Filed in Fourth Judicial District Court
5/30/2018 10:01 AM
Hennepin County, MN

STATE OF MINNESOTA DISTRICT COURT

COUNTY OF HENNEPIN FOURTH JUDICIAL DISTRICT

Case Type: Other Civil
(Consumer Protection)

State of Minnesota, by its Attorney General, Lori Swanson, and Minnesota Board of Pharmacy,

Court File No. _____

Plaintiffs,

COMPLAINT

vs.

Insys Therapeutics, Inc.,

Defendant.

The State of Minnesota, by its Attorney General, Lori Swanson, and the Minnesota Board of Pharmacy (the "State"), for its Complaint against Defendant Insys Therapeutics, Inc. ("Insys"), alleges as follows:

INTRODUCTION

1. Insys manufactures a form of fentanyl under the brand name Subsys. Subsys is an opioid painkiller that is approved by the U.S. Food and Drug Administration (FDA) to treat breakthrough pain for cancer patients. Insys unlawfully promoted Subsys in the State of Minnesota with aggressive sales tactics and unlawful payments to Minnesota prescribers. Although Subsys was only FDA-approved for use in cancer patients, the company illegally promoted Subsys to Minnesota prescribers for off-label uses. To encourage prescribers to write prescriptions, Insys paid them sham "speaker fees." The State of Minnesota, by its Attorney General, Lori Swanson, and the Minnesota Board of Pharmacy bring this action to enforce Minnesota law.

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PARTIES

2. Lori Swanson, Attorney General of the State of Minnesota, is authorized under Minnesota Statutes chapter 8; the Uniform Deceptive Trade Practices Act, Minnesota Statutes sections 325D.43–.48; the Consumer Fraud Act, Minnesota Statutes sections 325F.68–.694; and has common law authority, including *parens patriae* authority, to bring this action to enforce Minnesota's laws, to vindicate the State's sovereign and quasi-sovereign interests, and to remediate all harm arising out of violations of Minnesota's laws.

3. The Minnesota Board of Pharmacy is authorized under Minnesota Statutes section 214.11 to bring this action.

4. Insys Therapeutics, Inc. is a Delaware corporation with its principal place of business at 1333 South Spectrum Boulevard, #100, Chandler, Arizona 85286. At all relevant times, Insys did business in the State of Minnesota by marketing, selling, and promoting the prescription drug Subsys. At all relevant times, Insys engaged in various activities in the State of Minnesota, described in more detail below, constituting the sale of merchandise, and additional activities in connection with the sale of that merchandise, within the meaning of Minnesota Statutes sections 325F.68, subdivision 4, and 325F.69. Insys is a licensed drug manufacturer and wholesale drug distributor with the Minnesota Board of Pharmacy.

JURISDICTION

5. Minnesota Statutes sections 8.31 and 214.11, and common law authority, provide this Court with jurisdiction over the subject matter of this action.

6. This Court has personal jurisdiction over Insys pursuant to Minnesota Statutes section 543.19 because Insys transacted business within the State of Minnesota and committed acts causing injury to consumers located in Minnesota.

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VENUE

7. Venue in Hennepin County is proper under Minnesota Statutes section 542.09 because this cause of action arises in part in Hennepin County. Insys has done business in Hennepin County, and Insys's unlawful acts have affected Hennepin County residents, among others.

FACTUAL BACKGROUND

I. THE FDA APPROVED SUBSYS ONLY FOR THE MANAGEMENT OF BREAKTHROUGH CANCER PAIN IN ADULT OPIOID-TOLERANT PATIENTS.

A. Opioids Generally

8. Opioids encompass both naturally-occurring substances and synthetic and semisynthetic compounds that bind to and stimulate opioid receptors in the body. Their primary clinical use is as painkillers, due to their effect of reducing the intensity of pain signals that reach the brain. In addition to reducing pain, however, opioids trigger chemical processes that create intense feelings of euphoria, making them highly susceptible to addiction and abuse.

9. Commonly known opioids include both illegal substances like heroin and prescription painkillers like hydrocodone (*e.g.*, Vicodin), oxycodone (*e.g.*, OxyContin and Percocet), morphine, and codeine.

B. FDA Regulation of Prescription Drugs

10. With certain limited exceptions not relevant here, a drug may not be distributed in interstate commerce without the approval of the FDA.

11. Manufacturers are required to submit to the FDA a new drug application in order to gain approval to distribute prescription drugs, which requires the manufacturer to produce data

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from adequate, well-controlled clinical trials to demonstrate that the drug is safe and effective for a particular use, known as an indication.

12. As part of the new drug approval process, the FDA must approve the drug's labeling, which is required to set forth detailed information about the drug, including the approved medical indication(s), dosages, and patient population(s).

13. "Off-label" use refers to use of an approved drug for an indication, or in any manner, other than what is described in the drug's labeling. It includes treating a condition that is not indicated on the label, treating patients for whom the drug is not approved, or treating an indicated condition with a dose or frequency different from that which is specified on the label.

14. While doctors may prescribe a drug for off-label uses, manufacturers are prohibited by federal law from promoting the drug for such uses.[1]

15. The ban on off-label marketing encompasses indirect methods of promotion, including sponsorship of educational speaker programs that focus on off-label uses.

16. This ban on off-label marketing is intended to prohibit drug companies from deceiving and misleading prescribers and patients about indications that have not been approved by the FDA.

C. FDA Approval of Subsys

17. Subsys is a drug manufactured and promoted by Insys that consists of fentanyl, administered through a sub-lingual (under-the-tongue) spray. Because of its method of administration, it is absorbed rapidly into the bloodstream.

[1] If a manufacturer wants to market a drug for an additional use, it must submit a supplemental new drug application to the FDA, demonstrating that the drug is safe and effective for the newly proposed indication.

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18. Fentanyl is a Schedule II controlled substance.[2] Like other opioids, in addition to a high abuse potential, fentanyl can have serious side effects, including respiratory depression and death. It is among the most potent opioid drugs available—up to 100 times stronger than morphine and many times more potent than heroin. In fact, fentanyl is so dangerous that, in March 2015, the DEA issued a nationwide alert identifying illicit fentanyl as a significant threat to public health and safety.

19. Subsys was approved by the FDA in January 2012 "[f]or the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain." Its approval has never been extended beyond that limited indication, and any other use is unapproved and off-label.

20. This limited approval means that, for on-label use, patients who take Subsys must have cancer and must already be taking around-the-clock opioids to manage their pain. Subsys has not been approved to treat back pain, neck pain, migraines, or any other non-cancer pain.

21. Subsys's FDA-approved labeling states that "Subsys is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain."

[2] The federal Controlled Substances Act and its implementing regulations identify drugs and other substances as "controlled substances," and classifies them into one of five schedules based in part upon their potential for abuse, the degree of dependence they might cause, and their accepted medical use. *See generally* 21 U.S.C. §§ 801 *et seq.*; 21 C.F.R. §§ 1300–1399. Most prescription-opioid painkillers are Schedule II controlled substances, meaning they have a high potential for abuse, which may lead to severe psychological or physical dependence. *See* 21 U.S.C. § 812(b)(2). Health care providers that prescribe Schedule II controlled substances must register with the U.S. Drug Enforcement Administration (DEA) and comply with the Controlled Substances Act.

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22. Subsys's label explicitly and repeatedly warns that Subsys poses serious risks of misuse, abuse, addiction, overdose, and serious complications due to medication errors: "**Fatal respiratory depression has occurred in patients treated with [TIRF] products such as SUBSYS, including following use in opioid non-tolerant patients and improper dosing.**" (Emphasis in original.) The label also warns that "[s]erious or fatal respiratory depression can occur even at recommended doses."

23. Due to the risk of fatal respiratory depression, the FDA-approved labeling expressly states that Subsys "**must not** be used [to treat] opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic regimen of opioids." (Emphasis in original.) This is known as a contraindication—a circumstance under which the drug should not be used. Subsys is also contraindicated in the management of acute or postoperative pain, including headaches or migraines.

24. Subsys is a member of a class of drugs identified as Transmucosal Immediate-Release Fentanyl (TIRF) products, which are so-named because they deliver fentanyl rapidly via the oral mucosa.

25. When it was approved, Subsys became the sixth TIRF product approved by the FDA, each of which is indicated for the management of breakthrough cancer pain in opioid-tolerant patients.

26. In order to ensure that the benefits of Subsys and other TIRF products outweigh their inherently serious associated risks, the FDA instituted a Risk Evaluation and Mitigation Strategy (REMS) program for TIRF products, the purpose of which is to educate "prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose" of Subsys

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and other TIRF products. The FDA's approval of Subsys was subject to the drug's placement in the TIRF-REMS Access Program (the "Program").

27. The Program governs and restricts participants' access to Subsys and other TIRF products. It requires, among other things, that the prescriber, the patient, and the dispensing pharmacy all enroll in the Program and receive education about the risks associated with Subsys before it can be prescribed or dispensed. Participants must agree to comply with the Program's requirements, including, for prescribers and pharmacies, the passage of an online exam called a "Knowledge Assessment."

28. The Program also requires both patients and prescribers to sign a Patient-Prescriber Agreement Form, which details the risks and responsibilities involved with taking TIRF products.

29. Further, because the FDA determined that Subsys "pose[s] a serious and significant public health concern requiring distribution of FDA-approved patient information," 21 C.F.R. § 208.1, it required Insys as part of the Program to "develop [a Medication Guide] for distribution to each patient when [Subsys] is dispensed[.]" 21 U.S.C. § 355-1(e)(2). Among other things, the Medication Guide warns patients that Subsys can cause "**[b]reathing problems that can become life-threatening**[,]" "**[p]hysical dependence**[,]" and a "**chance of abuse or addiction.**" (Emphasis in original.)

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II. THE OPIOID EPIDEMIC IN MINNESOTA.

30. Opioids have caused a devastating public health crisis in Minnesota, which has seen a more than 700% increase in opioid overdose deaths between 2000 and 2016.[3] Opioid-related overdoses are now the leading cause of drug-related deaths in the state, with prescription opioids contributing to 216 deaths in 2015, almost twice as many as heroin. In 2016, the number of deaths attributed to opioids increased to 395.[4]

31. A recent study of drug abuse trends shows that opioid-related deaths increased by nearly 60 percent in Hennepin County alone from 2015 to 2016, resulting in 153 accidental opioid-related deaths.[5] Fentanyl-related deaths in Hennepin County increased over 400% from 2015 to 2016,[6] and more than doubled statewide.[7]

32. Increased opioid prescriptions have led to an increase in prescription drug abuse, which the CDC described in 2012 as the fastest-growing drug problem in the United States.

33. In 2016, almost one quarter of admissions to addiction treatment programs in the Twin Cities metro area were for opioid abuse, compared to just 4.7% in 2000.[8]

34. In 2008, the rate of opioid-related inpatient stays in Minnesota was 172 per 100,000.[9] By the end of 2014, the rate increased to 247 per 100,000 persons, above the national rate of 224.6.[10] By the first quarter of 2017, the rate jumped to 348 per 100,000.[11]

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[3] *See* Minn. Dep't of Health, *Drug Overdose Deaths Among Minnesota Residents, 2000-2016*, at 23, http://www.health.state.mn.us/divs/healthimprovement/content/documents-opioid/2016DrugOverdoseDeathReport_Final.pdf.
[4] *Id.* at 5.
[5] Carol Falkowski, *Drug Abuse Trends in the Minneapolis/St. Paul Metropolitan Area* 2 (April 2017), http://www.drugabusedialogues.com/drug_abuse_trends_reports/2017_April.pdf.
[6] *Id.*
[7] Jeremy Olson, *Minnesota Opioid Deaths Rise Despite Attention, Intervention*, Star Trib. (May 28, 2017), http://www.startribune.com/minnesota-opioid-deaths-rise-despite-attention-intervention/424836053/.

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35. The rate of opioid-related emergency department visits has also increased, rising to 134.1 per 100,000 persons in 2014, an 83% increase from 2009, accounting for the fourth-largest increase among the 27 states in which data is available.[12] In 2016, the figure jumped again to 196 visits per 100,000 persons.[13]

36. The addiction caused by the rise of prescription opioids has also resulted in the rapid resurgence of heroin use in Minnesota, as this illicit opioid is often cheaper and more easily available on the street than the prescription painkillers that initially hook Minnesotans.

37. Treatment admissions for heroin use in the Twin Cities metropolitan area rose sharply from 3.3% of admissions in 2000 to 17.3% in 2016.[14]

38. In 2016, there were 150 heroin overdose deaths in Minnesota, a more than fifteenfold increase from 2008.[15]

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[8] Falkowski, *supra* note 5, at 3.

[9] *HCUP Fast Stats—Opioid-Related Hospital Use*, Agency for Healthcare Research and Quality, www.hcup-us.ahrq.gov/faststats/opioid/opioiduse.jsp?location1=MN&characteristic1=01&setting1=IP&location2=US&characteristic2=01&setting2=IP&expansionInfoState=hide&dataTablesState=show&definitionsState=show&exportState=hide (last modified Apr. 24, 2018).

[10] Audrey Weiss et al., *Opioid-Related Inpatient Stays and Emergency Department Visits by State*, *2009-2014*, at 4, Agency for Healthcare Research and Quality (Jan. 2017), https://www.hcup-us.ahrq.gov/reports/statbriefs/sb219-Opioid-Hospital-Stays-ED-Visits-by-State.pdf.

[11] Agency for Healthcare Research and Quality, *supra* note 9.

[12] Weiss et al, *supra* note 10, at 8–9.

[13] Agency for Healthcare Research and Quality, *supra* note 9.

[14] Falkowski, *supra* note 5, at 3.

[15] Minn. Dep't of Health, *Opioid Dashboard*, http://www.health.state.mn.us/divs/healthimprovement/opioid-dashboard/#DeathTrends; Jon Collins, *Here's Why Minnesota Has a Big Problem with Opioid Overdoses*, MPR News (Apr. 18, 2016), www.mprnews.org/story/2016/04/18/opioid-overdose-epidemic-explained.

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III. INSYS EMPLOYED AN UNLAWFUL AND SOPHISTICATED MARKETING SCHEME TO EXPAND THE USE OF SUBSYS AND INCREASE ITS PROFITS—WITHOUT REGARD TO PATIENT SAFETY OR MINNESOTA LAW.

A. Insys Implemented an Aggressive Marketing Scheme Designed to Maximize Prescriptions By Deceiving and Misleading Prescribers and the Public.

39. Unlike many drug manufacturers, which typically pay large salaries to sales representatives, Insys compensates its Specialty Sales Professionals (or "sales representatives") with relatively modest salaries, often as low as $40,000, and focuses its compensation structure on bonuses based entirely on sales. This unusual compensation policy has the effect of incentivizing sales above education on the risks and proper use of Subsys.

40. Insys sales representatives are also encouraged and incentivized to sell high doses, because their bonuses are based on a percentage of the overall sale amount, rather than a flat commission per prescription. Because the cost of Subsys is directly proportional to the dose, sales representatives earn much more if prescribers write high-dosage prescriptions. Insys also ran contests by which sales representatives could earn additional bonuses for high dose sales.

41. Because commissions are tied to total sales, regardless of use, sales representatives are also encouraged and incentivized to promote Subsys for off-label uses.

42. Insys put its sales team under immense pressure to increase prescriptions, without regard to whether the prescriptions were for approved uses. Dozens of emails from Vice President of Sales Alec Burlakoff and other Insys executives or supervisors to its sales force set a quota of one or more new prescriptions per day, not taking into account individual market characteristics, patient demographics, or the need of any individual patient for the medication. The result was a quota that was impossible for sales representatives to meet if they were marketing Subsys properly.

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43. For example, in a November 2013 email to the entire Insys sales force, Burlakoff said "[o]ur only focus should be NEW patients. If you are not generating 1 NEW subsys patient prescription per day, you are setting yourself up for a quota that you will never be able to meet."[16]

44. In August 2013, Burlakoff wrote an email to Minnesota sales manager **A.B.**, copying CEO Michael Babich and National Director of Sales Richard Simon, instructing her to "make sure each of your reps has at least one doctor they can count on for a daily prescription."

45. This expectation was made crystal clear to Minnesota sales representatives, down to the decimal point. A.B. at one point criticized her sales team for a low prescription average, telling them "[i]f you can not average 1.7 Rx's per day you can not do this job." This expectation was reinforced by Regional Sales Director Sunrise Lee in an October 2013 email: "You have to achieve [an average of] 1.7 scripts per day."

46. If the number of prescriptions obtained by Insys's sales representatives was insufficient, management put them on a Performance Improvement Plan (PIP), threatening them with termination if they did not increase sales. Another former Minnesota sales representative, **R.P.**, who was experienced in pharmaceutical sales, indicated that it was not possible to meet the company's sales goals by promoting Subsys solely for approved uses and that it was understood that sales representatives needed to promote off-label.

47. Insys's conduct described herein is consistent with its nationwide sales and marketing tactics, which have triggered dozens of state and federal civil and criminal

[16] In another November 2013 email to the entire sales force, Burlakoff stated that "[y]our ONLY focus should be making 1 new sale each day[.]"

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investigations. Several former members of Insys's sales staff have pleaded guilty to violations of the federal anti-kickback statute. Others have been indicted and are awaiting trial.

48. One sales representative, who was responsible for visiting prescribers in both Minnesota and Michigan, carried out a deceptive scheme to pay the employee of one Michigan prescriber to steer patients to Subsys. As part of this scheme, the sales representative offered the prescriber's employee money orders and gift cards as long as she promised to "tell every patient to ask for [a] script."

49. The Minnesota Board of Medical Practice (BMP) found that a Minnesota physician assistant's prescribing practices posed a danger to her patients. In March 2017, this physician assistant signed a Stipulation and Order with the BMP. The Stipulation and Order stated that she prescribed medication and increased doses of narcotics without documenting a medical rationale and prescribed Subsys at doses that exceeded the recommended initial dose without medical justification. She also admitted that she prescribed Subsys to multiple patients without enrolling in the required TIRF-REMS program. Insys sales representatives visited this physician assistant 16 times from September 2014 to June 2015, during which time she wrote 52 Subsys prescriptions.

50. Insys's fraudulent marketing strategy was in large part designed by Insys's former Vice President of Sales, Alec Burlakoff. Burlakoff, along with several other high-level Insys employees and executives—including its former President and Chief Executive Officer (CEO) Michael Babich, National Director of Sales Richard Simon, Regional Sales Director Sunrise Lee, Regional Sales Director Joseph Rowan, and Vice President of Managed Markets Michael Gurry—was indicted in December 2016 on Insys-related charges of racketeering conspiracy, mail fraud conspiracy, and conspiracy to violate the federal anti-kickback statute, for conduct related

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to the fraudulent and deceptive marketing practices described here.[17] On October 24, 2017, a superseding indictment was issued, adding Insys founder, owner, and former CEO and Chairman of the Board of Directors John Kapoor.[18] Insys's conduct described herein was carried out under the direction of these and other individuals.[19]

i. Insys Deceptively Marketed Subsys for Off-Label Uses and to Prescribers It Knew Did Not Treat Cancer Patients.

51. Despite Subsys's limited approval for breakthrough cancer pain in opioid-tolerant patients, and despite warnings relating to its side effects and high abuse potential, Insys deceptively promoted Subsys for off-label purposes for patients with non-cancer pain, including chronic pain, without first establishing the drug's safety and efficacy for those uses and despite the lack of FDA approval for such uses. In fact, Insys promoted Subsys off-label to prescribers regardless of whether they treated cancer patients, which created a likelihood of confusion or misunderstanding among prescribers regarding Subsys's approved uses.

52. When Subsys was approved, it entered a crowded TIRF market, competing with better-known products like Actiq and Fentora that had been around for much longer.[20] Additionally, there were a relatively small number of patients for whom Subsys was appropriate.

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[17] Indictment, *United States v. Babich et al.*, No. 1:16-CR-10343 (D. Mass. Dec. 6, 2016).

[18] First Superseding Indictment, *United States v. Babich et al.*, No. 1:16-CR-10343 (D. Mass. Oct. 24, 2017).

[19] *See* Insys Therapeutics, Inc., Annual Report (Form 10-K), at 54 (April 3, 2017) (providing that Insys warned prospective investors that Kapoor—who owned almost 70% of Insys's stock at the end of 2016—had the power to "individually control [Insys's] direction and policies"). "By virtue of his holdings, Dr. Kapoor can and will continue to be able to effectively control the election of the members of our Board of Directors, our management and our affairs . . . ." *Id.*

[20] Actiq and Fentora are manufactured by Cephalon, which in 2008 pleaded guilty to criminal and civil charges that it promoted Actiq off-label for unapproved uses and targeted prescribers who did not routinely treat cancer patients. Insys has employed many former Cephalon employees, including Vice President of Sales Alec Burlakoff.

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53. Insys knew that focusing solely on oncologists and other prescribers who regularly treated cancer patients would drastically limit the number of prescriptions written, and thus its revenue. In a May 2013 strategy document, Insys identified this issue: "Onc[ologist]s who do prescribe tend to be low volume." Insys also knew that these prescribers were hesitant to prescribe opioids due to their dangerous and addictive nature. Insys described this reasonable and justifiable aversion to opioid therapy as "ridiculous paranoia[.]" When Minnesota sales manager A.B. and sales representative **S.P.** explained to Burlakoff that a Minnesota prescriber was "scared to prescribe" Subsys and did "not want a reason for the DEA to come after him," Burlakoff responded: "Stop with the excuses and start with solutions[.]"

54. Instead, Insys focused its promotion on prescribers it knew would provide Subsys with the broadest market—high-volume opioid prescribers who would prescribe Subsys not just for breakthrough cancer pain, but for all pain. It called these prescribers "low hanging fruit[.]"[21]

55. Insys knew that pain management specialists and family physicians who treated patients suffering from pain for a variety of medical conditions provided a source of off-label prescriptions, and thus made them its primary target by encouraging its sales representatives to obtain the majority of their sales from a relatively small number of high-volume prescribers.

56. For example, in an email to her supervisor, Minnesota sales representative S.P. stated that "Alec [Burlakoff] has been encouraging me to keep looking for my Dr in Minneapolis, and suggested I go to family practice, internal medicine, or anesthesiologists[.]" In a document titled "Territory Action Plan," S.P. described her top targets as pain management and primary care doctors.

[21] *See also* 2016 Insys Annual Report, *supra* note 19, at 2 ("Our sales and marketing efforts . . . focus on the highest prescribers.").

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57. Using third-party pharmacy data, Insys carefully tracked prescriptions, looking for prescribers who had written prescriptions not only for opioids or TIRF products, but also other analgesics and even anti-seizure medication.[22] Insys used this data to categorize and rank prescribers into deciles according to the amount of opioid and other prescriptions they wrote. In a May 2013 internal document, Insys wrote that to capture market share, it must "[i]ncrease [p]enetration on prescribers (ROO [rapid-onset opioid] deciles)."

58. Furthering its effort to expand Subsys beyond its narrowly indicated use of breakthrough cancer pain, Insys used the message "pain is pain" when instructing its sales representatives on promotion of Subsys to prescribers.

59. Insys also knew that the majority of Subsys prescriptions were off-label and were not written by oncologists. For example, an April 2014 internal Insys document shows that over 96% of Subsys prescriptions written nationwide were not written by oncologists, and over 97% of Subsys prescribers were not oncologists. Similarly, a recent news article reported that "only 4% of all Subsys prescriptions were written by oncologists."[23]

60. Insys thus focused its marketing and promotional efforts disproportionately at the highest volume prescribers, the vast majority of whom it knew were not oncologists or prescribers focused on treating cancer pain, and whom Insys further knew would write off-label prescriptions.

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[22] For example, because of its use among pain management doctors, Insys tracked prescriptions of Gralise, a drug indicated not for the management of breakthrough cancer pain, but rather for neuropathic pain. The active ingredient in Gralise, gabapentin, is an anticonvulsant. In one email, S.P. informed her supervisor that she planned her visits to prescribers by "using the Gralice [*sic*] list in Minneapolis."

[23] Evan Hughes, *The Pain Hustlers*, N.Y. Times Mag. (May 2, 2018), https://www.nytimes.com/interactive/2018/05/02/magazine/money-issue-insys-opioids-kickbacks.html.

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61. By focusing its promotion on a small number of prescribers who did not treat cancer patients, Insys encouraged and incentivized the promotion of Subsys for off-label uses.

62. Such promotion created a likelihood of confusion among prescribers because it was designed to lead prescribers to believe that Subsys was safe and effective for off-label uses.

63. Insys also failed to disclose that Subsys was not proven safe and effective for use in non-cancer patients.

64. Insys's strategy was successful. According to its 2016 annual report, Subsys prescriptions accounted for 42% of the nationwide TIRF market, making it the most prescribed product in its class.[24] In Minnesota, Insys sold $4,756,628 of Subsys from July 2013 through February 2017.

ii. Insys Sales Representatives "Lived With" Select High-Volume Prescribers in Order to Maximize Subsys Sales.

65. Unlike typical pharmaceutical sales positions, where sales representatives visit (or "detail") numerous prescribers, Insys encouraged its sales representatives to spend the vast majority of their time with one or two high-volume prescribers, doing whatever it took to get them to write Subsys prescriptions.

66. In an August 2013 email to Insys's sales managers, Vice President of Sales Alec Burlakoff described "the formula" as follows: "The reps need to find 1 or 2 doctors to **live** with . . . ." (Emphasis in original.) Burlakoff called these prescribers "the 'golden gem' physician[s.]"

67. Multiple company documents exemplify this tactic. In March 2013, Burlakoff wrote the entire company sales force, lauding the top selling sales representatives for focusing their entire efforts on one prescriber.

[24] 2016 Insys Annual Report, *supra* note 19, at 1.

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68. Insys instructed its Minnesota-based sales staff to follow these principles. Upon expanding Insys's territory in Minnesota, Burlakoff wrote to the Minnesota sales manager, A.B., that "the rep needs 1 doctor to be successful in this market[.]"

69. A.B. took this instruction to heart, and implemented it in Minnesota. In April 2013, she sent the following email to her sales team: "I want everyone to STOP the insane belief that one must visit a ton of customers and pharmacies every day. For your mental health, you must focus on the *simplicity* of identifying that ONE doctor to generate just ONE Rx." (Emphasis in original.)

70. In another email, copying Burlakoff, she stated that she expressly instructed one sales representative to "[l]iv[e] with [your] [c]urrent [c]ustomers[,]" to which Burlakoff replied "[w]ell done[.]" In September 2013, in connection with a sales contest for top-selling sales representatives, A.B. asked her team "[w]ho are you going to LIVE with these next 2 weeks?" An October 2013 email from Regional Sales Director Sunrise Lee, who also oversaw sales in Minnesota, instructed the sales team to "[f]ind your 1 to 2 docs and move in."

iii. Insys Made Misrepresentations to Prescribers Regarding the Use of Subsys for Mild Pain.

71. Insys aggressively engaged in unlawful promotion of Subsys by falsely and misleadingly marketing it as being approved for broader use to treat less severe pain symptoms.

72. As part of its Insys Speaker Program ("Speaker Program"), described in further detail below, Insys recruited prescribers to ostensibly present to other healthcare professionals about Subsys. Company policy required speakers to use pre-approved materials, one of which was the "core speaker slide deck." In its core speaker slide deck, which it used to market Subsys

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as part of its Speaker Program nationwide and in Minnesota, Insys deceptively defined breakthrough cancer pain to include "mild to severe" pain in an effort to expand its market.

73. As support for the inclusion of "mild" pain in its definition of breakthrough cancer pain, Insys cited to a 1990 article entitled "Breakthrough Pain: Definition, Prevalence and Characteristics." The article, however, did not support Insys's definition. In fact, the article specifically excluded mild pain, stating that breakthrough pain is "defined as a transitory increase in pain to greater than moderate intensity (that is, to an intensity of 'severe' or 'excruciating')," and "[b]y definition, all breakthrough pains had been rated by the patient as either severe or excruciating."

74. Insys knew its definition of breakthrough cancer pain was unsupported and misleading. Its internal notes on the slide deck indicate that Insys's intent was to market Subsys for a broader indication than that for which it was approved, stating that "[t]he broadest definition is probably the most useful."[25]

75. By misrepresenting the article's definition of breakthrough cancer pain, Insys deceptively represented to prescribers that Subsys was approved and was safe and effective to treat mild pain. These marketing practices created a likelihood of confusion among Minnesota prescribers regarding the use of Subsys for the treatment of mild pain.

76. According to records produced by Insys, from September 2013 through June 2015, Insys conducted 36 speaker programs led by Minnesota physicians, some of which contained the misrepresentation described above.

[25] Later Insys presentations narrowed the definition to "severe or excruciating" pain or a "flare of greater than moderate-to-severe pain."

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iv. "Under-Dosing Is Just As Dangerous As Over Dosing": Insys Inappropriately Encouraged the Promotion of Subsys at Unapproved and Dangerous Doses.

77. Insys also unlawfully promoted Subsys by encouraging its sales force to mislead Minnesota prescribers regarding proper dosage through its "effective dose" message.

78. Because of Subsys's high potential for abuse and the dangerous possibility of fatal overdose, the FDA determined that health care providers should prescribe the lowest possible dose that effectively treats a patient's symptoms (the "effective dose").

79. For painkillers like opioids, FDA-approved labeling generally requires that prescribers start patients at a low dose, and then incrementally increase or decrease dosage until they find a dosage that effectively relieves pain while minimizing side effects. This is called titration, and the purpose is to find the lowest possible dose that effectively manages pain.

80. Subsys's FDA-approved labeling, designed to protect patient safety, states that the initial dose prescribers should start patients at is "**always** 100 mcg [micrograms]." (Emphasis in original.)

81. Subsys's Medication Guide also warned patients that Subsys "comes in several strengths. When you are first prescribed Subsys, your healthcare provider will start you with the lowest strength medicine, and will change the dose until you and your healthcare provider find the right dose for you."

82. Instead of leaving dosage decisions in the hands of prescribers, and despite these explicit warnings, Insys inappropriately inserted itself into the titration process. It created a strategy it called the "effective dose" strategy, which was aimed at encouraging prescribers to prescribe Subsys at doses much greater than the recommended 100 mcg starting dose, and convincing prescribers to quickly titrate patients up to even larger maintenance doses.

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83. Insys tracked the dosage of Subsys prescriptions, and instructed its sales representatives to convince prescribers to titrate patients up when a prescriber wrote a so-called "low dose"—which Insys considered to be 400 mcg or lower, or four times the approved initial dose—regardless of whether the dose had been determined to be effective.

84. Thus, Insys sales representatives in Minnesota and throughout the country created a likelihood of confusion among prescribers by representing that the "effective dose" of Subsys was much higher than the FDA-approved starting dose.

85. This strategy had an obvious purpose. Stronger dose units are more expensive. The greater the dose of Subsys prescribed, the more money Insys and its sales representatives earned, dangerously encouraging promotion of unapproved high-dose prescriptions.

86. A slide deck from Insys's May 2012 Board of Directors meeting reflects its willingness to ignore the FDA's dosage requirement. Under a slide titled "Key Growth Parameters," Insys wrote "Increase utilization of higher doses[.]"

87. To implement this strategy, in 2014 Insys offered its sales force an extra bonus for high dose prescriptions (the "effective dose" bonus). Another incentive compensation plan distributed to the sales force in 2013 instructed sales representatives that "[h]igh dose . . . still gets the highest payout rate[.]"

88. Additional internal documents demonstrate this display of misplaced incentives. One slide deck distributed to the sales force, titled "Bring a Patient on Subsys, Get Paid Multiple Quarters," labeled patients who are prescribed Subsys "an annuity that keeps paying" and encouraged the sales force to "[s]ee how your payout will differ if the patient is on 100MCG, 400MCG, or 1200MCG doses throughout the course of the therapy[.]" The slide showed a

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payout of $340 per quarter for a patient on the FDA-approved 100 mcg starting dose, versus $2,352 for a 1200 mcg dose.

89. These compensation plans encouraged sales representatives to push off-label, high dose prescriptions, and caused a likelihood of confusion among prescribers as to Subsys's approved and effective doses. A June 2012 email from a non-Minnesota regional sales manager to CEO Michael Babich, among others, shows this was a company-wide strategy:

> Reps need to be able to understand the value of a script and how to increase it. Not every script is created equal and they need to better understand how units and strength influence the cost. . . . This will also lead to understanding what physicians use the lower doses and how those physicians will now need to be targeted with a titration message.

90. Emails sent to and from the Minnesota sales team demonstrate Insys's implementation of its deceptive and misleading "effective dose" strategy in Minnesota. In a June 2013 email, Minnesota sales manager A.B. instructed her sales team to "communicate with your TOP Physicians regarding titrating UP. At the end of business every Friday, I want a text confirmation from you about what was said. This will ensure accountable [*sic*] between your customer and yourself and accountability between the doctor and the patient!"

91. In another email, A.B. instructed a non-Minnesota sales representative on Insys's titration strategy: "under-dosing is just as dangerous as over dosing . . . TITRATION is the MOST IMPORTANT aspect of this product (and class) and you want to help [the prescriber] with this process."

92. At times Insys got involved in individual titration decisions, trying to substitute the medical judgment of the prescriber with its profit-driven motive to drive sales. Emails from Minnesota sales manager A.B. illustrate this conduct. In one, she wrote to a non-Minnesota sales

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representative that "[t]he 2 rx's from Oct 18 should have been titrated" and ordered her to "[a]sk [the prescriber] what happened???"

93. Insys's written marketing materials also demonstrate its "effective dose" messaging. Insys gave Minnesota prescribers branded materials stating that "75% of patients found an effective SUBSYS dose between 600 and 1600 mcg" and that "[o]nly 4% of patients reported 100 mcg as an effective dose."

94. Insys also distributed materials directly to patients instructing them to contact Insys for assistance with "reaching an effective dose."

95. Insys's efforts to convince prescribers to write high initial doses were successful. According to data produced by Insys, over 80% of initial prescriptions written by Minnesota prescribers were above the FDA-approved 100 mcg initial dosage.

96. In addition to pushing high doses, Insys also inappropriately inserted itself into the prescribers' decision as to *how many* doses of Subsys to prescribe. While Subsys's label warned that consumption should be limited to "four or fewer doses per day," Insys falsely and deceptively mischaracterized this as requiring *at least* four doses per day.

97. For example, in one email, Minnesota sales manager A.B. instructed her team to "CHALLENGE [THEIR] DOCTORS" to pressure prescribers into writing high unit prescriptions: "It is IMPERATIVE that you educate your docs to the point where they understand that **ONE RX = 120 UNITS**." (Emphasis in original.) She continued, falsely and deceptively mischaracterizing anything less than 120 units as "sub-therapeutic" and "going against guidelines[.]" Minnesota sales representative S.P. was explicitly told that her "patients should have prescriptions for 120 Units[.]"

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98. A later email from A.B. to her sales team stated that "the Number of Units you bring in is the absolute Bottom Line."

99. Insys also deceptively promoted Subsys off-label by encouraging prescribers to switch their patients from high doses of competing TIRF products, such as Actiq and Fentora, to the same high doses of Subsys, a program known as the "switch" program.

100. Insys's strategy to convince prescribers to switch to Subsys from competing TIRF products was implemented in direct contravention of the label's explicit instruction that "**Subsys is not bioequivalent with other fentanyl products. Do not convert patients on a mcg per mcg basis from other fentanyl products. . . . [T]he substitution of the same dose of Subsys for the same dose of any other fentanyl product may result in a fatal overdose**." (Emphasis in original.)

101. Nonetheless, Insys relentlessly pushed the switch program, sending emails to the sales force attaching lists of Actiq prescribers and reminding them of the bonuses they would receive if they successfully converted patients to Subsys.

102. For example, Insys's sales force in 2012 was told that activating new Subsys prescribers and converting Actiq and Fentora patients to Subsys would "help [them] make money" and "win BIG!"

103. An early 2014 sales contest offered cash incentives of up to $3,000 for sales representatives who got the most prescriptions from prescribers who had written Abstral or Lazanda (competing TIRF products) but had never written Subsys.

104. One Minnesota sales manager, **D.S.**, sent an email attaching an "Actiq list," and told his team that the prescribers on the list were "low hanging fruit ready for the picking."

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105. In response to an email expressing frustration that Minnesota sales representative S.P. was having trouble getting a physician to prescribe Subsys when he prescribed "more *branded* Actiq than anyone in [the] entire region combined," Vice President of Sales Alec Burlakoff replied: "3 words[:] Actiq switch program!"

106. These marketing and sales practices by Insys created a likelihood of confusion among Minnesota prescribers regarding Subsys's approved use and dosage.

B. Insys Created a Sham Speaker Program to Provide Payments to Prescribers To Boost Subsys Prescriptions.

107. State and federal law, and Insys's internal compliance policies, prohibited the offer or payment of any remuneration to encourage prescribers to write prescriptions or issue referrals.

108. Yet, Insys paid prescribers money disguised as bona fide honoraria for participation in sham "educational events" as part of its Speaker Program. Insys established the Speaker Program shortly after it introduced Subsys into the market.

109. Insys's Associate Director of Medical Marketing Communications warned Minnesota sales manager A.B. after she sent an email implying that the true purpose of the speaker program was to encourage prescriptions: "[E]xamples of improper practice would be promising a physician that speaking on behalf of SUBSYS will build his or her practice or offering speaking opportunities as enticement to write SUBSYS prescriptions."

110. Insys used the speaker program as a sham to reward high-volume prescribers and encourage them to prescribe—or continue to prescribe—Subsys.

111. For example, in June 2012, CEO Michael Babich sent an email with the subject line "Live Speaker Targets" to Insys's sales managers. The email was designed to ensure that

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sales representatives understood "the important nature of having one of their top targets as a speaker. It can pay big dividends for them."

112. Insys's payment of money to prescribers was key to its scheme to increase sales.[26] Internal communications and documents demonstrate the importance Insys put on the Speaker Program, which it viewed as being the "foundation" of its business model and "paramount to [the] success of Subsys[.]" The Speaker Program was sold to the sales force as "the best weapon in your arsenal" to increase sales.

113. For example, Vice President of Sales Alec Burlakoff described the Speaker Program as "the platform of Insys" and wrote that "Speaker Programs are by far and away the single most important thing we do from a sales and marketing point of view."

114. Likewise, in an email to her sales team, Minnesota sales manager A.B. characterized the Speaker Program as "the MOST IMPORTANT objective" for her sales team. She told her team that "[u]nless you are in an office pulling through a prescription ALL of your time, energy and budget should be geared towards [Speaker Programs]."

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[26] Recent studies have found a clear link between even minimal drug company payments and prescribing practices. For example, *ProPublica* found that "doctors who received industry payments were two to three times as likely to prescribe brand-name drugs at exceptionally high rates as others in their specialty." Charles Ornstein et al., *Now There's Proof: Docs Who Get Company Cash Tend to Prescribe More Brand-Name Meds*, ProPublica (March 17, 2016), https://www.propublica.org/article/doctors-who-take-company-cash-tend-to-prescribe-more-brand-name-drugs. Similarly, a 2016 study published in *JAMA Internal Medicine* found "a significant association between [a physician] attending a single meal promoting a specific drug . . . and the prescribing of the promoted drug over therapeutic alternatives." Colette DeJong et al., *Pharmaceutical Industry-Sponsored Meals and Physician Prescribing Patterns for Medicare Beneficiaries*, 176 JAMA Internal Med. 1114, 1121 (June 20, 2016). Further, "additional meals and costlier meals [are] associated with greater increases in prescribing of the promoted drug." *Id.* at 1120; *see also* Scott E. Hadland et al., Research Letter, *Association of Pharmaceutical Industry Marketing of Opioid Products to Physicians With Subsequent Opioid Prescribing*, JAMA Internal Med. (May 14, 2018) (finding that payments from pharmaceutical companies "were associated with greater opioid prescribing").

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115. Because of the Speaker Program's importance in generating sales, Insys targeted speakers who it knew would write a lot of prescriptions, rather than select speakers based on their clinical experience treating Insys's sole approved indication, breakthrough cancer pain. In fact, the Speaker Program nomination form did not even mention experience treating cancer patients in its list of relevant criteria in choosing a speaker.

116. Instead of recruiting and selecting speakers based on Insys's claimed criteria of "their ability to educate other HCPs" on approved uses of Subsys, Insys instructed its sales representatives to search publicly-disclosed data for prescribers who had accepted speaking fees from makers of fentanyl and other opioid products and were high-volume opioid prescribers.

117. For instance, according to an indictment of Insys's executives, Burlakoff sent a text message to a sales representative, assuring her that the participants in the Speaker Programs "do not need to be good speakers, they need to write a lot of [prescriptions]."

118. This was true nationwide and in Minnesota. In one email, Minnesota sales manager A.B. instructed her sales representatives to "[d]evelop speaker[s] by ensuring that [they are] rxing Subsys[.]"

119. If the prescribers did not respond to the "speaking fees" with a corresponding uptick in the number of Subsys prescriptions they wrote, Insys reduced their speaker programs or canceled their future speaking events altogether, unless and until the prescriber wrote more Subsys prescriptions.

120. For example, in an April 2013 email, Minnesota sales manager A.B. warned her sales team that "if an existing speaker is not prescribing they will be removed[,]" to which Vice President of Sales Alec Burlakoff replied "good email!"

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121. Two days later, she referred to Burlakoff's "decision to cancel" a non-Minnesota prescriber's speaking programs because of his "over-use of generics[.]" A.B. requested that Burlakoff give the speaker "a last chance to prove himself and increase his Subsys market share" in order to gain back his speaking events. Burlakoff responded an hour later: "nope."

122. When that prescriber contacted Burlakoff to express disdain that his speaking events were canceled, Burlakoff justified his decision on the prescriber's failure to write enough Subsys prescriptions:

> I have had a chance to do a bit of research, and it appears as if you only have a handful of patients on Subsys? I will say that this is certainly not the norm for Subsys speakers that vehemently stand behind the use of this product[.] . . . We typically see somewhere around 100 or so patients refilling our product on a monthly basis from each Subsys thought leader[.]

123. A.B. backed up this justification, assuring Burlakoff she was "cutting off any and all speakers who I don't deem fit." In an email with the subject "Canceled [Speaker Programs]" sent to one of her non-Minnesota sales representatives, A.B. explicitly tied failure to write enough prescriptions to canceled speaking events: "They're clearly not giving you enough of the business based on their market volume especially in light of the fact that they are both Fentora writers. This lack of ROI [return on investment] is the reason these [Speaker Programs] were deleted." She continued, explaining that to regain the speaking events, the speakers "simply must increase their clinical experience with Subsys in order to educate an audience of practitioners and this experience must match the national average."

124. In another email, expressing concern about a non-Minnesota speaker writing prescriptions for Fentora instead of Subsys, Minnesota sales manager A.B. said she was "collecting evidence for why I want to delete him."

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IV. INSYS SUCCESSFULLY USED THIS DECEPTIVE MARKETING STRATEGY IN MINNESOTA BY TARGETING AND PAYING MONEY TO TWO MINNESOTA DOCTORS RESPONSIBLE FOR THE VAST MAJORITY OF SUBSYS PRESCRIPTIONS.

A. Insys Specifically Targeted Two Minnesota Physicians Who Became Responsible for 90% of the Subsys Prescriptions in the State.

125. Insys implemented its deceptive marketing strategy in Minnesota by focusing on two Minnesota prescribers in particular, who quickly became responsible for the vast majority of Subsys sales in the state.

126. Insys knew that the Minnesota prescribers did not generally treat cancer patients, and that the vast majority of the Subsys prescriptions being written were for off-label uses. Yet, Insys unlawfully and aggressively marketed to those prescribers and, as described below, paid them thousands of dollars to promote Subsys as part of its Speaker Program.

127. According to data produced by Insys, these doctors were visited hundreds of times by Insys sales representatives between July 2013 and February 2017.

128. Minnesota's most prolific Subsys prescriber was **Physician 1**, whose clinics were responsible for over 50% of Minnesota Subsys prescriptions and over 50% of Insys's revenue in Minnesota.

129. Physician 1 is not an oncologist; rather, he is an anesthesiologist. The vast majority of his patients did not have cancer, and the majority of Subsys prescriptions he wrote were off-label.

130. Insys focused much of its effort in Minnesota on promoting Subsys to Physician 1, instructing Minnesota sales representative S.P. to follow Vice President of Sales Alec Burlakoff's formula by "living with" Physician 1. When S.P. complied, Minnesota sales

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manager A.B. wrote that she was "happy to hear that you've moved in with [Physician 1]. Awesome!!"

131. It was a major blow to Insys's revenue stream in Minnesota when Physician 1 stopped writing off-label prescriptions. In a September 2016 email, Physician 1's office informed Insys that he would no longer be putting new patients on Subsys "unless the patient has a diagnosis of cancer/neoplastic pain." Up to that point, Physician 1's prescriptions netted Insys an average of $44,190 per month.

132. In 2016 a number of Insys sales personnel were indicted in connection with their marketing of Subsys. Shortly thereafter, in early 2017, Physician 1 learned of the State's investigation into Insys when the State contacted him in connection with this matter. Internal Insys emails from April and May 2017 from a Minnesota sales representative, **M.R.**, and Minnesota sales manager, **M.V.**, reported that Physician 1 and his physician assistant would no longer prescribe Subsys "due to compliance reasons," demonstrating that Insys was aware of the off-label nature of the majority of his prescriptions.

133. The second highest prescriber of Subsys in Minnesota was **Physician 2**, who, along with his nurse practitioner, was responsible for 36% of Subsys prescriptions written in the state and 32% of Insys's revenue.

134. Physician 2 is not an oncologist; rather, he is a family physician who runs a pain and addiction clinic.

135. Most of Physician 2's Subsys prescriptions were written for non-cancer patients and for diagnoses unrelated to cancer pain, *i.e.*, off-label uses.

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B. Insys Paid Physicians 1 and 2 Through Insys's Speaker Program.

136. As stated above, from July 2013 to February 2017, Insys earned a total of $4,756,628 in gross revenue from Subsys sales written by Minnesota prescribers. Of the 665 Subsys prescriptions written during this period, over 90% were written by just two doctors—Physician 1 and Physician 2—or their physician assistants or nurse practitioners. These physicians were the only two Minnesota prescribers paid to speak by Insys.

137. In contrast, the 12 Minnesota Subsys prescribers who were not paid speaker fees wrote an average of fewer than 6 prescriptions each.

138. According to data produced by Insys, it collectively paid Physician 1 and Physician 2 over $43,000 in "speaker fees" for 36 Speaker Program events in 2013 and 2015. Insys made Physician 2 its top speaker in Minnesota, paying him $25,600 to "speak" at 22 events between September 2013 and September 2015, and paid Physician 1 $17,700 to "speak" at 14 events between July 2013 and June 2015.

139. In addition to paying for their meals, Insys paid Physician 1 and Physician 2 between $1,000 and $3,200 for each so-called ostensible "educational event," pursuant to a contract signed by Insys executives, including CEO Michael Babich.

140. Physician 1 described the Speaker Program events as informal meetings in doctor's offices, with the focus on gaining referrals for his clinic, not promoting Subsys to potential prescribers:

> We went to the office, had lunch, and [I] gave him my card and referral pads and talked about Subsys for a few minutes, and—Q. When you say 'referral pad,' what is that? A. Well, I bring, like, my referral pad for my clinic, my referral pad for if they needed a procedure or something ordered for their patients."

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141. Many of the "events" had very few, if any, attendees, further calling into question the stated educational and promotional intent of the program. Occasionally, according to data produced by Insys, the only attendees at such events were the prescriber leading the event and an Insys sales representative.

142. Other times, event attendees included the speaker's own office staff or family. Internal notes from Insys's Speaker Program compliance training materials demonstrate that Insys was aware of the impropriety of targeting office staff, warning that it "wouldn't look good if we pay a speaker to educate his own staff."

143. According to documents produced by Insys, of the 36 Speaker Program events led by Minnesota prescribers, not one was attended by an oncologist. This shows that, despite its professed purpose, Insys was not interested in marketing to prescribers who would actually write Subsys for its approved use.

144. For some events, Insys was unable to produce evidence that any prescribers attended at all.[27]

145. According to data produced by Insys, even when prescribers were in attendance, they often either did not have a DEA registration, or were not enrolled in the TIRF-REMS Program, and thus could not legally prescribe Subsys.

146. Some events also had repeat attendees, contradicting Insys's statement that the purpose of the speaker program was to "target[] [those] who may be relatively unfamiliar with the on-label use of Subsys[.]"

[27] One non-Minnesota sales representative, discussing the target audience for an Speaker Program event, joked that Minnesota sales manager A.B. instructed her that "a neighbors [*sic*] poodle will do[.]"

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147. In return for the payments, Insys expected Physician 1 and Physician 2 to write more Subsys prescriptions.

148. They complied. At the time Insys nominated its two Minnesota speakers, neither had written a prescription for Subsys. Within weeks of signing speaking contracts, however, both speakers began consistently writing Subsys prescriptions.

149. Both Physician 1 and Physician 2 gave their first presentation on behalf of Subsys within two weeks after writing their first prescriptions.

150. Despite the Minnesota prescribers' lack of familiarity with cancer patients, the presentation they gave as part of the Speaker Program was entitled "Advancements in the Treatment of Breakthrough Pain in Cancer Patients (BTCP)."

151. Insys sold the Speaker Program to Physician 1 as an opportunity to build a referral base, despite Insys's supposed policy that using the Speaker Program to help build a prescriber's practice would be "improper." Indeed, Insys knew the importance of getting Physician 1 to write prescriptions for Subsys, describing his approval to the Speaker Program as "make or break" for Minneapolis.

152. Physician 1 testified that his goal in speaking on behalf of Insys was to build his practice by gaining referrals from other doctors, and stated that Insys promised to use the speaker program as a way for him to do so: Insys "offered up . . . a way to get me in front of some other physicians[:]"

> I wanted to have a really good streamline approach with an oncology group in town. So I sort of saw this back then as an opportunity to maybe kind of break into that, you know, into that sphere, you know. I felt that that was probably a good way to do that. And if they are going to pay for the marketing and get me in front of these guys and I can talk to them, hey, I thought that was a

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> great idea. So that's an issue that attracted me to say, "Well, I think we can work together a little bit."
>
> . . .
>
> Q. So is it accurate to say that from your perspective, part of the reason you became involved with Insys was in order to try to establish those relationships [with oncologists]?
>
> A. ***That was literally the initial only reason***, you know. . . . But you know, if they said, "Yeah, we'll get you in front of oncology," think about it. If you are opening up a business and you are a young doctor and you are green to the world, and you are like, "Oh, yeah, whatever you can do to get me in front of doctors for marketing, that's great." "Oh, we'll take care of it all. We'll get you in front of it." And I said, "Yeah, that's a great idea. Let's do it."
>
> . . .
>
> So the speaker program – they would set up, you know, basically marketing events – well, they are trying to market their drug, obviously. ***But they would bill it as more of a way for you to introduce your practice to potential referring physicians***. (Emphasis added.)

153. Insys also knew Physician 2 would be a ripe target for speaker payments due to his history of prescribing TIRF products and acceptance of speaking fees from other pharmaceutical manufacturers. Insys nominated Physician 2 to join the Speaker Program in August 2013 because he wrote "[f]airly consistent scripts for F[entanyl] Citrate" and because he had previously received payments from Cephalon as a former speaker for Fentora.

154. Despite virtually no experience prescribing Subsys at the time he was retained, Physician 2 immediately became a strong proponent of the drug. After his first speaker program in September 2013, Minnesota sales representative S.P.—who was responsible for detailing him—emailed her supervisor, praising Physician 2's presentation: "[Physician 2] acted as though Subsys was his baby—discussing how far we've come with fentanyl, how it stacks up

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against its competitors, where it can be used appropriately in everyday practice, how it can change patients' lives, etc." This email was forwarded to, among others, Vice President of Sales Alec Burlakoff and Regional Sales Director Sunrise Lee. Burlakoff responded "[c]ongrats. . . ! [A]tt[a] gal!"

155. The next month, S.P. told her manager that, after spending time with Insys executives, including CEO Michael Babich, at a meeting in San Francisco, Physician 2 was "excited to come back and blow Awerbach out of the water!!" This is a reference to Dr. Gavin Awerbuch, one of the top Subsys prescribers in the country, who in 2016 pleaded guilty to health care fraud and distribution of controlled substances in connection with his Subsys prescriptions.

156. Physician 2 began consistently prescribing Subsys around the time of that meeting, and was thereafter responsible for more than 35% of all Subsys prescriptions written in Minnesota, resulting in over $1.5 million in revenue for Insys.

157. Internal Insys communications show that Insys intended its payments to encourage prescriptions, and believed that prescribers owed the company prescriptions because of the payments. In an email sent to National Director of Sales Richard Simon, Minnesota sales manager A.B. directly tied future speaking events to Physician 1's promise to prescribe Subsys: "After meeting with [Physician 1] this weekend (and putting [Minnesota sales representative S.P.] on a [Performance Improvement Plan]) there is a great deal of motivation now to honor commitments. I'd like to allocate 3 [speaking programs] for [Physician 1] for Sept."

158. Insys closely monitored the performance of these Minnesota speakers and made the expectation of prescriptions in exchange for payment clear to both the prescribers and sales representatives.

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159. For example, Minnesota sales representative S.P. was told that she needed to "identify 2 NEW patients per week" from each of Physician 1 and Physician 2, a virtually impossible task if limited to on-label promotion. In order to increase sales, she was told to "make a point to be present in [Physician 1's and Physician 2's] offices every day." S.P. was warned that "[i]f you do not raise your performance to an acceptable level . . . you may be removed from your position. . . ."

160. In another incident from July 2013, Minnesota sales manager A.B. emailed S.P., reprimanding her for the lack of prescriptions from Physician 1 despite his being a paid speaker: "**After today's [Speaker Program], you will sit in [Physician 1's] office and OPT IN FIVE PATIENTS. . . . [Physician 1] MUST prescribe for FIVE patients TODAY."** (Emphasis in original.)

161. In that same email, A.B. expressed frustration to S.P. that, despite being a paid speaker, Physician 1 had not written enough prescriptions: "We are heading into [Physician 1's] 2nd [Speaker Program] and now it's time for him to step it up with accountability. . . . He simply MUST identify the 'right' patients for this product and stop playing around. . . ." Vice President of Sales Alec Burlakoff, who was copied on the communication, replied "Nice e-mail []!"

162. The next month, explaining why she was placing S.P. on a Performance Improvement Plan, A.B. stated that Physician 2 "made a verbal commitment to identify and prescribe for 6 patients" after signing a speaker contract. Admonishing the sales representative, A.B. also said that there was "a disconnect between what [Physician 1] commits and what his staff is willing to commit."

163. Writing to Vice President of Sales Alec Burlakoff in August 2013 in advance of a weekend meeting with Physician 1, Minnesota sales manager A.B. indicated that Physician 1 was

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not following through on his commitment: "I am shocked and disappointed that [Physician 1] hasn't done more in that territory as he COMMITTED he would. . . . After this weekend, if he doesn't GET IT, I have doubts he will pull through."

164. Minnesota sales representative S.P. eventually resigned under the pressure she was facing, writing that she "did not feel comfortable asking [Physician 1 and Physician 2] for five prescriptions per week. It simply is too risky for both of them . . . and I do not want them to lose their licenses just to help me reach quota." She described Insys's management style as "scare tactics" used to pressure her to increase sales.

165. A few months before, in June 2013, Minnesota sales manager A.B. had told her sales team to "[r]emember that your customer is *just as accountable to you as you are to them*." The next month, she sent a similar email and instructed her sales team to "send those texts [to prescribers] asking for a script[.]"

166. Both Minnesota prescribers also faced another familiar Insys pressure: not to only prescribe Subsys, but to prescribe it at large dosages that maximized profit for the company. In deposition testimony, Physician 1 testified that Insys sales representatives told him "that almost nobody only prescribes the 100 micrograms." In one email, following an initial prescription for 200 mcg written by Physician 2, Minnesota sales manager A.B. instructed sales representative S.P. to ask Physician 2 to "get [the patient] to the proper dose[,]" and warned the sales representative that "[b]eing on an inadequate dose (too low) can be just as dangerous as being [on] one that is too high."

167. As it did with other speakers throughout the country, Insys retaliated against Physician 1 when he failed to prescribe enough Subsys to satisfy the company's expectations. In

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late 2013, Physician 1 was removed from the Speaker Program. In late 2014, after writing dozens of prescriptions throughout the year, Physician 1 was added back to the speaker program.

168. Insys again removed Physician 1 from its Speaker Program in mid-2015, claiming it did so because it believed he was no longer practicing medicine. This post-hoc justification, however, is belied by the fact that Insys was targeting Physician 1 for speaking events in July 2016, invited him to attend speaker training in July 2016, continued to call on him throughout 2016 and into 2017, scheduled him to speak in September 2016, and that he was consistently writing prescriptions for Subsys through 2016.

169. Physician 1 stopped writing Subsys prescriptions after the State contacted him in connection with this matter. A March 2017 email from Minnesota sales representative M.R. states that "[Physician 1] . . . had a few patients on this product and [he] decided back in January to no longer keep them on product this quarter and moving forward . . . because of [his] deposition with the Attorney General of Minnesota. . . ." Similarly, after the State contacted Physician 2, he reached out to Insys and "asked [the sales representative] not to call him or see him for a while until things settle down."

170. Special circumstances exist that triggered a duty on the part of Insys to disclose material facts about Subsys. First, Insys had special knowledge that Minnesota prescribers did not have at the time Insys promoted Subsys to them of Subsys's approved use and the risks inherent with its use. Not all prescribers Insys targeted possessed this special knowledge, particularly given that Insys focused its promotion on prescribers it knew did not treat cancer patients, and many attendees at its speaker programs were not enrolled in the TIRF-REMS program. Insys knew or had reason to know that potential prescribers would place their trust in Insys and rely on it to inform them of material facts relating to Subsys. Insys abused that trust by

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making false representations that Subsys was safe and effective for off-label uses, and did not disclose Subsys's inherent risks or that Subsys was not safe and effective for use in non-cancer patients, and was not approved for the treatment of conditions other than breakthrough cancer pain. Second, Insys did not say enough to prevent the representations it made to prescribers and others from being deceptive and misleading.

C. Insys Was Aware that Minnesota Law Prohibits Certain Payments to Health Care Practitioners, Yet Paid Them Anyway.

171. Minnesota law prohibits pharmaceutical manufacturers from paying health care practitioners more than $50 in a year. Minnesota Statutes section 151.461 states as follows:

> **GIFTS TO PRACTITIONERS PROHIBITED.**
>
> It is unlawful for any manufacturer or wholesale drug distributor, or any agent thereof, to offer or give any gift of value to a practitioner. A medical device manufacturer that distributes drugs as an incidental part of its device business shall not be considered a manufacturer, a wholesale drug distributor, or agent under this section. As used in this section, "gift" does not include:
>
> (1) professional samples of a drug provided to a prescriber for free distribution to patients;
>
> (2) items with a total combined retail value, in any calendar year, of not more than $50;
>
> (3) a payment to the sponsor of a medical conference, professional meeting, or other educational program, provided the payment is not made directly to a practitioner and is used solely for bona fide educational purposes;
>
> (4) reasonable honoraria and payment of the reasonable expenses of a practitioner who serves on the faculty at a professional or educational conference or meeting;
>
> (5) compensation for the substantial professional or consulting services of a practitioner in connection with a genuine research project;

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(6) publications and educational materials; or

(7) salaries or other benefits paid to employees.

172. Insys knew of this prohibition. Internal compliance training materials from 2013 state that Minnesota's Gift Ban Statute "prohibits drug manufacturers from giving 'any gift of value' to practitioner[s]." The materials note that the prohibition applies to meals.

173. Insys also knew of the exceptions to the Gift Ban Statute, noting in its compliance materials that exceptions include "[i]tems with [a] total combined retail value of not more than $50 per year[,]" samples, salaries, and "[c]ertain consulting services and conferences."

174. A September 2013 email regarding Minnesota speaker programs clarified the $50 per year limit: "Bear in mind that in Minnesota, we can only spend $50 TOTAL PER YEAR per health care professional."

175. Despite this prohibition, Insys made dozens of payments to Minnesota health care practitioners that exceeded the annual $50 limit. For example, Insys made 11 "speaker fee" payments of $1,000 to Physician 1 in 2013 and three payments of $1,600, $1,900, and $3,200 in 2015. Insys made 18 "speaker fee" payments of $1,000 to Physician 2 in 2013 and four $1,900 payments in 2015.

176. Such payments do not fall under any of the exceptions to the Gift Ban Statute. First, the payments exceeded the annual $50 limit. Second, they were not made to the sponsor of a medical conference, professional meeting, or educational program; rather, they were paid directly to the practitioners, and they were not used solely, if at all, for bona fide educational purposes. Third, the payments do not constitute "reasonable honoraria" to practitioners who served on the faculty at a professional or educational conference or meeting. Finally, the payments were not compensation for professional or consulting services in connection with a

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genuine research project. Instead, the payments were made for sham speaking events that had little to no educational value, and were designed to encourage and reward prescriptions.

177. Insys provided more than $50 in payments per year to other Minnesota health care practitioners in addition to Physicians 1 and 2. For example, including its payments to speakers, Insys paid four Minnesota physicians a total of $25,967.48 in 2013; Insys paid eight Minnesota physicians a total of $14,878.68 in 2014; Insys paid seven Minnesota physicians a total of $16,247.90 in 2015; and Insys paid two Minnesota physicians a total of $6,517.45 in 2016.[28]

COUNT I
UNIFORM DECEPTIVE TRADE PRACTICES ACT

178. The State realleges and incorporates each and every allegation contained in the preceding paragraphs of this Complaint.

179. Minnesota Statutes section 325D.44, subdivision 1, provides, in part:

> A person engages in a deceptive trade practice when, in the course of business, vocation, or occupation, the person:
>
> ***
>
> (2) causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
>
> ***
>
> (5) represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have;
>
> ***

[28] These are merely some of the representative and illustrative payments Insys made to Minnesota practitioners. The State's allegations are not confined to the payments described here. These payments are non-exclusive examples that generally illustrate Insys's unlawful conduct.

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> (7) represents that goods or services are of a particular standard, quality, or grade . . . if they are of another . . . [or]
>
> ***
>
> (13) engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding.

180. Insys is a "person" within the meaning of this statute.

181. Insys, by engaging in the deceptive and fraudulent practices described in this Complaint, has engaged in a course of trade or commerce which had the capacity or tendency to deceive and/or mislead, and therefore constitutes multiple violations of Minnesota law by deceptive trade practices.

182. Insys caused a likelihood of confusion or misunderstanding regarding the approval or certification of Subsys by, among other things, making representations designed to mislead Minnesota prescribers into believing that Subsys was safe and effective for off-label uses, like treating pain other than breakthrough cancer pain, falsely claiming that breakthrough cancer pain includes "mild" pain, and aggressively marketing Subsys to prescribers who were not oncologists and did not regularly treat patients with cancer pain.

183. Insys represented that Subsys had approvals, characteristics, ingredients, uses, and benefits that it did not have by, among other things, misrepresenting the drug's approved uses, deceptively asserting that Insys was safe and effective for off-label uses for conditions and in a manner as to which it has not been determined to be either safe or effective, and falsely claiming that Subsys could be appropriately prescribed at dangerously high doses that contravened the drug's FDA approval.

184. Insys misrepresented the qualities of Subsys by, among other things, deceptively asserting that the definition of breakthrough cancer pain included "mild" pain in order to

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represent that Subsys was approved and was safe and effective to treat mild pain and falsely claiming that Subsys could be appropriately prescribed at dangerously high doses that contravened the drug's FDA approval.

185. Insys further engaged in conduct that created a likelihood of confusion or misunderstanding about Subsys by, among other things, making false, deceptive, and/or misleading representations to Minnesota prescribers regarding the drug's safety and effectiveness for off-label uses, that the definition of breakthrough cancer pain included "mild" pain, that the "effective dose" of Subsys was higher than the FDA-approved starting dose, and by aggressively marketing Subsys to prescribers that were not oncologists and did not regularly treat patients with cancer pain.

186. Separately, Insys repeatedly violated Minnesota Statutes section 324D.44, subdivision 1, by omitting material information in the course of marketing Subsys that subsequently caused a likelihood of confusion or misunderstanding, including by failing to sufficiently disclose that Subsys was only approved to treat breakthrough cancer pain, that Subsys was not safe and effective for contraindicated and other off-label uses, that the FDA had approved Subsys to be initially prescribed only at the smallest available dose, and that the definition of breakthrough cancer pain does not include "mild" pain.

187. Defendant's conduct, practices, actions, and material omissions described in this Complaint constitutes multiple, separate violations of Minnesota Statutes section 325D.44, subdivision 1.

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COUNT II
PREVENTION OF CONSUMER FRAUD ACT

188. The State realleges and incorporates each and every allegation contained in the preceding paragraphs of this Complaint.

189. Minnesota Statutes section 325F.69, subdivision 1 provides:

> The act, use, or employment by any person of any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby, is enjoinable as provided in section 325F.70.

190. The term "merchandise" within the meaning of Minnesota Statutes section 325F.69 includes prescription drugs. *See* Minn. Stat. 325F.68, subd. 2.

191. The term "person" includes any corporation (domestic and foreign). Minn. Stat. § 325F.68, subd. 3. Insys is a "person" within the meaning of this statute.

192. Insys repeatedly violated Minnesota Statutes section 325F.69, subdivision 1, by engaging in deceptive and fraudulent practices, and making false and misleading statements, with the intent that others rely thereon in connection with the sale of its prescription drug Subsys. Those practices include, but are not limited to:

a. targeting Subsys promotion at high-volume opioid prescribers who did not routinely treat cancer patients;

b. promoting Subsys for pain other than breakthrough cancer pain, when in fact, Subsys is not approved for such use;

c. falsely representing to prescribers that Subsys is safe and effective for off-label uses;

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d. deceptively encouraging prescribers to prescribe Subsys off-label for conditions and in a manner which it has not been determined to be either safe or effective;

e. falsely and deceptively representing that higher doses of Subsys are more effective than lower doses;

f. deceptively promoting Subsys at dangerously high doses, in contradiction to the FDA-mandated titration schedule;

g. providing prescribers with false and misleading information, and omitting material facts, including facts about the FDA-approved uses for Subsys, to deceive prescribers so that they would write more Subsys prescriptions;

h. providing prescribers with false and misleading information about the definition of breakthrough cancer pain to deceive prescribers so that they would write more Subsys prescriptions; and

i. paying sham "speaker fees" to prescribers to encourage, and in exchange for, Subsys prescriptions.

193. By failing to disclose and omitting material facts, Insys has further engaged in deceptive and fraudulent practices in violation of the Prevention of Consumer Fraud Act. Those failures to disclose and omissions include, but are not limited to:

a. after making statements to Minnesota prescribers that would lead them to believe that Subsys is safe and effective for contraindicated and other off-label uses, Insys did not disclose that Subsys was not safe and effective and was not approved for the treatment of conditions other than breakthrough cancer pain; and

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b. omitting material facts about the definition of breakthrough cancer pain to deceive prescribers so that they would write more Subsys prescriptions.

194. Given the representations it made, its special knowledge, and the circumstances described in this Complaint, Insys had a duty to disclose material facts to prescribers and patients in connection with its marketing and offering of goods to Minnesota consumers. By not doing so, the company failed to disclose material information in violation of Minnesota Statutes section 325F.69, subdivision 1.

195. Insys's conduct, practices, actions, and material omissions described in this Complaint constitutes multiple, separate violations of Minnesota Statutes section 325F.69.

COUNT III
WHOLESALE DRUG DISTRIBUTION LICENSING ACT
MINN. STAT. § 151.461

196. The State realleges and incorporates each and every allegation contained in the preceding paragraphs of this Complaint.

197. Minnesota Statutes section 214.11 provides, in part:

> In addition to any other remedy provided by law, a licensing board may in its own name bring an action in district court for injunctive relief to restrain any unauthorized practice or violation or threatened violation of any statute or rule which the board is empowered to regulate or enforce.

198. Minnesota Statutes section 151.461 provides, in part:

> **GIFTS TO PRACTITIONERS PROHIBITED.**
>
> It is unlawful for any manufacturer or wholesale drug distributor, or any agent thereof, to offer or give any gift of value to a practitioner. A medical device manufacturer that distributes drugs as an incidental part of its device business shall not be considered a manufacturer, a wholesale drug distributor, or agent under this section. As used in this section, "gift" does not include:

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(2) items with a total combined retail value, in any calendar year, of not more than $50;

(3) a payment to the sponsor of a medical conference, professional meeting, or other educational program, provided the payment is not made directly to a practitioner and is used solely for bona fide educational purposes;

(4) reasonable honoraria and payment of the reasonable expenses of a practitioner who serves on the faculty at a professional or educational conference or meeting; [or]

(5) compensation for the substantial professional or consulting services of a practitioner in connection with a genuine research project[.]

***

199. Minnesota Statutes section 151.44 provides, in part:

As used in sections 151.43 to 151.51, the following terms have the meanings given in paragraphs (a) to (h):

(a) "Wholesale drug distribution" means distribution of prescription or nonprescription drugs to persons other than a consumer or patient or reverse distribution of such drugs . . . .

***

(b) "Wholesale drug distributor" means anyone engaged in wholesale drug distribution including, but not limited to, manufacturers; repackagers; own-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and pharmacies that conduct wholesale drug distribution. A wholesale drug distributor does not include a common carrier or individual hired primarily to transport prescription or nonprescription drugs.

(c) "Manufacturer" has the meaning provided in section 151.01, subdivision 14a.

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200. Minnesota Statutes section 151.01, subdivision 14a, defines "[m]anufacturer" as "any person engaged in manufacturing." Minnesota Statutes section 151.01, subdivision 14, subsequently provides:

> "Manufacturing" means the production, preparation, propagation, conversion, or processing of a drug, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis. Manufacturing includes the packaging or repackaging of a drug, or the labeling or relabeling of the container of a drug, for resale by pharmacies, practitioners, or other persons. Manufacturing does not include the prepackaging, extemporaneous compounding, or anticipatory compounding of a drug within a licensed pharmacy or by a practitioner, nor the labeling of a container within a pharmacy or by a practitioner for the purpose of dispensing a drug to a patient pursuant to a valid prescription.

201. Insys is a "manufacturer" and a "wholesale drug distributor" within the meaning of these statutes. Insys is currently licensed by the Minnesota Board of Pharmacy as both a manufacturer, with License Number 460531, and as a wholesale drug distributor, with License Number 363114.

202. Minnesota Statutes section 151.01, subdivision 23, provides, in part:

> "Practitioner" means a licensed doctor of medicine, licensed doctor of osteopathic medicine duly licensed to practice medicine, licensed doctor of dentistry, licensed doctor of optometry, licensed podiatrist, licensed veterinarian, or licensed advanced practice registered nurse. For purposes of section[] . . . 151.461, "practitioner" also means a physician assistant authorized to prescribe, dispense, and administer under chapter 147A. For purposes of section[] . . . 151.461, "practitioner" also means a dental therapist authorized to dispense and administer under chapter 150A.

203. According to publicly available data from the Center for Medicare and Medicaid Services' Open Payments database, Insys and its agents, in the course of promoting and

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marketing Subsys, made the following non-exclusive list of payments to Minnesota practitioners that exceeded $50 per practitioner in a given calendar year:

- In 2013, Insys paid four Minnesota physicians payments exceeding $50, totaling $25,967.48;
- In 2014, Insys paid eight Minnesota physicians payments exceeding $50, totaling $14,878.68;
- In 2015, Insys paid seven Minnesota physicians payments exceeding $50, totaling $16,247.90; and
- In 2016, Insys paid two Minnesota physicians payments exceeding $50, totaling $6,517.45.

204. By making these payments, Insys and its agents offered or gave items with a total combined retail value of more than $50 to practitioners in the calendar years of 2013, 2014, and 2015, and 2016.

205. The payments by Insys and its agents were not made to the sponsor of a bona fide medical conference, professional meeting, or other educational program, the payments were made directly to the practitioners, and the payments were not used solely for bona fide educational purposes, if at all, as provided in Minnesota Statutes section 151.461, subpart 3.

206. The payments by Insys and its agents were not reasonable honoraria and payment of the reasonable expenses of practitioners who serve on the faculty at professional or educational conferences or meetings, as provided in Minnesota Statutes section 151.461, subpart 4.

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207. The payments by Insys and its agents were not compensation for the substantial professional or consulting services of a practitioner in connection with a genuine research project, as provided in Minnesota Statutes section 151.461, subpart 5.

208. Instead, payments that Insys may attempt to categorize as "honoraria" or speaking fees were payments for sham speaking events with little to no actual educational value that were largely attended by practitioners and others who do not treat cancer patients and/or were not registered with the TIRF-REMS program.

209. Insys's conduct described in this Complaint constitutes multiple, separate violations of Minnesota Statutes section 151.461.

RELIEF

WHEREFORE, the State of Minnesota, by its Attorney General, Lori Swanson, and the Minnesota Board of Pharmacy respectfully ask this Court to award judgment against Insys and enter an Order as follows:

1. Declaring that Insys's acts described in this Complaint constitute multiple, separate violations of Minnesota Statutes sections 325F.69, 325D.44, and 151.461;
2. Enjoining Insys and its employees, officers, directors, agents, successors, assignees, affiliates, merged or acquired predecessors, parent or controlling entities, subsidiaries, independent contractors, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from violations of Minnesota Statutes sections 325F.69, 325D.44, and 151.461, including deceptive or misleading conduct and trade practices in the promotion and marketing of pharmaceutical products; making payments to health care providers to encourage the prescription or distribution of

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pharmaceutical products; and offering or giving prohibited payments to health care providers;

3. Awarding the State its costs, including costs of investigation and attorneys' fees, as authorized by Minnesota Statutes section 8.31, subdivision 3a; and

4. Granting such further relief as provided by law or equity, or as the Court deems appropriate and just.

Dated: May 30, 2018

Respectfully submitted,

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Attorney General
State of Minnesota

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/s/ Evan S. Romanoff
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STATE OF MINNESOTA, AND THE
MINNESOTA BOARD OF PHARMACY

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MINN. STAT. § 549.211
ACKNOWLEDGMENT

The party on whose behalf the attached document is served acknowledges through its undersigned counsel that sanctions may be imposed pursuant to Minn. Stat. § 549.211.

Dated: May 30, 2018

/s/ Evan S. Romanoff
EVAN S. ROMANOFF