1	MARK BRNOVICH	
2	Attorney General (Firm State Bar no. 14000)	
3	Matthew du Mée (Bar no. 28468)	
4	Office of the Attorney General 1275 West Washington Street	
5	Phoenix, Arizona 85007	
6	Telephone: (602) 542-3702 Facsimile: (602) 542-4377	
7	consumer@azag.gov	
8	Attorneys for the State of Arizona	
9	IN THE SUPERIOR COURT	FOR THE STATE OF ARIZONA
10	IN AND FOR THE CO	UNTY OF MARICOPA
11	STATE OF ARIZONA, ex rel. MARK	Case No
12	BRNOVICH, Attorney General,	
13	Plaintiff,	COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF
14	VS.	
15	INSYS THERAPEUTICS, INC.;	
16	ALEC BURLAKOFF, individually; ALEC BURLAKOFF and JANE DOE	
17	BURLAKOFF, as a marital community; ELIZABETH	
18	GURRIERI, individually;	
19	ELIZABETH GURRIERI and JOHN DOE GURRIERI, as a marital	
20	community; STEVE FANTO,	
21	individually; STEVE FANTO and JANE DOE FANTO, as a marital	
22	community; NIKESH SETH, individually; NIKESH SETH and	
23	JANE DOE SETH, as a marital	
24	community; SHELDON GINGERICH, individually;	
25	SHELDON GINGERICH and JANE	
26	DOE GINGERICH, as a marital community,	
27		
28	Defendants.	

II

Plaintiff, State of Arizona, *ex rel.* Mark Brnovich, Attorney General,
 alleges as follows:

In early 2012, the U.S. Food and Drug Administration ("FDA") approved a
new drug developed by INSYS Therapeutics, Inc. ("Insys"). The drug, called
SUBSYS ("Subsys"), carried risks of addiction and death, but could be helpful in
treating a small subset of patients—those experiencing breakthrough cancer
pain who were tolerant of other opioids.

8 2. Over the next five years, Insys engaged in a nationwide scheme in which
9 it deceived insurers, patients, and doctors. Insys lied to insurers, concealed key
10 facts from doctors and patients, and paid doctors sham "speaker fees" in
11 exchange for writing prescriptions, all in order to increase the sales of Subsys,
12 without regard for the health and safety of patients.

13 3. Three Arizona doctors—Steve Fanto, Nikesh Seth, and Sheldon
14 Gingerich—collected hundreds of thousands of dollars from Insys in sham
15 "speaker fees" in exchange for writing copious amounts of Subsys prescriptions
16 to patients.

17 4. Insys made hundreds of millions of dollars from its deceptive scheme, but
18 also put countless patients in harm's way, exposing them to unacceptable and
19 unnecessary risks of addiction and death.

5. The State of Arizona brings this action pursuant to the Arizona Consumer
Fraud Act, A.R.S. §§ 44-1521–44-1534, to obtain restitution, declaratory and
injunctive relief, civil penalties, disgorgement, attorneys' fees and costs,
investigative expenses, and other relief to prevent the unlawful acts and
practices alleged in this Complaint.

25

## JURISDICTION AND VENUE

26 6. This Court has jurisdiction over Defendants pursuant to A.R.S. § 44-1528.
27 7. Venue is proper in Maricopa County, Arizona.

1	PARTIES	
2	8. Plaintiff is the State of Arizona, ex rel. Mark Brnovich, the Attorney	
3	General of Arizona ("the State"), who is authorized to bring this action under the	
4	Arizona Consumer Fraud Act, A.R.S. §§ 44-1521–44-1534.	
5	9. Defendant Insys is a Delaware corporation with its principal place of	
6	business at 1333 South Spectrum Boulevard, Suite 100, Chandler, Arizona	
7	85286.	
8	10. At all relevant times, Insys did business in Arizona by marketing, selling,	
9	and promoting the prescription drug Subsys.	
10	11. Defendant Alec Burlakoff ("Burlakoff") is the former Vice President of	
11	Sales for Insys. Burlakoff is a resident of Mecklenburg County, North Carolina,	
12	and while employed by Insys, was a resident of Maricopa County, Arizona.	
13	12. Jane Doe Burlakoff is named in the event that Alec Burlakoff is married	
14	and that community property exists against which the State can obtain	
15	monetary relief in this matter. When the State learns the true identity of Jane	
16	Doe Burlakoff, it will move to amend its Complaint accordingly.	
17	13. Defendant Elizabeth Gurrieri ("Gurrieri") is the former Manager of	
18	Reimbursement Services for Insys, and is a resident of Pinal County, Arizona.	
19	14. John Doe Gurrieri is named in the event that Elizabeth Gurrieri is married	
20	and that community property exists against which the State can obtain	
21	monetary relief in this matter. When the State learns the true identity of John	
22	Doe Gurrieri, it will move to amend its Complaint accordingly.	
23	15. At all relevant times, Burlakoff and Gurrieri did business in Arizona by	
24	marketing, selling, and promoting the prescription drug Subsys.	
25	16. Defendant Steve Fanto ("Fanto") is a medical doctor and a resident of	
26	Maricopa County, Arizona.	
27	17. Jane Doe Fanto is named in the event that Steve Fanto is married and	
28	that community property exists against which the State can obtain monetary	

relief in this matter. When the State learns the true identity of Jane Doe Fanto, it
 will move to amend its Complaint accordingly.

3 18. Defendant Nikesh Seth ("Seth") is a medical doctor and a resident of
4 Maricopa County, Arizona.

5 19. Jane Doe Seth is named in the event that Nikesh Seth is married and that
6 community property exists against which the State can obtain monetary relief in
7 this matter. When the State learns the true identity of Jane Doe Seth, it will
8 move to amend its Complaint accordingly.

9 20. Defendant Sheldon Gingerich ("Gingerich") is a medical doctor and a10 resident of Pima County, Arizona.

11 21. Jane Doe Gingerich is named in the event that Sheldon Gingerich is
12 married and that community property exists against which the State can obtain
13 monetary relief in this matter. When the State learns the true identity of Jane
14 Doe Gingerich, it will move to amend its Complaint accordingly.

15 22. At all relevant times, Fanto, Seth, and Gingerich did business in Arizona
16 by selling medical services and prescribing medications, including Subsys, to
17 patients.

18

## **ALLEGATIONS**

19 23. Since March 2012 to the present date, Insys advertised and sold Subsys,
20 a Schedule II opioid as defined by the United States Controlled Substances Act,
21 U.S.C. § 801–971, in Arizona and nationwide.

22 24. A drug is categorized under Schedule II if (1) the drug has a high
23 potential for abuse, (2) the drug has a currently accepted medical use in the
24 United States or a currently accepted medical use with severe restrictions, and
25 (3) abuse of the drug may lead to severe psychological or physical dependence.
26 25. Subsys is Insys's primary product offering.

- 27
- 28

Subsys contains fentanyl, a powerful opioid that can reduce pain, but is
 also highly addictive and potentially lethal, especially if not prescribed or used
 properly.

4 27. Fentanyl can come in a variety of forms, including tablets or patches.

5 28. Subsys is a fentanyl spray applied under the tongue, allowing the fentanyl
6 to rapidly reach the bloodstream.

7 29. Subsys is a Transmucosal Immediate-Release Fentanyl ("TIRF")
8 medication, a class of opioid drugs that have a rapid onset from being absorbed
9 through the oral mucosa.

10 30. Like all TIRFs, Subsys is subject to a Risk Evaluation and Mitigation
11 Strategy ("REMS") mandated by the FDA, which requires both patients using
12 and physicians prescribing Subsys to enroll in an education program to
13 minimize "the risk of misuse, abuse, addiction, overdose and serious
14 complication" associated with TIRFs.

15 31. The FDA-approved label for Subsys highlights two dangers associated16 with Subsys: (1) fatal respiratory depression; and (2) potential for abuse.

17 32. The FDA has approved Subsys for a limited indication for use, namely:
18 "the management of breakthrough pain in cancer patients 18 years of age and
19 older who are already receiving and who are tolerant to around-the-clock opioid
20 therapy for their underlying persistent cancer pain."

33. Because of the dangers associated with Subsys, and in particular the
dangers of fatal respiratory depression, Subsys's FDA-approved label also
warns about contraindications—circumstances under which the drug should not
be used.

34. Regarding contraindications, the label states: "Due to the risk of fatal
respiratory depression, SUBSYS is contraindicated in opioid non-tolerant
patients and in management of acute or postoperative pain, including
headache/migraines."

35. In addition, the FDA TIRF REMS warns, "Life-threatening respiratory
 depression could occur at any dose in opioid non-tolerant patients. Deaths have
 occurred in opioid non-tolerant patients treated with some fentanyl products."

4 36. Despite the dangers associated with the use of Subsys and its limited
5 indication, Insys engaged in a multi-pronged scheme designed to mislead
6 insurers, doctors, and patients in order to increase Subsys's sales in Arizona
7 and across the nation.

8 37. This scheme had three closely related components that worked in
9 tandem to mislead insurers, doctors, and patients into approving, prescribing,
10 and using Subsys.

11 38. First, Insys provided insurers and pharmacy benefit managers ("PBMs"),
12 companies hired by insurers to help control the costs of prescription drugs, with
13 false and misleading information in order to obtain prior authorization for
14 patients' Subsys prescriptions.

15 39. Second, Insys provided healthcare professionals ("HCPs") with false and
16 misleading information in order to deceive them into believing the FDA had
17 approved Subsys for more uses than the FDA had actually approved.

18 40. Third, Insys paid sham "speaker fees" to doctors to run supposed
19 educational events, but the fees were primarily intended to reward doctors for
20 prescribing Subsys and incentivize them to prescribe more Subsys to patients.

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22

## A. Insys Misled Health Insurers and PBMs into Paying for

## Subsys.

41. Because of Subsys's limited indication, significant patient risks, and high
cost, health insurers and PBMs routinely require prior authorization before
paying for Subsys.

26 42. Without prior authorization, Subsys prescriptions would have to be paid27 for by the patient or a third party.

43. Given how expensive Subsys is, and the availability of other, more
affordable alternatives, the denial of prior authorization typically results in no
one paying to fill the Subsys prescription.

4 44. Typically, prior authorization requests are submitted by HCPs' offices to
5 insurers and PBMs.

6 45. The requests include patient information, including past medical history
7 and current conditions, typically using standardized codes to classify diseases
8 and injuries.

9 46. After evaluating that information, insurers and PBMs initially granted prior10 authorization for Subsys prescriptions at a relatively low rate.

11 47. For example, in November 2012, the rate of prior authorization for Subsys12 was between 30% and 33%.

13 48. The State is currently aware of 292 prior authorization forms submitted by14 Arizona HCPs to Insys.

49. Approximately 67% of the patients represented on those 292 forms did
not have breakthrough cancer pain, but instead had other conditions such as
back pain, migraines, and chronic pain syndrome—some of which were
expressly contraindicated by the FDA for the use of Subsys.

19 50. If insurers and PBMs had limited prior authorization to the Arizona
20 patients who had breakthrough cancer pain, the prior authorization rate would
21 have been approximately 33%, in line with the November 2012 prior
22 authorization rates obtained by HCPs.

23 51. Insys devised a scheme to deceive insurers and HCPs in order to24 increase the rate of prior authorizations, and thereby increase sales of Subsys.

25 52. In or about January 2013, Insys launched the Insys Reimbursement
26 Center ("IRC").

27 53. IRC is an Insys program and call center designed to obtain prior28 authorization for Subsys from insurers and PBMs.

1 54. IRC is located in Arizona at Insys's corporate headquarters.

2 55. After creating IRC, Insys directed its sales professionals to encourage
3 HCPs to utilize IRC for prior authorizations.

4 56. Participating HCPs sent the IRC "Reimbursement Assistance/Prior
5 Authorization Request" forms that included patients' identifying information, as
6 well as their diagnoses.

7 57. Defendant Elizabeth Gurrieri directly supervised and instructed IRC
8 employees from approximately January 2013 through July 2016.

9 58. In or about March 2013, Insys promoted Gurrieri and named her the10 Manager of Reimbursement Services for Insys.

11 59. IRC employees, as directed by Insys and Gurrieri, communicated directly
12 with insurers and PBMs to attempt to secure payment by insurers for Subsys
13 prescriptions written by participating HCPs.

14 60. In those communications, as described below, IRC employees, as15 directed by Insys and Gurrieri, used a number of deceptive and unfair practices.

16 61. By taking control of the prior authorization process and manipulating the
17 information provided to insurers, Insys and Gurrieri were able to rapidly and
18 dramatically increase the likelihood that each Subsys prescription written would
19 translate into additional units of Subsys sold.

20 62. A July 2013 presentation from the Insys Board of Directors Meeting
21 indicated that the IRC was obtaining prior authorizations for Subsys over 75% of
22 the time.

63. A November 2013 presentation from the Insys Board of Directors Meeting
indicated that the IRC was obtaining prior authorizations for Subsys 100% of the
time.

26 64. The IRC practices described below are responsible for most or all of the
27 dramatic difference between the IRC prior authorization rates and the 30-33%
28 rate of prior authorization obtained by HCPs in November 2012.

65. Through the IRC, Insys and Gurrieri engaged in deceptive and unfair
 practices to increase the likelihood that insurers and PBMs granted prior
 authorization for Subsys prescriptions.

66. On June 19, 2017, Gurrieri pled guilty in federal court to conspiracy to
commit wire fraud for her role in directing IRC employees to engage in the
practices described below.

## 1. <u>The IRC Concealed that Calls Were Coming from Insys, Not</u> <u>HCPs.</u>

9 67. Insys and Gurrieri knew that insurers and PBMs were less likely to give
10 prior authorization for Subsys if the insurers or PBMs knew that the call came
11 from an Insys employee, rather than an employee of the HCP.

12 68. Insys and Gurrieri directed employees in the IRC to lead insurers and
13 PBMs to believe that they were calling from HCPs' offices, when in fact they
14 were calling directly from Insys.

15 69. Insys and Gurrieri directed employees in the IRC to pose as employees16 of HCPs' offices, when in fact they worked for Insys.

17 70. Insys and Gurrieri blocked the IRC phone numbers, so that insurers and
18 PBMs could not observe that the area code of the IRC differed from most of the
19 HCPs' offices.

20 71. Because Insys's employees were posing as employees of HCPs' offices,
21 their representations carried more weight than if the Insys employees had
22 disclosed that: (1) they were employed by Insys; (2) they had no connection to
23 the HCPs or the patient; and (3) they were in no position to describe the HCPs'
24 knowledge or thought process.

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## 2. <u>The IRC Falsely Claimed that Patients Had Cancer.</u>

26 72. Insys and Gurrieri knew that insurers and PBMs were less likely to give
27 prior authorization for Subsys if patients did not have cancer, given that the FDA
28 only approved Subsys to treat breakthrough cancer pain.

1 73. Insys and Gurrieri directed employees in the IRC to tell insurers and 2 PBMs that patients had cancer when in fact those patients did not have cancer, 3 and had never had cancer. 4 74. Insys and Gurrieri directed employees in the IRC to tell insurers and 5 PBMs that patients were being treated for cancer, when in fact those patients 6 had recovered from cancer or were in remission. 7 75. An FBI agent filed an affidavit in connection with Gurrieri's criminal 8 indictment (the "FBI Agent Affidavit"). 9 76. According to the FBI Agent Affidavit, employees attributed the following 10 statements to Gurrieri: 11 a. "[I]f there was any history of cancer . . . give the breakthrough 12 cancer pain code." 13 b. "I got a chart and you know, I need you guys to do whatever you 14 have to do. If you have to give them the cancer code, give it to them to 15 get it approved, because it's a new script. Who wants it?" 16 З. The IRC Falsely Claimed that Patients Had Breakthrough 17 Cancer Pain. 18 77. Insys and Gurrieri knew that insurers and PBMs were less likely to give 19 prior authorization for Subsys if patients did not have breakthrough cancer pain, 20 which was the FDA-approved use for Subsys. 21 Insys and Gurrieri directed employees in the IRC to lead insurers and 78. 22 PBMs to believe that patients were being treated for breakthrough cancer pain 23 when in fact that was not the case. 24 79. Insys and Gurrieri directed employees in the IRC to read the following 25 statement to insurers and PBMs when those entities asked whether the patient 26 at issue was being treated for breakthrough cancer pain: "The physician is 27 aware that the medication is intended for the management of breakthrough pain 28 10

in cancer patients. The physician is treating the patient for their pain (or
 breakthrough pain, whichever is applicable)."

80. By stating that the patient was being treated for "pain" or "breakthrough
pain" immediately after acknowledging the intended use for breakthrough
cancer pain, Insys and Gurrieri avoided directly stating that the patient did not
have breakthrough *cancer* pain, while implying that the patient was in fact being
treated for breakthrough cancer pain.

8 81. The statement also implied that the person reading the statement had
9 knowledge of the doctor's awareness, when in fact the person reading the
10 statement was an IRC employee who (in all likelihood) had never even spoken
11 with the doctor.

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## 4. <u>The IRC Falsely Claimed that Patients Had Difficulty</u>

#### <u>Swallowing.</u>

14 82. Insys and Gurrieri knew that insurers and PBMs were less likely to give
15 prior authorization for Subsys if patients did not have difficulty swallowing, as
16 those patients could take pain medications in other, less expensive forms, such
17 as pills.

18 83. Insys and Gurrieri directed employees in the IRC to tell insurers and
19 PBMs that patients had dysphagia (difficulty swallowing) when in fact that was
20 not the case.

84. Insys and Gurrieri and its employees made these false dysphagia claims
because the claim of dysphagia increased the likelihood of the insurer or PBM
granting prior authorization.

24 85. According to the FBI Agent Affidavit, employees attributed the following
25 statements to Gurrieri:

- 26 a. "Put dysphagia [difficu
- 27
- 28

a. "Put dysphagia [difficulty swallowing] on every single authorization."

b. [When asked if a patient had difficulty swallowing,] "No, but we have to say that. That's what we have to do to get it approved or else they won't approve it."

# 5. <u>The IRC Falsely Claimed that Patients Had Tried Other</u> <u>Medications and Found Them Ineffective.</u>

86. Insys and Gurrieri knew that insurers and PBMs were less likely to give
prior authorization for Subsys if patients had not tried other "preferred"
medications that were less expensive, less addictive, or less dangerous.

9 87. Insys and Gurrieri directed employees in the IRC to tell insurers and
10 PBMs that patients had tried other preferred medications and that those
11 medications were ineffective in treating their medical conditions, when in fact
12 patients had not tried those medications.

13 88. According to the FBI Agent Affidavit, an employee stated that Gurrieri
14 instructed employees to use a "cheat sheet" of preferred drugs and tell insurers
15 that the patient had found all of the drugs on the cheat sheet to be ineffective,
16 when in fact this was false.

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# B. Insys Misled Doctors Regarding the Use of Subsys for Mild Pain.

19 89. In order to increase the pool of patients who would be prescribed Subsys,
20 Insys engaged in deceptive and misleading practices to deceive doctors about
21 the uses the FDA had approved for Subsys.

90. The FDA approved Subsys only for "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."

26 91. Insys used a document called a core visual aid in its sales presentations27 to HCPs.

92. Insys required the members of its sales force to use the core visual aid to
 market Subsys in sales presentations to HCPs.

- 3 93. HCPs doing presentations for Insys were also supposed to use a slide
  4 deck that included a definition of breakthrough pain.
- 5 94. Initially, Insys defined breakthrough cancer pain on its core visual aid as
  6 "intense increases in pain that occur with rapid onset even when pain-control
  7 medication is being used."
- 8 95. For that definition, Insys cited to a 1990 article by Russell K. Portenoy
  9 and Neil A. Hagen entitled "Breakthrough Pain: Definition, Prevalence and
  10 Characteristics."
- 11 96. However, in or around June 2012, Insys changed the definition on its core
  12 visual aid to "a flare of *mild-to-severe* pain in patients with otherwise stable
  13 persistent pain" (emphasis added).
- 14 97. Insys's definition of breakthrough cancer pain as including mild pain is15 unsupported and misleading.
- 16 98. In an attempt to justify its new definition of breakthrough cancer pain,17 Insys again cited to the Portenoy and Hagen article.
- 18 99. That article, however, did not support Insys's definition of breakthrough19 cancer pain as "mild-to-severe" pain.
- 20 100. In fact, Portenoy and Hagen's definition of breakthrough pain specifically
  21 *excluded* mild and moderate pain.
- 101. Portenoy and Hagen wrote: "Breakthrough pain was defined as a
  transitory increase in pain to greater than moderate intensity (that is, to an
  intensity of 'severe' or 'excruciating') . . . ."
- 25 102. Insys misrepresented the article that it cited.
- 26 103. Insys made these misrepresentations in order to deceive HCPs into
  27 believing that mild pain was included in the definition of breakthrough cancer
  28 pain.

1 104. By using this definition of breakthrough cancer pain in its core visual aid 2 in presentations to HCPs, Insys falsely represented to HCPs that the FDA had 3 approved Subsys as a safe and effective treatment for mild pain. 4 105. Insys continued to make this misrepresentation through approximately 5 September 2013. 6 106. From June 2012 through September 2013, Insys's sales force conducted 7 approximately 2,400 sales visits in Arizona. 8 107. In addition, from October 2012 through September 2013, Insys conducted 9 at least 42 "speaker programs" in Arizona, at which HCPs were supposed to 10 use the slide deck supplied by Insys, which contained the misrepresentation 11 described above. 12 C. Insys Paid Top Prescribers Sham "Speaker Fees" in Exchange 13 for Those Prescribers Writing Subsys Prescriptions. 14 108. From March 2012 through April 2017, Insys secured a total of 15 approximately \$51.87 million in gross sales of Subsys in Arizona. 16 109. Sixty-four percent of Insys's sales from Subsys in Arizona during this 17 time frame came from prescriptions written by only three doctors—Defendants Fanto, Seth, and Gingerich. 18 19 110. Over that time frame, Defendants Fanto, Seth, and Gingerich wrote an 20 average of *nearly 1,000 Subsys prescriptions apiece*. 21 111. In contrast, over the same timeframe, the 145 prescribers of Subsys in

- 22 Arizona who were not paid speaker fees by Insys wrote an average of *less*
- 23 than 14 prescriptions apiece.
- 24 112. The dramatic difference in prescription numbers directly correlates with
  25 large payments Insys made to Defendants Fanto, Seth, and Gingerich.
- 26 113. Between March 2012 and April 2017, Defendants Fanto, Seth, and
  27 Gingerich were paid, on average, about \$200,000 apiece by Insys.
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114. Before Insys began paying them, Defendants Fanto, Seth, and Gingerich
 collectively wrote an average of about nine Subsys prescriptions a month.

3 115. During the time Insys paid them, Defendants Fanto, Seth, and Gingerich
4 collectively wrote an average of about 62 Subsys prescriptions a month—nearly
5 seven times their previous volume.

6 116. These startling statistics were no accident. Instead, they were the
7 predictable and calculated results of a scheme operated by Insys both in
8 Arizona and nationwide.

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# 1. <u>Insys's Speaker Fee Scheme Was a Primary Driver of</u> <u>Subsys Sales to Patients.</u>

11 117. Nationwide, Insys has sold hundreds of millions of dollars of Subsys in
12 just over five years, despite its limited indication and the dangers associated
13 with the drug.

14 118. As a result of these sales, Insys has made hundreds of millions of dollars
15 in profits, including nearly \$200 million in profits in 2014, over \$300 million in
16 profits in 2015, and over \$215 million in profits in 2016.

17 119. A primary driver of Subsys's remarkable sales was a scheme designed
18 and implemented by top officers at Insys, under which certain HCPs received
19 "speaker fees" conditioned on the HCPs prescribing a high volume of Subsys to
20 their patients.

21 120. Insys advertised Subsys to HCPs through the use of its sales force of22 specialty sales professionals ("SSPs").

23 121. Each SSP was responsible for advertising Subsys to HCPs assigned to24 him or her.

122. As a sales tactic, Insys directed SSPs across the country to schedule
regular speaker programs at which one of the SSPs' assigned HCPs would
purportedly present an Insys-prepared PowerPoint presentation regarding
Subsys in exchange for a speaker fee.

1 123. Insys allowed the programs to take place in the HCP's office and last as
2 little as 30 minutes.

3 124. Insys typically paid HCPs between \$2,400 and \$4,700 per presentation.

4 125. Insys primarily intended its speaker programs to reward Subsys
5 prescriptions and generate Subsys sales from the physicians who were paid the
6 speaker fees, rather than to educate other physicians, who would then
7 presumably prescribe Subsys. This intent is demonstrated by the following
8 facts:

9 126. First, Insys directed SSPs to sell Subsys by focusing on one or two
10 doctors whom Insys could rely on to write one Subsys prescription per day (as
11 opposed to a broad base of HCPs writing prescriptions as appropriate);

12 127. Second, Insys's speaking programs did not result in HCPs other than the
paid speakers writing a significant number of Subsys prescriptions, yet Insys
continued to pay the speaker-HCPs who prescribed more Subsys but were
ineffective at encouraging other HCPs to prescribe Subsys; and

16 128. Third, many of the speaker programs Insys paid for had few or no17 attendees with the license necessary to prescribe Subsys.

18 129. Insys's sales strategy was developed and implemented in Arizona and19 nationwide shortly after Subsys launched in March 2012.

20 130. On September 17, 2012, Alec Burlakoff, former Vice President of Sales at
21 Insys, emailed the Subsys sales force and emphasized the connection between
22 the speaker programs and prescriptions written by the paid speakers.

131. In that email, Burlakoff stated that "if your speaker does not have at least
24 20 patients on Subsys (QTD), he or she should not be booked to speak at this
25 juncture. You should cancel or suspend your programs until you and your
26 manager have had ample chance to think this investment entirely through."

27

1 132. Burlakoff told the sales force that they "must hold off on the conduction of
2 these valuable speaker programs," until they knew "for absolute sure" that "if
3 you use a specific speaker that the program will yield positive results."

4 133. At a national sales meeting held on September 21, 2012, Burlakoff told
5 the Subsys sales force that a "critical success factor" in selling Subsys was to
6 schedule a "[h]igh and consistent number of ISP's with top 20 targets."

7 134. "ISP" stands for Insys Speaker Programs, and "targets" refers to HCPs.

8 135. Burlakoff's directive was an attempt to drive sales with a relatively small,
9 targeted group of HCPs by frequently paying them thousands of dollars in
10 "speaker fees."

11 136. At the same meeting, Burlakoff, analogizing doctors to race horses, told
12 his sales force to: "Make sure you chose the correct horse / horses . . . . Give
13 your horses all the TLC they need . . . . Ride your horses every chance you
14 get."

15 137. Burlakoff also urged the sales force, in text displayed over a picture of a16 horse race, that "IF YOU WANT TO WIN it is time to start cracking the whip!"

17 138. On April 26, 2013, Burlakoff again directed the Subsys sales force to
18 reward HCPs for writing Subsys prescriptions, stating: "Lastly – your doctors
19 need to know their support of Subsys was noticed. These important clinicians
20 MUST promptly be rewarded with positive reinforcement immediately . . . ."

21 139. The "positive reinforcement" Burlakoff referred to was frequent ISPs and
22 tens or hundreds of thousands of dollars' worth of speaker fees for those
23 prescribers.

24 140. Insys was only willing to pay HCPs speaker fees, however, if those HCPs
25 wrote enough Subsys prescriptions.

26 141. On March 7, 2013, Burlakoff wrote an email to regional sales managers
27 (or "RSMs") regarding the RSMs' and SSPs' expenditures, and how the value

1 of those expenditures was ultimately determined by return on investment
2 ("ROI"). Burlakoff wrote:

3 I am inclined to find myself more excited by the larger amounts of 4 money I see the managers spending, although—it all comes down 5 to ROI. If you are going to spend the most money, you should 6 probably b[e] #1 in the region. Do not b[e] shy, it takes money to 7 make money . . . Spend some money and close some deals (that's 8 what you were hired for) . . . . As far as the reps are concerned . . . 9 [s]ame rules apply: -If the rep spent the least money, we would 10 probably assume that he or she is not working / following our 11 direction[.] –If the rep spent the most money, he or she better be 12 able to answer your questions around their specific plan of action 13 with each customer [HCP] they are spending money on (they are 14 most likely ranked at the top of the company, based on my 15 experience)[.]

16 142. On April 1, 2013, Burlakoff acknowledged the critical importance that
17 speaker programs played in driving Subsys sales. Burlakoff wrote: "I said it a
18 thousand times. ISP's are the most important thing you will do to increase your
19 business. ISP's are basically the ONLY thing you should be focusing on to
20 increase your sales."

21 143. Burlakoff went on to say that SSPs should be "living, eating, and
22 breathing ISP's to drive sales . . . PROGRAMS ARE THE ONLY THING THAT
23 MATTERS, WHY DO SOME OF YOU REFUSE TO ACKNOWLEDGE THIS
24 PROVEN FACT?"

25 144. Further, Burlakoff directed SSPs to drive sales by focusing on one or two26 doctors.

27 145. On March 19, 2013, Burlakoff wrote an email to the Subsys sales force28 praising the top five selling SSPs. Burlakoff wrote:

"The below 5 names mentioned at the top of the company rankings – literally have their entire business being driven by basically 1 customer. . . . [These top five sales representatives] found a customer to 'own', and they packed the proverbial suitcase and moved in. . . . Every winning team, must have their 'MVP' player."

6 146. Burlakoff went on to say, "It is and has always been your assignment to
7 find this key player. If you have not found this doctor, throw the decile list, call
8 list, routing, ROO list, etc. out the window. You have to start prospecting and
9 develop a key doctor."

10 147. The "MVP players" Burlakoff referenced in his March 19, 2013 email were
11 the top five Subsys prescribers nationwide, all of whom were highly
12 compensated speakers for Insys.

13 148. These five "MVP" speakers/Subsys prescribers have all been the subject
14 of criminal lawsuits, civil lawsuits, or disciplinary actions on the basis of
15 improper prescribing (or otherwise fraudulent) practices, as follows:

a. Dr. Gavin Awerbuch pled guilty to charges of health care fraud and
distribution of controlled substances on November 7, 2016, and agreed to
forfeit \$4.1 million. The basis of Awerbuch's plea included that he
knowingly and intentionally prescribed Subsys to patients for no
legitimate medical purpose.

b. Dr. Xiulu Ruan was found guilty of accepting illegal kickbacks from
Insys, as well as other crimes, and was sentenced to 21 years in prison
on May 26, 2017. The indictment notes that although the money paid to
Ruan by Insys "was ostensibly paid for 'speaking fees,' it was actually
paid to induce, and in exchange for, Ruan . . . prescribing high volumes of
Subsys."

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c. Dr. Steven Y. Chun paid \$750,000 to settle a False Claims Act lawsuit in February 2014. The lawsuit alleged that Chun's pain clinic billed Medicare for physician office visits not actually performed.

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d. Dr. Judson Somerville was disciplined by the Texas Medical Board (the "Board"). On December 11, 2013, the Board noted three of Somerville's patients had died in the latter half of 2012 from drug toxicity. When Somerville's office was inspected, the Board discovered that Somerville had pre-written 93 prescriptions for Schedule II medication and directed his employees to use these forms to "write" renewal prescriptions. The Board prohibited Somerville from prescribing Schedule II controlled substances (including Subsys). In 2016, the Board suspended Somerville's license because he "continued to prescribe very high doses of opioids in an escalating fashion."

e. Dr. Jerrold Rosenberg was indicted by a federal grand jury on
February 1, 2017, for conspiring to receive kickbacks in the form of
\$180,000 in speaker fees from Insys in exchange for writing Subsys
prescriptions. Among other things, the indictment charges that
Rosenberg refused to switch patients off of Subsys, even if it was causing
debilitating side effects.

20 149. In addition to those listed above, other HCPs have also been indicted on
21 charges stemming from accepting speaker fees from Insys in exchange for
22 writing Subsys prescriptions:

a. On June 23, 2015, Heather Alfonso, a former advanced practice registered nurse, entered a guilty plea for accepting kickbacks in the form of speaker fees from Insys in exchange for writing Subsys prescriptions.

b. Dr. John Couch was found guilty of accepting illegal kickbacks from Insys, as well as other crimes, and was sentenced to 20 years in prison on May 25, 2017. The indictment notes that although the money paid to Couch by Insys "was ostensibly paid for 'speaking fees,' it was actually paid to induce, and in exchange for . . . Couch prescribing high volumes of Subsys."

4 150. Furthermore, on February 17, 2016, Natalie Perhacs, the Insys SSP
5 responsible for selling Subsys to Dr. Xiulu Ruan and Dr. John Couch, pled guilty
6 to conspiring to pay illegal kickbacks for her role in providing Ruan and Couch
7 with speaker fees in exchange for them writing Subsys prescriptions.

8 151. On July 9, 2013, Burlakoff again emailed his sales force encouraging
9 them to develop one or two prescribers from whom they could generate
10 prescriptions on demand:

"The goal is 1 rx per day . . . . Are you still calling on multiple
doctors a day giving a 'stand up message' in the hall way? If so,
you don't stand a chance of lasting in this market. Do you have 1 or *2 customers* whom [sic] have now become your best friend, *that you can rely on at [l]east 1 rx per day* and are you visiting this
office every single day? If the answer is no, you are truly in a very
bad situation." (Emphasis added.)

18 152. As demonstrated by Burlakoff's emails, Insys did not intend for speaker19 programs to generate a broad base of prescribers.

20 153. The speaker programs provided Insys with a means of paying a small
21 number of HCPs to write large amounts of Subsys prescriptions and
22 dramatically increase the profits of the entire company.

23 154. Insys and Burlakoff consistently directed the Insys sales force to sell
24 Subsys by scheduling speaking programs with one or two doctors who would, in
25 exchange, write Subsys prescriptions.

26 155. Insys's speaker program was a means of putting money into HCPs'
27 pockets, which Insys and Burlakoff primarily intended to be a system to reward

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and incentivize those HCPs to write Subsys prescriptions, not a program meant
to educate other HCPs about the characteristics of Subsys.

3 156. On December 6, 2016, former Insys CEO Michael Babich, Burlakoff, and
4 four other former Insys employees were indicted by a federal grand jury on
5 charges of conspiracy to violate the federal anti-kickback statute for their roles
6 in the speaker fee scheme.

7 2. <u>Defendant Fanto Participated in the Speaker Fee Scheme.</u>
8 157. Insys SSP Brianna Smith was responsible for interacting with Arizona
9 HCPs.

10 158. One of Smith's top targets in Arizona from whom she expected large
11 numbers of Subsys prescriptions was Dr. Steven Fanto, a doctor based in
12 Scottsdale whose practice primarily dealt with pain management.

13 159. Insys directed Smith to schedule ISPs for Fanto.

14 160. Insys made the decision to target Fanto as a paid speaker and as a top15 prescriber of Subsys as early as October 2012.

16 161. On October 22, 2012, Smith's regional sales manager, Darin Fila,
17 emailed her, stating, "You have to submit some programs today for Fanto, as
18 there is a lot of pressure to get these in."

19 162. Smith responded, "I am doing what I can. Do I need to have all eight20 scheduled by eod?"

21 163. On October 25, 2012, Insys paid Fanto his first speaker fee, totaling
22 \$2,400.

23 164. On November 9, 2012, then-Insys CEO Michael Babich emailed Burlakoff
24 and Matthew Napoletano, Insys's Vice President of Marketing, stating, "[Fanto]
25 needs to start crankin[g] or he gets taco bell."

26 165. Within minutes, Burlakoff responded, giving context to Babich's
27 statement. Burlakoff replied, "Actually –when you look at WAC revenue (which

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includes strength and units) NOT total scripts—[Fanto] is our 5<sup>th</sup> biggest
producer at INSYS and we have not even begun!"

- 3 166. Hours later, Burlakoff forwarded the above email thread to Smith, the
  4 SSP who advertised Subsys to Fanto.
- 5 167. Within a month of Burlakoff's November 9, 2012 email, Insys gave Fanto
  6 four more speaker programs, and paid him \$2,400 for each.
- 7 168. Over the next four years, through at least December 2016, Fanto
  8 received a high number of speaker engagements, typically two or more a
  9 month.
- 10 169. Insys intended the speaker fees it paid to Fanto to be a reward for
  11 Fanto's previous Subsys prescriptions and an incentive for Fanto to write
  12 additional Subsys prescriptions.
- 13 170. For example, on her "ISP Representative Evaluation Form" for Fanto's
  14 speaker program on November 29, 2012, Smith wrote that an anticipated
  15 outcome of the program was that "Dr. Fanto is making a shift toward switching
  16 many of his current patients to [S]ubsys."
- 17 171. Fanto's prescribing pattern changed around the time that he started18 receiving payments from Insys.
- 19 172. From December 2012 to January 2013, Fanto wrote 24 Subsys
  20 prescriptions, nearly five times the Subsys prescriptions he had written from
  21 October to November 2012.
- 22 173. In January 2013, Insys learned that Smith was having a "consensual23 relationship with Dr. Fanto."
- 24 174. Insys took no corrective action and allowed Smith to continue advertising
  25 Subsys to Fanto, and told Smith in February 2013 that Insys "fully" supported
  26 her continuing to do so.
- 27 175. In fact, in April 2013, Insys gave Smith a \$5,000 raise because of her
  28 sales—which were almost entirely driven by prescriptions written by Fanto.

Fanto had single-handedly accounted for 75% of Subsys sales in Arizona the
previous quarter, and generated the ninth-most revenue for Insys out of all
HCPs nationwide that quarter.

4 176. From March 2012 through April 2017, Fanto wrote a total of 1,294 Subsys
5 prescriptions—far and away the most of any HCP in Arizona.

6 177. Before receiving speaker fees, from March 2012 to October 2012, Fanto
7 wrote 43 Subsys prescriptions—approximately five prescriptions per month.

8 178. During the time Insys paid Fanto speaker fees, Fanto wrote a total of

9 1,172 Subsys prescriptions—approximately 23 prescriptions per month,
10 nearly five times as much as he wrote prior to Insys paying him speaker
11 fees.

12 179. In other words, before Insys paid him speaker fees, Fanto prescribed
13 Subsys about once a week on average. After Insys paid him speaker fees,
14 Fanto prescribed Subsys about once *every working day* on average—meeting
15 the goal Burlakoff had given to the Insys sales force of finding one doctor they
16 could count on for "1 rx per day."

17 180. Before receiving speaker fees, from March 2012 to October 2012, Fanto
18 generated an average of \$16,296 a month in Subsys prescriptions for Insys.

19 181. During the time Insys paid Fanto speaker fees, Fanto generated an
20 average of *\$349,570 a month* in Subsys prescriptions for Insys.

21 182. Fanto's additional prescriptions above his prior average generated a total
22 of approximately \$16,663,726 in additional revenue for Insys.

23 183. From October 25, 2012 to December 15, 2016, Insys paid Fanto24 \$308,380 in speaker fees.

25 184. The following chart shows Fanto's history of Subsys prescriptions and26 Insys speaker fees, based on data collected from Insys:

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10 185. Insys paid Fanto speaker fees even though he posed a danger to his
11 patients by inappropriately prescribing opioids.

12 186. On July 12, 2017, based, in part, on Fanto's prescribing of Subsys, Fanto
13 signed an interim consent agreement (the "Consent Agreement") with the
14 Arizona Medical Board that prohibits him from engaging in the practice of
15 medicine.

16 187. The Consent Agreement states that between 2011 and 2016, Fanto
17 deviated from the standard of care by *initiating* off-label Subsys treatment at
18 the highest available dose of 800 mcg with at least three patients, contrary to
19 directions contained in Subsys's FDA-approved label.

20 188. Subsys's FDA-approved label referenced in the Consent Agreement
21 instructs HCPs to titrate patients, initially starting patients off at the lowest
22 possible dose of Subsys—100 mcg—and then slowly increasing the patient's
23 dosage level "until the patient reaches a dose that provides adequate analgesia
24 using a single SUBSYS dose per breakthrough cancer pain episode with
25 tolerable side effects."

26 189. Furthermore, any HCP enrolled in the TIRF REMS program is required to27 sign a Prescriber Enrollment Form in which he or she acknowledges that "I

understand that the initial starting dose for TIRF medicines for <u>all</u> patients is the
 lowest dose . . . ."

3 190. The Consent Agreement states that Fanto prescribed one of the three
4 patients at issue 120 units of Subsys 800 mcg monthly for six months, even
5 though the patient reported only using approximately 30 units per month.

6 191. The Consent Agreement also states that Fanto prescribed the 800 mcg
7 dose of Subsys to one of the three patients at issue despite the patient having
8 sleep apnea, thereby deviating from the standard of care, and did so contrary to
9 the opinion of the patient's pulmonologist.

10 192. The Consent Agreement states that Fanto's Subsys prescriptions put at
11 least two patients "at risk of potentially fatal arrhythmias" and "at risk of the
12 potential harms associated with long term opioid use including abuse, addiction,
13 diversion and accidental overdose."

14 193. Fanto's initial prescriptions of Subsys at high doses put patients at risk,
15 but they also generated substantial revenue for Insys; the higher the dose of
16 Subsys, the more money Insys made.

17 194. Insys gave its SSPs an economic incentive to have their HCPs write
18 higher doses because Insys paid the SSPs more compensation for higher dose
19 prescriptions than for lower dose prescriptions.

20 195. Indeed, Burlakoff urged Insys SSPs at the September 21, 2012 national
21 sales meeting to "be sure your horses [HCPs] are 'unit' conscience [sic]" and
22 "be sure your horses [HCPs] are 'dosage' conscience [sic]."

196. Similarly, when a HCP followed the titration schedule and started his or
her patients at any dose 400 mcg or lower, Insys referred to that dose as a "low
dose" and automatically sent an email to the HCP's SSP that demanded that
the SSP "report back to your manager within 24 hours on WHY the low dose
was used and HOW the doctor plans to titrate the patient to effective dose."

1 З. Defendant Seth Participated in the Speaker Fee Scheme. 2 197. Defendant Seth wrote the second-highest number of Subsys 3 prescriptions in Arizona from March 2012 through April 2017. During this time 4 period, Seth wrote a total of 884 Subsys prescriptions. 5 198. Like Fanto, Seth's practice focused on pain management. 6 199. Before 2014, Seth had only prescribed Subsys twice, but between 7 January and May 2014, Seth prescribed Subsys 62 times. 8 200. Insys began paying Seth speaker fees on June 10, 2014. 9 201. Insys intended the speaker fees it paid to Seth to be a reward for Seth's 10 previous Subsys prescriptions and an incentive for Seth to write additional 11 Subsys prescriptions. 12 202. Seth's prescribing pattern changed around the time that he started 13 receiving payments from Insys. 14 203. Before receiving speaker fees, between March 2012 and February 2014, 15 Seth had written a total of 11 Subsys prescriptions over two years. 161 204. In the three months immediately before Insys first paid Seth speaker fees, 17 between March 2014 and May 2014, Seth wrote 53 Subsys prescriptions-18 approximately 18 per month. 19 205. During the time Insys paid Seth speaker fees, Seth wrote 820 Subsys 20 prescriptions—approximately 23 per month. 21 206. Insys did not pay Seth speaker fees until he started to prescribe far more 22 Subsys than he had previously. 23 207. While Insys paid him speaker fees, Seth prescribed Subsys about once every working day on average-meeting the goal Burlakoff had given to the 24 Insys sales force of finding one doctor they could count on for "1 rx per day." 25 26 208. Before receiving speaker fees, between March 2012 and May 2014, Seth 27 generated an average of \$8,301 a month in Subsys prescriptions for Insys. 28

209. While Insys paid him speaker fees from June 2014 to September 2016,
 Seth generated an average of *\$207,050 a month* in Subsys prescriptions for
 Insys.

4 210. Seth's additional prescriptions above his prior average generated a total
5 of approximately \$5,511,473 in additional revenue for Insys.

6 211. From June 10, 2014 to September 26, 2016, Insys paid Seth \$229,187.50
7 in speaker fees.

8 212. After September 2016, Insys did not pay Seth any more speaker fees.

9 213. After Insys stopped paying Seth speaker fees, Seth's prescribing of
10 Subsys paralleled his pre-speaker-fee averages. Seth wrote 13 Subsys
11 prescriptions over the next seven months, averaging just under two
12 prescriptions per month.

13 214. The following chart shows Seth's history of Subsys prescriptions and14 Insys speaker fees, based on data collected from Insys:



#### 4. Defendant Gingerich Participated in the Speaker Fee

## <u>Scheme.</u>

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25 215. Defendant Gingerich wrote the third-highest number of Subsys
26 prescriptions in Arizona from March 2012 through April 2017. During this time
27 period, Gingerich wrote a total of 741 Subsys prescriptions.

<sup>1</sup> 216. Like Fanto and Seth, Gingerich's practice focused on pain management.

2 217. Before May 2013, the highest number of Subsys prescriptions Gingerich
3 had ever written in a month was three prescriptions, but by July 2013, Gingerich
4 was writing 14 Subsys prescriptions a month, much more than anyone else in
5 Arizona except for Fanto.

6 218. Gingerich received his first speaker fee check from Insys on August 1,7 2013.

8 219. Insys intended the speaker fees it paid to Gingerich to be a reward for
9 Gingerich's previous Subsys prescriptions, and an incentive for Gingerich to
10 write additional Subsys prescriptions.

11 220. Gingerich's prescribing pattern changed around the time that he started12 receiving payments from Insys.

13 221. Before receiving speaker fees, between March 2012 and April 2013,
14 Gingerich wrote 7 Subsys prescriptions—averaging less than one prescription
15 per month.

16 222. In the three months immediately before Insys first paid Gingerich speaker
17 fees, between May 2013 and July 2013, Gingerich wrote 29 Subsys
18 prescriptions—approximately 10 per month.

19 223. During the time Insys paid Gingerich, Gingerich wrote 392 Subsys
20 prescriptions—approximately *16 per month*.

21 224. Insys did not pay Gingerich speaker fees until he started to prescribe far22 more Subsys than he had previously.

23 225. While Insys paid him speaker fees, Gingerich prescribed Subsys about
24 two out of every three business days on average—nearly meeting the goal
25 Burlakoff had given to the Insys sales force of finding one doctor they could
26 count on for "1 rx per day."

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226. Before receiving speaker fees, between March 2012 and July 2013,
 Gingerich generated an average of \$7,060 a month in Subsys prescriptions for
 Insys.

4 227. After he started receiving speaker fees, Gingerich generated an average
5 of *\$138,274 a month* in Subsys prescriptions for Insys.

6 228. Gingerich's additional prescriptions above his prior average generated a
7 total of approximately \$3,149,133 in additional revenue for Insys.

8 229. From August 1, 2013 to July 31, 2015, Insys paid Gingerich \$83,100 in
9 speaker fees, plus \$7,200 in consulting fees.

10 230. After Insys stopped paying Gingerich speaker fees, he initially continued
11 to prescribe Subsys prescriptions at a similar level, but the numbers gradually
12 decreased, and by Q1 2017, Gingerich was only writing seven or eight Subsys
13 prescriptions a month, similar to the amount he wrote in May and June 2014,
14 before Insys began paying him.





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1 232. Collectively, once Fanto, Seth, and Gingerich began receiving speaker 2 fees, their additional prescriptions (above their historical averages) generated 3

## over \$25 million for Insys.

4 233. Collectively, Insys paid Fanto, Seth, and Gingerich nearly \$600,000 in 5 speaker fees.

6 234. Collectively, for every dollar Insys gave Fanto, Seth, and Gingerich in 7 speaker fees, Insys received, on average, over 40 dollars in revenue.

8 235. Collectively, in terms of "ROI," as Burlakoff put it, Insys obtained over 9 4,000% return on investment from its payments to Fanto, Seth, and Gingerich.

10 236. In July 2017, the State issued civil investigative demands to Fanto, Seth, 11 and Gingerich, asking whether they disclosed that they were paid speakers for 12 Insys to the patients to whom they were prescribing Subsys.

13 237. As of the date of the filing of this complaint, Fanto, Seth, and Gingerich 14 each refused to answer, or failed to answer, the State's civil investigative 15 demands.

16 238. Given the failure to respond and the amount of Subsys prescriptions each 17 HCP wrote while being paid by Insys, it is reasonable to infer that Fanto, Seth, 18 and Gingerich each prescribed Subsys to consumers without disclosing: (1) the 19 fact that Insys was paying them tens of thousands of dollars a year (sometimes 20 in excess of \$100,000 per year for a single HCP) and (2) the fact that Insys was 21 paying them in exchange for prescribing Subsys.

22 239. At all relevant times, Insys controlled, funded, and acted in concert with 23 the HCPs it paid through its speaker programs (including Fanto, Seth, and Gingerich) to prescribe high volumes of Subsys. 24

240. At all relevant times, these HCPs (including Fanto, Seth, and Gingerich) 25 26 acted as Insys's agents in prescribing high volumes of Subsys to patients while 27 Insys was paying the HCPs.

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At all relevant times, Insys conspired with these HCPs (including Fanto,
 Seth, and Gingerich) with regard to the HCPs' conduct in prescribing high
 volumes of Subsys to patients in exchange for payments from Insys.

## 4 5

# D. Insys Failed to Warn Consumers about the Risks of Harm Resulting from Its Scheme

*Insys failed to warn consumers about the IRC's practices.*242. Insys provided documents and other communications to consumers, but
failed to warn consumers that Insys was using the IRC to deceive and mislead
insurers and PBMs.

10 243. For example, Insys developed a "Patient Savings Program" handout for
11 consumers, promising them that Insys "can HELP with your Prior Authorization."
12 244. The handout informed consumers that if they activated their "Patient
13 Savings Program" card, they could "Save up to \$500 off each additional
14 prescription."

15 245. Insys noted that by activating the card, consumers would automatically be16 enrolled in the Prior Authorization Assistance Program.

17 246. Insys did not disclose the existence of the IRC, the nature of the IRC18 process, or any of the IRC practices described above.

19 247. Instead, Insys represented to consumers that the program worked as
20 follows: "A PA form with your information will be sent to your prescriber who will
21 then complete it and send to your insurance company."

22 248. This representation of the program was false.

23 249. The PA form with the patient's information was not sent by the prescriber24 to the insurance company.

25 250. Instead, the PA form with the patient's information was sent to the IRC.

26 251. As described above, in many cases, the IRC then manipulated,
27 misrepresented, or altered the patient's information in order to get prior
28 authorization for Subsys.

1 252. Insys made the same false representations on at least one other 2 consumer publication, entitled "Your Guide to Treatment with SUBSYS." 3 253. Although Insys's website disclosed the existence of the IRC, it still failed 4 to disclose any of the IRC practices described above. 5 254. Insys's website represented that the IRC would merely "assist with 6 logistics," but the "healthcare provider completes the appropriate forms and/or 7 calls the MCO [Managed Care Organization] to seek approval." 8 255. This representation of the program was false and misleading. 9 256. As described above, under the IRC program, the HCP did not call the 10 insurer to seek approval, and IRC employees did not merely "assist [HCPs] with 11 logistics"-they called the insurers directly. 12 Insys failed to warn consumers of the risks of harm resulting 2. 13 from Insys deceiving their doctors. 14 257. Insys provided documents and other communication to consumers, but 15 failed to inform them that it had misled HCPs regarding the definition of 16 "breakthrough cancer pain." 17 258. For example, the publication "Your Guide to Treatment with SUBSYS" 18 touted Subsys to consumers as the "first and only sublingual spray for 19 breakthrough cancer pain," without disclosing that Insys had misled HCPs about 20 what constituted "breakthrough cancer pain." Insys failed to warn consumers of the risks of harm resulting 21 З. 22 from their doctors being paid by Insys. 23 259. Insys provided documents and other communication to consumers, but 24 failed to warn consumers that Insys was paying HCPs to reward them for 25 prescribing Subsys and to incentivize them to prescribe additional Subsys. 26 260. For example, Insys provided an "INSYS Reimbursement Center Patient 27 Authorization & Referral Form" to HCPs and their patients. 28 33

261. The form contained a variety of checkboxes that could be used to justify
Subsys prescriptions, including that Subsys was a "provider-preferred product."

3 262. The form included three-quarters of a page of fine print under which
4 consumers agreed to be contacted by Insys.

5 263. The form did not disclose the Insys Speaker Program or the fact that the
6 HCP who "preferred" Subsys and was prescribing Subsys might be receiving
7 payments from Insys in exchange for prescribing Subsys.

8 264. After receiving the completed forms from consumers, Insys had the
9 prescriber information, the consumer contact information, and the consumers'
10 consent to be contacted.

11 265. Nevertheless, Insys did not inform those consumers when the HCP who
12 prescribed Subsys to them was being paid by Insys in exchange for prescribing
13 Subsys.

14 266. Instead, Insys used the information from the forms to obtain prior
15 authorizations for Subsys through its IRC, often employing deceptive and unfair
16 practices, as described above.

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#### **VIOLATIONS OF LAW**

18 267. The State realleges all preceding paragraphs as though fully set forth19 herein.

268. Defendants Insys Therapeutics, Inc., Burlakoff, and Gurrieri engaged in
deception, deceptive or unfair acts or practices, fraud, false pretense, false
promise, misrepresentation, or concealment, suppression or omission of
material facts with the intent that others rely upon such concealment,
suppression or omission, in connection with the sale or advertisement of
prescription drugs in violation of the Arizona Consumer Fraud Act, A.R.S. §§
44-1521–44-1534, including, but not limited to:

a. Insys and Gurrieri engaged in deceptive and unfair acts and
 practices by providing insurers and PBMs with false and misleading

information, and concealing, suppressing, or omitting material facts, including facts related to the identity of the IRC employees and patient health histories, to obtain prior authorization for patients' Subsys prescriptions and sell more Subsys;

b. Insys engaged in deceptive and unfair acts and practices by misleading consumers about the prior authorization process and the IRC's practices;

c. Insys engaged in deceptive and unfair acts and practices by concealing, suppressing, or omitting material facts from consumers, including facts related to the practices used by the IRC, and by failing to warn consumers about the IRC's practices, even though it knew, or had reason to know that the HCPs using the IRC would not be in a position to reduce foreseeable risks of harm from the IRC's practices;

d. Insys engaged in deceptive and unfair acts and practices by providing HCPs with false and misleading information, and concealing, suppressing, or omitting material facts, including facts about the definition of "breakthrough cancer pain" and the FDA-approved uses for Insys, to deceive HCPs so that they would prescribe more Subsys to patients;

e. Insys engaged in deceptive and unfair acts and practices because it knew, or had reason to know, that the HCPs to whom it provided this false and misleading information would not be in a position to reduce foreseeable risks of harm from Subsys and from Insys's practices, and Insys failed to warn consumers of those risks;

f. Insys and Burlakoff engaged in deceptive and unfair acts and practices by creating, promoting, and executing a scheme in which Insys provided sham "speaker fees" to HCPs to induce, and in exchange for, the HCPs writing Subsys prescriptions;

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g. Insys engaged in deceptive and unfair acts and practices by concealing, suppressing, or omitting material facts to insurers, PBMs, and patients, including facts related to the conflict of interest Insys created by paying HCPs sham "speaker fees" to induce, and in exchange for, the HCPs writing Subsys prescriptions, and by failing to warn patients of these facts.

7 269. In all matters alleged in the preceding paragraphs, Defendants Insys,
8 Burlakoff, and Gurrieri acted willfully, subjecting themselves to enforcement and
9 penalties as provided in A.R.S. § 44-1531(A).

10 270. Defendants Fanto, Seth, and Gingerich engaged in deception, deceptive 11 or unfair acts practices, fraud, false or pretense, false promise, 12 misrepresentation, or concealment, suppression or omission of material facts 13 with the intent that others rely upon such concealment, suppression or 14 omission, in connection with the sale or advertisement of prescription drugs in violation of the Arizona Consumer Fraud Act, A.R.S. §§ 44-1521-44-1534, 15 16 including, but not limited to:

a. Fanto, Seth, and Gingerich engaged in deceptive and unfair acts
and practices by accepting payment from Insys in exchange for writing
Subsys prescriptions, and

b. Fanto, Seth, and Gingerich engaged in deceptive and unfair acts
and practices by concealing, suppressing, or omitting material facts when
prescribing Subsys to their patients, including the fact that they were
being paid by Insys in exchange for prescribing Subsys.

24 271. In all matters alleged in the preceding paragraphs, Defendants Fanto,
25 Seth, and Gingerich acted willfully, subjecting themselves to enforcement and
26 penalties as provided in A.R.S. § 44-1531(A).

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1	PRAYER FOR RELIEF	
2	WHEREFORE, Plaintiff, State of Arizona, respectfully requests that this	
3	honorable Court:	
4	272. Permanently enjoin and restrain Defendants, their agents, employees,	
5	and all other persons and entities, corporate or otherwise, in active concert or	
6	participation with any of them, from engaging in unfair, deceptive, or misleading	
7	acts or practices that violate the Arizona Consumer Fraud Act, A.R.S. §§ 44-	
8	1521–44-1534, pursuant to A.R.S. § 44-1528(A)(1);	
9	273. Order the Defendants to pay restitution to consumers and other persons,	
10	pursuant to A.R.S. § 44-1528(A)(2);	
11	274. Order the disgorgement of all profits, gain, gross receipts, or other benefit	
12	obtained by the Defendants as a result of the illegal conduct alleged herein,	
13	pursuant to A.R.S. § 44-1528(A)(3);	
14	275. Order the Defendants to pay the State of Arizona a civil penalty of up to	
15	\$10,000 for each willful violation by each Defendant, pursuant to A.R.S. § 44-	
16	1531;	
17	276. Order the Defendants to pay the State of Arizona its investigative and	
18	attorneys' costs and fees related to this lawsuit, pursuant to A.R.S. § 44-1534;	
19	and	
20	277. Order other and further relief as the Court may deem just and proper.	
21	DATED this 20 <sup>th</sup> day of August 2017	
22	DATED this 30 <sup>th</sup> day of August, 2017.	
23	MARK BRNOVICH ATTORNEY GENERAL	
24		
25	By: <u>/s/ Matthew du Mée</u>	
26	Matthew du Mée Assistant Attorney General	
27	Attorneys for Plaintiff State of Arizona	
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