

**SECOND SUPERSEDING
INDICTMENT**

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,)
)
 v.)
)
(1) MICHAEL L. BABICH)
)
(2) ALEC BURLAKOFF)
)
(3) MICHAEL J. GURRY)
)
(4) RICHARD M. SIMON)
)
(5) SUNRISE LEE)
)
(6) JOSEPH A. ROWAN)
)
(7) JOHN N. KAPOOR)
)
 Defendants.)

CRIMINAL NO. 16CR10343ADB
VIOLATIONS:

18 U.S.C. § 1962(d)
(Racketeering Conspiracy)

18 U.S.C. § 1963 (Forfeiture)

SECOND SUPERSEDING INDICTMENT



The Grand Jury charges that:

COUNT 1
(18 U.S.C. § 1962(d) – Racketeering Conspiracy)

At all times relevant to the allegations in this Indictment:

THE ENTERPRISE

1. Insys Therapeutics, Incorporated, was a Delaware corporation with headquarters in Chandler, Arizona (“Insys” or “the Company”). Insys developed and owned a drug called “Subsys,” a liquid formulation of fentanyl to be applied under the tongue. From in or about March 2012, until in or about September 2018, Insys manufactured, marketed, and sold Subsys in interstate commerce, including in the District of Massachusetts. Insys constituted an “enterprise” as defined by Title 18, United States Code, Section 1961(4), that is, a legal entity which engaged in, and the activities of which affected, interstate commerce.

THE MARKET FOR SUBSYS

2. Opioids were a therapeutic class of drugs used to relieve pain. Fentanyl and analogues of fentanyl were among the most potent opioids available for human use. The United States Food and Drug Administration (“FDA”) approved Subsys in or about January 2012 for the management of breakthrough pain in patients 18 years of age or older with cancer who were already receiving, and who were already tolerant to, opioid therapy for their underlying persistent cancer pain. The FDA determined that Subsys was in a category of drugs it called Transmucosal Immediate Release Fentanyl (“TIRF”) products, which included other fentanyl-based rapid onset opioids that competed with Subsys for market share.

3. Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, 21 U.S.C. §§ 801-971, were collectively referred to as the “Controlled Substances Act” or the “CSA.” The CSA and its implementing regulations identified drugs and

other substances defined by federal law as “controlled substances,” and classified every controlled substance into one of five schedules based in part upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the controlled substance might cause.

4. Fentanyl, and analogues of fentanyl, were designated as Schedule II controlled substances. As such, products that contained fentanyl or analogues of fentanyl, including Subsys, were subject to the restrictions imposed on all Schedule II substances.

5. The CSA created a closed system of distribution for products such as Subsys that contained Schedule II controlled substances. Every entity that handled a Schedule II controlled substance was required to register with the Drug Enforcement Administration (“DEA”) unless subject to an exemption not applicable here. In this system, Subsys was always under the control of a DEA-registered entity until it reached the patient or it was destroyed. All DEA registrants were required to notify the DEA of suspicious orders, including orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Demand: The Role of the Practitioner

6. Federal law mandates that to be effective, a prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. Subsys could only be prescribed by a licensed medical practitioner, who was registered with the DEA and able to prescribe opioids in the usual course of professional practice, for a legitimate medical purpose.

7. Practitioners owed a fiduciary duty to their patients to prescribe medication in the usual course of professional practice for a legitimate medical purpose.

8. Market demand for Subsys was driven by the practitioners who wrote prescriptions

for their patients. Practitioners willing to write prescriptions for Subsys had a large number of competing medications from which to choose. In addition to other brand name TIRF drugs, practitioners could also prescribe a generic alternative.

Supply: The Role of Wholesalers

9. Subsys was produced at a manufacturing facility under contract with Insys (the “contract manufacturer”). After assembling and packaging the drug, the contract manufacturer shipped the completed product to a storage and shipping facility called a third party logistics provider (“3PL”). From the launch of Subsys in 2012, Insys directed its 3PL to ship Subsys to wholesale distributors (“wholesalers”). For a fee, wholesalers then distributed Subsys to their retail customers, usually pharmacies.

10. In order to meet their obligations as DEA registrants to monitor suspicious orders, wholesalers often limited the amount of controlled substances they were willing to distribute to pharmacy customers. These limits, called “Schedule II caps” and “thresholds,” were set for each pharmacy, and were usually imposed on categories, or families, of Schedule II drugs for a given period of time. As a fentanyl-based drug, Subsys was in a category of drugs for which wholesalers imposed Schedule II caps.

11. Some DEA registrants, including wholesalers, permitted their pharmacy customers to request an increase in the Schedule II cap for a particular drug family. If the DEA registrant did not increase the cap, the pharmacy would not receive the additional drugs until the threshold period was over.

Supply: The Role of Pharmacies and Pharmacists

12. As the last entity within the distribution chain of controlled substances, pharmacies interacted with drug companies, wholesalers, practitioners, insurers, and patients. Further, while

the prescribing practitioner was responsible for the proper prescribing and dispensing of controlled substances, pharmacists also held a corresponding responsibility and could not provide a patient a Schedule II substance without a valid prescription issued for a legitimate medical purpose by a licensed practitioner acting in the usual course of professional practice.

Payment: The Role of Insurers

13. Subsys, like many of its competitors, was expensive. Depending upon the dosage and number of units prescribed, a prescription for Subsys usually cost thousands of dollars per month. Most patients relied upon commercial insurance and/or publicly-funded insurance, including Medicare and Medicaid, to subsidize the cost of Subsys.

14. Insurers and their agents, including pharmacy benefit managers or “PBMs” (hereinafter “insurers”), controlled the costs of prescription drugs by using, among other restrictions, prior authorizations. While their specific requirements varied, almost all insurers required patients to obtain prior authorization before agreeing to pay for a Subsys prescription. In such cases, insurers would not authorize payment if the prescription was written: (a) in exchange for a bribe or kickback; (b) outside the usual course of professional practice; or (c) not for a legitimate medical purpose. In general, patients had to receive a particular medical diagnosis before the insurer would authorize payment for Subsys. In addition, many insurers would not pay for Subsys until the patient had tried and failed certain other preferred medications.

15. If the insurer authorized payment for Subsys, the insurer paid most, but not all, of the cost of the drug. Without prior authorization, the prescription was not filled unless the patient or a third party paid for the entire cost of Subsys.

THE DEFENDANTS

16. The defendant **JOHN N. KAPOOR** (“**KAPOOR**”) founded and owned Insys. **KAPOOR** held executive management positions at Insys, including Executive Chairman of the Board of Directors, and for a time, Chief Executive Officer (“**CEO**”).

17. Defendant **MICHAEL L. BABICH** (“**BABICH**”) held executive management positions at Insys, including President and CEO.

18. Defendant **ALEC BURLAKOFF** (“**BURLAKOFF**”) held executive management positions at Insys, including Regional Sales Manager for the Southeast Region and Vice President of Sales.

19. Defendant **MICHAEL J. GURRY** (“**GURRY**”) held executive management positions at Insys, including Vice President of Managed Markets.

20. Defendant **RICHARD M. SIMON** (“**SIMON**”) held executive management positions at Insys, including Regional Sales Manager for the Central Region and National Director of Sales.

21. Defendant **SUNRISE LEE** (“**LEE**”) held executive management positions at Insys, including Regional Sales Manager for the Mid-Atlantic Region, Regional Director for the Central Region, and Regional Director for the West Region.

22. Defendant **JOSEPH A. ROWAN** (“**ROWAN**”) held executive management positions at Insys, including Regional Sales Manager for the Southeast Region and Regional Director for the East Region.

THE RACKETEERING CONSPIRACY

23. From in or about May 2012, and continuing until in or about December 2015, within the District of Massachusetts and elsewhere,

(1) BABICH, (2) BURLAKOFF, (3) GURRY,

(4) SIMON, (5) LEE, (6) ROWAN, and (7) KAPOOR,

defendants herein, and others known and unknown to the Grand Jury, being persons employed by and associated with Insys, which enterprise engaged in, and whose activities affected, interstate commerce, did knowingly conspire to violate Title 18, United States Code, Section 1962(c), that is, to conduct and participate, directly and indirectly, in the conduct of the affairs of such enterprise through a pattern of racketeering activity, as defined in Title 18, United States Code, Sections 1961(1) and (5).

24. The pattern of racketeering activity through which the defendants, along with others known and unknown to the Grand Jury, agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the enterprise consisted of multiple:

- a. acts indictable under Title 18, United States Code, Section 1341 (mail fraud);
- b. acts indictable under Title 18, United States Code, Sections 1341 and 1346 (honest services mail fraud);
- c. offenses involving the distribution of controlled substances in violation of Title 21, United States Code, Section 841(a)(1) ();
- d. acts indictable under Title 18, United States Code, Section 1343 (wire fraud); and
- e. acts indictable under Title 18, United States Code, Sections 1343 and 1346 (honest services wire fraud).

25. It was part of the conspiracy that each of the defendants agreed that a conspirator would commit at least two acts of racketeering activity, as described in paragraph 24 above, in the conduct of the affairs of the enterprise.

OBJECT OF THE CONSPIRACY

26. The defendants and their co-conspirators sought to increase profits for the enterprise and themselves by conducting the affairs of the enterprise through bribes, fraud, and the illicit distribution of Subsys, a product containing a Schedule II opioid.

MANNER AND MEANS: BRIBING PRACTITIONERS

27. In furtherance of the conspiracy to conduct and participate, directly and indirectly, in the conduct of the affairs of the enterprise through each of the types of racketeering activity described in paragraph 24, **KAPOOR, BABICH, BURLAKOFF, SIMON, LEE, and ROWAN**, and other co-conspirators known and unknown to the Grand Jury, intentionally bribed and provided kickbacks to practitioners in order to increase Subsys sales. The defendants did not attempt to bribe all practitioners who prescribed Subsys and other rapid-onset opioids. Instead, the defendants used pharmacy data acquired from third parties to identify practitioners who either prescribed unusually high volumes of rapid-onset opioids, or had demonstrated a capacity to prescribe unusually large volumes of rapid-onset opioids. The defendants then bribed and provided kickbacks to these targeted practitioners, some of whom are identified below, in exchange for the practitioners: (1) increasing the number of new Subsys prescriptions; and (2) increasing the dosage and number of units of Subsys for new and existing prescriptions.

28. In some cases, the defendants expressly required practitioners to write a minimum number of Subsys prescriptions, write prescriptions at a minimum dosage, and write prescriptions for a minimum number of units of Subsys, in order to continue to receive bribes and kickbacks. In all cases, the defendants measured the effect of their bribes and kickbacks on each practitioner's prescribing habits and, correspondingly, the effect of their bribes on the

revenue that each bribed practitioner generated for the enterprise and the defendants. The defendants reduced or eliminated bribes and kickbacks paid to those practitioners who failed to meet the minimum prescription requirements set by the defendants, or who otherwise failed to generate enough revenue to justify additional bribes and kickbacks.

29. The bribes and kickbacks took multiple forms. For example, the defendants paid bribes and kickbacks that were disguised as honoraria purportedly for practitioners' participation in educational events regarding the use of Subsys. The defendants also paid the salaries of members of the office staff for certain targeted practitioners and provided Insys employees to perform administrative tasks that the practitioners would have otherwise had to pay someone else to perform.

30. The defendants used the bribes and kickbacks to:

- a. fraudulently cause insurers to pay for new prescriptions, as well as for increases in dosages and units of new and existing prescriptions;
- b. deprive patients of the honest services of their practitioners; and
- c. cause practitioners to prescribe Subsys without regard to the medical condition affecting individual patients, and, therefore, outside the usual course of professional practice and not for a legitimate medical purpose.

31. Had the insurers known that the defendants gave bribes and kickbacks to the targeted practitioners, the insurers would not have authorized payment for Subsys because insurers do not authorize payment for prescriptions that are written: (a) in exchange for a bribe or kickback; (b) outside the usual course of professional practice; or (c) not for a legitimate medical purpose.

32. The defendants sought to arrange, coordinate, and pay bribes and kickbacks to targeted practitioners throughout the United States, including in the District of Massachusetts.

33. The defendants arranged and coordinated the bribes and kickbacks using interstate

wire transmissions, including emails, texts, and telephone calls.

34. The defendants caused bribes and kickbacks to be sent and delivered by the United States Postal Service and by private and commercial interstate carriers.

Targeted Practitioners

35. Among the practitioners who accepted bribes and kickbacks from the defendants in the manner described above were the following eight practitioners:

36. Practitioner #1 and Practitioner #2, both licensed to practice medicine in Alabama, were recruited by the defendants and known to prescribe unusually large volumes of opioids. Practitioner #1 and Practitioner #2 owned and co-directed a pain management clinic in two locations in or around Mobile, Alabama. Practitioner #1 and Practitioner #2 also owned a pharmacy, which was located in the same building as one of their clinics.

37. Practitioner #3, a physician licensed to practice in Michigan, was recruited by the defendants and known to prescribe unusually large volumes of opioids. Practitioner #3 owned and operated a pain management clinic in Saginaw, Michigan. The clinic, which included ancillary clinics in several locations throughout Michigan, served approximately 5,000 patients during dates relevant to the Indictment.

38. Practitioner #4, a physician licensed to practice in Arkansas, was recruited by the defendants and known to prescribe unusually large volumes of opioids. Practitioner #4 owned and managed a pain management clinic in Sherwood, Arkansas, where he saw as many as 75 to 100 patients a day. Practitioner #4 also owned and operated a pharmacy, which was located in the same building as his pain management clinic.

39. Practitioner #5, a physician licensed to practice in Texas, was recruited by the defendants and known to prescribe unusually large volumes of opioids. Practitioner #5 owned

and operated pain management clinics in Laredo, Texas, and Corpus Christi, Texas.

40. Practitioner #6, a physician licensed to practice in Illinois and Indiana, was recruited by the defendants and known to prescribe unusually large volumes of opioids.

41. Practitioner #7, an Advanced Practice Registered Nurse licensed to practice in Connecticut, worked at a pain management practice with offices in Derby and Meriden, Connecticut. The practice was targeted by the defendants because it was known to prescribe unusually large volumes of opioids.

42. Practitioner #8, a physician licensed to practice in Florida, was recruited by the defendants and known to prescribe unusually large volumes of opioids. Practitioner #8 owned and managed a pain management practice in southwest Florida.

43. The defendants knew or suspected that some of the practitioners they chose to target were involved in the illicit distribution of opioids—that is, the distribution of opioids outside the usual course of professional practice and not for a legitimate medical purpose.

44. For example, in or about September 2012, the Insys sales representative assigned to Arkansas notified **BABICH, SIMON, and BURLAKOFF** that he believed Practitioner #4 was under investigation by law enforcement for illicit opioid distribution and that the pharmacy owned by Practitioner #4 had been shut down due to the high volume of opioids it dispensed. Thereafter, in or about October 2012, **SIMON** and the Insys sales representative took Practitioner #4 to dinner, during which they promised him bribes in exchange for Subsys prescriptions.

45. Similarly, on or about September 17, 2012, an Insys sales representative assigned to the Chicago area informed **BABICH** via email that she frequently called upon Practitioner #6 and that Practitioner #6 ran a “very shady pill mill.” A “pill mill” is a colloquial term used to

describe a pain clinic engaged in illicit opioid distribution. In the weeks following the email, **LEE** offered Practitioner #6 bribes and kickbacks in exchange for Subsys prescriptions.

Speaker Honoraria Used as Bribes and Kickbacks

46. One of the principal ways in which the defendants provided bribes and kickbacks to targeted practitioners was to disguise the payments as honoraria for speaking engagements. In or about March 2012, Insys planned and funded a marketing program (the “Speaker Program”) purportedly intended to increase brand awareness of Subsys using peer-to-peer educational lunches and dinners. Sales representatives were required to recruit licensed practitioners to give lectures regarding the use of Subsys during dinners and lunches arranged by Insys. In exchange for practitioners educating other prescribers about Subsys, Insys agreed to pay each speaker a fee, also referred to as an honoraria, for each speaking event.

47. While some speaking engagements and corresponding payments to key opinion leaders functioned as legitimate marketing events, payments to the targeted practitioners, including those identified above, were instead bribes and kickbacks paid and authorized by the defendants to increase the targeted practitioners’ Subsys prescriptions.

48. Beginning in or about August 2012, and continuing through November 2015, **KAPOOR, BABICH, BURLAKOFF, SIMON, LEE, ROWAN**, and other co-conspirators known and unknown to the Grand Jury, directed the payment of bribes and kickbacks disguised as speaker honoraria in exchange for new prescriptions, and for raising the dosage and volume of new and existing prescriptions, without regard for the needs of, and physicians’ duties to, their patients.

49. **KAPOOR, BABICH, BURLAKOFF, SIMON, LEE, and ROWAN** often required that practitioners meet certain prescribing levels or revenue targets in exchange for the

continued payment of bribes and kickbacks.

50. For example, in or about February 2013, **SIMON** agreed to pay Practitioner #5 bribes and kickbacks in exchange for Practitioner #5 increasing the number of units of each Subsys prescription refill, without regard to the medical needs of Practitioner #5's Subsys patients.

51. Similarly, in or about April 2013, acting at the direction of **BURLAKOFF**, the Insys Sales Representative and District Manager assigned to Connecticut agreed to increase the speaker honoraria paid to Practitioner #7 in exchange for Practitioner #7 writing one new Subsys prescription per week, without regard to the medical needs of Practitioner #7's Subsys patients.

52. The speaker program bribes were successful in increasing profits for the enterprise and for the defendants. Accordingly, **KAPOOR, BABICH, BURLAKOFF, SIMON, LEE,** and **ROWAN** significantly increased the amount of money the enterprise paid for speaker bribes over the course of the three years from 2012 through 2014.

Services of Insys Employees Used as Bribes and Kickbacks

53. Obtaining prior authorizations from insurance companies was time-consuming and costly for practitioners. A practitioner had to dedicate support staff, and the money necessary to compensate them, to navigate the prior authorization processes and associated paperwork.

54. To further the object of the conspiracy, in or about June 2013, **KAPOOR, BABICH, BURLAKOFF, SIMON,** and **GURRY** created the Area Business Liaison ("ABL") position, later referred to as Business Relations Managers ("BRM"). ABLs and BRMs were employees paid by Insys who worked inside the medical offices of prescribing practitioners and related pharmacies.

55. **KAPOOR, BABICH, BURLAKOFF,** and **SIMON** offered the services of ABLs

and BRMs to targeted practitioners as bribes and kickbacks to induce and reward practitioners for issuing new Subsys prescriptions or increasing the dosage or units of new and existing Subsys prescriptions.

56. For example, in or about September 2013, **BABICH, BURLAKOFF, SIMON**, and **LEE** hired a woman known to be employed by Practitioner #3 as an administrative assistant. The employee's job responsibilities stayed essentially the same, except that Insys, rather than Practitioner #3, paid her salary. The purpose of paying this employee's salary was to bribe Practitioner #3 to write more prescriptions for Subsys.

57. Similarly, in or about September 2013, **BABICH, BURLAKOFF**, and **ROWAN** hired a woman known to be the girlfriend of Practitioner #8 as an ABL at a pharmacy associated with Practitioner #8. The purpose of hiring this employee was to bribe Practitioner #8 to write more prescriptions for Subsys, and at higher dosages and units per prescription.

58. Similarly, in or about March 2014, **BABICH, BURLAKOFF**, and **ROWAN** hired a woman known to be a full-time support staff previously employed by Practitioner #4. The employee's job responsibilities stayed essentially the same, except that Insys, rather than Practitioner #4, paid her salary. The purpose of Insys paying this employee's salary was to bribe Practitioner #4 to write more prescriptions for Subsys.

Measuring the Effect of Bribes and Kickbacks

59. To ensure that their speaker program bribes and kickbacks were working as designed, **KAPOOR, BABICH, BURLAKOFF, SIMON, LEE, ROWAN**, and co-conspirators known and unknown to the Grand Jury, calculated and closely tracked the effect that their bribes and kickbacks had on practitioners' prescribing habits. They referred to the effect of these payments as the "return on investment" ("ROI"). The defendants calculated ROI for each

targeted practitioner receiving speaker program bribes and kickbacks by comparing the net revenue earned from prescriptions written by each targeted practitioner with the total value of bribes and kickbacks paid to that practitioner.

60. **KAPOOR, BABICH, BURLAKOFF, SIMON**, and co-conspirators known and unknown to the Grand Jury, personally participated in frequent meetings and discussions to monitor the effect of these bribes and kickbacks on the speaker-practitioners throughout the United States. **KAPOOR, BABICH, BURLAKOFF, SIMON, LEE**, and **ROWAN** directed that speaker program bribes and kickbacks be reduced or entirely taken away from a practitioner when the net revenue Insys earned from prescriptions written by that practitioner was less than twice the total amount of bribes and kickbacks (disguised as honoraria) paid to that practitioner.

61. The speaker program bribes and kickbacks resulted in significant increases in Subsys prescriptions. For instance, in or about the week of June 30, 2012, Practitioner #1 averaged approximately 2.2 prescriptions for Subsys per week. During the week of his first scheduled speaker programs, in or about August 8, 2012, Practitioner #1 wrote 18 prescriptions for Subsys. By on or about September 28, 2012, the end of the third quarter, Practitioner #1 averaged approximately 11 prescriptions for Subsys per week, an approximately 500% increase in weekly Subsys prescriptions from prior to the speaker program bribes and kickbacks.

62. Similarly, in or about the first week of October 2012, **BURLAKOFF** traveled to Michigan and took Practitioner #3 to dinner. During the dinner, **BURLAKOFF** agreed to pay Practitioner #3 speaker program bribes in exchange for new Subsys prescriptions. During the seven months between the launch of Subsys and his first speaker program event in or about October 11, 2012, Practitioner #3 wrote approximately 94 prescriptions for the drug. In the roughly two months between his dinner with **BURLAKOFF** and the end of November 2012,

Practitioner #3 wrote approximately 120 prescriptions for Subsys, an over 400% increase per month. During that same period of time, the defendants and their co-conspirators paid

Practitioner #3 for two speaker program events and he was scheduled to “speak” at six more.

MANNER AND MEANS: FRAUDULENT PRIOR AUTHORIZATION REQUESTS

63. In furtherance of the conspiracy to conduct and participate, directly and indirectly, in the conduct of the affairs of the enterprise through each of the types of racketeering activity described in paragraph 24, **KAPOOR, BABICH, BURLAKOFF, GURRY, SIMON, LEE, ROWAN**, and other co-conspirators known and unknown to the Grand Jury, instructed Insys employees to make false and misleading representations and omissions to insurers in order to secure payment for Subsys prescriptions.

64. The defendants and their co-conspirators recognized that the potential for profits generated by their bribes and kickbacks could not be fully realized unless insurers authorized payment for Subsys prescriptions. To increase the rate of payment authorizations for Subsys prescriptions, **KAPOOR, BABICH, GURRY**, and co-conspirators known and unknown to the Grand Jury, created and operated a special unit within Insys (referred to herein as the “Insys Reimbursement Center”) that was dedicated to obtaining prior authorization of Subsys prescriptions directly from insurers. Acting at the direction of **KAPOOR, BABICH, GURRY**, and other co-conspirators, Insys Reimbursement Center employees provided insurers with false and misleading representations about patient diagnoses, including the type of pain being treated and the patients’ prior course of treatment with other medications, in order to secure payment authorizations.

65. **KAPOOR, BABICH**, and **GURRY** planned and created the Insys Reimbursement Center in or about October 2012, and subsequently operated it until in or about December 2015.

The Insys Reimbursement Center, located at the Arizona headquarters of Insys, was designed to shift the burden of seeking prior authorization for Subsys from practitioners to Insys, thereby allowing Insys to determine what medical information was presented to insurers.

66. Practitioners using the Insys Reimbursement Center were required to provide Insys with detailed information for all patients prescribed Subsys. This information included, among other things, patient names, dates of birth, medical diagnoses, and in many cases, medical records. Insys sales employees located throughout the United States, including in the District of Massachusetts, often obtained these records from practitioners and transmitted them by interstate wire to the Insys Reimbursement Center in Arizona.

67. **KAPOOR, BABICH, GURRY**, and others tracked communications between Insys Reimbursement Center employees and insurers to learn why insurers denied specific authorization requests for Subsys. Based on those findings, **KAPOOR, BABICH**, and **GURRY** instructed Insys Reimbursement Center employees to mislead insurers by misrepresenting patient diagnoses, the type of pain being treated, and the patient's prior course of treatment with other medications. Insys Reimbursement Center employees also misled insurers by failing to disclose that they worked for Insys; instead, they posed as employees of the practitioner or stated they were calling from the practitioner's office—all at the direction of **KAPOOR, BABICH**, and **GURRY**.

68. For example, **GURRY, BABICH**, and co-conspirators known and unknown to the Grand Jury, learned that insurers were more likely to authorize payment for Subsys if the practitioner diagnosed a patient with difficulty swallowing, called dysphagia. Therefore, to increase payments by insurers, **GURRY, BABICH**, and co-conspirators known and unknown to the Grand Jury, instructed Insys Reimbursement Center employees to claim that the patient

suffered from dysphagia when communicating with insurers, regardless of whether the patient in fact had difficulty swallowing, or in fact had been diagnosed by a medical professional with dysphagia.

69. **GURRY, ROWAN**, and co-conspirators known and unknown to the Grand Jury, also understood that insurers were more likely to authorize payment for Subsys if a patient were being treated for cancer-related pain. As a result, **GURRY, ROWAN**, and co-conspirators known and unknown to the Grand Jury, directed employees, including sales employees, to review the medical history of patients to determine if the patient had, at any time, been diagnosed with cancer. If a patient was previously treated for cancer, **GURRY** and co-conspirators known and unknown to the Grand Jury, instructed Insys Reimbursement Center employees to tell insurers that Subsys was prescribed to treat breakthrough pain purportedly caused by that cancer, without regard to whether the medical records actually supported such a statement. In addition, **BABICH, GURRY**, and co-conspirators known and unknown to the Grand Jury, instructed Insys Reimbursement Center employees that, when asked if a patient was being treated for breakthrough cancer pain, to answer using a script designed to obscure whether the patient was in fact being treated for breakthrough pain related to cancer, or breakthrough pain related to another condition. These misrepresentations were material, as some insurers would not have approved payment for Subsys to treat breakthrough pain unrelated to cancer.

70. **KAPOOR, BABICH, GURRY**, and co-conspirators known and unknown to the Grand Jury, also learned that insurers were more likely to authorize payment for Subsys if patients had previously tried, but failed to achieve satisfactory results from, certain other pain medications. Therefore, **KAPOOR, BABICH, GURRY**, and co-conspirators known and unknown to the Grand Jury, tracked communications with agents of insurers to learn which

medications each insurer required the patient to have tried before approving payment for Subsys. **KAPOOR, BABICH, GURRY**, and co-conspirators known and unknown to the Grand Jury, then directed employees to misrepresent what medications had previously been tried and failed, without regard to the patient's actual treatment history, knowing that such misrepresentations would cause insurers to pay for Subsys prescriptions that the insurers otherwise might not have authorized.

MANNER AND MEANS: AVOIDING DETECTION

71. In furtherance of the conspiracy to conduct and participate, directly and indirectly, in the conduct of the affairs of the enterprise through each of the multiple types of racketeering activity described in paragraph 24, **KAPOOR, BABICH, BURLAKOFF, SIMON, LEE**, and **ROWAN** engaged in conduct to prevent detection of their illegal activities by the DEA and others.

72. For example, **KAPOOR, BABICH, ROWAN**, and co-conspirators known and unknown to the Grand Jury, knew that the DEA monitored, and directed others – such as wholesalers – to monitor suspicious shipments of Subsys. Accordingly, those defendants were concerned about the effect such monitoring might have on their ability to carry out the objects of the conspiracy. To minimize this risk of detection by the DEA, in February 2014, **KAPOOR, BABICH**, and **ROWAN** travelled to a meeting with Practitioner #1 and Practitioner #2 in Mobile, Alabama, where, among other things, they agreed that Insys would ship Subsys directly to the pharmacy owned by Practitioner #1 and Practitioner #2, thereby reducing the possibility of the wholesaler reporting suspicious activity to the DEA regarding the volume of Subsys purchased by that pharmacy.

73. Likewise, in February 2014, **KAPOOR** and **BABICH** agreed that Insys would ship

Subsys directly to a pharmacy preferred by Practitioner #3, to reduce the possibility of the wholesaler reporting suspicious activity to the DEA which would uncover the volume of Subsys prescribed by Practitioner #3.

All in violation of Title 18, United States Code, Section 1962(d).

RACKETEERING FORFEITURE ALLEGATION
(18 U.S.C. § 1963)

The Grand Jury further finds:

74. Upon conviction of the offense in violation of Title 18, United States Code, Section 1962(d), set forth in Count One of this Second Superseding Indictment,

**(1) BABICH, (2) BURLAKOFF, (3) GURRY,
(4) SIMON, (5) LEE, (6) ROWAN, and (7) KAPOOR,**

,

defendants herein, shall forfeit to the United States pursuant to Title 18, United States Code, Section 1963:

- a. any interest acquired or maintained in violation of Title 18, United States Code, Section 1962;
- b. any interest in, security of, claim against, or property or contractual right of any kind affording a source of influence over, any enterprise established, operated, controlled, conducted, or participated in the conduct of, in violation of Title 18, United States Code, Section 1962; and
- c. any property constituting, or derived from, any proceeds obtained, directly or indirectly, from racketeering activity in violation of Title 18, United States Code, Section 1962.

The property to be forfeited includes, but is not limited to:

- a. any and all shares of the Company (NASDAQ) stock, or options to purchase shares of the Company stock, held by or on behalf of the defendants herein;
- b. any and all securities, salaries, bonuses, stock distributions, retirement contributions and accounts, health and life insurance benefits including premium payments, and any and all other benefits obtained through employment by and association with the entities named in the racketeering enterprise alleged in Count One from 2012 through December 2015; and
- c. an Order of Forfeiture (money judgment) equal to the amount of proceeds each Defendant obtained, directly or indirectly, as a result of the offense alleged in Count One of the Second Superseding Indictment;

75. If any of the property described in Paragraph 74, above, as being forfeitable pursuant to Title 18, United States Code, Section 1963, as a result of any act or omission of the defendants –


- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third party;
- c. has been placed beyond the jurisdiction of the court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property that cannot be divided without difficulty,

it is the intention of the United States, pursuant to Title 18, United States Code, Section 1963(m), to seek forfeiture of any other property of the defendants up to the value of the property described in paragraph 74..

All pursuant to Title 18, United States Code, Section 1963.

A TRUE BILL


Foreperson of the Grand Jury


K. NATHANIEL YEAGER
DAVID G. LAZARUS
DAVID J. D'ADDIO
Assistant United States Attorneys

DISTRICT OF MASSACHUSETTS: September 11, 2018

Returned into the District Court by the Grand Jurors and filed.


Deputy Clerk