1	MARK BRNOVICH		
2	ATTORNEY GENERAL		
	(Firm State Bar No. 14000)		
3	MATTHEW DU MÉE (BAR NO. 28468)		
4	NEIL SINGH (BAR NO. 021327)		
5	ANDRIJA SAMARDZICH (BAR NO. 026160) ASSISTANT ATTORNEYS GENERAL		
	OFFICE OF THE ATTORNEY GENERAL		
6	2005 North Central Avenue		
7	Phoenix, AZ 85004		
8	Telephone: (602) 542-3725		
9	Facsimile: (602) 542-4377		
	consumer@azag.gov		
10	Attorneys for Plaintiff State of Arizona		
11			
12	IN THE SUPERIOR COURT OF THE STATE OF ARIZONA		
	IN AND FOR THE COUNTY OF MARICOPA		
13	CTATE OF ADIZONA and MADE	Casa Na - CV2010	
14	STATE OF ARIZONA, ex rel. MARK BRNOVICH, Attorney General,	Case No.: CV2019	
15	Bict vo vicii, retoiney deneral,	COMPLAINT FOR INJUNCTIVE	
16	Plaintiff,	AND OTHER RELIEF	
17	V.	(Complex Court Assignment Requested)	
18	TOTAL MARKATANA	/I T: ID 1 D	
19	JOHN KAPOOR, individually; JOHN KAPOOR and JANE DOE KAPOOR, as a	(Jury Trial Demanded)	
	marital community; MICHAEL BABICH,		
20	individually; MICHAEL BABICH and		
21	NATALIE LEVINE, as a marital		
22	community; MICHAEL GURRY,		
23	individually; MICHAEL GURRY and		
	JANE DOE GURRY, as a marital		
24	community,		
25	Defendants.		
26	Defendants.		
27			

<7981677-v9>

28

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

INTRODUCTION

- 1. In early 2012, the U.S. Food and Drug Administration (the "FDA") approved a new drug developed by INSYS Therapeutics, Inc. ("Insys"). The drug, called SUBSYS ("Subsys"), carried risks of addiction and death, but the FDA approved it for the treatment of a small subset of patients—those experiencing intense breakthrough cancer pain who were already using opioids around-the-clock.
- 2. Over the next five years, Insys executives engineered and engaged in a nationwide scheme that deceived insurers and patients. Insys executives directed employees to lie to insurers, conceal key facts from patients, and pay doctors sham "speaker fees" that were effectively bribes in exchange for writing prescriptions, all in order to increase the sales of Subsys, without regard for the health and safety of patients.
- 3. In fact, Insys made the following admission on June 5, 2019, to settle claims brought by the U.S. Department of Justice relating to Insys's fraudulent marketing of Subsys:

Insys admits, accepts, and acknowledges responsibility for conduct occurring from August 2012 until June 2015, involving the agreement to pay and payment of remuneration to certain licensed, medical practitioners, including physicians and physician assistants, with the intent to bribe and improperly influence the medical practitioners to improperly increase their prescriptions and dosages of SUBSYS® (hereafter "Subsys"), which is fentanyl-based pain medication intended to treat cancer patients suffering intense breakthrough pain. In exchange for the remuneration, the medical practitioners improperly prescribed large numbers and high dosages of Subsys for patients, most of whom were not diagnosed with cancer

(Emphasis added.)

<8029395-v1A> -2-

¹ Insys is a Delaware corporation with its principal place of business at 1333 South Spectrum Boulevard, Suite 100, Chandler, Arizona 85286. Insys is one of the named defendants in a separate lawsuit filed by the State as CV2017-012008. However, Insys has filed a Chapter 11 bankruptcy case in the U.S. District Court for the District of Delaware, and as part of that case, the State has agreed to stay its state proceeding as to Insys. The stay has no bearing on the claims or parties involved in this Complaint, which does not name Insys as a defendant.

- 4. Also on June 5, 2019, an Insys subsidiary, Insys Pharma, Inc., agreed to plead guilty to five counts of felony mail fraud relating to its part in Insys's fraudulent scheme to increase sales of Subsys by bribing healthcare professionals ("HCPs"), as well as misleading insurers and consumers.
- 5. As local, non-exhaustive examples of Insys's scheme, three Arizona doctors—Steve Fanto, Nikesh Seth, and Sheldon Gingerich—collected hundreds of thousands of dollars from Insys in sham "speaker fees" in exchange for writing copious amounts of Subsys prescriptions to patients. Insys collected over \$25 million in revenue from the Subsys prescriptions written by these three doctors alone.
- 6. The deceptive scheme engineered and executed by Insys executives made hundreds of millions of dollars for Insys, but also put countless patients in harm's way, exposing them to unacceptable and unnecessary risks of addiction and death. The named Defendants knowingly created, perpetuated, condoned, and profited from the fraudulent acts described in this Complaint, as set forth below.
- 7. The State of Arizona brings this action pursuant to the Arizona Consumer Fraud Act, Arizona Revised Statutes ("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.

JURISDICTION AND VENUE

- 8. This Court has jurisdiction over Defendants pursuant to A.R.S. § 44-1528.
- 9. Venue is proper in Maricopa County, Arizona, pursuant to A.R.S. § 12-401.

PARTIES

- 10. Plaintiff is the State of Arizona, *ex rel*. Mark Brnovich, the Attorney General of Arizona ("the State"), and is authorized to bring this action under the Arizona Consumer Fraud Act, A.R.S. §§ 44-1521–44-1534.
- 11. Defendant John Kapoor ("Kapoor") is the founder and, at all relevant times, has been the majority shareholder of Insys. Kapoor has served in various capacities at Insys,

<8029395-v1A> -3-

28 | 19. S

including as Executive Chairman of the Board of Directors from 2006 to 2017, as the President and Chief Executive Officer from 2015 to 2017, and finally as a director until his resignation from Insys's Board of Directors in October 2017. At all relevant times, Kapoor was a resident of Maricopa County, Arizona.

- 12. Jane Doe Kapoor is named in the event that John Kapoor is married and that community property exists against which the State can obtain monetary relief in this matter. If Kapoor is married and the State learns the true identity of Jane Doe Kapoor, it will move to amend its Complaint accordingly.
- 13. Defendant Michael Babich ("Babich") was employed by Insys from 2007 to 2015. From 2011 to 2015, Babich served as Insys's Chief Executive Officer. At all relevant times, Babich was a resident of Maricopa County, Arizona.
- 14. Natalie Levine is named as the spouse of Michael Babich, in order to ensure access to community property that exists and against which the State can obtain monetary relief in this matter. The State alleges that all acts by Michael Babich were taken in furtherance of the marital community.
- 15. Defendant Michael Gurry ("Gurry") is the former Vice President of Managed Markets for Insys from approximately August 2012 through October 2016, and was, at all relevant times, a resident of Maricopa County, Arizona.
- 16. Jane Doe Gurry is named in the event that Michael Gurry is married and that community property exists against which the State can obtain monetary relief in this matter. If Defendant Michael Gurry is married and the State learns the true identity of Jane Doe Gurry, it will move to amend its Complaint accordingly.
- 17. At all relevant times, Kapoor, Babich, and Gurry did business in Arizona by marketing, promoting, and selling the prescription drug Subsys.

ALLEGATIONS

- 18. Since March 2012 to the present date, Insys advertised and sold Subsys as Insys's primary product offering in Arizona and nationwide.
 - 19. Subsys is a Schedule II opioid, as defined by the United States Controlled

<8029395-v1A> -4-

Substances Act, 21 U.S.C. § 801–971.

- 20. A drug is categorized under Schedule II if (1) the drug has a high potential for abuse, (2) the drug has a currently accepted medical use in the United States or a currently accepted medical use with severe restrictions, and (3) abuse of the drug may lead to severe psychological or physical dependence.
- 21. Subsys contains fentanyl, an extremely powerful opioid that can reduce pain, but is also highly addictive and potentially lethal, especially if not prescribed or used properly.
 - 22. Fentanyl can come in a variety of forms, including tablets or patches.
- 23. Subsys is a Transmucosal Immediate-Release Fentanyl ("TIRF") medication, a class of opioid drugs that have a rapid onset from being absorbed through the oral mucosa. Subsys is sprayed under the tongue, allowing the fentanyl to reach the bloodstream rapidly.
- 24. Like all TIRFs, Subsys is subject to a Risk Evaluation and Mitigation Strategy ("REMS") mandated by the FDA, which requires both patients using and physicians prescribing Subsys to enroll in an education program to minimize "the risk of misuse, abuse, addiction, overdose and serious complication" associated with TIRFs.
- 25. The FDA-approved label for Subsys highlights two dangers associated with Subsys: (1) fatal respiratory depression; and (2) potential for abuse.
- 26. The FDA approved Subsys for a limited indication, namely: "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."
- 27. 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.
- 28. 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."

<8029395-v1A> -5-

- 29. 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."
- 30. Despite the dangers associated with the use of Subsys and its limited indication, Defendants Kapoor, Babich, and Gurry engineered and engaged in a multi-pronged scheme designed to mislead insurers and patients in order to increase Subsys's sales in Arizona and across the nation.
- 31. This scheme had two closely-related and unlawful components that worked in tandem to increase dramatically the number of prescriptions written by doctors, approved by insurers, and ultimately used by patients.
- 32. First, Defendants directed and authorized their subordinates at Insys to provide insurers and pharmacy benefit managers ("PBMs"), companies hired by insurers to help control the costs of prescription drugs, with false and misleading information in order to trick insurers into giving prior authorization for patients' Subsys prescriptions.
- 33. Second, Defendants Kapoor and Babich directed and authorized their subordinates at Insys to pay sham "speaker fees" to doctors to run supposed educational events, but the fees were primarily intended to reward doctors for prescribing Subsys and incentivize them to prescribe more Subsys to patients.

A. Defendants Misled Health Insurers and PBMs into Paying for Subsys.

- 34. Because of Subsys's limited indication, significant patient risks, and high cost, health insurers and PBMs routinely require prior authorization before paying for Subsys.
- 35. Without prior authorization, Subsys prescriptions would have to be paid for by the patient or a third party.
- 36. Given the fact that a single package of Subsys could cost thousands of dollars, and the availability of other, more affordable alternatives, the denial of prior authorization typically results in no one paying to fill the Subsys prescription.
- 37. Typically, prior-authorization requests are submitted by HCPs' offices to insurers and PBMs.

<8029395-v1A> -6-

- 38. The requests include patient information, including past medical history and current conditions, typically using standardized codes to classify diseases and injuries.
- 39. After evaluating that information, insurers and PBMs initially granted prior authorization for Subsys prescriptions at a relatively low rate.
- 40. For example, in November 2012, the rate of prior authorization for Subsys was between 30% and 33%.
- 41. To drive up the rate of prior authorizations, and thereby increase sales of Subsys, Kapoor, Babich, and Gurry directed or authorized their subordinates to operate a scheme to deceive insurers and PBMs.
- 42. In or about November 2012, Kapoor, Babich, and Gurry authorized the launch of a pilot program, whereby Insys employees would assist patients and doctors in attaining prior authorization for Subsys prescriptions from insurers and PBMs.
- 43. In or around January 2013, after initial success, Kapoor, Babich, and Gurry expanded the Subsys pilot program by authorizing the launch of the Insys Reimbursement Center ("IRC").
- 44. The IRC consisted of a call center designed to obtain prior authorization for Subsys from insurers and PBMs.
 - 45. The IRC is located in Arizona near Insys's corporate headquarters.
- 46. After creating the IRC, Kapoor, Babich, and Gurry directed Insys sales personnel to encourage each HCP to utilize the IRC instead of the HCP's staff for prior authorizations.
- 47. Participating HCPs sent the IRC "Reimbursement Assistance/Prior Authorization Request" forms that included patients' identifying information, as well as their diagnoses.
- 48. Defendant Gurry supervised and coordinated the creation and operation of the pilot program and the IRC from approximately November 2012 through May 2014, and did so under the supervision of Kapoor and Babich.
- 49. Defendant Gurry supervised Elizabeth Gurrieri ("Gurrieri"), who is the former Manager of Reimbursement Services for Insys. Gurrieri has pled guilty to one count of wire fraud conspiracy—a federal felony—for her part in the Insys scheme, which included directly

<8029395-v1A> -7-

supervising and instructing IRC employees from approximately January 2013 through July 2016.

- 50. IRC employees, as directed or authorized by Kapoor, Babich, Gurry, and Gurrieri, communicated directly with insurers and PBMs to attempt to secure payment by insurers for Subsys prescriptions written by participating HCPs.
- 51. In those communications, as described below, IRC employees, as directed or authorized by Kapoor, Babich, Gurry, and Gurrieri, used a number of deceptive and unfair acts and practices.
- 52. By taking control of the prior-authorization process and manipulating the information provided to insurers, Kapoor, Babich, and Gurry rapidly and dramatically increased the likelihood that each Subsys prescription written would translate into additional units of Subsys sold.
- 53. A mere six months after the creation of the IRC, a July 2013 presentation from the Insys Board of Directors meeting indicates that the IRC was obtaining prior authorizations for Subsys over 75% of the time. This is in contrast to the 30% to 33% prior-authorization rate for Subsys before Insys began manipulating the information provided to the insurers and PBMS.
- 54. 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.
- 55. The State is currently aware of 292 prior-authorization request forms submitted by Arizona HCPs to Insys for prescriptions of Subsys.
- 56. 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.
- 57. If insurers and PBMs had limited prior authorization to the Arizona patients who had breakthrough cancer pain, the prior-authorization rate would have been approximately 33%, in line with the November 2012 prior-authorization rates obtained by HCPs.

<8029395-v1A> -8-

- 58. The IRC acts and practices described below are responsible for most or all of the dramatic difference between the IRC prior-authorization rates and the 30% to 33% rate of prior authorization obtained by HCPs in November 2012, before Kapoor, Babich, and Gurry began to execute their scheme to deceive insurers and PBMs.
- 59. Kapoor purposefully sought information on the criteria used by specific insurance plans to approve Subsys prescriptions, and he met with top executives, including Gurry and Babich, to brainstorm how Insys employees could manipulate these criteria to obtain more prior authorizations.
- 60. Gurry directed the IRC to provide false information to insurance companies to obtain prior authorization for Subsys.
- 61. With the approval of Kapoor and Babich, and under the direction of Gurry, the IRC engaged in deceptive and unfair acts and practices to increase the likelihood that insurers and PBMs would grant prior authorization for Subsys prescriptions.
- 62. Because of the deceptive and unfair acts and practices employed by Insys, every or almost every prior-authorization call the IRC placed contained lies and misrepresentations.
 - 1. The IRC Concealed That Calls Were Coming from Insys, Not HCPs.
- 63. Kapoor, Babich, and Gurry knew that insurers and PBMs were more likely to give prior authorization for Subsys if the insurers or PBMs thought that the call was coming from a member of the HCP's staff, rather than from an Insys employee.
- 64. Gurry directed IRC employees to lead insurers and PBMs to believe that they were calling from HCPs' offices, when in fact they were calling directly from Insys.
- 65. Gurry directed IRC employees to pose as employees of HCPs' offices, when in fact they worked for Insys.
- 66. Under the direction or authorization of Kapoor, Gurry blocked the IRC phone numbers, so that insurers and PBMs could not observe that the area code of the IRC differed from most of the HCPs' offices.
- 67. Because Insys's employees were posing as employees of HCPs' offices, their representations carried more weight than if the Insys employees had disclosed that: (1) they

<8029395-v1A> -9-

were employed by Insys; (2) they had no connection to the HCPs or the patient; and (3) they were in no position to describe the HCPs' knowledge or thought processes.

68. Kapoor and Babich were aware that IRC phone numbers were blocked in order to deceive insurers and PBMs, and approved of these deceptive acts and practices in order to increase prior-authorization rates for Subsys. In fact, Babich testified in U.S. District Court in the federal criminal case against Insys executives that Kapoor specifically directed Babich to block the IRC's phone numbers.

2. <u>The IRC Misrepresented That Patients Had Cancer.</u>

- 69. Kapoor, Babich, and Gurry knew that insurers and PBMs were more likely to give prior authorization for Subsys if patients had cancer, given that the FDA only approved Subsys to treat breakthrough cancer pain.
- 70. Gurry and Gurrieri directed IRC employees to leave insurers and PBMs with an impression that patients had cancer, when in fact those patients did not have cancer, and had never had cancer.
- 71. If a patient's medical history showed any history of cancer, IRC employees were directed by Gurry and Gurrieri to provide insurers and PBMs the medical code for breakthrough cancer pain regardless of whether the patient was currently being treated for cancer.
- 72. Gurry and Gurrieri directed IRC employees to tell insurers and PBMs that patients were being treated for cancer, when in fact those patients had recovered from cancer or were in remission.
- 73. Gurry and Gurrieri informed Kapoor and Babich that IRC employees were misrepresenting to insurers and PBMs that patients were being treated for cancer, and Kapoor and Babich approved of these deceptive acts and practices in order to increase prior-authorization rates for Subsys.

3. The IRC Falsely Claimed That Patients Had Breakthrough Cancer Pain.

74. Kapoor, Babich, and Gurry knew that insurers and PBMs were more likely to give prior authorization for Subsys if patients had breakthrough cancer pain, which was the

<8029395-v1A> -10-

FDA-approved use for Subsys.

- 75. Gurry and Gurrieri directed IRC employees to lead insurers and PBMs to believe that patients were being treated for breakthrough cancer pain, when in fact that was not the case.
- 76. Gurry and Gurrieri directed IRC employees to tell insurers and PBMs that HCPs had prescribed Subsys to treat breakthrough cancer pain and to use the standardized codes for breakthrough cancer pain, when in fact those HCPs had prescribed Subsys to treat a different condition.
- 77. Gurry and Gurrieri directed IRC employees to read the following statement to insurers and PBMs when those entities asked whether the patient at issue was being treated for breakthrough cancer pain: "Yes. The physician is aware that the medication is intended for the management of breakthrough pain in cancer patients. The physician is treating the patient for their pain (or breakthrough pain, whichever is applicable)."
- 78. By responding "Yes" and by responding that the patient was being treated for "pain" or "breakthrough pain" immediately after acknowledging the intended use for breakthrough cancer pain, Gurry and Gurrieri taught employees to avoid directly stating that the patient did not have breakthrough *cancer* pain, while stating or implying that the patient was in fact being treated for breakthrough cancer pain.
- 79. The statement also implied that the person reading the statement had knowledge of the HCP's awareness, when in fact the person reading the statement was an IRC employee who (in all likelihood) had never even spoken with the HCP.
- 80. Gurry and Gurrieri informed Kapoor and Babich that IRC employees were misrepresenting to insurers and PBMs that patients were prescribed Subsys to treat breakthrough cancer pain, and Kapoor and Babich approved of these deceptive acts and practices in order to increase prior-authorization rates for Subsys.

4. The IRC Falsely Claimed That Patients Had Difficulty Swallowing.

81. Kapoor, Babich, and Gurry knew that insurers and PBMs were more likely to give prior authorization for Subsys if patients had difficulty swallowing, as those patients could

<8029395-v1A> -11-

not take pain medications in other, less expensive forms, such as pills.

- 82. Gurry and Gurrieri directed IRC employees to tell insurers and PBMs that patients had dysphagia (difficulty swallowing) when in fact that was not the case.
- 83. Insys's employees made these false dysphagia claims because the claim of dysphagia increased the likelihood of the insurer or PBM granting prior authorization.
- 84. Gurry and Gurrieri directed employees to put dysphagia on every authorization without regard for whether the patient actually suffered from dysphagia.
- 85. Gurry and Gurrieri informed Kapoor and Babich that IRC employees were misrepresenting to insurers and PBMs that patients suffered from dysphagia, and Kapoor and Babich approved of these deceptive acts and practices in order to increase prior-authorization rates for Subsys.
 - 5. <u>The IRC Falsely Claimed That Patients Had Tried Other Medications and Found Them Ineffective</u>.
- 86. Kapoor, Babich, and Gurry knew that insurers and PBMs were more likely to give prior authorization for Subsys if patients had tried and found ineffective other "preferred" medications that were less expensive, less addictive, and/or less dangerous.
- 87. Gurry and Gurrieri directed IRC employees to tell insurers and PBMs that patients had tried other preferred medications and that those medications were ineffective in treating their medical conditions, when in fact patients had not tried those medications or the IRC had no factual basis for that claim.
- 88. Gurry and Gurrieri instructed employees to use a "cheat sheet" of preferred drugs and tell insurers that the patient had found all of the drugs on the cheat sheet to be ineffective, when this was unknown or false.
- 89. Gurry and Gurrieri informed Kapoor and Babich that IRC employees were misrepresenting to insurers and PBMs that the patients had tried alternative medications, and Kapoor and Babich approved of these deceptive acts and practices in order to increase prior-authorization rates for Subsys.

<8029395-v1A> -12-

- 6. <u>Defendants Have Pled To, or Been Convicted of, Federal Crimes Related</u> to the Operation of the IRC.
- 90. On June 19, 2017, former Insys employee Gurrieri pled guilty in federal court to conspiracy to commit wire fraud for her role in directing IRC employees to engage in the acts and practices described above.
- 91. On January 9, 2019, Defendant Babich pled guilty in federal court to conspiracy and mail fraud charges partly for his participation in the IRC's deceptive acts and practices. In the parties' Agreed Statement of Facts filed in the federal case in connection with Babich's guilty plea, Babich named Kapoor as having directed the IRC to provide false information to insurance companies to obtain prior authorization for Subsys.
- 92. On May 2, 2019, Kapoor was found guilty in federal court of conspiring to conduct or to participate in the affairs of an enterprise through racketeering, in part for his participation in the operation of the IRC and the deceptive scheme to provide false and misleading information to insurers and PBMs to obtain prior authorization for Subsys.
- 93. The jury unanimously found that Kapoor agreed that he or another conspirator would intentionally commit more than two acts of illegal distribution of a controlled substance, more than two acts of mail fraud, more than two acts of wire fraud, more than two acts of honest services mail fraud, and more than two acts of honest services wire fraud.
- 94. On May 2, 2019, Defendant Gurry was found guilty in federal court of conspiring to conduct or to participate in the affairs of an enterprise through racketeering, in part for his participation in the operation of the IRC and the deceptive scheme to provide false and misleading information to insurers and PBMs to obtain prior authorization for Subsys.
- 95. The jury unanimously found that Gurry agreed that he or another conspirator would intentionally commit more than two acts of mail fraud and more than two acts of wire fraud.
- 96. At all relevant times, Kapoor, Babich, and Gurry were aware that Insys was fraudulently using the IRC to deceive insurers and PBMs in order to increase the prior-authorization rate of Subsys and make more money for Insys.

<8029395-v1A> -13-

- B. Defendants Kapoor and Babich Engineered and Executed a Scheme in Which Insys Paid Top Prescribers Sham "Speaker Fees" in Exchange for Subsys Prescriptions.
- 97. From March 2012 through April 2017, Insys secured a total of approximately \$51.87 million in gross sales of Subsys in Arizona.
- 98. *Sixty-four percent* of Insys's sales from Subsys in Arizona during this time frame came from prescriptions written by only three doctors—Steven Fanto, Nikesh Seth, and Sheldon Gingerich.
- 99. Over that time frame, Fanto, Seth, and Gingerich wrote an average of *nearly* 1,000 Subsys prescriptions apiece.
- 100. In contrast, over the same timeframe, the 145 prescribers of Subsys in Arizona who were not paid speaker fees by Insys wrote an average of *less than 14 prescriptions apiece*.
- 101. The dramatic difference in prescription numbers directly correlates with large payments Insys made to Fanto, Seth, and Gingerich.
- 102. Between March 2012 and April 2017, Fanto was paid over \$300,000 by Insys; Seth was paid over \$225,000 by Insys; and Gingerich was paid over \$100,000 by Insys.
- 103. Before Insys began paying them, Fanto, Seth, and Gingerich collectively wrote an average of about nine Subsys prescriptions a month.
- 104. During the time Insys paid them, Fanto wrote an average of approximately 23 Subsys prescriptions a month, averaging approximately one prescription per business day; Seth wrote an average of approximately 23 Subsys prescriptions a month, also averaging approximately one prescription per business day; and Gingerich wrote an average of approximately 16 Subsys prescriptions a month. These averages are nearly *seven times* the average prescription volume of these doctors before they were being paid by Insys.
- 105. These startling statistics were no accident. Instead, they were the predictable and calculated results of a scheme engineered and executed by Kapoor and Babich, both in Arizona and nationwide.

<8029395-v1A> -14-

8

6

9 10 11

1213

1415

1617

18

19

2021

2223

2425

2627

28

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

- 106. Nationwide, Insys sold over a billion dollars of Subsys, despite its limited indication and the dangers associated with the drug.
- 107. Insys reported nearly \$200 million in revenue in 2014, over \$300 million in revenue in 2015, and over \$215 million in revenue in 2016.
 - 108. Nearly all of this revenue came from Subsys sales.
- 109. A primary driver of Subsys's remarkable sales was a scheme designed and implemented by Kapoor, Babich, and other top officers at Insys, under which certain HCPs received "speaker fees" conditioned on the HCPs prescribing a high volume of Subsys to their patients.
- 110. Insys advertised Subsys to HCPs through the use of its sales force of "specialty sales professionals" ("SSPs").
 - 111. Each SSP was responsible for advertising Subsys to HCPs assigned to him or her.
- 112. As a sales tactic, Insys directed SSPs across the country to schedule regular speaker programs at which one of the SSP's assigned HCPs would purportedly present an Insys-prepared PowerPoint presentation regarding Subsys in exchange for a lucrative speaker fee.
- 113. Insys allowed the programs to take place in the HCP's office, last as little as 30 minutes, and go forward even if no other HCPs were present.
 - 114. Insys typically paid HCPs between \$2,400 and \$4,700 per presentation.
- 115. Kapoor and Babich directed or authorized their subordinates to use Insys speaker programs to pay doctors for prescribing Subsys.
- 116. As noted above, Insys has admitted publicly that it bribed doctors through speaker fees.
- 117. The true nature of these bribes was demonstrated in a number of ways, including the following:

<8029395-v1A> -15-

9

15

16 17 18

19 20

21

22

23 24

25

26 27 28

- First, Insys directed SSPs to sell Subsys by focusing on one or two doctors per marketing region whom Insys could rely on to write one Subsys prescription per day (as opposed to a broad base of HCPs writing prescriptions as appropriate);
- b. 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
- Third, many of the speaker programs Insys paid for had few or no attendees with the license necessary to prescribe Subsys.
- 118. Insys's sales strategy was developed and implemented by Kapoor and Babich in Arizona and nationwide shortly after Subsys launched in March 2012.
- 119. On or about March 2012, in a meeting of top Insys executives, Kapoor voiced his belief that the speaker program was for the speakers (as opposed to the attendees) and that every speaker was expected to write Subsys prescriptions.
- Matthew Napoletano, the former Vice President of Marketing at Insys, initially resisted this strategy because he believed it was illegal, but Babich persuaded Napoletano to give Kapoor what he wanted: metrics tracking the number of prescriptions written by the speakers in the program (not the attendees) so that Insys could assure a positive return on investment ("ROI") from the speaker program.
- Kapoor and Babich directed Alec Burlakoff ("Burlakoff"), former Vice President of Sales at Insys, to operate the speaker program in this manner.
- 122. As Burlakoff has admitted in a multi-million dollar consent judgment with Plaintiff, "From approximately September 2012 to December 2015, Defendant Burlakoff, acting on instruction from Insys CEO Michael Babich and Insys founder John Kapoor, directed regional sales managers and lower level pharmaceutical company representatives to use the award of speaker programs to induce the doctors and physicians' assistants in the Insys Speaker Bureau to prescribe more Subsys."

-16-<8029395-v1A>

- 123. On September 17, 2012, Burlakoff emailed the Subsys sales force and emphasized the connection between the speaker programs and prescriptions written by the paid speakers.
- 124. In that email, Burlakoff stated that "if your speaker does not have at least 20 patients on Subsys (QTD), he or she should not be booked to speak at this juncture. You should cancel or suspend your programs until you and your manager have had ample chance to think this investment entirely through."
- 125. Burlakoff told the sales force that they "must hold off on the conduction of these valuable speaker programs," until they knew "for absolute sure" that "if you use a specific speaker that the program will yield positive results."
- 126. At a national sales meeting held on September 21, 2012, Burlakoff told the Subsys sales force that a "critical success factor" in selling Subsys was to schedule a "[h]igh and consistent number of ISP's with top 20 targets."
 - 127. "ISP" stands for Insys Speaker Programs, and "targets" refers to HCPs.
- 128. Burlakoff's directive was an attempt to drive sales with a relatively small, targeted group of HCPs by frequently paying them thousands of dollars in "speaker fees."
- 129. At the same meeting, Burlakoff, analogizing doctors to race horses, told his sales force to: "Make sure you chose the correct horse / horses Give your horses all the TLC they need Ride your horses every chance you get."
- 130. Burlakoff also urged the sales force, in text displayed over a picture of a horse race, that "IF YOU WANT TO WIN it is time to start cracking the whip!"
- 131. On April 26, 2013, Burlakoff again directed the Subsys sales force to reward HCPs for writing Subsys prescriptions, stating: "Lastly your doctors need to know their support of Subsys was noticed. These important clinicians MUST promptly be rewarded with positive reinforcement immediately"
- 132. The "positive reinforcement" Burlakoff referred to was frequent ISPs and tens or hundreds of thousands of dollars in speaker fees for those prescribers.

<8029395-v1A> -17-

133. Kapoor and Babich were only willing to pay HCPs speaker fees, however, if those HCPs wrote enough Subsys prescriptions.

134. On March 7, 2013, Burlakoff wrote an email to regional sales managers (or "RSMs") regarding the RSMs' and SSPs' expenditures, and how the value of those expenditures was ultimately determined by ROI. Burlakoff wrote:

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

- 135. On September 17, 2012, Burlakoff, with Babich cc'd, emailed an SSP and counseled her that: "Your local speaker should be your 'business partner'. You do not work for him, nor does he work for you. You are partners in this endeavor, if your speaker does not see it this way . . . (then it is time to identify another speaker)." Of course, business partners are expected to deliver business, in this case, in the form of Subsys prescriptions.
- 136. On April 1, 2013, Burlakoff acknowledged the critical importance that speaker programs played in driving Subsys sales. Burlakoff wrote: "I said it a thousand times. ISP's are the most important thing you will do to increase your business. ISP's are basically the ONLY thing you should be focusing on to increase your sales." Burlakoff went on to say that SSPs should be "living, eating, and breathing ISP's to drive sales PROGRAMS ARE THE ONLY THING THAT MATTERS, WHY DO SOME OF YOU REFUSE TO ACKNOWLEDGE THIS PROVEN FACT?" Further, Burlakoff directed SSPs to drive sales by focusing on one or two doctors.
- 137. On March 19, 2013, Burlakoff wrote an email to the Subsys sales force praising the top five selling SSPs. Burlakoff wrote:

<8029395-v1A> -18-

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.

- 138. Burlakoff went on to say, "It is and has always been your assignment to find this key player. If you have not found this doctor, throw the decile list, call list, routing, ROO list, etc. out the window. You have to start prospecting and develop a key doctor."
- 139. The "MVP players" Burlakoff referenced in his March 19, 2013 email were the top five Subsys prescribers nationwide, all of whom were highly compensated speakers for Insys.
- 140. These five "MVP" speakers/Subsys prescribers all have been the subject of criminal lawsuits, civil lawsuits, or disciplinary actions on the basis of 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."
 - 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.
 - d. Dr. Judson Somerville was disciplined by the Texas Medical Board (the "Texas Board"). On December 11, 2013, the Texas Board noted three of Somerville's patients had died in the latter half of 2012 from drug toxicity. When

<8029395-v1A> -19-

Somerville's office was inspected, the Texas 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 Texas Board prohibited Somerville from prescribing Schedule II controlled substances (including Subsys). In 2016, the Texas 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. He ultimately pled guilty, was sentenced to 51 months in prison, and was ordered to pay over \$750,000 in restitution.
- 141. In addition to those listed above, other HCPs also have pled guilty, been sanctioned, or been convicted on charges stemming from accepting speaker fees from Insys in exchange for writing Subsys prescriptions:
 - a. Heather Alfonso, a former advanced practice registered nurse, pled guilty in June 2015 to accepting kickbacks in the form of speaker fees from Insys in exchange for writing Subsys prescriptions.
 - b. Dr. Michael Frey, the former co-owner of Advanced Pain Management Specialists, pled guilty in February 2019 to conspiracy fraud charges for receiving illegal kickbacks and defrauding Medicare, in part relating to his participation with Insys's speaker program. He was sentenced to 18 months in federal prison. He also paid \$2.8 million to settle the investigation into his fraudulent practices.
 - c. 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 in May 2017. The indictment notes that although the money paid to Couch by Insys "was

<8029395-v1A> -20-

ostensibly paid for 'speaking fees,' it was actually paid to induce, and in exchange for . . . Couch prescribing high volumes of Subsys."

- d. Dr. Alexandru Burducea pled guilty in February 2019 to conspiracy to violate the federal Anti-Kickback Statute by taking approximately \$68,400 in speaker fees from Insys. Insys additionally hired Burducea's then-girlfriend to work as his Insys sales representative in order to induce further his prescribing of Subsys.
- e. Dr. Todd Schlifstein pled guilty in June 2019 to conspiracy to violate the federal Anti-Kickback Statute, and agreed to forfeit \$127,000. Insys paid Schlifstein approximately \$127,100 in the form of speaker fees in exchange for Subsys prescriptions. In the second quarter of 2015 alone, Schlifstein's Subsys prescriptions generated \$593,373 in total net sales for Insys.
- f. Christopher Clough, a former New Hampshire physician assistant, was found guilty in December 2018 of conspiring and receiving kickbacks in relation to a federal healthcare program, in connection to his participation in the Insys speaker program. Clough received over \$49,000 in speaker fees from Insys in exchange for writing 672 Subsys prescriptions, many of which were deemed medically unnecessary. Prescriptions written by Clough are estimated to have generated \$8 million in revenue for Insys. In June 2019, Clough was sentenced to four years in prison.
- g. Dr. Vivienne Matalon entered into a Consent Order in 2018 with the New Jersey State Board of Medical Examiners (the "New Jersey Board"), which revoked her medical license and assessed a civil penalty of \$40,000. Matalon's license had been suspended since October 2016, following the death of a patient to whom she had prescribed Subsys for fibromyalgia. Prior to prescribing the patient Subsys, Matalon allowed an Insys SSP to sell the patient on the drug, during which time both the SSP and Matalon failed to inform the patient that Subsys was an opioid-based drug. Approximately 14 months later, the patient

<8029395-v1A> -21-

died from a fatal dose of Subsys. Among other things, the New Jersey Board found that Matalon engaged in gross negligence and professional misconduct when she prescribed Subsys to three patients outside the standard of medical care.

- 142. A series of indictments and other actions against other HCPs involved in the Insys speaker program remain pending, including:
 - a. Dr. Gordon Freedman was indicted in 2018 for conspiring to receive kickbacks in the form of \$308,600 in speaker fees from Insys in exchange for writing Subsys prescriptions. In the fourth quarter of 2014, Freedman was the fourth-highest prescriber of Subsys nationally. In 2014 Freedman was the highest-paid Insys speaker, having received \$143,000 that year. Freedman also was indicted in 2019 for 16 counts of distributing oxycodone, fentanyl, and other controlled substances to a particular patient, including one count for distributing fentanyl that caused the patient's death
 - b. Dr. Jeffrey Goldstein was indicted in 2018 for, among other things, switching patients over to Subsys from competitor products as a result of pressure from Insys SSPs. Goldstein received approximately \$196,000 in speaker fees from Insys in exchange for writing Subsys prescriptions. Goldstein was the fifth highest prescriber of Subsys nationally in 2014.
 - c. Dr. Dialecti Voudouris was indicted in 2018 for her part in the Subsys kickback scheme. She received approximately \$119,400 in speaker fees from Insys in exchange for prescribing Subsys. At the time when Voudouris was first approached by an Insys SSP, she was not TIRF REMS enrolled and thus was ineligible to prescribe Subsys. To become eligible to prescribe Subsys, Voudouris authorized Insys SSP Fernando Serrano to enroll her in the TIRF REMS Program and take the TIRF REMS exam for her. Serrano used an answer key provided to him by his Insys district sales manager Jonathan Roper to pass the exam. Both Roper and Serrano pled guilty in 2017 to charges connected to their participation in the Insys bribery and kickback scheme.

<8029395-v1A> -22-

d. Dr. Kenneth Sun was indicted in June 2019 for soliciting and receiving kickbacks totaling \$140,000 in speaker fees from Insys in exchange for writing Subsys prescriptions. Sun had practices in both Pennsylvania and New Jersey before having his licenses revoked for his participation in the Insys kickback scheme. The indictment also charges that Sun caused the federal Medicare program to pay in excess of \$847,000 for Subsys prescriptions that Insys paid Sun to prescribe.

- e. Dr. Nilesh Jobalia was indicted in June 2018 on 114 counts, including 17 violations of the federal Anti-Kickback Statute, for his role in the Insys speaker program. The indictment alleges that, between April 2013 and July 2015, Jobalia received more than \$103,000 in kickbacks from Insys in the form of sham speaker fees in exchange for Subsys prescriptions, and that Jobalia caused Medicare to pay \$546,652.75 for Subsys prescriptions in 2013 and 2014.
- 143. Furthermore, in addition to Defendants Kapoor, Babich, and Gurry, several former Insys employees were convicted or pled guilty to crimes relating to their work for Insys, including:
 - a. As part of the same trial in which Defendants Kapoor and Gurry were convicted, three other Insys executives were convicted in May 2019 of RICO conspiracy for their roles in the fraudulent scheme to pay kickbacks to HCPs in exchange for Subsys prescriptions: (1) Richard Simon, the former National Director of Sales; (2) Joseph Rowan, a former Regional Sales Director; and (3) Sunrise Lee, a former Regional Sales Director.
 - b. Natalie Perhacs, the Insys SSP responsible for selling Subsys to Dr. Ruan and Dr. Couch, pled guilty in February 2016 to conspiring to pay illegal kickbacks for her role in providing Ruan and Couch with speaker fees in exchange for writing Subsys prescriptions.

<8029395-v1A> -23-

- c. Jeffrey Pearlman, a former district sales manager at Insys, pled guilty in August 2018 for his part in the fraudulent scheme to pay kickbacks to HCPs to increase Subsys prescriptions.
- d. Karen Hill, a former regional sales manager at Insys, pled guilty in July 2017 to conspiring to pay kickbacks to HCPs, and was sentenced to six months of home confinement in May 2019 for her role in the Insys scheme to bribe HCPs.
- e. Former Insys SSP Michelle Breitenbach pled guilty in May 2018 to conspiracy to commit commercial bribery for her role in the Insys scheme to bribe HCPs.
- f. Defendant Natalie Levine, 2 a former Insys sales representative, pled guilty in July 2017 to conspiracy to violate the federal Anti-Kickback Statute. Levine was responsible for prescriptions written by HCPs that are estimated to have cost Medicare Part D plans \$4.5 million. Levine's top prescribers included Heather Alfonso and Christopher Clough. In June 2019, Levine was sentenced to six months' home confinement and five years' probation.
- g. Former Insys district manager Jonathan Roper pled guilty in 2017 to violating the federal Anti-Kickback Statute in connection with his participation in the Insys scheme to bribe HCPs. Roper admitted that he explicitly told the SSPs he supervised that Insys speaker programs were intended to induce HCPs to prescribe Subsys. He currently awaits sentencing.
- h. Former Insys sales representative Fernando Serrano pled guilty in 2017 to violating the federal Anti-Kickback Statute in connection with his participation in the Insys scheme to bribe HCPs. Serrano admitted that he held sham speaker programs to pay kickbacks and bribes to HCPs, and that he forged the names of HCPs on program sign-in sheets. He currently awaits sentencing.

<8029395-v1A> -24-

² Defendant Levine is named in this Complaint solely with respect to her access to community property shared with her spouse, Defendant Babich.

- 144. Kapoor, Babich and other top Insys executives discussed these top prescribing HCPs on a weekly or daily basis to ensure that the HCPs were prescribing large amounts of Subsys in exchange for speaker fees.
- 145. On July 9, 2013, Burlakoff again emailed his sales force encouraging them to develop one or two prescribers from whom they could generate 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.)

- 146. As demonstrated by Burlakoff's emails, Kapoor and Babich did not intend for speaker programs to generate a broad base of prescribers.
- 147. The speaker programs provided Insys with a means of paying a small number of HCPs to write large amounts of Subsys prescriptions and dramatically increase the profits of the entire company.
- 148. Burlakoff consistently directed the Insys sales force to sell Subsys by scheduling speaking programs with one or two doctors who would, in exchange, write Subsys prescriptions.
- 149. Insys's speaker program was a means of putting money into HCPs' pockets, which Kapoor and Babich primarily intended to be a system to reward and incentivize those HCPs to write Subsys prescriptions, not a program primarily meant to educate other HCPs about the characteristics of Subsys.
 - 2. <u>In Arizona, Three HCPs Primarily Benefited from Insys's Speaker Program.</u>
- 150. The following examples of three Arizona doctors serve as representative illustrations of the operation of Insys's nationwide scheme:
 - a. Dr. Steven Fanto
 - 151. Insys SSP Brianna Smith ("Smith") was responsible for interacting with Arizona

<8029395-v1A> -25-

HCPs.

- 152. One of Smith's top targets in Arizona from whom she expected large numbers of Subsys prescriptions was Dr. Steven Fanto ("Fanto"), a doctor based in Scottsdale whose practice primarily dealt with pain management.
 - 153. Insys directed Smith to schedule ISPs for Fanto.
- 154. Babich made the decision to target Fanto as a paid speaker and as a top prescriber of Subsys as early as November 2012.
- 155. On October 22, 2012, Smith's regional sales manager, Darin Fila, emailed her, stating, "You have to submit some programs today for Fanto, as there is a lot of pressure to get these in."
- 156. Smith responded, "I am doing what I can. Do I need to have all eight scheduled by eod?"
 - 157. On October 25, 2012, Insys paid Fanto his first speaker fee, totaling \$2,400.
- 158. On November 9, 2012, Babich emailed Burlakoff and Matthew Napoletano, Insys's Vice President of Marketing, stating, "[Fanto] needs to start crankin[g] or he gets taco bell."
- 159. Within minutes, Burlakoff responded, giving context to Babich's statement. Burlakoff replied, "Actually –when you look at WAC revenue (which includes strength and units) NOT total scripts—[Fanto] is our 5th biggest producer at INSYS and we have not even begun!"
- 160. Hours later, Burlakoff forwarded the above email thread to Smith, the SSP who promoted Subsys to Fanto.
- 161. Within a month of Burlakoff's November 9, 2012 email, Insys gave Fanto four more speaker programs, and paid him \$2,400 for each.
- 162. Over the next four years, through at least December 2016, Fanto received a high number of speaker engagements, typically two or more a month.
- 163. Kapoor and Babich intended the speaker fees Insys paid to Fanto to be a reward for Fanto's previous Subsys prescriptions and an incentive for Fanto to write additional Subsys

<8029395-v1A> -26-

prescriptions.

- 164. For example, on her "ISP Representative Evaluation Form" for Fanto's speaker program on November 29, 2012, Smith wrote that an anticipated outcome of the program was that "Dr. Fanto is making a shift toward switching many of his current patients to [S]ubsys."
- 165. Fanto's prescribing pattern changed around the time that he started receiving payments from Insys.
- 166. From December 2012 to January 2013, Fanto wrote 24 Subsys prescriptions, nearly five times the Subsys prescriptions he had written from October to November 2012.
- 167. In January 2013, Insys learned that Smith was having a "consensual relationship with Dr. Fanto."
- 168. Insys took no corrective action and allowed Smith to continue promoting Subsys to Fanto, and told Smith in February 2013 that Insys "fully" supported her continuing to do so.
- 169. In fact, in April 2013, Insys gave Smith a \$5,000 raise because of her 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-highest revenue for Insys out of all HCPs nationwide that quarter.
- 170. Babich kept apprised of Fanto's prescriptions to make sure Insys was getting a return on its investment in Fanto. In an email sent to Xun (Sean) Yu, Insys's then-Director of Sales Operations, on March 18, 2013, Babich expressed concern that Fanto was "slipping" in his prescription count and asked for data indicating how much of Fanto's (and other doctors') ROO (rapid-onset opioids) business Insys was losing to other manufacturers.
- 171. From March 2012 through April 2017, Fanto wrote a total of 1,294 Subsys prescriptions—far and away the most of any HCP in Arizona.
- 172. Before receiving speaker fees, from March 2012 to October 2012, Fanto wrote 43 Subsys prescriptions—approximately five prescriptions per month.
- 173. During the time Insys paid Fanto speaker fees, Fanto wrote a total of 1,172 Subsys prescriptions—approximately 23 prescriptions per month, nearly *five times* as much as he wrote prior to Insys paying him speaker fees.

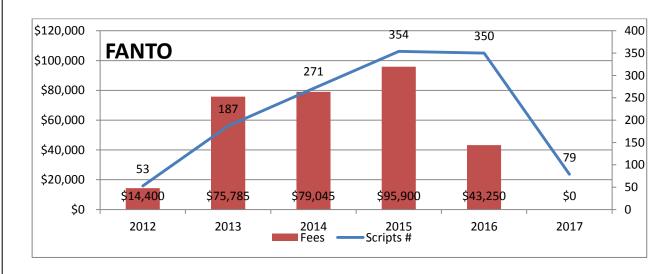
<8029395-v1A> -27-

about once a week on average. After Insys paid him speaker fees, Fanto prescribed Subsys about once every working day on average—meeting the goal Burlakoff had given to the Insys sales force of finding one doctor they could count on for "1 rx per day."

175. Before receiving speaker fees, from March 2012 to October 2012, Fanto

In other words, before Insys paid him speaker fees, Fanto prescribed Subsys

- 175. Before receiving speaker fees, from March 2012 to October 2012, Fanto generated an average of \$16,296 a month in Subsys prescription revenue for Insys.
- 176. During the time Insys paid Fanto speaker fees, Fanto generated an average of \$349,570 a month in Subsys prescription revenue for Insys.
- 177. Fanto's additional prescriptions above his prior average generated a total of approximately \$16,663,726 in additional revenue for Insys.
- 178. From October 25, 2012 to December 15, 2016, Insys paid Fanto \$308,380 in speaker fees.
- 179. The following chart shows Fanto's history of Subsys prescriptions and Insys speaker fees, based on data collected from Insys:



- 180. Insys, under the direction of Kapoor and Babich, paid Fanto speaker fees even though he posed a danger to his patients by inappropriately prescribing opioids.
- 181. On July 12, 2017, based, in part, on Fanto's prescribing of Subsys, Fanto signed an interim consent agreement (the "Fanto Consent Agreement") with the Arizona Medical

<8029395-v1A> -28-

Board that prohibits him from engaging in the practice of medicine.

- 182. The Fanto Consent Agreement states that between 2011 and 2016, Fanto deviated from the standard of care by initiating off-label Subsys treatment at the highest available dose of 800 mcg with at least three patients, contrary to directions contained in Subsys's FDA-approved label.
- 183. Subsys's FDA-approved label referenced in the Fanto Consent Agreement instructs HCPs to titrate patients, initially starting patients off at the lowest possible dose of Subsys—100 mcg—and then slowly increasing the patient's dosage level "until the patient reaches a dose that provides adequate analgesia using a single SUBSYS dose per breakthrough cancer pain episode with tolerable side effects."
- 184. Furthermore, any HCP enrolled in the TIRF REMS program is required to 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"
- 185. The Fanto Consent Agreement states that Fanto prescribed one of the three patients at issue 120 units of Subsys 800 mcg monthly for six months, even though the patient reported only using approximately 30 units per month.
- 186. The Fanto Consent Agreement also states that Fanto prescribed the 800 mcg dose of Subsys to one of the three patients at issue despite the patient having sleep apnea, thereby deviating from the standard of care, and did so contrary to the opinion of the patient's pulmonologist.
- 187. The Fanto Consent Agreement states that Fanto's Subsys prescriptions put at least two patients "at risk of potentially fatal arrhythmias" and "at risk of the potential harms associated with long term opioid use including abuse, addiction, diversion and accidental overdose."
- 188. Fanto's initial prescriptions of Subsys at high doses put patients at risk, but they also generated substantial revenue for Insys; the higher the dose of Subsys, the more money Insys made.

<8029395-v1A> -29-

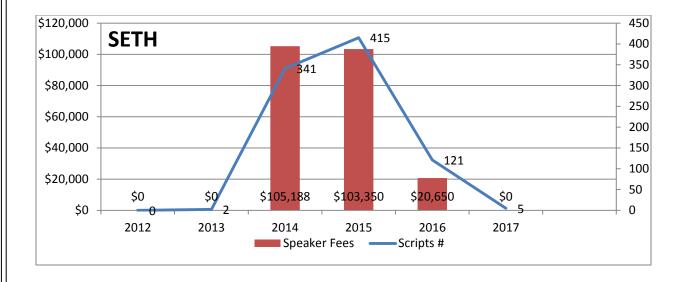
- 189. In fact, Kapoor and Babich designed a compensation program whereby Insys paid the SSPs more compensation for higher dose prescriptions than for lower dose prescriptions, thus providing the SSPs with an incentive to get their HCPs to write higher doses for patients.
- 190. Indeed, Burlakoff urged Insys's SSPs at the September 21, 2012 national sales meeting to "be sure your horses [HCPs] are 'unit' conscience [sic]" and "be sure your horses [HCPs] are 'dosage' conscience [sic]."
- 191. 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."
- 192. Kapoor and Babich regularly reviewed reports detailing the payments to HCPs and the resulting ROIs, and approved of the techniques used to funnel monies to Fanto to ensure that he prescribed Subsys at a high rate to his patients.

b. Dr. Nikesh Seth

- 193. Dr. Nikesh Seth ("Seth") wrote the second-highest number of Subsys prescriptions in Arizona from March 2012 through April 2017. During this time period, Seth wrote a total of 884 Subsys prescriptions.
 - 194. Like Fanto, Seth's practice focused on pain management.
- 195. Before 2014, Seth had only prescribed Subsys twice. During 2014, Insys's SSPs made repeated phone calls to Seth, visited his office, and paid for breakfast or lunch meetings. Seth responded to this attention by increasing his prescription rate of Subsys to his patients.
 - 196. Insys began paying Seth speaker fees on June 10, 2014.
- 197. Kapoor and Babich intended the speaker fees Insys paid to Seth to be a reward for Seth's previous Subsys prescriptions and an incentive for Seth to write additional Subsys prescriptions.
- 198. Seth's prescribing pattern changed around the time that he started receiving payments from Insys.

<8029395-v1A> -30-

- 199. Between March 2012 and February 2014, Seth had written a total of 11 Subsys prescriptions over two years.
- 200. In the three months immediately before Insys first paid Seth speaker fees, between March 2014 and May 2014, Seth wrote 53 Subsys prescriptions—approximately 18 per month.
- 201. During the time Insys paid Seth speaker fees, Seth wrote 820 Subsys prescriptions—approximately 23 per month.
- 202. Insys did not pay Seth speaker fees until he started to prescribe far more Subsys than he had previously.
- 203. While Insys paid him speaker fees, Seth prescribed Subsys about once every working day on average—meeting the goal Burlakoff had given to the Insys sales force of finding one doctor they could count on for "1 rx per day."
- 204. Before receiving speaker fees, between March 2012 and May 2014, Seth generated an average of \$8,301 a month in Subsys prescription revenue for Insys.
- 205. While Insys paid him speaker fees from June 2014 to September 2016, Seth generated an average of \$207,050 a month in Subsys prescription revenue for Insys.
- 206. Seth's additional prescriptions above his prior average generated a total of approximately \$5,511,473 in additional revenue for Insys.
- 207. From June 10, 2014 to September 26, 2016, Insys paid Seth \$229,187.50 in speaker fees.
 - 208. After September 2016, Insys did not pay Seth any more speaker fees.
- 209. After Insys stopped paying Seth speaker fees, Seth's prescribing of Subsys paralleled his pre-speaker-fee averages. Seth wrote 13 Subsys prescriptions over the next seven months, averaging just under two prescriptions per month.
- 210. The following chart shows Seth's history of Subsys prescriptions and Insys speaker fees, based on data collected from Insys:



211. Kapoor and Babich regularly reviewed reports detailing the payments to HCPs and the resulting ROIs, and approved of the techniques used to funnel monies to Seth to ensure that he prescribed Subsys at a high rate to his patients.

c. Dr. Sheldon Gingerich

- 212. Dr. Sheldon Gingerich ("Gingerich") wrote the third-highest number of Subsys prescriptions in Arizona from March 2012 through April 2017. During this time period, Gingerich wrote a total of 741 Subsys prescriptions.
 - 213. Like Fanto and Seth, Gingerich's practice focused on pain management.
- 214. Before May 2013, the highest number of Subsys prescriptions Gingerich had ever written in a month was three prescriptions, but by July 2013, Gingerich was writing 14 Subsys prescriptions a month, much more than anyone else in Arizona except for Fanto.
 - 215. Gingerich received his first speaker fee check from Insys on August 1, 2013.
- 216. Kapoor and Babich intended the speaker fees Insys paid to Gingerich to be a reward for Gingerich's previous Subsys prescriptions, and an incentive for Gingerich to write additional Subsys prescriptions.
- 217. Gingerich's prescribing pattern changed around the time that he started receiving payments from Insys.

- 218. Before receiving speaker fees, between March 2012 and April 2013, Gingerich wrote seven Subsys prescriptions—averaging less than one prescription per month.
- 219. In the three months immediately before Insys first paid Gingerich speaker fees, between May 2013 and July 2013, Gingerich wrote 29 Subsys prescriptions—approximately 10 per month.
- 220. During the time Insys paid Gingerich, Gingerich wrote 392 Subsys prescriptions—approximately 16 per month.
- 221. Insys did not pay Gingerich speaker fees until he started to prescribe far more Subsys than he had previously.
- 222. While Insys paid him speaker fees, Gingerich prescribed Subsys about two out of every three business days on average—nearly meeting the goal Burlakoff had given to the Insys sales force of finding one doctor they could count on for "1 rx per day."
- 223. Before receiving speaker fees, between March 2012 and July 2013, Gingerich generated an average of \$7,060 a month in Subsys prescription revenue for Insys.
- 224. After he started receiving speaker fees, Gingerich generated an average of \$138,274 a month in Subsys prescription revenue for Insys.
- 225. Gingerich's additional prescriptions above his prior average generated a total of approximately \$3,149,133 in additional revenue for Insys.
- 226. From August 1, 2013 to July 31, 2015, Insys paid Gingerich \$83,100 in speaker fees, plus \$7,200 in consulting fees.
- 227. After Insys stopped paying Gingerich speaker fees, he initially continued to prescribe Subsys prescriptions at a similar level, but the numbers gradually decreased, and by Q1 2017, Gingerich was only writing seven or eight Subsys prescriptions a month, similar to the amount he wrote in May and June 2014, before Insys began paying him.
- 228. The following chart shows Gingerich's history of Subsys prescriptions and Insys speaker fees, based on data collected from Insys:

<8029395-v1A> -33-

- 229. Kapoor and Babich regularly reviewed reports detailing the payments to HCPs and the resulting ROIs, and approved of the techniques used to funnel monies to Gingerich in order to ensure that he prescribed Subsys at a high rate to his patients.
 - d. <u>The Aggregate Return on Insys's Bribes to Only Three Arizona Doctors Is</u> Stunning.
- 230. Collectively, once Fanto, Seth, and Gingerich began receiving speaker fees, their additional prescriptions (above their historical averages) generated over \$25 million for Insys.
- 231. Collectively, Insys paid Fanto, Seth, and Gingerich nearly \$600,000 in speaker fees.
- 232. Collectively, for every \$1 Insys gave Fanto, Seth, and Gingerich in speaker fees, Insys made, on average, over \$40 in revenue.
- 233. Collectively, in terms of "ROI," as Burlakoff put it, Insys obtained more than a 4,000% return on investment from its payments to Fanto, Seth, and Gingerich.
 - 3. <u>Defendants and Other Former Insys Employees Have Pled to, or Been Convicted of, Federal Crimes Related to Insys's Sham "Speaker Fee" Program.</u>
- 234. On March 28, 2019, Burlakoff stipulated to a consent judgment with Plaintiff, wherein Burlakoff admitted to his role, at the direction of Kapoor and Babich, in orchestrating, directing, and perpetuating the fraudulent scheme to bribe HCPs in order to increase Subsys

|| <8029395-v1A> -34-

prescriptions; admitted that he knew these things were fraudulent; and admitted that he did them willfully.

- 235. Furthermore, on November 28, 2018, Burlakoff pled guilty in U.S. District Court to one count of racketeering conspiracy as a result of his part in the Insys scheme to bribe HCPs.
- 236. As discussed in Paragraph 91, above, on January 9, 2019, Defendant Babich pled guilty in U.S. District Court to federal felony conspiracy and mail fraud charges for his role in Insys's fraud. In addition to admitting his part in the fraudulent acts and practices of Insys's IRC, Babich further admitted in the relevant Agreed Statement of Facts that he, at the direction of Kapoor, "conspired with others . . . to use the Insys Speaker Program [] as a vehicle to bribe doctors and other clinicians to prescribe Subsys for their patients rather than a competitor drug."
- 237. On May 2, 2019, Kapoor was found guilty in federal court of conspiring to conduct the affairs of an enterprise through racketeering partly for his participation in the scheme to pay doctors to prescribe Subsys.
- 238. The convictions and plea agreements listed above further demonstrate that Kapoor and Babich operated a nationwide scheme through Insys to pay HCPs speaker fees in exchange for writing Subsys prescriptions.
- 239. At all relevant times, at Kapoor and Babich's direction, Insys controlled, funded, and acted in concert with the HCPs it paid through its speaker programs to prescribe high volumes of Subsys.
- 240. At all relevant times, these HCPs acted as Insys's agents in prescribing high volumes of Subsys to patients while Insys was paying the HCPs.
- 241. At all relevant times, Insys conspired with these HCPs with regard to the HCPs' conduct in prescribing high volumes of Subsys to patients in exchange for payments from Insys.
- 242. At all relevant times, Kapoor and Babich were aware that Insys was conspiring with HCPs, including paying them sham "speaker fees," but approved of the scheme to increase

<8029395-v1A> -35-

sales of Subsys.

C. Defendants' Unlawful Acts Were Extremely Profitable.

- 243. Creating and running the fraudulent IRC was incredibly profitable for Insys, Kapoor, Babich, and Gurry, but the IRC's acts and practices had no benefit on market competition, harmed consumers, and the harm was not reasonably avoidable by consumers.
- 244. Similarly, paying HCPs for prescriptions was incredibly profitable for Insys, Kapoor, Babich, and Burlakoff, but those acts and practices also had no benefit on market competition, harmed consumers, and the harm was not reasonably avoidable by consumers.
- 245. The following chart shows the rise of Insys's public stock price during the 2013 to 2016 period in which Insys was employing the fraudulent IRC acts and practices to increase Subsys prior authorizations, and the fraudulent "speaker fee" payments to increase Subsys prescriptions. The chart also demonstrates the subsequent fall as the fraudulent acts and practices began to be discovered and were eventually stopped:



- 246. Upon information and belief, Defendant Kapoor became a billionaire in 2013, due in part to the skyrocketing price of Insys stock. It is estimated that Kapoor's net worth peaked in 2015 at \$3.3 billion dollars at the height of the fraudulent activities at Insys.
- 247. In addition to the Insys stock held by Kapoor, Plaintiff believes, and here alleges, that, from 2013 to 2017, Kapoor received nearly \$500,000 in annual salary; over \$150,000 in board "fees"; over \$125,000 in bonuses; over \$200,000 in other compensation; and stock

<8029395-v1A> -36-

options valued as follows: \$149,904 in 2013, \$160,972 in 2014, and \$310,033 in 2015, with Kapoor owning 47,094,030 shares in Insys by 2017.

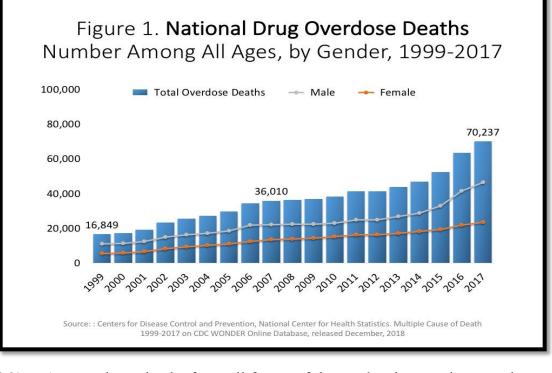
- 248. All of the money that Kapoor received may have been acquired by means of deceptive and unlawful acts and practices he created or condoned at Insys, including his fraudulent direction of the IRC and the scheme to bribe HCPs as alleged in this Complaint. In addition, Kapoor authorized Insys to provide paid dinner events to HCPs at Roka Akor, a national restaurant chain in which Kapoor owns a significant financial interest, thus providing additional revenues to Kapoor through Insys's fraud.
- 249. Upon information and belief, Plaintiff alleges that Defendant Babich was paid at least \$325,000 per year, plus bonuses and stock options, for his work at Insys. Per his testimony in U.S. District Court on February 14, 2019, Babich earned in excess of \$45 million from Insys.
- 250. All of the money that Babich received may have been acquired by means of deceptive and unlawful acts and practices he created or condoned at Insys, including his fraudulent direction of the IRC as alleged in this Complaint.
- 251. Upon information and belief, Plaintiff alleges that Defendant Gurry was paid at least \$140,000 per year, plus bonuses and stock options, for his work at Insys. During the times relevant to this Complaint, Gurry earned in excess of \$1.5 million from Insys, in part as a result of his fraudulent direction of the IRC and the scheme to bribe HCPs as alleged in this Complaint.
- 252. All of the money that Gurry received may have been acquired by means of deceptive and unlawful acts and practices he created or condoned at Insys, including his fraudulent direction of the IRC as alleged in this Complaint.
- 253. As part of his consent judgment with Plaintiff, Burlakoff agreed to forfeit the \$5,200,000 he earned as a result of his work at Insys from September 2012 through December 2015, which included his admitted role in the scheme to bribe HCPs.

<8029395> **-37-**

D. Insys's IRC Program and Speaker Fee Scheme Contributed to the Opioid Epidemic.

- 1. The Societal Costs of Defendants' Misconduct Are Extraordinary.
- 254. Defendants made millions from their misconduct, but society paid the costs.
- 255. By deceiving insurers through the operation of the IRC, Insys, Kapoor, Babich, and Gurry tricked them into paying hundreds of millions of dollars for prescriptions that the insurers otherwise would not have approved.
- 256. By bribing HCPs to prescribe Subsys, Insys, Kapoor, and Babich deprived consumers of the objective medical advice for which they paid, and increased the risk that HCPs would write inappropriate Subsys prescriptions in inappropriate quantities.
- 257. This behavior resulted in additional costs to health insurers. But in the end, the costs primarily fell upon consumers. Consumers paid for biased medical advice. Consumers paid for inappropriate prescriptions. Consumers paid increased insurance premiums. And most importantly, many consumers who were prescribed Subsys unwittingly took on an unnecessary risk of addiction and death.
 - 258. Consumers were unable reasonably to avoid any of these costs.
- 259. In particular, patients who were unaware that their HCPs were bribed to prescribe Subsys were unable to reasonably avoid the dangers of the unfair business practice that cost them money and may have put their lives in jeopardy.
- 260. The number of Americans who died from drug overdoses in general was 16,849 in 1999. In 2017, this figure was 70,237:

| | <8029395> -38-



- 261. Among these deaths from all forms of drugs, the sharpest increase has come from fentanyl and fentanyl analogs, according to data from the Center for Disease Control.
- 262. The National Institute on Drug Abuse estimates a total of 217,530 deaths in the United States from 1999 to 2017, related to prescription opioids alone.
- 263. From 2017 to the most recent available data on April 18, 2019, the Arizona Department of Health estimates a total of 20,541 opioid overdoses of Arizonans, of which 2,886 resulted in death. Approximately 1,344 Arizona infants were born with neonatal abstinence syndrome during this same time period.
- 264. Opioid overdoses have devastated both rural and urban areas of Arizona. Among the most impacted areas of Arizona, identified by the Arizona Department of Health as currently suffering the highest rates of opioid overdose deaths, are Bullhead City, Buckeye, Marana, Glendale, and Flagstaff.
- 265. CDC data reflects that, from 2006 to 2017, Mohave County, Arizona had more opioid prescriptions issued to its population than its actual population. Data is not available prior to 2006.

<8029395> -39-

266. The peak years for prescription opioids in Mohave County were 2010 to 2014. In 2014, 142.2 prescriptions were issued for every 100 residents of the county.

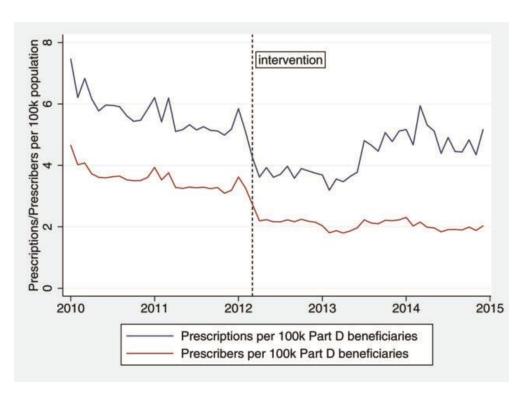
267. During that time period, in 2013, Defendant Kapoor took Insys public with its initial public offering on NASDAQ. In its Annual Report for the 2014 fiscal year, published in March 2015, Insys touted the performance of Subsys as follows:

Within the first four weeks of product launch, Subsys realized greater market share than the previous three branded products combined at their respective peak market penetration levels according to Source Healthcare Analytics. In December 2014, Subsys was the most prescribed TIRF product with 40.2% market share on a prescription basis according to IMS. Through our ongoing commercial initiatives, we believe we can continue to grow our market share and net revenue for Subsys. According to Source Healthcare Analytics, in 2014, TIRF products generated \$450.4 million in annual U.S. product sales. Traditionally, the physician prescriber base for TIRF products is concentrated, with approximately 1,594 physicians writing 90% of all TIRF product prescriptions in 2014, according to IMS. As a result, our commercial organization has been able to promote Subsys using a highly targeted approach designed to maximize impact with physicians who are TIRF REMS enrolled.

- 268. The "highly targeted approach designed to maximize impact with physicians" was successful for Insys. Its stock price peaked at \$46.17 a share in August 2015.
- 269. In addition to deaths from opioid overdoses, opioid addictions that were partly fueled and contributed to by Defendants' conduct have caused a wide variety of harms to the State of Arizona in particular, and the country in general.
- 270. Such harms include, but are not limited to, the impact of opioid addictions on law enforcement resources, resources of the medical community, and economic harms suffered by the State and by Arizonans.
 - 271. Neither Insys nor Defendants are solely to blame for the opioid epidemic.
- 272. However, it is inarguable that the conduct of Defendants only made the opioid epidemic worse.

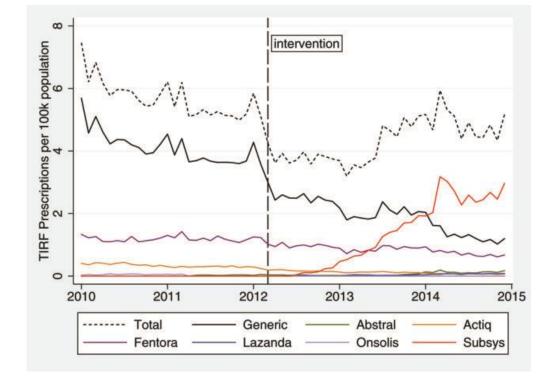
<8029395> **-4**0-

273. In particular, the actions of Defendants appear to have reversed a downward trend in TIRF prescriptions nationwide. The following chart shows a steady decline in TIRF prescriptions from 2010 to 2013, with a steep decline after the FDA's implementation of the TIRF-REMS program to protect consumers (marked as "Intervention" below). It also shows an increase in prescriptions in 2013, without a corresponding increase in prescribers:



274. The following chart demonstrates that this increase in TIRF prescriptions was driven *entirely* by Subsys prescriptions, as other TIRF medications continued to decrease after 2013:

<8029395> -41-



By misleading insurers and PBMs about patients' medical histories to increase prior-authorization rates for Subsys, Kapoor, Babich, and Gurry not only expanded Insys's market for immediate-release fentanyl products, they expanded the TIRF market itself and fanned the flames of an opioid epidemic.

By paying HCPs to prescribe Subsys, Kapoor, and Babich not only expanded Insys's market for immediate-release fentanyl products, they expanded the TIRF market itself and fanned the flames of an opioid epidemic.

VIOLATIONS OF LAW

- 277. The State realleges all preceding paragraphs as though fully set forth here.
- Defendants Kapoor, Babich, and Gurry engaged in deception, deceptive or unfair 278. 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

-42-<8029395>

prescription drugs in violation of the Arizona Consumer Fraud Act, A.R.S. §§ 44-1521–44-1534, including, but not limited to:

- a. Kapoor, Babich, and Gurry engaged in deceptive acts and practices by creating, promoting, and executing a scheme in which Insys employees provided insurers and PBMs nationwide with false and misleading information, in order to obtain prior authorization for patients' Subsys prescriptions and sell more Subsys;
- b. Kapoor, Babich, and Gurry concealed, suppressed, or omitted material facts, including facts related to the identity of the IRC employees and patient health histories, and did so with intent that others rely on such concealments, suppressions, or omissions, in order to obtain prior authorization for patients' Subsys prescriptions and sell more Subsys;
- c. Kapoor and Babich engaged in unfair acts and practices by creating, promoting, and executing a scheme in which Insys employees provided insurers and PBMs nationwide with false and misleading information after September 13, 2013, in order to obtain prior authorization for patients' Subsys prescriptions and sell more Subsys;3 and
- d. Kapoor and Babich engaged in unfair acts and practices by creating, promoting, and executing a scheme in which Insys provided sham "speaker fees" to HCPs nationwide to induce, and in exchange for, the HCPs writing Subsys prescriptions after September 13, 2013.
- 279. The unfair acts and practices alleged in the preceding paragraphs caused or were likely to cause substantial injury to consumers that were not reasonably avoidable by consumers and were not outweighed by countervailing benefits to consumers or to competition.
- 280. In all matters alleged in the preceding paragraphs, Defendants Kapoor, Babich, and Gurry knew or should have known that their conduct was unlawful, subjecting themselves to enforcement and penalties as provided in A.R.S. § 44-1531(A).

<8029395> **-4**3-

³ The addition of "unfair" to A.R.S. § 44-1522(A) became effective on September 13, 2013, and was not retroactive.

- 281. In addition to violating the Arizona Consumer Fraud Act, the conduct of Defendants Kapoor, Babich, and Gurry described above also constitutes civil racketeering under the Arizona Racketeering Act, A.R.S. § 13-2301 *et seq.*, including, but not limited to:
 - a. By engaging in the fraudulent acts described in Paragraph 278(a)-(d), above, Kapoor, Babich, and Gurry were operating a criminal syndicate, as defined by A.R.S. § 13-2301(C)(7);
 - b. As described in Paragraph 91, above, Babich pled guilty to felony conspiracy and mail fraud charges, relating to bribes paid to doctors and misleading information provided to insurance providers. Those charges carry a sentence that exceeds one year, and therefore constitute racketeering under A.R.S. § 13-2301(D)(4);
 - c. As described in Paragraphs 92-95, above, Kapoor and Gurry were found guilty of committing felony acts that included conspiring to conduct or to participate in the affairs of an enterprise through racketeering for their participation in the operation of the IRC and the deceptive scheme to provide false and misleading information to insurers and PBMs to obtain prior authorization for Subsys. Those charges carry a sentence that exceeds one year, and therefore constitute racketeering under A.R.S. § 13-2301(D)(4);
 - d. Babich, Kapoor, and Gurry participated in a criminal syndicate by furnishing advice or direction in the conduct, financing or management of a criminal syndicate's affairs with the intent to promote or further the criminal objectives of a criminal syndicate, as proscribed by A.R.S. § 13-2308(A)(3);
 - e. Babich, Kapoor, and Gurry also assisted a criminal syndicate by committing the felony offenses described above, with the intent to promote or further the criminal objectives of the criminal syndicate, as proscribed by A.R.S. § 13-2308(C);
 - f. Babich, Kapoor, and Gurry illegally conducted an enterprise by being employed by and associated with a criminal enterprise, and by conducting such

<8029395> **-44**-

enterprise's affairs through racketeering, and/or by participating directly or indirectly in the conduct of any enterprise that the person knows is being conducted through racketeering, as proscribed by A.R.S. § 13-2312(B);

- g. Pursuant to their scheme to defraud, Babich, Kapoor, and Gurry knowingly obtained benefits by means of false or fraudulent pretenses, representations, promises or material omissions, as proscribed by A.R.S. § 13-2310(A); and
- h. Babich and Kapoor, through their role in the speaker fee scheme, engaged in racketeering based on the following criminal acts: (1) bribery, (2) participation in a criminal syndicate, (3) asserting false claims, including false claims asserted through fraud, and (4) a scheme or artifice to defraud; and all the criminal acts were committed for financial gain, as proscribed by A.R.S. § 13-2301(D)(4)(b)(vi), (xiii), (xv), and (xx).
- 282. As described in Paragraph 279 and its subparts listed above, Babich has pled guilty to, and Kapoor and Gurry have been convicted of, criminal acts that meet the definition of racketeering under A.R.S. § 13-2301(D)(4). As a result, and pursuant to A.R.S. § 13-2313, Plaintiff is entitled to recover treble damages, costs, and fees to prevent, restrain, or remedy the racketeering of Kapoor, Babich, and Gurry, as established by A.R.S. § 13-2314(A)(4).
- 283. Plaintiff demands a jury trial as to all triable issues of fact.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, State of Arizona, respectfully requests that this honorable Court:

- 284. Permanently enjoin and restrain Defendants, their agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in deceptive or unfair acts or practices that violate the Arizona Consumer Fraud Act, A.R.S. §§ 44-1521–44-1534, pursuant to A.R.S. § 44-1528(A)(1);
- 285. Permanently enjoin and restrain Defendants, their agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of

<8029395> -45-

them, from engaging in acts or practices that violate the Arizona Racketeering Act, A.R.S. § 13-2301 *et seq.*;

- 286. Order the Defendants to pay restitution to consumers and other persons, pursuant to A.R.S. § 44-1528(A)(2), in an amount no less than \$875,052,000, representing the Subsys revenue that may have been acquired by Insys through unlawful acts and practices from 2013 to 2016;
- 287. Order the disgorgement of all profits, gain, gross receipts, or other benefit obtained by the Defendants as a result of the illegal conduct alleged herein, pursuant to A.R.S. § 44-1528(A)(3), as follows:
 - a. Against Defendant Kapoor, disgorgement in an amount no less than \$3.09 million, plus any amount received from the sale of his Insys stock, representing the approximate profits earned by Kapoor through unlawful acts and practices from September 13, 2013 through January 2017;
 - b. Against Defendant Babich, disgorgement in an amount no less than \$45 million, plus any amount received from the sale of his Insys stock, representing the approximate profits earned by Babich through unlawful acts and practices from September 13, 2013 to November 2015;
 - c. Against Defendant Gurry, disgorgement in an amount no less than \$1.5 million, plus any amount received from the sale of his Insys stock, representing the approximate profits earned by Gurry through unlawful acts and practices from September 13, 2013 to October 2016;
- 288. Order the Defendants to pay the State of Arizona a civil penalty of up to \$10,000 for each willful violation by each Defendant, pursuant to A.R.S. § 44-1531 as follows:
 - a. Against Defendant Kapoor, civil penalties in an amount no less than \$910 million, representing \$10,000 per violation for an estimated 9,750 prior authorizations obtained through deceptive acts and practices and \$10,000 per violation for over 81,250 unfair payments to HCPs from September 13, 2013 to January 2017;

<8029395> **-46-**

	2
	3
	4
	5
	6
	7
	8
	9
1	0
1	1
1	2
1	3
1	4
1	5
1	6
1	7
1	8
1	9
2	0
2	1
2	2
2	3
2	4
2	5
2	6
2	7

1

- b. Against Defendant Babich, civil penalties in an amount no less than \$599.2 million, representing \$10,000 per violation for an estimated 6,420 prior authorizations obtained through deceptive acts and practices and \$10,000 per violation for over 53,500 unfair payments to HCPs from September 13, 2013 to November 2015;
- c. Against Defendant Gurry, civil penalties in an amount no less than \$94.5 million, representing \$10,000 per violation for an estimated 9,450 prior authorizations obtained through deceptive acts and practices from September 13, 2013 to October 2016.
- 289. Order the Defendants to pay treble damages, costs, and fees related to this lawsuit, pursuant to A.R.S. § 13-2314(A);
- 290. Order the Defendants to pay the State of Arizona its investigative and attorneys' costs and fees related to this investigation and lawsuit, pursuant to A.R.S. § 44-1534;
- 291. Order the Defendants permanently enjoined from advertising, engaging in the marketing of, and selling pharmaceutical products in or from the state of Arizona, pursuant to A.R.S. § 44-1528(A)(4); and
 - 292. Order other and further relief as the Court may deem just and proper.

 DATED this 17th day of July, 2019

Mark Brnovich Attorney General

Matthew du Mée Neil Singh Andrija Samardzich Assistant Attorneys General

Attorneys for Plaintiff State of Arizona

<8029395> **-47-**