd he doesn't believe her. Thinks she wants pill. Sd he wants her to have Dur b/c it's "non-addictive". I showed him DAWN and sd pts could get tolerant to it and physically

		dep on it, but bc it doesn't give a euphoric feelings, it does have less potential for abuse and diversion. He agreed. Ult-oa pt with flare, Smith study/ They still have bags of Ult in closet." (Trial Tr. (5/31/19 a.m. &J: Deem-Eshleman) at 74:22-76:17; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Angela Rogers	March 18, 2005 Moore, OK	"2 ways to reduce Lortab business. Use before Lortab with proper dosing for comparable efficacy. I closed for strains/sprains pts from spring break. Nice weather, people become more active and skiing trips. Duragesic updates and importance of daw. Closed for conversion pts with DAW. (Trial Tr. (5/31/19 p.m. &J: Deem-Eshleman) at 48:15-49:8; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Holly Abraham	March 22, 2005 Oklahoma City, OK	"GOOD HIT ON USING ULTRACET FOR SPRING BREAKS, SPRAINS AND STRAINS BEFORE LORTAB, HE SAYS THAT HE DOES NOT USE LORTAB IF HE CAN HELP IT. WHEN PT PAIN PROGRESSES MOVE THAT PT TO DUR AND WRITE DAW ON RX AND EDUCATE PT NOT TO ACCEPT GENERIC." (Trial Tr. (5/31/19 p.m. &J: Deem-Eshleman) at 52:5-53:1; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	September 10, 2003 Tulsa, OK	"Dur-showed Milligan. He asked what other measurements were used. "were there 10 and Dur just scored better in these 4?". Told him new vis aid shows all the measurements and Dur is fav in majority and tied in a couple." (Trial Tr. (5/31/19 a.m. &J: Deem-Eshleman) at 34:4-35:4; Ct. Ex. 17 (excerpts from S-2481 – S-2492))

Melinda Dickson	September 15, 2003 Tulsa, OK	"Lunch. Sd he uses "a lot of patches". But stated he sends pts to pain clinic and they come back on methadone. Talked about clb oa pt on atc sao's. Used Milligan and talked about vitality and better sleep. Brought up cost again. Took those pts out and asked if there is any reason he wouldn't use Dur. "no". For pts where cost is an issue, use vouchers to trial. NC-one question, don't let him let me get off message w/ meth." (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 37:3-40:24; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	August 4, 2006 Tulsa, OK	"Coffee mug, Allan, Milligan, sleep. Ult-Dr. Lade asked about risk of seizures. Told him there was a warning, however studies showed that pts on ultc did not exp more inc risk of seizure due to lower amount of tramadol. Dr. M sd he had taken it once for his back and made him "feel funny"." (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 33:6-35:4; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Kelly VanBurkleo	July 1, 2002 Tulsa, OK	He sd he mainly uses Dur. 50mcg patch. I asked him what doses does he start Oxy. He sd mainly 40bid, some 80bid, but rarely 20bid. He sd he likes the cont. serum levels of dur. and less constipation. I askedso why does he not use dur. first line. He sd alot of factor he has to consider- will the women like wearingthe patch in the summer. He likes to give the patient a choice. I discussed pat. preference- Allan and Payne study. (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 40:22-41:22; Ct. Ex. 17 (excerpts from S-2481 – S-2492))

Eric Thornhill	July 23, 2002 Shawnee, OK	"Dur - Seer Dur somewhat equivalent to Oxy. Uses in cancer pain and degenerative spine diseases. NC: Show Allan Study (non-malignant). Go head to head with Oxy & discuss quality of life benefits Aci – Uses much. NC: Find out why he chooses what Spor - Like pulse dosing, requested samples." (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 41:23-47:17; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Holly Abraham	February 26, 2003 Oklahoma City, OK	"FOLLOWED UP FROM LAST CALL,WENT OVER CALCULATOR, DISCUSSED. ALLAN REPRINT AND DAWN DATA. SAID HE HAS FEW PEOPLE IN MIND TO START ON DUR. HIT ON ACX" (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 49:24-50:16; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Michael Hull	April 16, 2003 Lawton, OK	"Dur - discussion of allen study and how o/a pat with clbp will see significant improvement in social functioning if converted to Dur from round clock sao, Dr agreed. dr stated that key is to try on Dur when first going to lao. Don't go to morphine if you can go to Dur first. Aci - new msg, why wait, went over new indication and brought back to GERD pat will see relief on day one." (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 50:17-51:6; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Michael Hull	August 4, 2003 Anadarko, OK	"Dr stated that he is begining to use more lao and Dur has become first choice due to low abuse potential and 72 hr dosing. discussed allen study and o/a pat will imp s/f if

		converted to Dur from round clock loratab, dr agreed." (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 52:22-53:14; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	November 3, 2003 Tulsa, OK	"you told me that last time". Showed him Milligan instead of Allan. Sd he likes Dur and he likes it and uses it all the time." (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 53:15-54:8; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Eric Thornhill	November 13, 2003 Ada, OK	"dur- he asked me why he should write dur over avi. we went through the 72 hrs vs 24hr. follow up with peaks and troughs from the orals on that point. we went through the side effect profile. he agreed dur was a better med for the pt he was describing. reinforce the consistency dur has compared to other orals and refer to the allan for global efficacy compared to mor." (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 54:9-55:4; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	April 1, 2004 Okmulgee, OK	"Asked him what would keep him from rxing Dur? Sd if we take that out of it, then Dur is best choice. Showed him Allan and talked about "younger" pt and inc. functionality. Compared it to Oxy cost-wise and stressed that Dur was less in higher doses and comparable in low doses. Ult-"other end of pain" 3 reasons." (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 57:14-58:16; Ct. Ex. 17 (excerpts from S-2481 – S-2492))

Holly Abraham	August 4, 2004 Edmond, OK	"TALKED ABOUT PT WITH CLBP DUE TO INJURY ON SA ATC TO BE MOVED TO DUR OVER KADIAN. WENT OVER ALLAN TO VALIDATE WHY DURAGESIC IS BETTER CHOICE WHEN TAKING PT TO LA FROM SA.HE ALSO WANTED TO KNOW HOW DUR IS METABLIZED BC HAS PT WITH ONE KIDNEY.WENT OVER PI WITH HIM.HIT ON ULTRACET" (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 58:17-63:7; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Kelly VanBurkleo	July 13, 2002 Tulsa, OK	"Dur: Still says that some patients like taking pills b/c they think they have control over their pain. Told him that no, they are being reminded that they have pain every time they have to take a pill. NC Keep showing the Allen and Simpson study that patients prefer the patch. SPX: Went over Lft and contraindication information." (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 63:8-24; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Kelly Elfstrom	October 11, 2002 Roland, OK	"used simpson study to show dur can work in non-malignant disease states nc: continue to show simpson/allan/milligan and equal analgesia data aci: nc sell against prevacid" (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 66:2-10; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Holly Abraham	July 30, 2003 Oklahoma City, OK	"CLOSED FOR CLBP PT ON SA ATC,5-6-7 LORATAB WHICH IS EQUAL TO 25MCG,TO BE MOVED TO DUR FOR BETTER PAIN CONTROL AND INCREASED FUNCTIONALITY. WENT OVER SIMPSON STUDY TO BACK UP

		INFO. NEXT CALL ASK IF EVER A TIME THAT HE WOULD USE AN ORAL OVER DUR. SHOW DAWN DATA BC HE MENTIONED THAT HE DOES NOT LIKE NARCOTICS. (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 68:3-70:13; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Eric Thornhill	May 19, 2004 Oklahoma City, OK	"dur-clbp pt with oa, taking sao atc - when pts complain about sleep, does that influence your prescribing of a lao? he said it didn't and we looked at the simpson and how compelling evidence shows that this is a major concern for cp pts. he said he would consider this area of fx and give this pt dur instead of oxy if this is a complaint. ult-ub4 (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 73:14-74:8; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	July 22, 2004 Tulsa, OK	"Simpson. Coffee mug. Sleep, clb pt. Ult-3" (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 74:9-20; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Lovekesh Babbar	January 9, 2002 Oklahoma City, OK	"FU on the benefit the visual aid has brought to the nurses and if pts are using them as well. Bring pain rulers when I recieve them." (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 76:18-77:8; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Kelly Elfstrom	October 4, 2002 Heavener, OK	"dur: said he had not had the opportunity to try the vouchers yet. asked him why he does not prescribe dur unless orals fail? responded cost. said that he prescribes some generic oxycodone. told him that vouchers could help with cost. when asked how important

		functionality is when treating cp he said it is. showed the allan study in vis aide. nc: reshow allan study in the visual aide, ask if this shows in his mind how dur allows his patients to restore functionality over the orals? if not clarify why. CLOSE with dr, now that i have shown you superiority of dur over orals in terms of allowing your pat to regain their QOL will you use a dur voucher and allow your next pat on s.a. around the clock to experience dur over orals?" (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 77:9-79:1; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	October 17, 2002 Fairfax, OK	"Went over DAWN data in vis aid. Sd pts who he titrated up are all doing very well now that they are on appropriate dose. Spx-just started a young pt yesterday with tinea vers." (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 79:2-12; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Michael Hull	December 2, 2002 Lawton, OK	"Dr said that she does not like to prescribe opioids. Dr said that opioids are "last option" and Dr is concerned with abuse potential. Went over Dawn data and explained that Dur has a low abuse profile and over 10 years of proven efficacy. Next time ask if Dr has had any new experiences with Dur and explain benefits of Dur." (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 91:1-19; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	January 27, 2003 Miami, OK	"Dur-left 2 vouchers and talked about use for OA and back pain. Sd he used to write Vicodin, but he tried not to put anyone on SAO, mainly Nsaids and Cox 2's. Asked him

		to rx for any OA who is on rc SAO. Mentioned 21yo who got hold of 100 mcg of cancer pt rel who died and had them. Sd he OD'd on it. Shared DAWN in response to that and he agreed that Dur low abuse potential. NC-do more of "paint the picture" with OA and remind that he "doesn't like" to put pts on SAO due to abuse potential. ACI-he and wife both on it and says it works great. Set up Teletopic for 3/5 with Dan D." (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 91:1-19; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Holly Abraham	February 20, 2003 Oklahoma City, OK	"DINNER. GOOD CALL,UNCOVER BIG OBJECTION TO DUR AND THAT IS ABUSE. FOR SOME REASON THINKS DUR IS ABUSABLE,TALKED ABOUT DAWN DATA.TREAT MAINLY CLBP AND NECK PAIN. WILL USE MS COTIN OR OXY. TRIED DUR ONCE AND PT FREAKED OUT ON IT. DOESNT KEEP PT ON SA WILL SEND OUT.PAINTED PICTURE OF PAT WITH CP ON SA VRS DUR LOOK LIKE. TALKED ABOUT BENEFITS OF DUR. HIT ON CONVERSION,BRING HIM CALCULATOR, ALLAN AND SIMPSON STUDY. CLOSED FOR PAT TO BE STARTED ON DUR,HE SAID IT WILL HAVE TO BE PT HE CONVERTS OVER FROM CURRENT REGIME BC ISNT SEEING NEW CP PATIENTS." (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 92:24-94:10; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Holly Abraham	June 30, 2003 Stillwater, OK	"WALKED IN TALKING ABOUT ABUSE OF DUR AND HOW TO ABUSE IT WITH SUCKING IT OUT OF PATCH.BROUGHT UP DAWN DATA TO SHOW LOW ABUSE POTENTIAL OF DUR. ASKED

		WHERE HE USING DUR EITHER AFTER SA ATC OR AFTER OXY OR MS HAS FAILED. SAI DHE USES IT EVERYWHERE. WENT INTO ALLAN STUDY TO SHOW BENEFITS OF DUR OVER ORAL AND HIT ON FUNCTIONLITY. CLOSED FOR THAT CLBP PT ON SA ATC NOT GETTING PAIN CONTROL THAT HE IS HAPPY WITH TO BE MOVED TO DUR." (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 94:23-96:8; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Michael Hull	July 15, 2003 Altus, OK	"Dr brought up abuse potential due to 19 yr old pat that was abusing oxy and was just sent to Drug rehab. Discussed Dur low abuse potential and went over Dawn data. Dr stated that none of his pat's abuse med's. Then discussed improvement in s/f o/a pat will see if converted to Dur. Aci - day one, why wait" (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 96:9-97:14; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	August 20, 2003 Tulsa, OK	"Lunch with Jeri. Dr. mentioned pt who had been taken to ER for injecting Dur. Pt was found in car passed out. Left ER AMA. Is this the first pt you've had shown up at the ER on short or long acting opioids? Possible? But don't bring it up unless he does. Shared DAWN, he mentioned hydrocodone. Suspect he has many pts on hydrocodone. Sd that every few months he "cleans his practice out". How does he do that? Where do they go? Dr. is dieting. NC-explore clb pt that he ?'d me about last visit. Allan. Becky is gatekeeper." (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 97:15-98:18; Ct. Ex. 17 (excerpts from S-2481 – S-2492))

Melinda Dickson	October 14, 2003 Tulsa, OK	"Dur-sd that it's going to be worse with all the pub about R. Limbaugh and Oxy. I sd the main reason to rx Dur is the pain control and inc function pts get, but STRONGLY emphasized low abuse potential for Dur and shared DAWN. I'm sure Avz is saying that Dur has high abuse potential. Aci-United HC. Asked to switch PRIL and ome pts to Aci. Dr. sd "I don't do that, Joanne does". So I asked Joanne to please switch." (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 98:19-100:8; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	February 19, 2004 Tulsa, OK	"Saw him with Greg. Sd only thing we coudl do for him is bring him any info. on ways to divert Dur. I showed hin DAWN and sd it's no street value and low abuse potential. Greg suggested we could bring DEA agent to talk to him. Emphasized when someone does divert it's usually not repeated. Either fatal or they do not get affect they are looking for." (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 100:9-103:13; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	November 4, 2003 Tulsa, OK	"Gave him Pinnacles in PM mug and materials. According to Yvette, he went through a period of "not wanting to rx any narc's". I probed more and asked what narc's spec? She just sd all, then sd they seem to have more problems with Soma and Lortabs. I shared DAWN and sd that if he was concerned about abuse, then I didn't understand why he does't rx more Dur due to it's low abuse potential. She agreed. Sd they are trying to do more screening up front and wants to make it harder for pts to get the meds. They have also been doing drug screens. Maybe now he won't give pts the choice, which is what he has told me is the reason he does't rx as much Dur."

		(Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 105:10-106:9; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	November 10, 2003 Tulsa, OK	"So hard to get anything solid with him. Was talking about pt he just fired b/c he claimed his mom took his pills. Emphasized that Dur has no street value. Sd "well, I changed my rxing habits after a couple of pts died". I again shared DAWN and sd people will be much more likely to abuse Oxy or Lortabs. He agreed and sd he wasn't going to give Lortabs out. While I was there, Joanne came in and sd fem pt wanted to take more breakthrough meds. He looked through chart and sd "I haven't ever put her on Oxy, rx 15mg of Oxy". Sheesh!" (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 106:10-107:6; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Holly Abraham	March 12, 2004 Yukon, OK	"BREAKFAST SPEAKER PROGRAM. HIT ON KEY POINT WITH DRABEK. HE DID AGREE WITH SPEAKER BUT WAS A LITTLE RESISTENT AT TIMES. SPEAKER PUSHED USING DUR FIRST BC LOW ABUSE POTENTIAL." (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 107:7-110:10; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Holly Abraham	April 20, 2004 Yukon, OK	"HE STARTED TALKING ABOUT PT WHO WAS FORGING RX OF NARCOTICS. BROUGHT UP FACT THAT DUR IS LESS ABUSABLE THEN THE OTHER SA AND LA ON THE MARKET. CLOSED FOR PT WITH CLBP DUE TO INJURY ON SA ATC NOT SLEEPING THROUGH THE NIGHT TO BE MOVED TO DUR FOR 72 HRS OF PAIN CONTROL.TALKED ABOUT HOW SLEEP DETERMINES MOOD AND DAY

		OF THESE PAIN PT. HIT ON ULTRACET BEFORE LORATAB" (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 110:14-112:5; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Holly Abraham	July 30, 2004 Yukon, OK	"HIT ON MOVING PT WITH CLBP DUE TO INJURY ON SA ATC NOT SLEEPING THROUGH THE NIGHT TO DUR. WENT OVER LOW ABUSE POTENTIAL BC HE TOLD ME LAST TIME THAT HE CONCERNED WITH ABUSE WITH CP PT.HIT ON ULTRACET" (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 112:6-23; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	January 30, 2003 Muskogee, OK	"Dur-sd he just started cancer pt. Sd he really tries not to write narc for non-cancer pain. Sd there probably is some DJD clb pts with CP that is worse than cancer pain, but avoids them. Lortabs are SAO of choice and sd he does have DJD pts on 4-6 a day. Enforced that 25 mcg is equalanalgesic to that and showed him DAWN data and greater likelihood that pts would abuse lortabs than Dur. That seems to be his major issue. He agreed it made sense to put on Dur. Gave him 3 more vouchers. ACI-showed us his "nasty gram" about Protonix deal with hosp. Asked him to rx ACI for office pts." (Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 112:24-114:15; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Michael Hull	June 25, 2003 Frederick, OK	"Dr stated that she will go to lao asap, due to abuse potential of hydrocodone. Discussed that not only does Dur have low abuse potential but because of 72 hr dosing, the steady serum level will help improve pat's mental health. Aci - Fast, why wait."

		Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 114:16-115:3; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Michael Hull	July 14, 2003 Stillwater, OK	"Dr stated that she is very concerned with ability to abuse lao's. Discussed DAWN data and that Dur should be first choice when going to lao because of this, but also because of improvement in social functioning if converted to Dur from round clock sao. Dr said she wants to convert asap and get off of sao's. Went over Allen study and also pain contracts, together Rx and conversion chart." Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 115:4-116:1; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Heather Stewart	August 26, 2003 Oologah, OK	"Asked what pt gets Oxy. Says he goes to the orals first? Why? he feels pt are more compliant. He mentioned abuse and that he had a pt in the nursing home that had to be warched when discarding the Dur patch. TT re Oxy being more abused than Dur. Asked to go to Dur First. He asked for some vouchers." Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 116:2-21; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Eric Thornhill	September 4, 2003 Newcastle, OK	"dur-we went through the pain chronicles over lunch and they felt there were some key takeaways that would influence them in their prescribing. most of all it triggered their minds seeing qualified professionals put them at ease. we addressed how to identify aberrant behavior, what to do with those pts and why dur is the only option for the potentially abusive pt." Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 116:22-117:23; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Holly Abraham	October 13, 2003 Oklahoma City, OK	"GOOD CALL ON DUR.TOLD ME THAT AVINZA TOLD HIM HOW DUR COULD

		BE ABUSED.TOLD HIM THAT WAS A MYTH AND IT IS UNFORTUNATE THAT THEY HAVE TO SELL LIKE THAT WHEN I SELL DUR BENEFITS AND HOW IT WILL HELP YOUR PAIN PT. HIT ON ACX" Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 121:8-122:17; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	November 5, 2003 Tulsa, OK	"Sd her pts on Dur are still doing well. I probed a little more and she sd, "well one lady liked it so well, she put too many on". She is going to refer her to PS. Asked which ones she refers to and she sd dep on ins. Nurse sd usually Christopher or Tulsa Pain. Asked nurse about pt she was talking about using too much. She sd she was using too much of all her meds and orals got her put in hospital. She sd they did not think it was the patches. I emphasized low abuse potential and fact that putting multiple ones on can cause some prob's. She sd she was "self meding". Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 122:18-124:13; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	December 1, 2003 Sapulpa, OK	"Talked about difference bet abuse and addiction. Believes addicts don't abuse as they don't have a choice, but people who abuse have a choice. I stressed that some docs are hesitatnt to rx opioids b/c they get dependence and addiction confused. He agreed. He had not used any vouchers, but sd he was still rxing, just hadn't needed to use vouchers. Avz is down!" Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 124:14-127:15; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Michael Hull	November 10, 2003 Ardmore, OK	"Dur - clbp pat on round the clock sao, conv to Dur. 3 key benifits of Dur over oral's. 1) q

		72 hr, 2) imp in functionality 3) dawn data. Dr stated that he is only seeing a few pain pat's due to abuse problems with med's, but because of dawn data, will only prescrive dur from this point forward. If pat can't be controlled on Dur he will refer to pain specialist in okcity. Aci- core msg, formulary status" Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 127:16-128:24; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Holly Abraham	January 20, 2004 Enid, OK	"HIT ON DUR AND ULTRACET. SAID HE RESERVES DUR FOR HIS NURSEING HOME PT BC HE HEARD THAT PEOPLE USE LEFT OVER DUR AND PUT A HAIR DRYER TO IT. ASSURED HIM THAT DUR HAS LOW ABUSE POTENTIAL. SHOW HIM DAWN DATA NEXT TIME.HIT ON HIM USING IT FOR CLBP,OA RA.SAID SINCE HE IS HAVING SUCCESS IN NURSING HOME WILL HAVE SUCCESS IN CLINIC PT.HE WILL REFER CANCER PT OUT.HIT ON ULTRACET.HE LIKES I BC IT IS NOT A SCHEDULED DRUG" Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 128:25-130:3; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Eric Thornhill	January 22, 2004 Oklahoma City, OK	"dur-he has some confidence in dur but has a itchy trigger finger if they complain. he is getting more and more comfortable with it but still has some small objections he's needing to overcome. continue to focus on function because it is extremely important to him. reinforce the low abuse of dur and importance of proper application but get back to function. speak about the pts who are in pain and not as much about those potentially abusing meds."

		Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 130:4-131:6; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Michael Hull	January 26, 2004 Lawton, OK	"Discussed clbp pat on 6 loratab per day. If pat is converted to dur pat will see imp in s/f and get 72 hr of pain relief. Dr agreed and stated that he had pat on dur that was just picked up by police with possession of meth. Dr stated that dur can be abused just like oral meds. Went over DAWN data and dr felt better after seeing this info. Ult - comp to hydrocodone" Trial Tr. (5/31/19 a.m. J&J: Deem-Eshleman) at 131:7-133:15; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Holly Abraham	February 26, 2004 Woodward, OK	"GOOD HIT ON MOVING THAT PT WITH CLBP DUE TO INJURY ON LORATAB ATC NOT SLEEPING THROUGH THE NIGHT TO DUR BC DUR IS THE ONLY LA TO OFFER 72 HRS OF PAIN CONTROL.HE DID AGREE THAT WE ARE THE ONLY ONE TO DO THAT. TOLD ME ABOUT LAW SUIT THAT HE WAS INVOLVED IN OVER DUR AND NURSING HOME PT WHO DID BC SHE HAD 3 PATCHES ON. ALSO TOLD ME THAT PT SON WAS GIVING HER HIS LORATAB AS WELL. ASKED HIM IF THIS WILL EFFECT HIM RX DUR. SAID HE STILL USES IT BUT IS MORE SCARED TO USE LA IN NURSING HOMES. WENT OVER LOWER ABUSE POTENTIAL WITH DUR AND THE FACT THAT YOU CANT SHARE YOU PATCHES LIKE YOU CAN LORATABS SO THAT IS WHY IT IS IMPORTANT TO MOVE THOSE PT TO DUR. HIT ON ULTRACET" Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 5:8-6:20; Ct. Ex. 17 (excerpts from S-2481 – S-2492))

Melinda Dickson	September 1, 2004 Tulsa, OK	"Vouchers. RS Medical rep there and was talking about Dur chiclets and heat. Kim had heard at pain nurse program about abuses for Dur. I emphasized how rare it is comparatively speaking and no street value. NC-matrix tech piece and DAWN." Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 20:14-25; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Angela Rogers	December 3, 2004 Purcell, OK	"We talked about her tx of pain. She said she avoids oxycontin due to drug seekers. We talked about duragesic and how the abuse potential is very small. She talked about referring pts to pain specialist because they are more qualified to deal with pain. We talked about ultracet being non scheduled and comparable to hydrocodones. This call took place on 11/24/04." Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 24:18-25:22; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Angela Rogers	December 6, 2004 Norman, OK	"Introduced self and new products. He said he avoided using scheduled drugs. I talked to him about his tx regimen. He said he refers patients to pain management. He discussed hassles of drug seekers. I hit on patch technology and low abuse potential. I hit on DAW. I asked him for trial patient when he uses lao. He agreed. He said he uses ultracet wherever possible." Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 25:23-26:21; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Eric Thornhill	February 1, 2005 Oklahoma City, OK	"dual speaker program - speakers covered off on efficacy/safety/regulation. abuse potential was the foremost directive the speakers addressed. florete spoke about his practice in how abuse potential is recognized and what they are looking for in a cp med. he addressed some critical differences bw dur

		and the matrix and reinforced DAW. coleman touched on the regulatory side of rx'ing. documentation and other means to protect yourself were the premise of his discussion. he too reinforced the favor dur has in the eyes of the dea. not only is it difficult to abuse, documentation and early refills are much less." Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 26:21-27:16; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Holly Abraham	February 23, 2005 Oklahoma City, OK	"USED PS THAT I HAVE 2 WAYS TO HELP HIM AVOID RX SAO. BY USING ULTRACET INSTEAD OF LORATAB FOR PT WITH SPRIANS AND STRIANS AND WHEN A PT IS ON COX 2'S AND HAVING FLARE UP PAIN AND WHEN THAT PT PROGRESS TO LORATAB ATC MOVE THEM TO DUR FOR 3 DAYS OF PAIN CONTROL.RX DUR DAW. SAID THAT HE IS CONCERNED WITH RX SO MUCH DUR AND I REASSURED HIM THAT DUR HAS NO STREET VALUE AND IS LEAST ABUSED." Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 27:17-28:19; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Angela Rogers	April 29, 2005 Ardmore, OK	"DAW reminders to all nurses and thanked them for their help. We talked about abuse in the ardmore area. Benefits of dur discussed: less abuse potential, family members less likely to steal from loved ones and consistent relief for 3 days." Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 28:20-31:5; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Holly Abraham	March 21, 2005 Oklahoma City, OK	"GOOD HIT ON ULTRACET FOR HIS SPRING BREAKS,SPRIANS AND STRAINS RX ULTRACET BEFORE LORATAB BC OF BETTER SIDE

		EFFECT PROFILE AND LESS ABUSE POTENTIAL. HIT ON DUR AND COMMITTMENT TO WRITE DAW ON RX." Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 50:24-52:4; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Angela Rogers	March 22, 2005 Ardmore, OK	"Luncheon: Ultracet spring break blitz. I talked to doctors and staff about ultracet for spring break's, sprains and strains. I asked them to use ultracet w/proper dosing over lortab. P.A. told story about problem pt and using tramadol. I talked about using ultracet for pts because it is not a narcotic but will effectively relieve pain. I asked them to use ult instead of others. They said they have been using ult. DAW reminders for all doctors and nurses. Ronnie remembers." Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 55:8-57:3; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Holly Abraham	March 23, 2005 Reno, OK	"2 WAYS TO REDUCE LORATAB IN CLINIC,ULTRACET FOR SPRING BREAKS,SPRAINS AND STRAINS AND WHEN PAIN PROGRESS RX DUR DAW AND EDUCATE PTS TO SAY NO TO GENERIC SINCE NOT ALOT IS KNOWN ABOUT THEM AND ELIMINATE HASSEL OF PAPERWORK ON CASE FAILS GENERIC." Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 57:18-58:25; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Angela Rogers	March 24, 2005 Shawnee, OK	"Duragesic - Daw reminder with rebate coupons and mc update. ult - before lortab with proper dosing for spring break strains and sprains. Agreed."

		Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 59:1-11; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Angela Rogers	March 24, 2005	"Ultracet before lortab for spring break pts. We talked about march madness and how pts are more active when weather gets nice. Closed for proper dosing of ultracet for this pt types before lortab. Agreed. daw- he said he forgets to write daw. I told him that is what I am for. I talked about situation at pharmacy and importance of writing daw. Talked about how long it takes to get pts pain controlled and how pts shouldn't risk getting switched. Reviewed rebates." Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 59:1-11; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Angela Rogers	March 30, 2005 Duncan, OK	"DAW message and importance of keeping pts on pain relief they have worked so hard to control. I asked them to use rebate coupons. They talked to me about hospice pts. They agreed to write daw. ult - proper dosing for spring breaks sprains and strains." Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 60:5-61:2; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	March 29, 2005 Bartlesville, OK	"Fast Break Spring Break Blitz. 2 tab dosing. Reduce # of lortab rxs coming out of your office. DAW Dur. "got it'." Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 62:1-14; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	April 8, 2005 Tulsa, OK	"Uct-spring break message, gave him 2 water bottles. Sd to use 2 Uct for people who come in with sprains and strains after going out roller blading, etc. Mentioned UK phase out of co-proxamol. "what??? there won't be anything left on market." in light of Bextra. He asked why and I said due to negative risk/benefit ratio. He just rolled his eyes. I sd

		due to potential for cns se's and cardiac issues particularly in elderly. He wasn't convinced. I asked about giving him link to website and he just said he'd written maybe 7-8 e-mails in his whole life. Not real pc savvy, I guess. Dur-reminder to use coupons and DAW." Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 62:15-23; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Angela Rogers	April 12, 2005 Mcalester, OK	"Breakfast: 2 ways to reduce lortab conversion of 5-6 can't sleep thru night; Confusion at pharmacy, importance of DAW. Process of coupons reviewed with staff. Ult - 2468 1/2 side effects comparable relief - spring break strains; Weather" Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 62:24-63:9; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Angela Rogers	March 30, 2005 Duncan, OK	"Inservice : DAW message brought with sonic. I talked to them about importance of keeping pts on duragesic. Ult - proper dosing for spring break/sprains." Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 63:10-70:1; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Michael Hull	February 24, 2003 Duncan, OK	"Discussed pat asst program for Dur and also Discussed the ability for pat to improve mental health when converted to Dur from round clock SAO. Dr is very concerned with abuse potential. Discussed DAWN data and Dr stated Oxy rep said Dur is abused more than any other LAO. Dr was upset at Oxy rep and said he would re-evaluate his LAO prescribing habits." Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 75:7-76:7; Ct. Ex. 17 (excerpts from S-2481 – S-2492))

Melinda Dickson	July 28, 2003 Tulsa, OK	"Dur-sd she wished she get all her pts on lao and sao on Dur. Sd many don't want to give up pills, but those who are truly in pain "love it" (i.e. Duragesic. Gave her 2 vouchers and asked her to use to convert pts. from sao's to Dur. Showed her conversion chart and she agreed it's a much better product. Sd "you hardly can abuseit', I showed her DAWN. She sd she'd heard a lady's dog had eaten used patches and was in ER for it." Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 77:2-19; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	September 25, 2003 Tulsa, OK	"Gave him 2 more packs of vouchers. Told him last week I'd bring more by. Sure he's being hit by Avinza with theirs, so need to keep him stocked. He sd when he runs out of vouchers, he doesn't start new pts on Dur. May or may not be true, but want to make sure he has them anyway. b" Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 77:20-78:13; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	October 24, 2003 Tulsa, OK	"Rescheduled talk for 11/13. He sd he wants to keep informal. He gave me list of docs he said want to come. Told him my main goal was to help PCP's ID more pts appropriate for Dur. Many just have niched for cancer and elderly. Told him I want him to talk about expanded use of Dur with other cp pts." Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 78:14-79:15; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Melinda Dickson	April 21, 2004 Tulsa, OK	"Amiable - I need to throttle back a LOT. Dur-hasn't used it. Sd cost is big factor. But confirmed he'd used Oxy. Also meth. Spoke to inc. function. Low abuse potential. Asked how it's abused. Exp, but showed him DAWN and before I could say it he said

		"most people don't want to work that hard". I agreed and sd there was so many other rx's available for abuse and easier to get and easier to abuse. Gave him Pt assistance info. Sd he mainly txs back pain. Ult-I NEED more of that business. He rxs a ton of Lortabs. Explained Ultracet. Uses Ultram, but wasn''t familliar with Ultracet. Left him samples. NC-Simpson and Fricke." Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 79:18-84:10, 89:19-90:23; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Angela Rogers	June 14, 2005 McAlester, OK	"5-6 lortab pts who can't sleep thru night with daw. He is a big lortab man. He is a pushover. He said his pts request lortab. I asked him if he lets his pts decide how to manage their pain. He said okla. has more addicts than he has ever seen. I talked about benefits of consistent pain relief, sleep thru night, less abuse potential and less freq. dosing. Closed for one new start. acx - intro with highest ph." Trial Tr. (5/31/19 p.m. J&J: Deem-Eshleman) at 90:25-93:10; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Eric Thornill	February 25, 2003 Oklahoma City, OK	"dur - asked him to try his 4-5 patients currently on oxy on dur. i gave him the placebo patches and asked him to try using them when discussing the conversion. he said he would. i also told him that the cost of dur was less than oxy and it had the same coverage. aci - he asked if aci had good coverage. after telling him, he said he would begin writing aci. his biggest concern is cost." Trial Tr. (6/3/19 a.m. J&J: Deem-Eshleman) at 44:21-45:14; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Eric Thornhill	April 4, 2003 Tulsa, OK	"Dur - said he was having lunch with the oxy rep today. we discussed some things to keep

		in mind as he considers what benefits of oxy compared to dur are. aci - main usage comes from tinker" Trial Tr. (6/3/19 a.m. J&J: Deem-Eshleman) at 45:15-46:13; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Eric Thornhill	May 29, 2003 Midwest City, OK	"dur - still has no difinitive reason apparently for going to oxy or dur when leaving a sao. we discussed both the features fentanyl offers as well as the benefits the pt recieves around functioning. NC: Ask the physician, if your pts are going to fail on a medication, have them fail on dur first. Do baseball game anaolgy of going to a big league game vs little league. Aci - reinforced the Aetna message and asked for conversions with coupons" Trial Tr. (6/3/19 a.m. J&J: Deem-Eshleman) at 46:14-47:20; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Frank Lawler	April 25, 2003 Oklahoma City, OK	"dur - said that an oxy rep was in earlier in the week who asked him how he made his decision b/w oxy and dur. he said he didn't know. we discussed at length several reasons among the four doctors present why dur is a better route. it basically was an opportunity to paint the picture of specific patients and how their lives lack funtion but are in continuous pain. they concurred dur was a great direction for cp management." Trial Tr. (6/3/19 a.m. J&J: Deem-Eshleman) at 47:21-48:22; Ct. Ex. 17 (excerpts from S-2481 – S-2492))
Holly Abraham	September 23, 2003 Stillwater, OK	"HIT ON THE PERFECT DUR PT.MOVING THAT CLBP PT ON SA ATC TO DUR AFTER THEY ARE ON 5-6 LORATAB. WENT OVER STEADY STATE AND LESS PILL POPPING. STARTED TELLINGME THAT HE WANTS TO SPEAK OR JANSSEN. TOLD

		HIM THAT HE IS GOING TO HAVE TO RX MORE DUR AND MORE CLINICAL EXPERIENCE WITH IT. STARTED TELLING ME ABOUT DUR AND ABUSE AND NURSES TAKING THE OLD PATCHES. I SAID HOW MANY MORE PEOPLE DO YOU THINK ARE ABUSING ORAL BC THEY ARE EASIER TO GET AND GET HIGH FROM. (Trial Tr. (6/13/19 a.m., Kolodny) at 98: 7 – 99: 9; Ct. Ex. 61 (excerpts from S-2481 – S-2492))
Eric Thornhill	May 9, 2005 Oklahoma City, OK	"asked for the pts taking lort atc be moved to dur. She sees much Medicaid. Asked linda at the front desk to dispense the coupon and police the DAW's on each script. She get's a Power Aid Sonic when 5 coupons are gone. Follow up on the dinner with Dr. Nguyen first on June. Gave defend message which she agreed to continue putting daw on each script. Covered off on ultracet" (Trial Tr. (5/31/19 a.m., Kolodny) at 99: 10 - 102: 2 ; Ct. Ex. 61 (excerpts from S-2481 – S-2492))
Bradley Dean	April 22, 2004 Chickasha, OK	"Dur: Asked him what he dislikes about CII drugs, he said that they are addictive. I showed him the DAWN Data and told him that was one of the benefits of Dur, the low abuse potential. I told him that when prescribing dur he doesn't have to worry about it when compared to other Rx. Ult: Said that he likes to use Ult because of the low abuse potential. Left samples with a P.A Bill Ohl as well. 30+30=60." (Trial Tr. (5/31/19 a.m., Kolodny) at 102: 3 – 104: 9); Ct. Ex. 61 (excerpts from S-2481 – S-2492))
Melinda Dickson	April 1, 2004 Tulsa, OK	"Sd he finally had someone abuse Dur by eating it, ended up in hospital and almost died. Showed him DAWN and he agreed that it was rare people abuse it. Ult-he uses

		it. He was very down. Sd he was going to divorce lawyer." (Trial Tr. (5/31/19 a.m., Kolodny) at 104: 10 – 105: 2); Ct. Ex. 61 (excerpts from S-2481 – S-2492))
Melinda Dickson	October 9, 2004 Tulsa, OK	"Spencer cooked breakfast. Briefly spoke to Dr. C about Dr. K. Sd he came to her talk in Stillwater. which pleased her. They took more vouchers, but I'm not sure they needed them. She sd she had a pt waiting on the 12. I need to push her to use more Dur. Her #'s are actually down since Ad Board. Hopefully they'll go up after Kessler talk." (Trial Tr. (5/31/19 a.m., Kolodny) at 105: 3 - 15); Ct. Ex. 61 (excerpts from S-2481 – S-2492))
Holly Abraham	March 24, 2003 Oklahoma City, OK	"DAWN DATA TO PUT CONCERN AT EASE" (Trial Tr. (5/31/19 a.m., Kolodny) at 105: 16 - 24); Ct. Ex. 61 (excerpts from S-2481 – S-2492))
Bradley Dean	February 22, 2006 Oklahoma City, OK	"Had lunch with Larry Norton. Larry covered Levaquin and aciphex. I talked about Ultram ER and went over dosing. This office see's more chronic lower back pain as opposed to OA. We need to find out what other types of chronic pain they see and then target those patient types. If anyone finds out soon please let me know. The office is secure with Tramadol but now we need to move them to ER. Went over dosing and left 30 bottles and need to follow up with those trial scripts." (Trial Tr. (5/31/19 a.m., Kolodny) at 105: 25 – 106: 24); Ct. Ex. 61 (excerpts from S-2481 – S-2492))
Melinda Dickson	July 17, 2003 Tulsa, OK	"Long Lunch. Dinner with Lloyd set for 7/24. Talked about conversion/titration. Seems a bit nervous about higher doses of

		Dur or Oxy. Somewhat concerned about abuse, Need to share DAWN. Sd most of his pts on Dur or Oxy still use breakthrough. Seems that he's more comfortable with 100 q48 or 40 bid Dur/Oxy and more sao breakthrough, than just going higher up iwth the lao. Need to continue to bring up his comfort level for using higher doses of Dur when necessary and reduce breakthrough pain. Show clb Simpson and pts pref. Lloyd coaching - want him to be more comfortable using Dur and dosing it higher. Where you use it?" (Trial Tr. (5/31/19 a.m., Kolodny) at 106: 25 –107: 24); Ct. Ex. 61 (excerpts from S-2481 – S-2492))
Drue Diesselhorst	June 30, 2009 Lawton, OK	"had the lunch and went all over all the new info with him-said that he would try it out!" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 184: 1-6; Ct. Ex. 163 (excerpts from S-4497))
Drue Diesselhorst	July 8, 2009 Oklahoma City, OK	"saw Kevin-brought him starbucks-he has been writing it and debi" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 184: 7-10; Ct. Ex. 163 (excerpts from S-4497))
Drue Diesselhorst	July 13, 2009 Norman, OK	"did a lunch there" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 184: 11-14; Ct. Ex. 163 (excerpts from S-4497))
Drue Diesselhorst	July 6, 2009 Norman, OK	"went over all the new Nucynta info with him and mike-brining them lunch next" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 184: 19-21; Ct. Ex. 163 (excerpts from S-4497))
Drue Diesselhorst	July 13, 2009 Norman, OK	"went over Nucynta and also went over ultram er info-booked a lunch." (Trial Tr. (7/2/19 p.m., Diesselhorst) at 184: 19-21; Ct. Ex. 163 (excerpts from S-4497))
Drue Diesselhorst	July 13, 2009 Norman, OK	"had the lunch-went over nucynta and also he said that he had written one script so far"

		(Trial Tr. (7/2/19 p.m., Diesselhorst) at 184: 22-24; Ct. Ex. 163 (excerpts from S-4497))
Drue Diesselhorst	July 13, 2009 Norman, OK	"quick hit with Nucynta-wenot ver all the new info and booked a lunch" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 184: 24-25; Ct. Ex. 163 (excerpts from S-4497))
Drue Diesselhorst	August 6, 2009 Oklahoma City, OK	"brought them breakfast this morning-wrote a n scrpt while I was there" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 185: 1-4; Ct. Ex. 163 (excerpts from S-4497))
Drue Diesselhorst	September 3, 2009 Lawton, OK	"quick hit with nucynta -went over all the info again and scheduled a lunch" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 185: 5-8; Ct. Ex. 163 (excerpts from S-4497))
Aline Nowlin	September 10, 2002 Oklahoma City, OK	"diss ideal for pts in rehab, sd he doesn't have any pts on tid oxy.took 2 pts off oxy b/c of ortho hyp.switched to methadone b/c didn't want them to have w/drawl. Tries to get pts off meds when they leave the hospital,will try to use ultracet or something. Invite to program.sd would be coming" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 187: 16 - 22; Ct. Ex. 162 (excerpts from S2481-S2492))
Eric Thornhill	September 17, 2004 Oklahoma City, OK	"dur-complains about all lao cost issues. he prefers meth first. he likes dur for the reasons we discussed but he deals with many workers comp pts who he thinks need to off opioids all together. he takes them off their lao, puts them on meth for 2-3 wks and takes them completely off their med. ult-ub4" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 187: 23 – 188: 8; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	July 8, 2019 Oklahoma City, OK	"followed up on speaker program" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 193: 20 - 23; Ct. Ex. 163 (excerpts from S-4497))

Drue Diesselhorst	July 28, 2009 Oklahoma City, OK	"quick hit with Nucynta and also ultram er-300 mg dose and reminder of workers comp" (Trial Tr. (7/2/19 a.m., Diesselhorst) at 193: 24 – 194: 2; Ct. Ex. 163 (excerpts from S-4497))
Drue Diesselhorst	August 4, 2009 Oklahoma City, OK	"had my speaker program with moorad" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 194: 3 - 4; Ct. Ex. 163 (excerpts from S-4497))
Drue Diesselhorst	August 24, 2009 Oklahoma City, OK	"followed back up with him from speaker programs and touch base on his use of nucynta -and went ultram er" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 194: 5 - 8; Ct. Ex. 163 (excerpts from S-4497))
Drue Diesselhorst	September 9, 2009 Oklahoma City, OK	"quick hit with nucynta and ultram er" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 194: 9 - 11; Ct. Ex. 163 (excerpts from S-4497))
Drue Diesselhorst	December 14, 2009 Oklahoma City, OK	"quick hit with n and u" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 194: 20-24; Ct. Ex. 163 (excerpts from S-4497))
Drue Diesselhorst	January 11, 2010 Oklahoma City, OK	" " (blank) (Trial Tr. (7/2/19 p.m., Diesselhorst) at 194: 25-195: 1; Ct. Ex. 163 (excerpts from S-4497))
Drue Diesselhorst	Septembr 6, 2011 Oklahoma City, OK	" " (blank) (Trial Tr. (7/2/19 p.m., Diesselhorst) at 195: 20 - 25; Ct. Ex. 163 (excerpts from S-4497))
Drue Diesselhorst	June 26, 2009 Oklahoma City, OK	"went over all the nucynta info and he said that he would start writing it-told me to go by moore rexall to get it stalked there" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 199: 2 - 13; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	July 10, 2009 Oklahoma City, OK	"quick hit with nucynta info-went over how dr. moorad was coming to speak with him next week"

		(Trial Tr. (7/2/19 p.m., Diesselhorst) at 199: 14 - 23; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	July 17, 2009 Oklahoma City, OK	"went over all the new info with them about nucynta and had dr. moorad come in and speak with them" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 200: 7 - 16; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	July 24, 2009 Oklahoma City, OK	"said that he wrote nucynta-5 scripts-brought them lunch" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 200: 17 - 21; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	August 4, 2009 Oklahoma City, OK	"quick hit with nucynta info and also quit hit with the medicaid issue" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 200: 22 - 25; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	August 5, 2009 Oklahoma City, OK	"quick hit with nucynta and followed up on medicaid-hasstle!" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 201: 1 - 14; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	August 13, 2009 Oklahoma City, OK	"wnet over nucynta and callback issue with medicaid" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 201: 1 - 14; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	August 22, 2009 Oklahoma City, OK	"quick hit with nucynta and ultram er-brought breakfast" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 201: 15 - 18; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	September 4, 2009 Oklahoma City, OK	"quick hit wiht nucynta and ultram er-had the breakfast"

		(Trial Tr. (7/2/19 p.m., Diesselhorst) at 201: 19 – 202: 1; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	September 17, 2009 Oklahoma City, OK	"quick hit with nucynta and ultram er - broguht them a morning snack -talked about problems with mediciad" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 202: 2 - 8; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	October 2, 2009 Oklahoma City, OK	"quick hit with ultram er and nucynta" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 202: 2 - 5; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	October 6, 2009 Oklahoma City, OK	"quick hit with nucynta and ultram er" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 202: 2 - 5; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	October 12, 2009 Oklahoma City, OK	"quick hit with nucynta and ultram er" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 202: 2 - 5; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	October 29, 2009 Oklahoma City, OK	"quick hit with nucynta and ultram er" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 202: 2 - 5; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	November 6, 2009 Oklahoma City, OK	"quick hit with nucynta and ultram er" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 202: 2 - 5; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	December 2, 2009 Oklahoma City, OK	"lunch" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 202: 9 - 14; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	December 8, 2009	"n and u"

	Oklahoma City, OK	(Trial Tr. (7/2/19 p.m., Diesselhorst) at 202: 9 - 14; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	January 5, 2010 – January 3, 2012 Oklahoma City, OK	" " (blank) (Trial Tr. (7/2/19 p.m., Diesselhorst) at 202: 15 - 17; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	July 14, 2009 Oklahoma City, OK	"left all the info for nucynta" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 217: 4 - 11; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	July 21, 2009 Oklahoma City, OK	"quick hit with nucynta-went over all the info" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 217: 12 - 14; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	July 28, 2009 Oklahoma City, OK	"quick hit with nucynta and also wnet over all the info" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 217: 15 - 16; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	August 4, 2009 Oklahoma City, OK	"speaker program with moorad over nucynta and ultram er" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 217: 17 - 24; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	August 22, 2009 Oklahoma City, OK	"quick hit with nucynta" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 217: 25 - 218: 4; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	September 1, 2009 Oklahoma City, OK	"quick hit with nucynta" (Trial Tr. (7/2/19 p.m., Diesselhorst) at 217: 25 - 218: 4; Ct. Ex. 162 (excerpts from S2481-S2492))
Drue Diesselhorst	September 9, 2009	"quick hit with nucynta and ultram er"