SEALED

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,	CRIMINAL NO. 16Cr10343ADB
v.	VIOLATIONS:
(1) MICHAEL L. BABICH	18 U.S.C. § 1962(d) (Racketeering Conspiracy)
(2) ALEC BURLAKOFF	18 U.S.C. § 1349 (Mail Fraud Conspiracy)
(3) MICHAEL J. GURRY	
(4) RICHARD M. SIMON	18 U.S.C. § 1349 (Wire Fraud Conspiracy)
(5) SUNRISE LEE	18 U.S.C. § 371 (Conspiracy)
(6) JOSEPH A. ROWAN	
(7) JOHN N. KAPOOR	18 U.S.C. §§ 1963, 982(a)(7) and 981(a)(1)(C); and 28 U.S.C. §2461(c) (Forfeiture)
Defendants.	

FIRST SUPERSEDING INDICTMENT

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THE GRAND JURY CHARGES THAT:

INTRODUCTION TO ALL COUNTS

At all times material hereto, unless otherwise alleged:

I. Overview

A. The Defendants

1. The defendant **JOHN N. KAPOOR** ("**KAPOOR**") resided in Phoenix, Arizona. **KAPOOR** founded and owned a corporation located in Arizona ("the Company"). At various times relevant to the First Superseding Indictment, **KAPOOR** held executive management positions in the Company, including Executive Chairman of the Board of Directors, and for a time, Chief Executive Officer ("CEO") of the Company. At various times between in or about March 2012 and October 2017, the Company manufactured, marketed, and sold a fentanyl spray ("Fentanyl Spray") in interstate commerce, including in the District of Massachusetts. As founder, owner, CEO, and Executive Chairman of the Board of the Company, **KAPOOR** managed and directed the development, promotion, distribution, and sale in interstate commerce of the Fentanyl Spray.

2. The defendant **MICHAEL L. BABICH** ("**BABICH**") resided in Scottsdale, Arizona. At various times relevant to the First Superseding Indictment **BABICH**, was President and CEO of the Company. As Such, **BABICH** managed and directed the development, promotion, distribution, and sale in interstate commerce of the Fentanyl Spray.

3. The defendant **ALEC BURLAKOFF** ("**BURLAKOFF**") resided in Charlotte, North Carolina. At various times relevant to the First Superseding Indictment, **BURLAKOFF** held executive management positions at the Company, including Regional Sales Manager for the Southeast Region and Vice President of Sales.

4. The defendant **MICHAEL J. GURRY** ("**GURRY**") resided in Scottsdale, Arizona. At various times relevant to the First Superseding Indictment **GURRY**, held executive management positions at the Company, including Vice President of Managed Markets.

5. The defendant **RICHARD M. SIMON** ("**SIMON**") resided in Seal Beach, California. At various times relevant to the First Superseding Indictment, **SIMON** held executive management positions at the Company, including Regional Sales Manager for the Central Region and National Director of Sales.

6. The defendant **SUNRISE LEE** ("**LEE**") resided in Byron Center, Michigan. At various times relevant to the First Superseding Indictment, **LEE** held executive management positions at the Company, including Regional Sales Manager for the Mid-Atlantic Region, Regional Director for the Central Region, and Regional Director for the West Region.

7. The defendant **JOSEPH A. ROWAN** ("**ROWAN**") resided in Panama City, Florida. At various times relevant to the First Superseding Indictment, **ROWAN** held various positions at the Company, including Regional Sales Manager for the Southeast Region and Regional Director for the East Region.

B. Co-Conspirator Practitioners

8. Licensed medical practitioners who were registered with the Drug Enforcement Administration ("DEA") and able to prescribe opioids in the usual course of professional practice for a legitimate medical purpose, owed a fiduciary duty to their patients to refrain from accepting or agreeing to accept bribes and kickbacks in exchange for prescribing any drug. At times relevant to the First Superseding Indictment, certain licensed medical practitioners associated with the Company ("the co-conspirator practitioners") conspired with the defendants and other persons and entities known and unknown to the Grand Jury to engage in various

criminal activities as described below. These medical practitioners included, but are not limited to, the following practitioners whose identities are known to the Grand Jury:

a. Practitioner #1 was a physician licensed to practice in Alabama.

b. Practitioner #2 was a physician licensed to practice in Alabama.

c. Practitioner #3 was a physician licensed to practice in Michigan.

d. Practitioner #4 was a physician licensed to practice in Arkansas.

e. Practitioner #5 was a physician licensed to practice in Texas.

f. Practitioner #6 was a physician licensed to practice in Illinois and Indiana.

g. Practitioner #7 was an Advanced Practice Nurse ("APRN") licensed to practice in Connecticut.

h. Practitioner #8 was a Physician Assistant licensed to practice in New Hampshire.

i. Practitioner #9 was a physician licensed to practice in Florida.

j. Practitioner #10 was a physician licensed to practice in Florida.

C. The Co-Conspirator Pharmacies

9. Pharmacies registered with the DEA were able to distribute the Fentanyl Spray to patients presenting a valid prescription, written for a legitimate medical purpose, and in the usual course of professional practice. At times relevant to the First Superseding Indictment, certain licensed pharmacies (the "co-conspirator pharmacies"), conspired with the defendants and other persons and entities known and unknown to the Grand Jury to engage in various criminal activities as described below. These pharmacies included, but are not limited to, the following entities whose identities are known to the Grand Jury:

a. Pharmacy #1 was a pharmacy located in New York.

b. Pharmacy #2 was a pharmacy located in Alabama.

c. Pharmacy #3 was a pharmacy located in Michigan.

d. Pharmacy #4 was a pharmacy located in Arkansas.

D. Summary of the Allegations

10. In or about late March of 2012, the Company launched the Fentanyl Spray, a powerful and potentially dangerous opioid, approved to treat breakthrough cancer pain, into a small national market crowded with competitor drugs.

11. Because of the potential dangers posed by the misuse and abuse of opioids, fentanyl was designated as a schedule II controlled substance, and therefore, products that contain fentanyl were part of a tightly controlled system of distribution. In this system, licensed practitioners could only prescribe the Fentanyl Spray in the usual course of professional practice, for a legitimate medical purpose. Likewise, pharmacists filling the prescription held a "corresponding responsibility" and could not provide a patient the Fentanyl Spray without a valid prescription issued for a legitimate medical purpose by a licensed individual practitioner acting in the usual course of professional practice. Further, as a product that contained a schedule II substance, the Fentanyl Spray was required to be under the control of a DEA-registered entity at all times until it reached the patient or was destroyed. Each of the entities that handled the Fentanyl Spray in this closed system of distribution, including manufacturers, wholesalers, and pharmacies, 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.

12. In addition to being tightly controlled, the Fentanyl Spray was also expensive. While their specific requirements varied, almost all insurers required patients to obtain prior authorization before the insurer would agree to pay for a prescription for the Fentanyl Spray.

Without prior authorization, a prescription for the Fentanyl Spray was not filled, unless the patient or a third party paid for the entire cost of the drug.

13. Following the launch of the Fentanyl Spray in 2012, **KAPOOR** and **BABICH** quickly grew dissatisfied with the success of the drug during its first three months on the market. From in or about May 2012, and continuing until in or about December 2015, the Company, **KAPOOR**, **BABICH**, **BURLAKOFF**, **SIMON**, **LEE**, **ROWAN**, and co-conspirators known and unknown to the Grand Jury, sought to devise and foster a scheme to profit by using bribes and fraud to cause the illicit distribution of the Fentanyl Spray.

14. Beginning in or about May 2012 and continuing until in or about December 2015, the defendants and their co-conspirators sought to bribe practitioners to prescribe the Fentanyl Spray outside the usual course of their professional practice. The defendants and their co-conspirators used bribes and kickbacks to try to cause practitioners to issue new prescriptions for the Fentanyl Spray, as well as increases in the dosage, and volume, of existing prescriptions for the Fentanyl Spray. The bribes and kickbacks took different forms, including speaker fees and honoraria for marketing events, food and entertainment, administrative support, and fees paid to co-conspirator pharmacies.

15. While bribes paid to co-conspirator practitioners and co-conspirator pharmacies succeeded at generating new prescriptions for the Fentanyl Spray, insurers, private sector employer-sponsored employee benefit plans (referred to herein as "insurers"), and their agents, were reluctant to approve payment for the drug when it was prescribed for patients without cancer. The potential for profits generated by the bribes could not be fully realized unless insurers authorized payment. Accordingly, in or about November 2012, the Company, **KAPOOR**, **BABICH** and **GURRY**, together with co-conspirators known and unknown to the

Grand Jury, sought to mislead and defraud insurers, and the agents of insurers, into authorizing payment for the Fentanyl Spray.

16. **KAPOOR**, **BABICH**, **BURLAKOFF**, **SIMON**, **LEE**, and **ROWAN** directed employees, including sales force employees, and co-conspirators, known and unknown to the grand jury, to obtain information necessary to defraud insurers. From a call center at corporate headquarters, the Company employees, acting at the direction of **BABICH** and **GURRY**, and co-conspirators known and unknown to the Grand Jury, defrauded insurers and caused the illicit distribution of fentanyl by disguising the identity and location of their employer, and by misrepresenting patient diagnoses, the type of pain being treated, and the patient's course of treatment with other medications.

17. Knowing that the increased volume of prescriptions and sales for the Fentanyl Spray risked subjecting the Company, the defendants, and their co-conspirators to increased scrutiny by the DEA, the defendants and their co-conspirators engaged in conduct designed to prevent the detection of their illegal activities and to promote the carrying on of those activities. The conduct engaged in by various members of the conspiracy included using the position of the Company, as well as the professional authority of the co-conspirator pharmacies and other entities within the controlled system of distribution, to subvert reporting requirements of the DEA, including 21 C.F.R. § 1301.74, and thereby conceal bribes paid to co-conspirator practitioners and the illicit sale and distribution of fentanyl.

18. By bribing practitioners and pharmacies, subverting the reporting requirements of the DEA, providing false and misleading information, including false diagnoses and medical histories to insurers, the defendants and their co-conspirators sought to cause the illicit distribution and sale of the Fentanyl Spray, a product containing a schedule II opioid.

II. The Fentanyl Spray and its Risks

19. 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. Fentanyl produced effects that were practically indistinguishable from those produced by the opioids morphine and heroin, but fentanyl had a greater potency and a shorter duration of action. Fentanyl was rapidly distributed to the brain, heart, lungs, kidneys and spleen.

20. The Fentanyl Spray was a liquid formulation of fentanyl to be applied under the tongue, also called a sublingual spray.

The Label

21. Every manufacturer of a new drug was required to obtain approval of a new drug application ("NDA") from the United States Food and Drug Administration ("FDA") before introducing its new drug into interstate commerce, unless subject to an exemption not applicable here. To obtain approval of an NDA, the manufacturer had to demonstrate to the FDA that the new drug was safe and effective for its intended uses. Labeling on the drug also had to be truthful, accurate and non-misleading.

22. On or about March 4, 2011, the Company submitted an NDA to the FDA seeking approval of the Fentanyl Spray. The FDA approved the Fentanyl Spray in or about January 2012 for the management of breakthrough pain in patients with cancer, 18 years of age or older, who were already receiving and who were already tolerant to opioid therapy for their underlying persistent cancer pain. The label for the Fentanyl Spray warned that the drug posed risks of misuse, abuse, addiction, overdose, and serious complications due to medication errors. Explicit warnings on the Fentanyl Spray label included that as an opioid agonist the drug could be abused in a manner similar to other opioid agonists, legal or illicit.

TIRF REMS

23. The FDA determined that the Fentanyl Spray was in a category of drugs it called Transmucosal Immediate Release Fentanyl ("TIRF") products, which included other fentanyl-based rapid onset opioids. Each of the TIRF drugs was indicated for the management of breakthrough pain in patients with cancer, 18 years of age or older, who were already receiving and who were already tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

24. The FDA required that all TIRF drugs be approved subject to a class-wide Risk Evaluation and Mitigation Strategy (REMS) called the TIRF REMS Access Program. The TIRF REMS Access Program was designed to mitigate the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors with the use of TIRF medicines.

25. The TIRF REMS Access Program included several elements. The program required, among other things, that TIRF medicines only be dispensed to an outpatient when the practitioner prescribing the drug, the patient, and the pharmacy dispensing the TIRF medicine had each been educated about the risks associated with the drug.

Dosage

26. The dosage strength of the Fentanyl Spray and other TIRF medications was measured in micrograms (mcg). The Fentanyl Spray was initially sold in five dosage strengths. The lowest dose of the Fentanyl Spray was 100 mcg.

27. Both the rate and extent of absorption of the Fentanyl Spray were determined to be substantially different from other fentanyl products. As a result of these differences, the substitution of the same dose of the Fentanyl Spray for the same dose of any other TIRF drug created a risk of fatal overdose. From in or about March 2012 until in or about the present,

patients switching from a competitor product to the Fentanyl Spray were generally supposed to start the Fentanyl Spray at a lower dosage, usually 100 mcg.

28. Switching a patient to the Fentanyl Spray presented a number of challenges. Practitioners had to follow the patient closely, increasing the strength of the prescription until the patient reached the adequate dosage strength. This process was called titration.

Schedule II

29. 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 drug or other substance might cause. To be placed in "schedule II," a drug had to have, among other things, a high potential for abuse.

30. Fentanyl was designated as a schedule II controlled substance. As such, products that contained fentanyl, including the Fentanyl Spray, were subject to the restrictions imposed on all schedule II substances.

III. The Fentanyl Spray in the Market: Demand, Supply, and Payment

31. The Company began selling the Fentanyl Spray in or about March 2012. From the beginning, the drug faced a number of market challenges.

Demand: The Role of the Practitioner

32. The Fentanyl Spray 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. Market demand for the Fentanyl Spray, like many schedule II medications, was not driven only by the patient population in need of the drug, but by the practitioners who wrote prescriptions for that patient population.

33. During the year following the launch of the Fentanyl Spray, fewer than 1,900 practitioners wrote approximately 90 percent of all TIRF product prescriptions in the United States. During that same time, fewer than 200 practitioners nationwide wrote approximately 30 percent of all TIRF prescriptions.

34. While the Fentanyl Spray was the first TIRF product to be delivered as a spray for sublingual administration, each of the TIRF formulations delivered fentanyl rapidly via the oral mucosa in a variety of dosage forms. Practitioners willing to write prescriptions for the Fentanyl Spray had a large number of TIRF medications to choose from. At the time of its launch, the Fentanyl Spray was the fourth new branded drug in the TIRF market in four years. In addition to brand name drugs, practitioners could also prescribe a generic TIRF medicine. The Fentanyl Spray entered a market in 2012 in which the generic forms of TIRF medicines comprised nearly two-thirds of all TIRF prescriptions.

Supply: The Closed System of Distribution

35. The CSA created a closed system of distribution for products that contained schedule II controlled substances like the Fentanyl Spray. Every entity that handled a schedule II substance was required to be a DEA registrant unless subject to an exemption not applicable here. In this system, the Fentanyl Spray was always under the control of a DEA-registered entity until it reached the patient or was destroyed. All DEA registrants were required to maintain complete and accurate inventories and records of all regulated transactions involving controlled substances and listed chemicals, as well as to maintain security controls to prevent

their diversion. 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.

36. The Fentanyl Spray was produced at a manufacturing facility contracted by the Company ("contract manufacturer"). After assembling and packaging the drug, the contract manufacturer shipped the completed product to a storage and shipping facility. The storage facility stored the newly manufactured packages of the Fentanyl Spray in a secure vault, where they remained until the facility was provided further direction on when and where to ship the drug.

Supply: The Role of Wholesalers

37. From the launch of the Fentanyl Spray in 2012, the Company usually directed its storage facility to ship the Fentanyl Spray to a wholesale distributor ("wholesaler"). For a fee, wholesalers then distributed the Fentanyl Spray to their retail customers, usually pharmacies.

38. In order to meet their obligations as DEA registrants, distributors, which included drug wholesalers and contractors responsible for storing and shipping the Fentanyl Spray, called "third party logistics providers" and "3PLs," 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 by categories, or families, of schedule II drugs. Fentanyl based drugs were a category of drugs for which distributors imposed thresholds.

39. Caps, or thresholds, were used by DEA registrants, including wholesalers and 3PLs, for a specific period, usually 30 days. If a pharmacy customer placed an order that exceeded their cap, the DEA registrant usually would not fill the order until the threshold period was over.

40. Some DEA registrants, including wholesalers and 3PLs, permitted their pharmacy customers to request an increase in the schedule II cap for a particular drug family. If the DEA registrant agreed, the pharmacy would receive additional drugs in that category. 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

41. As the last entity within the distribution chain of controlled substances, pharmacies interacted with drug companies, wholesalers, 3PLs, practitioners, insurers, and patients. Pharmacies, like other entities in the distribution chain of controlled substances, were required to register with the DEA, and as 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. 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 individual practitioner acting in the usual course of professional practice.

Payment: The Role of Insurers

42. The Fentanyl Spray, like other TIRF drugs, was expensive. Depending upon the dosage and number of units prescribed, a prescription for the Fentanyl Spray usually cost thousands of dollars each month.

43. While most patients relied upon commercial insurance to subsidize the cost of taking prescribed TIRF medicines, publicly funded insurance also subsidized the costs of prescribed TIRF medication for its enrollees. Federal health care benefit programs that

subsidized payment for the cost of the Fentanyl Spray included, among others, the Medicare program ("Medicare") and the Medicaid program ("Medicaid").

44. Many insurers controlled the costs of health care by managing the form and substance of care provided to their enrollees and by employing organizations that specialized in managing the costs of prescription pharmaceuticals, called pharmacy benefit managers ("PBMs"). Insurers and their agents, pharmacy benefit managers, controlled the costs of prescription drugs by using, among other restrictions, prior authorizations.

45. While their specific requirements varied, almost all insurers required patients to obtain prior authorization from the insurer of TIRF medications, including the Fentanyl Spray, before agreeing to pay for a prescription. In general, patients had to have a specific medical diagnosis before the insurer would authorize payment for the medication. Many insurers and pharmacy benefit managers would not pay for an expensive drug until the patient had tried and failed certain other preferred medications.

46. If prior authorization was granted, 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 drug.

IV. The Scheme

47. Beginning in or about May 2012 and continuing until in or about December 2015, the Company, **KAPOOR**, **BABICH**, **BURLAKOFF**, **GURRY**, **SIMON**, **LEE**, and **ROWAN**, the co-conspirator practitioners (including but not limited to those described in paragraph 9) the co-conspirator pharmacies (including but not limited to those described in paragraph 10) and other persons and entities known and unknown to the Grand Jury, conspired with one another to profit from the illicit distribution of the Fentanyl Spray, by using bribes and fraud.

A. Bribes Related to the Speaker Program

Speaker Honoraria

48. In or about March 2012 through in or about August 2012, the Company planned and funded a marketing program (the "Speaker Program") purportedly intended to increase brand awareness of the Fentanyl Spray using peer-to-peer educational lunches and dinners (the "events"). Company policy required sales representatives, also called Specialty Sales Professionals, to recruit licensed practitioners to lecture regarding the use of the Fentanyl Spray for the treatment of breakthrough cancer pain in opioid-tolerant patients. Company policy also required speakers to be chosen and approved based upon various criteria, including skill in the use of opioids, experience with the Fentanyl Spray, geography, prominence, and experience as speakers. In exchange for practitioners speaking to other prescribers about the Fentanyl Spray, the Company agreed to pay each speaker a fee, also referred to as an "honoraria," for each event.

49. Speakers were required to sign written agreements with the Company, which, among other things, required them to attend organized training sessions. Sales representatives began looking for qualified speakers during the second quarter of 2012. The Company began training speakers in or about June and July 2012.

50. April through June 2012 was the first full fiscal quarter during which the Fentanyl Spray was sold in the United States. By the end of June 2012, **KAPOOR** and **BABICH** had grown dissatisfied with sales of the drug. **KAPOOR** and **BABICH**, together with co-conspirators known and unknown to the Grand Jury, began making personnel changes within the Company.

51. In or about late June 2012, approximately one month before the Company was to begin conducting Speaker Program events, **KAPOOR** and **BABICH** replaced the Company's Southeast Regional Sales Manager with **BURLAKOFF**.

52. On or about June 27, 2012, approximately one week after **BURLAKOFF** joined the Company, **BABICH** sent an email to his sales managers, including the private email address of **BURLAKOFF**. The email, entitled "Live Speaker Targets," directed **BURLAKOFF** and the other managers to ensure that sales representatives understood "the important nature of having one of their top targets as a speaker. It can pay big dividends for them."

53. Almost immediately, **BURLAKOFF** began using in-person meetings, telephone calls, and texts to inform sales representatives that the key to sales was using the Speaker Program to pay practitioners to prescribe the Fentanyl Spray. **BURLAKOFF** texted one sales representative, telling her not to worry about the communication skills of practitioners speaking about the Fentanyl Spray: "[t]hey do not need to be good speakers, they need to write a lot of ...[prescriptions for the Fentanyl Spray]."

54. Sales in the Southeast District increased under **BURLAKOFF**. In or about September 2012, approximately three months after he was hired, **BURLAKOFF** was promoted to Vice President of Sales for the Company. In that role, **BURLAKOFF** supervised all of the Company's sales managers and sales representatives.

55. The Company hired new sales employees throughout the summer and autumn of 2012, including **SIMON**, **ROWAN**, and **LEE**.

56. **SIMON** was promoted to Director of Sales for the Company in or about July of 2013. As Director of Sales, **SIMON** reported directly to **BURLAKOFF** and was responsible for supervising the Company sales force, which was organized into East, Central, and West

regions. **LEE** and **ROWAN** were promoted to Regional Directors, responsible for supervising all of the sales managers and sales representatives working in their respective regions. As Regional Directors, **LEE** and **ROWAN** reported directly to **SIMON**.

57. Using pharmacy data acquired from third parties, **KAPOOR**, **BABICH**, **BURLAKOFF**, **SIMON**, **LEE**, and **ROWAN**, and other co-conspirators known and unknown to the Grand Jury, tracked the success of competitor brands in the TIRF market and circulated to interested staff lists of practitioners who had written prescriptions for TIRF products, including the Fentanyl Spray. The lists ranked practitioners in groups (called "deciles") one to ten, according to the number of TIRF prescriptions written by each. A practitioner who wrote the fewest TIRF prescriptions was a "decile 1," while a practitioner who wrote the most TIRF prescriptions was a "decile 10." The Company sales force targeted "high decile" practitioners.

58. On his first day as Vice President of Sales for the Company, in September 2012, **BURLAKOFF** emailed a newly hired sales representative, copying all Regional Sales Managers and **BABICH**, as follows:

> ...it all starts with choosing the right LOCAL speaker. 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).

59. **KAPOOR**, **BABICH**, **BURLAKOFF**, **SIMON**, **LEE**, and **ROWAN**, and other co-conspirators known and unknown to the Grand Jury, tracked and circulated the total number of planned Speaker Program events for each speaker, the number of Speaker Program events completed, the number of prescriptions for the Fentanyl Spray written by the speaker, the percentage of Fentanyl Spray prescriptions versus its competitor drugs written by the speaker, the net revenue of profit that the Company earned from each speaker, and the total amount of

honoraria paid to the speaker, and for a time, explicitly calculated the ratio of return on investment ("ROI") for each speaker.

60. On September 17, 2012, **BURLAKOFF** sent an email to the Company's entire sales force. The email, which copied **BABICH** and blind-copied **KAPOOR**, warned sales reps that Speaker Programs, "have been offered to you as the #1 opportunity to grow your business, unfortunately –a scheduled speaker does not by any means solidify a return on investment." **BURLAKOFF** continued, "sales representatives that are not willing to take a calculated risk, will inevitably find themselves in the middle or bottom of the pack (year after year)." The email included a warning, "your program will absolutely NEVER be successful if your speaker does not have at least 10 times more clinical experience than all of your attendees combined."

61. On December 10, 2012, the Company's Vice President of Marketing sent an email to **BABICH**, **BURLAKOFF**, and another. In it, he referenced an attachment stating, "let's discuss if this is what we want to share with **JK** tomorrow..." The attachment, entitled "Speaker Bureau Assessment," explicitly computed the ROI for the Speaker Program using a ratio of honoraria paid to each individual speaker versus the net revenue generated by prescriptions that individual speaker had written. The attachment noted that, "Speakers with programs generated ~6xs more revenue per prescriber than those with no programs." Two days later, on December 12, 2012, the Company's Vice President of Marketing sent an email to **BABICH**, as well as the Company's Chief Financial Officer ("CFO"), and another. The email, which forwarded a PowerPoint entitled, "2013 Proposed Marketing Budget," contained a single line, "To send to **JK**..." The attached PowerPoint included slides discussing "Speaker ROI" and "Speaker ROI Management." Like the proposal two days before, the attachment identified

a "7.5:1 ROI, Honoraria to Net Rev." The PowerPoint also advised that speakers with less than 2:1 ROI had been "flagged" and that candidates to "soft delete" had been identified.

62. Between August 2012 and 2013, the use of speaker fees to bribe high decile targets to write prescriptions for the Fentanyl Spray outside of the usual course of their professional practice became endemic within the Company sales force.

63. In July 2013, a sales rep in New Jersey emailed **KAPOOR**, then the Executive Chairman of The Board of Directors, directly, complaining about another email in which the Company V.P. of Sales, **BURLAKOFF**, stated that the top ten sales reps were "carrying the company." The rep asked **KAPOOR**, "but how much speaker money is being thrown at these Doctors?" After discussing the success of other sales reps with "UNCAPPED" speaker programs, the sales rep complained to **KAPOOR** that, "[n]obody has offered my Doctors unlimited speaker programs to put me in the top ten (I think I'm at #11 or #12 this week)." The sales rep asked, "Does the speaker money grow on a special speaker money tree?"

64. The total money **KAPOOR** and **BABICH** budgeted for Speaker Programs in 2013, the year in which the sales rep referenced the "speaker money tree," was roughly $2,250,000. The total money **KAPOOR** and **BABICH** budgeted by for 2014 Speaker Programs, the year after the sales rep referenced the "speaker money tree," was more than $10,000,000.

Dinner and Entertainment

65. Honoraria paid to speakers were the most common form of bribes and kickbacks paid to co-conspirator practitioners in order to induce those co-conspirator practitioners to issue more prescriptions for the Fentanyl Spray outside the usual course of their professional practice and to change the dosages and volumes prescribed. **KAPOOR**, **BABICH**, **BURLAKOFF**, **SIMON**, **LEE**, and **ROWAN** sought to and did use other forms of bribes and kickbacks associated with the

Speaker Program to reward co-conspirator practitioners for their prescribing practices. In exchange for Fentanyl Spray prescriptions:

a. **BABICH**, **BURLAKOFF**, **SIMON**, **LEE**, and **ROWAN** sought to schedule Speaker Program events at and to purchase food from establishments owned or operated by practitioners, and their families or friends.

b. **KAPOOR, BABICH**, **BURLAKOFF**, **SIMON**, **LEE**, and **ROWAN** sought to use the food and drink furnished at Speaker Program events as bribes and kickbacks. Speaker Program events were often just social gatherings at high-priced restaurants that involved no education and no presentation. Frequently, Speaker Program events involved the same repeat attendees, who were often friends of the co-conspirator practitioner. Speaker Program events also frequently did not have attendees who were licensed to prescribe the Fentanyl Spray, but rather only included the speaker's support staff. Many Speaker Program events had no attendees at all. When this occurred, sales representatives were told by **LEE** and **ROWAN** to falsify the names of attendees and their signatures on Company sign-in sheets. Sham Speaker Program events occurred at restaurants within the District of Massachusetts and elsewhere, and functioned as bribes in the form of free dinners with friends.

Quid Pro Quo: Prescriptions

66. In return for bribes and kickbacks, co-conspirator practitioners were expected to prescribe the Fentanyl Spray to their patients.

67. If a co-conspirator practitioner did not write an appropriate number of prescriptions, the defendants and their co-conspirators known and unknown to the Grand Jury, reduced the number of scheduled Speaker Programs for which the co-conspirator practitioner was to be paid

(or canceled the Speaker Programs), unless and until the practitioner wrote more prescriptions for the Fentanyl Spray.

68. In or about November 2013, **BABICH** received a list that identified medical practitioners, including co-conspirator practitioners, who had written prescriptions for a competitor drug.

69. In response, **BABICH** sent an email to **BURLAKOFF** and others. In the email **BABICH** indicated that a quid pro quo with co-conspirator practitioners was expected: "I thought we owned the high decile folks? Lot of big names on there."

B. Bribes Related to Administrative Support

70. Obtaining prior authorizations 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.

ABLs and BRMs

71. Co-conspirator practitioners who wrote large numbers of prescriptions for the Fentanyl Spray were given the benefit of Area Business Liaisons ("ABLs") and Business Relations Managers ("BRMs"). ABLs and BRMs were support staff, employed and compensated by the Company, to work (in most cases) at the office of certain co-conspirator practitioners.

72. **KAPOOR**, **BABICH**, **BURLAKOFF**, **GURRY**, **SIMON**, **LEE**, and **ROWAN**, and other co-conspirators known and unknown to the Grand Jury, required sales representatives and ABLs to assist the office staff of co-conspirator practitioners with filling out and faxing prior authorization paperwork and other documentation. The defendants used this, and other administrative support from the ABLs and BRMs, as a bribe and kickback to compensate co-conspirator practitioners for writing Fentanyl Spray prescriptions.

73. In some cases, **BABICH**, **BURLAKOFF**, **SIMON**, **LEE**, and **ROWAN** sought to compensate co-conspirator practitioners for writing Fentanyl Spray prescriptions by employing the co-conspirator practitioners' friends and family members as ABLs and BRMs at the Company's expense.

Pharmacy #1

74. In or about October 2012, the Company contracted with Pharmacy #1, a mail order specialty pharmacy based in New York that said it could ship the Fentanyl Spray to 32 states, including Massachusetts. In exchange for a fee, Pharmacy #1 agreed to generate revenue for the Company by assisting with the prior authorization process. **GURRY** instructed the Company sales force to market Pharmacy #1 as a way for practitioners to reduce the administrative burden of the prior authorization process.

75. In or about November 2012 the head pharmacist at Pharmacy #1 reported to **GURRY** and another, "November 8th marked the first month of our service agreement. I am very pleased with our results so far. We are seeing many more PA's being satisfied and insurance paying for ... [the Fentanyl Spray]."

C. Intending the Illicit Distribution of Fentanyl

76. **KAPOOR**, **BABICH**, **BURLAKOFF**, **GURRY**, **SIMON**, **ROWAN**, and **LEE** knew that many of the co-conspirator practitioners diverted the movement of the Fentanyl Spray, a product containing the schedule II opioid fentanyl, from legitimate medical distribution to illicit commercial drug distribution.

Targeting Pain Clinics

77. **KAPOOR**, **BABICH**, **BURLAKOFF**, **SIMON**, **LEE**, and **ROWAN**, and co-conspirators known and unknown to the Grand Jury, knew from tracked data that physicians

focused on treating cancer were not high decile prescribers. As a result, **BABICH**, **BURLAKOFF**, and **SIMON**, and other co-conspirators known and unknown to the Grand Jury, continuously targeted practitioners who prescribed TIRF medicines not just for breakthrough cancer pain, but for all pain.

78. The discipline of pain medicine is an accepted and recognized medical subspecialty practiced by physicians throughout the United States. Legitimate pain medicine specialists used a multi-disciplinary approach to treat patients suffering from chronic pain. Other such specialists knowingly engaged in illicit commercial drug distribution in order to profit. At times, pain clinics engaged in illicit drug distribution were colloquially called "pill mills."

79. On one occasion, **SIMON** texted a sales representative stating,

> I need confirmation from YOU that you had a conversation with... [the practitioner] where he will not ONLY promote for cancer patients. If he does this he will single handedly take down the whole company. He MUST creatively share how docs write this product everywhere. Please get back to me ASAP with confirmation that he will share with our other speakers how effective ... [the Fentanyl Spray] will be to treat ALL BTP [Breakthrough Pain].

80. Likewise, at a national sales meeting, in or about 2014, **BURLAKOFF** told the Company's assembled sales force,

> [t]hese [doctors] will tell you all the time, well, I've only got like eight patients with cancer. Or, I only have, like, twelve patients that are on a rapid-onset opioids [sic]. Doc, I'm not talking about any of those patients. I don't want any of those patients. That's, that's small potatoes. That's nothing. That's not what I'm here doing. I'm here selling [unintelligible] for the breakthrough pain. If I can successfully sell you the [unintelligible] for the breakthrough pain, do you have a thousand people in your practice, a thousand patients, twelve of them are currently on a rapid-onset opioids [sic]. That leaves me with at least five hundred patients that can go on this drug.

81. **KAPOOR**, **BABICH**, **BURLAKOFF**, **SIMON**, **LEE**, and **ROWAN**, and other co-conspirators known and unknown to the Grand Jury, actively recruited practitioners known to

have questionable prescribing habits as potential co-conspirators in their bribery and kickback scheme.

Titration

82. Sometime before March 2012, the FDA approved the Package Insert and the Medication Guide for the Fentanyl Spray. At its launch in March 2012, the Package Insert for the Fentanyl Spray warned practitioners prescribing the drug that, "[t]he initial dose of ... [the Fentanyl Spray] to treat episodes of breakthrough cancer pain is always 100mcg. ... Prescribe an initial titration supply of 100 mcg, which limits the number of units in the home during titration." The Medication Guide for the Fentanyl Spray also warned patients that the drug "comes in several strengths. When you are first prescribed ... [the Fentanyl Spray] your healthcare provider will start you with the lowest strength medicine, and will change the dose until you and your healthcare provider find the right dose for you."

83. The Package Insert for the Fentanyl Spray stated that, "[f]rom the 100 mcg initial dose, closely follow patients and change the dosage level until the patient reaches a dose that provides adequate analgesia...Patients should record their use of ... [the Fentanyl Spray] over several episodes of breakthrough cancer pain and review their experience with their physicians to determine if a dosage adjustment is warranted." Thereafter, the package insert stated that, "[i]f there is a need to titrate to a 200 mcg dose, prescribe 200 mcg .... Subsequent titration steps are 400 mcg, 600 mcg, 800 mcg, 1200 mcg and 1600 mcg."

84. Despite these explicit warnings, **KAPOOR**, **BABICH**, **BURLAKOFF**, and **GURRY** were concerned that patients would not continue to use the Fentanyl Spray if they were only prescribed 100 mcg. In July 2012, after the Fentanyl Spray had only been on the market for four months, **BABICH** sent an email to the Company sales force announcing a contest.

BABICH told the sales force, "3 out of 4 patients ... in the clinical trial titrated to 600 mcg or higher. The top 5 sales reps who have the highest number of UNITS written for 600 mcg or higher will receive an extra $1500 and the overall winner will get $2000."

85. In or about September 2012, **KAPOOR**, **BABICH**, **BURLAKOFF**, and **GURRY** instituted a new practice for prescriptions written for 100 mcg or 200 mcg. On September 13, 2012, **BURLAKOFF** sent an email to all sales reps in the southeast sales district. In the email, which was copied to **KAPOOR**, **BABICH**, and others, **BURLAKOFF** wrote:

> Effective immediately, I need a reply ...each and every single time you receive a message ... indicating you had a prescription written for less than 400 mcg. In addition, you must follow up with the physician within 24 hours and provide specific details to the conversation. You should treat and react to this emails [sic] with the very same sense of urgency you do when receiving a 'reversal' e—mails [sic]. In fact, based on the internal data – I would have to say this requires an even greater sense of urgency. 100mcg or 200mcg of ...[the Fentanyl Spray] does NOT work. We would be better off having the doctor write a prescription for one of our competitors rather than write for 100mcg or 200mcg of ...[the Fentanyl Spray]. At least then – we would theoretically still have a chance of proving our drug to be efficacious if and when we sell the doctor on 'effective dosing'.
>
> I am not being overly dramatic when I say this! Think about it, you only have 1 chance to make a good impression. I rather [sic] hold off, than blow that critical opportunity. THIS IS VERY SERIOUS.
>
> 'Reversals' often times work themselves out within a few days, conversely – prescriptions for less than 400 mcg will almost always destroy your chances of proving this drug to be efficacious in any way, shape or form. I do not know how I can stress enough just how detrimental prescriptions for 200mcg and 100 mcg are to the company, patient, and overall state of the business.
>
> Anyone who ignores these instructions is subject to immediate negative consequences...

86. While the language regarding the importance of higher dosages was often accompanied by the assertion that titration was in the interests of patients, the financial impact of patients seeking alternative medicines was explicitly and repeatedly emphasized. **BABICH**,

BURLAKOFF, **SIMON**, **LEE**, and **ROWAN** routinely gave instruction to the Company sales force that ignored the dangers of misuse, abuse and addiction in favor of higher sales.

87. One week after his email to the southeast district, **BURLAKOFF** sent another email to the entire Company sales force, copied, once again to **BABICH** and others, and blind copied to **KAPOOR**. The email read in part:

> After today's conversation in the home office, I felt it to be imperative that I send you an e-mail pertaining to the below correspondences you will be receiving on a daily basis. As you know by now, you will receive an email ... each and every time a prescriber in your territory writes for a [Fentanyl Spray] prescription at 100 mcg or 200mcg. ...
>
> ...
>
> Each new ... [Fentanyl Spray] patient should be started at 100 mcg, per the package insert.
>
> To be clear, the last thing we want you to think is that we are harassing you for generating sales. What we are attempting to do is; help you to maintain these newly generated ... [Fentanyl Spray] patients by rapidly informing you of the fact that they wrote for a dose and number of units that is simply **NOT** effective. We are 100 percent sure that those patients whom are prescribed 60 units of 100mcg, do not end up filling a prescription for ...[the Fentanyl Spray] the following month. This is information that we feel obligated to share with you, as there is no good at all that comes out of withholding the very data that will determine your quarterly bonus payouts. We understand that you are not out here to just give away free product, we know that your goal is the same as ours. The goal is to generate ... [Fentanyl Spray] patients whom believe in the safety and efficacy behind this product, hence these patients will continuously refill their months prescriptions indefinitely. This of course equates to residual income for you! ...

88. The pressure applied to sales reps to encourage prescribers to write higher doses, as well as larger numbers of units, was not limited to instructions. The Company paid its sales reps a low base salary, but offered uncapped bonuses for sales. The bonus paid to each sales rep was calculated by considering the percentage of net sales generated by the rep. This meant that the larger dosages of the Fentanyl Spray would naturally generate larger bonuses. However, **KAPOOR**, **BABICH**, and **BURLAKOFF** doubled the percentage used to calculate bonuses for sales of prescriptions for the Fentanyl Spray of 600 mcg or higher.

89. During a conference call in or about June 2013, a senior Company executive warned **KAPOOR** and **BABICH** that the bonus structure employed by the Company was dangerous. Despite the warning, **KAPOOR** and **BABICH** continued to reward sales reps for prescriptions written at higher doses.

"Great by Choice"

90. **KAPOOR**, **BABICH**, **BURLAKOFF** and **SIMON** knew that their efforts to profit from titration were controversial amongst some sales reps.

91. A video prepared for the National Sales Meeting in 2015 encouraged sales reps to push practitioners to prescribe higher doses of the Fentanyl Spray. The video, entitled "Great by Choice," featured prominent Company sales reps rapping and singing about titration, set to a song by the artist A$AP Rocky. Throughout the video, Company employees danced with a life size, 1600 mcg bottle of the Fentanyl Spray, the largest dosage of the drug available for sale in the United States. As they dance, the sales reps repeat the refrain, "I love titration, and that's not a problem!" The person wearing the Fentanyl Spray costume in the video was **BURLAKOFF**, the Company V.P. of Sales. The video concluded with **BURLAKOFF** removing his costume, then shouting, "Woo! I love titration, ya that's not a problem!"

Suspicious Orders

92. **KAPOOR**, **BABICH**, **GURRY**, **SIMON**, and **ROWAN,** together with co-conspirators known and unknown to the Grand Jury, recognized the importance of wholesalers and pharmacies in their scheme to use bribes and fraud to profit from the distribution of fentanyl. At times, co-conspirator practitioners willing to accept bribes from the Company in exchange for writing prescriptions were inhibited by the requirement imposed on DEA registrants, including wholesalers and pharmacies, to notify the DEA of suspicious orders. When this occurred,

KAPOOR, **BABICH**, **SIMON**, and **ROWAN**, together with co-conspirators known and unknown to the Grand Jury, endeavored in several ways to escape the DEA's scrutiny of suspicious orders:

a. Despite the Company's existing preference for Pharmacy #1, several co-conspirator practitioners insisted upon using smaller, local pharmacies. In some cases, the co-conspirator practitioners were owners of the pharmacy filling prescriptions for the Fentanyl Spray. This meant that the co-conspirator practitioner stood to profit, not just from bribes and kickbacks paid by for writing the Fentanyl Spray prescription, but also from filling each prescription for the Fentanyl Spray.

b. Even if the co-conspirator practitioner did not hold an interest in the co-conspirator pharmacy, using a trusted local pharmacist eliminated the risk that the pharmacy would report to the DEA unusual, excessive, or unnecessary prescribing activity by a co-conspirator practitioner.

c. Wholesalers were registered with the DEA as distributors, and were required to notify the DEA of suspicious orders. When co-conspirator pharmacies could not obtain the Fentanyl Spray from their wholesaler because of existing schedule II thresholds, **KAPOOR**, **BABICH**, **BURLAKOFF**, and **SIMON**, together with co-conspirators known and unknown to the Grand Jury, sought to avoid triggering suspicious activity reports to the DEA by redirecting the chain of distribution to a new distributor, which was unaware of previous ordering patterns and willing, at the Company's direction, to distribute a larger quantity of the Fentanyl Spray.

d. In 2014, **KAPOOR**, **BABICH**, and **GURRY**, together with co-conspirators known and unknown to the Grand Jury, agreed to eliminate the wholesaler, and ship directly from the 3PL to pharmacies ("direct shipment"). Direct shipment to pharmacies occurred only when the Company entered an "Authorized Retail Agreement" ("Agreement") with the pharmacy. The

Agreement required the pharmacy receiving the Fentanyl Spray to make payments to the Company, rather than a wholesaler. In exchange, the Company agreed to refund the pharmacy a percentage of the pharmacy's gross monthly purchases of the Fentanyl Spray. Direct shipment therefore made the Fentanyl Spray significantly more profitable for a pharmacy than sales of other TIRF medicines.

D. Defrauding Insurers to Obtain Payment

93. After targeting pain clinics and bribing practitioners, **KAPOOR**, **BABICH**, and **BURLAKOFF** began to see an increase in the number of new Fentanyl Spray prescriptions. **KAPOOR**, **BABICH**, **BURLAKOFF**, and other co-conspirators known and unknown to the Grand Jury knew, however, that they still needed insurers and pharmacy benefit managers to authorize payment for the new prescriptions.

94. At or about the end of the second quarter of 2012, **BABICH** began to focus more attention on prior authorizations. In or about August 2012, **BABICH** hired **GURRY** as Vice President of Managed Markets. In or about September 2012, **KAPOOR**, **BABICH**, **GURRY**, **BURLAKOFF**, and other co-conspirators known and unknown to the Grand Jury sought to create a comprehensive plan to increase profits by increasing prior authorizations.

95. In or about October 2012, **KAPOOR**, **BABICH**, **GURRY**, and other co-conspirators known and unknown to the Grand Jury, launched the Prior Authorization Tracking Program ("PA Tracking Program"). The PA Tracking Program tracked several types of information, including comprehensive data regarding prior authorizations. In or about the same month, **BABICH** and **GURRY** hired a "prior authorization specialist" ("PA specialist").

96. As part of the pilot program, **BABICH** and **GURRY** directed the PA specialist, who worked at corporate headquarters in Arizona, to seek prior authorizations directly from insurers

and pharmacy benefit managers on behalf of patients from select practitioners based in several locations around the country. After the first week, the prior authorization rate for prescriptions handled by the PA specialist increased to 46 percent.

97. Using information learned from the pilot program, in or about January 2013 through in or about December 2015, **KAPOOR**, **BABICH**, **GURRY**, and other co-conspirators known and unknown to the Grand Jury created and operated a Company-based unit dedicated to obtaining prior authorizations directly from insurers and pharmacy benefit managers. The name of the unit (referred to herein as the "Reimbursement Center" or "RC") changed a number of times, but its purpose and functions remained roughly the same.

98. Practitioners using the Company Reimbursement Center were required to fill out "Opt-In" forms, which sought patient identifiers and other confidential information such as name and date of birth, insurer information, prescriber information, pharmacy information, and the medical diagnosis and corresponding codes associated with the diagnosis. **BABICH, BURLAKOFF, GURRY, SIMON, LEE,** and **ROWAN**, and co-conspirators known and unknown to the Grand Jury, directed Company employees to obtain, and to assist practitioners in obtaining, the information required to fill out Opt-In forms, including, at times, the private medical records of patients.

99. Completed Opt-In forms and medical records were faxed or emailed from the offices of practitioners to the RC in Arizona by staff paid either by the practitioner or by the Company, including sales representatives, ABLs, and BRMs. The RC, in turn, became the entity that sought prior authorization directly from the insurer and pharmacy benefit manager.

100. **KAPOOR**, **BABICH**, **GURRY**, and other co-conspirators known and unknown to the Grand Jury created a pay structure for RC employees that rewarded prior authorization

approvals with substantial financial bonuses. Every week **GURRY**, together with another co-conspirator, set a weekly minimum threshold, called a "gate," for the entire RC. A Reimbursement Center employee, no matter how productive, could not qualify for a bi-weekly bonus until the entire RC reached each week's threshold number of approvals. Once the Reimbursement Center met its threshold, an employee could earn a bonus based upon the number of prior authorizations obtained.

101. **GURRY**, and other co-conspirators known and unknown to the Grand Jury, held team meetings with RC employees, in which the group shared best practices for obtaining authorizations from insurers and pharmacy benefit managers. The practices included materially false and fraudulent pretenses, representations, and promises used to obtain payment from insurers and pharmacy benefit managers. RC employees were taught how to mislead and deceive insurers regarding their employment, patient diagnoses, and tried and failed medications. **BABICH**, **GURRY**, and other co-conspirators known and unknown to the Grand Jury approved and fostered the use of these fraudulent practices.

102. After the RC received the Opt-In forms and accompanying medical records, RC employees placed telephone calls to insurers and pharmacy benefit managers located in several different states. Relying in part on the Opt-Ins and accompanying documents, RC employees misled and deceived insurers regarding their employment, patient medical history, patient diagnoses, and tried and failed medications during those calls. Through the use of the RC, the defendants, together with co-conspirators known and unknown to the Grand Jury, often concealed that the Fentanyl Spray had been prescribed outside of the usual course of professional practice.

Disguising the Reimbursement Center

103. After the RC launched, in or about January of 2013, **KAPOOR, BABICH, GURRY**, and other co-conspirators known and unknown to the Grand Jury, learned that insurers and pharmacy benefit managers were often unwilling to engage representatives of a pharmaceutical company such as the Reimbursement Center in the prior authorization process.

104. **BABICH, GURRY**, and other co-conspirators known and unknown to the Grand Jury responded to this problem by seeking to conceal the identity of RC employees communicating directly with insurers and pharmacy benefit managers. The defendants and their co-conspirators promoted the RC to practitioners as a free source of additional administrative support, but the existence of the unit was deliberately shielded from insurers and pharmacy benefit managers.

105. **BABICH, GURRY**, and other co-conspirators known and unknown to the Grand Jury instructed RC employees to lead agents of insurers and pharmacy benefit managers to believe that they were calling from the office of the practitioner, as if they were employees of the practitioner. Initially, **BABICH, GURRY**, and other co-conspirators told RC employees to tell agents of insurers and pharmacy benefit managers that they were calling "from" the doctor's office. Later, employees were instructed to tell agents of insurers and pharmacy benefit managers that they were calling "on behalf of" a specific doctor, and were "with" a specific doctor's office. Even after this change, **GURRY** and another co-conspirator instructed RC employees to hang up when agents of insurers and pharmacy benefit managers pursued the identity of their employer. Reimbursement Center employees were instructed instead to call back later, in hopes of connecting with a new, less persistent agent. **BABICH** was aware of, and approved of, the practice.

106. **KAPOOR**, **BABICH**, **GURRY**, and other co-conspirators known and unknown to the Grand Jury also sought to mask the geographical location from which RC employees were calling. **BABICH**, **GURRY**, and other co-conspirators set up the RC phone system to block access to the unit's number, so that agents of insurers and pharmacy benefit managers would not notice that RC employees were calling from an area code different than the area code of the prescribing practitioner. Employees at the Reimbursement Center did not identify the Company when answering the phone.

Breakthrough Pain

107. While practitioners acting in the usual course of professional practice possessed the authority to write a prescription for any legitimate medical purpose, **KAPOOR**, **BABICH**, **GURRY**, and co-conspirators known and unknown to the Grand Jury knew that insurers and pharmacy benefit managers were less likely to authorize payment for a drug prescribed for a use that was not recognized on the drug's label.

108. All of the co-conspirator practitioners worked at pain clinics. While a few of their patients did in fact have cancer, none of the co-conspirator practitioners were oncologists. **KAPOOR**, **BABICH**, **BURLAKOFF**, **GURRY**, **SIMON**, **LEE**, and **ROWAN**, and co-conspirators known and unknown to the Grand Jury, knew that the Company would lose substantial profits if insurers and pharmacy benefit managers only authorized payment for the Fentanyl Spray when it was prescribed according to its label – for the management of breakthrough pain in patients with cancer, 18 years of age or older, who were already receiving and who were already tolerant to opioid therapy for their underlying persistent cancer pain.

109. **GURRY**, and co-conspirators known to the Grand Jury, instructed RC employees, when agents of insurers and pharmacy benefit managers asked if a patient was being treated for breakthrough cancer pain, to answer using a written script, sometimes called "the spiel":

> '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).'

110. **GURRY** and co-conspirators known to the Grand Jury approved different versions of "the spiel."

Fake diagnoses

111. Even with the identity of the RC disguised, insurers and pharmacy benefit managers reacted differently to prior authorization requests. For some insurers and pharmacy benefit managers, the RC's use of the term "breakthrough pain," rather than "breakthrough cancer pain," was enough to gain payment for the Fentanyl Spray. But when agents of insurers and pharmacy benefit managers asked for additional information, RC employees, following the directions of **GURRY** and co-conspirators known to the Grand Jury, made additional misleading statements and misleading omissions to agents of insurers and pharmacy benefit managers in order to gain prior authorization.

112. Medical facilities, practitioners, insurers and pharmacy benefit managers, government entities, and pharmacies employed a set of codes to classify diseases and injuries. The codes, which were recognized around the world, were called the International Statistical Classification of Disease and Related Health Problems 9th Revision ("ICD-9"), and later International Classification of Diseases, 10th Revision ("ICD-10"). Both revisions, ICD-9 and ICD-10, are referred to herein as ICD-9. There was a recognized ICD-9 code for each medical diagnosis.

113. Insurers and practitioners used ICD-9 codes to communicate about prior authorizations. Information sought by the Company Opt-In forms included a description of the diagnosis for which the Fentanyl Spray was prescribed, as well as the corresponding ICD-9 code.

114. **KAPOOR, BABICH, GURRY**, and co-conspirators known and unknown to the Grand Jury tracked communications with agents of insurers and pharmacy benefit managers to learn why insurers and pharmacy benefit managers denied specific claims. **GURRY** and co-conspirators known and unknown to the Grand Jury used that information to instruct RC employees regarding when and how to deceive insurers and pharmacy benefit managers.

i. Dysphagia

115. As a sublingual spray, the Fentanyl Spray was not swallowed, but absorbed into the blood stream after being applied beneath the tongue. **KAPOOR, BABICH, GURRY,** and co-conspirators known and unknown to the Grand Jury, learned that insurers and pharmacy benefit managers were more willing to grant prior authorization when a patient was diagnosed with dysphagia, or difficulty swallowing. **GURRY**, and co-conspirators known and unknown to the Grand Jury, instructed RC employees to add the diagnosis of dysphagia when communicating with insurers and pharmacy benefit managers regardless of whether the patient in fact had difficulty swallowing.

116. The Company supplied practitioners with model letters of medical necessity, to be used when appealing a denied authorization. Use of the dysphagia code became so common that difficulty swallowing was included as part of the company's model letter of medical necessity:

> I have treated (Full name) in my clinic since (xx/xx/xxxx). (Mr. /Mrs.). Is a (age) year old (man/woman) with severe (Diagnosis). (He/She) has difficulty swallowing and digesting oral medications, and (he/she) is in almost constant severe pain. The pain gives Mr. /Mrs. (Name) a significantly limited quality of

life. (He/She) is unable to sit, stand, walk or reach- which includes participating in family life and riding in automobiles - for more than 2 to 3 hours per day.

117. At a leadership meeting, **BABICH**, **GURRY**, and **BURLAKOFF** were presented the dysphagia diagnosis and the procedures the Reimbursement Center used to gain prior authorization from insurers and pharmacy benefit managers using the dysphagia diagnosis.

ii. A Diagnosis of Cancer

118. **GURRY** and co-conspirators known and unknown to the Grand Jury also used false cancer diagnoses to deceive insurers and pharmacy benefit managers to obtain payment for the Fentanyl Spray. **GURRY** and co-conspirators known and unknown to the Grand Jury directed RC employees to review the medical history of patients in order to determine if the patient had ever been diagnosed with cancer. If a patient was previously treated for cancer, **GURRY** and co-conspirators known and unknown to the Grand Jury told RC employees to tell insurers and pharmacy benefit managers that the Fentanyl Spray was prescribed to treat the previously diagnosed cancer, using the specific form of cancer previously diagnosed. At times co-conspirators known and unknown to the Grand Jury also instructed RC employees to assert a cancer diagnosis regardless of the patient's history and regardless of whether the practitioner had prescribed the Fentanyl Spray for a different diagnosis.

Tried and Failed Medications

119. **KAPOOR**, **BABICH**, **GURRY,** and co-conspirators known and unknown to the Grand Jury knew that insurers and pharmacy benefit managers often required patients to have tried and failed with other TIRF drugs before granting a prior authorization. The medications required before authorization was granted varied among insurers and pharmacy benefit managers. **KAPOOR**, **BABICH**, **GURRY**, and co-conspirators known and unknown to the Grand Jury, tracked communications with agents of insurers and pharmacy benefit managers to

learn the tried and failed medications for specific insurers and pharmacy benefit managers. **GURRY** and co-conspirators known and unknown to the Grand Jury used that information to instruct RC employees regarding when and how to deceive insurers and pharmacy benefit managers. Reimbursement Center employees routinely falsely confirmed lists of tried and failed medications to insurers and pharmacy benefit managers in order to obtain prior authorization for the Fentanyl Spray. The practice was discussed and approved at Company leadership meetings attended by **BABICH**, **BURLAKOFF**, and **GURRY**.

V. Examples

120. The defendants' efforts to profit from the illicit distribution of the Fentanyl Spray using bribes and kickbacks to gain influence over and control of market demand for the Fentanyl Spray, and to obtain money and property by means of materially false pretenses, representations, and promises made to insurers and pharmacy benefit managers, included, but are not limited to, the criminal activities described below.

Practitioner #1 and Practitioner #2

121. 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 Pharmacy #2, which was next to one of their clinic locations.

122. In or about March of 2012, a Company sales representative approached Practitioner #1 and Practitioner #2 because both had been identified as pain specialists who wrote a substantial number of prescriptions for schedule II drugs. Practitioner #1 and Practitioner #2 began writing prescriptions for the Fentanyl Spray soon after the drug was launched. By the end of the second quarter of 2012, in or about the week of June 30, 2012, Practitioner #1 averaged approximately 2.2 prescriptions for the Fentanyl Spray per week. Practitioner #2 averaged roughly one prescription for the Fentanyl Spray every other week.

123. Within weeks of joining the Company as the Regional Manager for the Southeast, **BURLAKOFF** hired defendant **ROWAN**. **BURLAKOFF** and **ROWAN** had previously worked together selling a TIRF drug for a competitor pharmaceutical company. **BURLAKOFF** assigned **ROWAN** to call on a single physician, Practitioner #1.

124. On or about July 28, 2012, **BURLAKOFF** emailed **ROWAN** that the previous sales representative assigned to Practitioner #1,

> ...made 7K off... [Practitioner #1] last quarter. He wrote ... 26 prescriptions. So, thats [sic] basically 1 script every 3rd day for 60 days. If he wrote just 1 script every day ... you would make 22k. If he does 2 ... [prescriptions for the Fentanyl Spray] a day for one straight quarter, you would make at least 40 grand for the quarter!"

125. Approximately two weeks after **ROWAN** joined the Company, Practitioner #1 participated in his first two Speaker Program events. During the same week Practitioner #1 wrote 18 prescriptions for the Fentanyl Spray. By on or about September 28, 2012, the end of the third quarter of 2013, Practitioner #1 averaged approximately 11 prescriptions for the Fentanyl Spray per week.

126. On or about December 20, 2012, **BURLAKOFF** sent an email to the Southeast District sales team in which **BURLAKOFF** addressed **ROWAN** directly, stating, "Joe...Congrats, you are now officially #1 in the company (with only one doctor). I am pretty sure your formula worked, you may want to pass it along to your team." Between his first Speaker Program event in or about August 2012 and the first week of December 2012, the Company paid Practitioner #1 approximately $24,000 in bribes and kickbacks.

127. While Practitioner #1 and Practitioner #2 were business partners, **ROWAN**'s relationship with Practitioner #2 was not as strong as with Practitioner #1. As a result, in April 2013, **BURLAKOFF** and **ROWAN** hired a new sales representative to serve Practitioner #2.

ROWAN, who supervised the new sales representative, agreed with her that the "ultimate goal" was to get Practitioner #2 to write as many prescriptions for the Fentanyl Spray as did Practitioner #1.

128. The new sales representative immediately sought to use the Speaker Program to pay Practitioner #2 bribes and kickbacks. Practitioner #2 began receiving Speaker Program assignments and the accompanying honoraria more regularly during the second quarter of 2013. By on or about July 19, 2013, Practitioner #2 averaged approximately 6.8 prescriptions for the Fentanyl Spray each week.

129. On or about August 1, 2013, **ROWAN** sent an email to **BURLAKOFF** stating that where the new sales representative "has taken... [Practitioner #2] is out of this world. He is now a top seven prescriber for... [the Company]."

130. In or about October 2013, **KAPOOR**, **BABICH**, **BURLAKOFF**, **SIMON**, and **ROWAN** were aware that the number of prescriptions for the Fentanyl Spray written by Practitioner #1 and Practitioner #2 were "way down."

131. On or about December 12, 2013, **BURLAKOFF** and **ROWAN** became concerned that a TIRF competitor had agreed to distribute directly to Pharmacy #2, the pharmacy owned by Practitioner #1 and Practitioner #2. On or about the same night, the Director of Trade for the Company informed **BABICH**, **BURLAKOFF**, **SIMON**, and **ROWAN** that:

> As a requirement for distribution of ... [schedule IIs]. A wholesaler must conduct site visits to qualify the store. It is also required that shipments are monitored and threshold be established. While we know our customers to be good stewards of health care the DEA has ALL wholesale companies taking very stiff stance on the ordering activities of pharmacies.

132. The next day the Director of Trade informed **BABICH**, **BURLAKOFF**, **SIMON**, and **ROWAN** that if Pharmacy #2 moved to a process where monitoring was absent, "certain parties would be at risk. Stay tuned."

133. Approximately one month later, on January 18, 2014, the Company's Vice President of Marketing sent an email to **BABICH**, **BURLAKOFF**, **GURRY**, **SIMON**, and another. In the email, the marketing executive recounted conversations he and **BURLAKOFF** had held with a "handful of docs." Throughout the email, the Company's Vice President of Marketing repeatedly expressed concern about the efforts of a competitor company. The email notes:

> 1. [Pharmacy #2] ... is hitting supply chain ... [schedule II] caps on ... [the Fentanyl Spray] and is forced to use alternatives. Don't know, but going direct might address.
> 2. Pharmacy #2 is not currently buying [the competitor TIRF medication] ... direct, but [it's manufacturer] ...is believed to be aggressively pursuing.

134. Eleven days later the Director of Trade informed **BABICH**, **BURLAKOFF**, **GURRY** and **ROWAN**, that he had spoken to pharmacists at Pharmacy #2 and that the pharmacy wanted to order direct to address limits on schedule II drugs imposed by their current wholesaler.

135. In February 2014, **KAPOOR** and **BABICH** traveled to Mobile, Alabama in order to meet with Practitioner #1 and Practitioner #2. During their stay, **KAPOOR**, **BABICH**, **ROWAN**, Practitioner #1, Practitioner #2, and two pharmacists associated with Pharmacy #2 had dinner at a steakhouse in Mobile.

136. During dinner, the group began talking about the difficulty that Pharmacy #2 faced in acquiring enough supply of the Fentanyl Spray to fill prescriptions at Pharmacy #2. **BABICH** proposed that the "availability" problem might be solved if the Company set up a

"direct account" for Pharmacy #2. The group also discussed the financial benefits for Pharmacy #2. Specifically, the group acknowledged that by shipping direct, the Company could give Pharmacy #2 the benefit of the 7% normally paid to the wholesaler.

137. On February 17, 2014, just four days after the dinner with **KAPOOR**, **BABICH**, and **ROWAN**, one of the pharmacists in attendance sent **BABICH** a letter. In the letter, the pharmacist stated,

> Thank you for meeting with us in Mobile, February 13th. We are awed that you and Dr. Kapoor thought enough of our situation to personally travel and to meet with us regarding ... [Fentanyl Spray] distribution .... We will do all that we can to make the distribution arrangement work profitably for you and for ... [Pharmacy #2].

138. Between in or about February 2014 until in or about May 2015, for the purpose of executing their scheme and artifice to defraud and for obtaining money and property, the defendants, and other co-conspirators known and unknown to the Grand Jury, directly shipped the Fentanyl Spray to Pharmacy #2, and during such time paid Pharmacy #2 approximately 7% of its monthly gross purchases of the Fentanyl Spray.

139. In addition to the arrangement with Pharmacy #2, **KAPOOR**, **BABICH**, **BURLAKOFF**, **SIMON**, **ROWAN**, **LEE**, and co-conspirators known and unknown to the Grand Jury continued to pay both Practitioner #1 and Practitioner #2 bribes and kickbacks disguised most frequently as speaker honoraria.

140. Between in or about August 2012 and in or about May 2015, the defendants and other co-conspirators known and unknown to the Grand Jury, sent and caused to be sent to Practitioner #1 checks totaling approximately $229,640.00 for Speaker Program bribes and kickbacks. Many of the Speaker Program events led or attended by Practitioner #1 were sham

events that were mere social gatherings also attended by friends and office staff of Practitioner #1.

141. Between in or about August 2012 and in or about May 2015, insurers and pharmacy benefit managers authorized payment for approximately 2,148 prescriptions for the Fentanyl Spray written by Practitioner #1. During that same time period, Reimbursement Center employees working in Arizona placed telephone calls on behalf of the defendants and their co-conspirators, known and unknown to the Grand Jury, to obtain money and property by means of materially false pretenses, representations, and promises. For example, RC Employee #1 called Insurer #1. During the call, an employee of Insurer #1 asked if he was speaking with the "provider or provider's office." RC Employee #1 answered, "provider's office." RC Employee #1 then requested prior authorization for 120 units of a 400 mcg dose the Fentanyl Spray for a patient of Practitioner #1 who was insured by Insurer #1. Further, RC Employee #1 informed the insurer that the patient had been prescribed the Fentanyl Spray for a diagnosis of dysphagia and cancer pain. Medical records demonstrate that at the time of the call, the patient had not been diagnosed with dysphagia, nor did the patient have cancer.

142. Between in or about February 2013 and May 2015, the defendants, and other co-conspirators known and unknown to the Grand Jury, sent and caused to be sent to Practitioner #2 checks totaling approximately $103,350.00 for Speaker Program bribes and kickbacks. Many of the Speaker Program events led or attended by Practitioner #2 were sham events that were mere social gatherings also attended by friends and office staff of Practitioner #2.

143. Between in or about February 2013 and May 2015 insurers and pharmacy benefit managers authorized payment for approximately 984 prescriptions for the Fentanyl Spray written by Practitioner #2. During that same period, Reimbursement Center employees working in

Arizona placed telephone calls on behalf of the defendants and their co-conspirators, known and unknown to the Grand Jury, to obtain money and property by means of materially false pretenses, representations, and promises. For example, in or about December 2014, RC Employee #2 called Insurer #1. During the call, RC Employee #2 requested prior authorization for 120 units of a 400 mcg dose of the Fentanyl Spray for a patient of Practitioner #2 who was insured by Insurer #1. When asked if the patient's pain was from cancer, RC Employee #2 informed the insurer, "that's what we have in the chart...." At the time, the patient had not been diagnosed with cancer.

Practitioner #3

144. Practitioner #3 owned and operated a pain management clinic in Saginaw, Michigan. The clinic, which served more than 5,000 patients, also had ancillary clinics in several locations throughout Michigan.

145. Practitioner #3 began prescribing the Fentanyl Spray the month after it was launched. By on or about September 28, 2012, Practitioner #3 averaged approximately four Fentanyl Spray prescriptions each week.

146. **BURLAKOFF** was not satisfied with the number of prescriptions for the Fentanyl Spray written by Practitioner #3. In or about the first week in October 2012, **BURLAKOFF** traveled to Michigan and took Practitioner #3 to dinner. The next day **BURLAKOFF** sent an email to **BABICH**, **LEE,** and another, telling them, "expect a nice 'bump' fellas...."

147. During the next year and a half, **KAPOOR**, **BABICH**, **BURLAKOFF**, and **LEE** used the Speaker Program, and other Company resources, to pay bribes and kickbacks to Practitioner #3 in exchange for prescriptions for the Fentanyl Spray.

148. During the seven months between the launch of the Fentanyl Spray and the day before his first Speaker Program event in or about October 11, 2012, Practitioner #3 wrote approximately 94 prescriptions for the Fentanyl Spray. Within approximately one month of the dinner with **BURLAKOFF**, Practitioner #3 had attended two Speaker Program events and was scheduled to "speak" at six more. In the roughly two months between his dinner with **BURLAKOFF** and the end of November 2012, Practitioner #3 wrote approximately 120 prescriptions for the Fentanyl Spray.

149. By on or about January 11, 2013, Practitioner #3 was averaging approximately 19 prescriptions for the Fentanyl Spray each week. The Company paid Practitioner #3 for 18 Speaker Program events during the first quarter of 2013. Throughout 2013, Practitioner #3 wrote a large volume of prescriptions for the Fentanyl Spray.

150. Many of the Speaker Program events led or attended by Practitioner #3 were sham events that were mere social gatherings also attended by the friends and office staff of Practitioner #3. At times, the Speaker Program events led or attended by Practitioner #3 had no attendees at all.

151. Between in or about November 2012 through in or about June 2014, insurers and pharmacy benefit managers authorized payment for approximately 2,847 prescriptions for the Fentanyl Spray written by Practitioner #3. During the same time period, Reimbursement Center employees working in Arizona placed telephone calls on behalf of the defendants, and other co-conspirators known and unknown to the Grand Jury, to obtain money and property by means of materially false pretenses, representations, and promises. For example, in or about January 2014, RC Employee #3 called Insurer #1. During the call, an employee of Insurer #1 asked if she was "speaking with the provider's office." RC Employee #3 answered, "yes." When asked

for the office address, RC Employee #3 answered, "we are located at," and then provided the address of Practitioner #3. RC Employee #3 then requested prior authorization for 120 units of a 200 mcg dose of the Fentanyl Spray for a patient of Practitioner #3 who was insured by Insurer #1. When the employee for Insurer #1 sought to confirm a diagnosis of "malignant cancer pain," RC Employee #3 answered, "yes, Ma'am, for the breakthrough pain of it." At the time of the call, the patient had not been diagnosed with cancer.

152. Between in or about November 2012 through in or about June 2014, the defendants, and other co-conspirators known and unknown to the Grand Jury, sent and caused to be sent to Practitioner #3 checks totaling approximately $138,435.07 for Speaker Program bribes and kickbacks.

153. The bribes and kickbacks paid to Practitioner #3 were not limited to Speaker Program events. By the spring of 2013, Practitioner #3's office staff were overwhelmed with prior authorization requests. On or about May 2, 2013, an RC employee sent an email to **BURLAKOFF** and **GURRY** stating that the Reimbursement Center had 153 charts of Practitioner #3's "in progress, ... and ... 88 charts that we have not worked on yet."

154. **BABICH**, **BURLAKOFF**, **GURRY**, **SIMON**, **LEE**, and **ROWAN**, and other co-conspirators known and unknown to the Grand Jury, recognized the lost profits caused by having so many prescriptions awaiting prior authorizations. In or about June 2013, **BABICH**, **BURLAKOFF**, **SIMON**, and **GURRY** created the ABL (Area Business Liaison) position. ABLs were paid by the Company, but worked inside the medical offices of high prescribing co-conspirator practitioners. The ABL was responsible for providing the RC with all of the patient information needed to navigate the prior authorization process.

155. In or about September 2013, the Company sought to hire an employee working in one of Practitioner #3's clinics as an ABL. On or about September 12, 2013, **LEE** emailed the Company Human Resource office ("HR"), copying **BURLAKOFF**, **SIMON**, and another, to ask, "please tell me what the status is for the new Detroit ABL, ...She is very anxious." **BURLAKOFF** responded with an email to HR, copying **BABICH**, stating, "[a]s a point of reference, Mike Babich described this hire as "strategic" .... This is [Practitioner #3's] ... niece. ...Mike understands our rational[e] for this ABL..." While the new ABL was not in fact Practitioner #3's niece, she was a woman close to Practitioner #3. **BABICH** approved the hire the same day.

156. The volume and forms of bribes and kickbacks paid to Practitioner #3 were considered a model within the Company. In or about September 2013 **BURLAKOFF** sent an email to his regional managers, including **LEE** and **ROWAN** with copies to **SIMON**, **BABICH**, and **GURRY**, in which he wrote, "[l]ets make some money, and stop playing BS games trying to manage rookies. It's the [Practitioner #3s] of the world that keep us in business, lets [sic] get a few more and the rest ...of this job is a 'joke.'"

157. As with Practitioner #1 and Practitioner #2, the volume of business driven by Practitioner #3 was so lucrative that **KAPOOR**, **BABICH**, **BURLAKOFF**, **GURRY**, **SIMON**, and **ROWAN** became alarmed about the efforts of a competitor pharmaceutical manufacturer to woo the doctor. On January 18, 2014, the Company's Vice President of Marketing sent an email to **BABICH**, **BURLAKOFF**, **GURRY**, **SIMON**, and another. In the email, the marketing V.P. relayed a recent conversation with Practitioner #3,

> [Practitioner #3] ... only writes [prescriptions for the competitor's drug]... for patients who are unable to get ... [the Fentanyl Spray.] ([Practitioner #1] ... told us same).

158. Just days later, on January 22, 2014, the Company's Director of Trade sent an email to **BABICH** regarding Pharmacy #3, located in Flint Michigan. The Director of Trade wrote:

> Met with the gentlemen from ... [Pharmacy #3] in warm Flint MI.
>
> Here is the bottom line:
>
> [Pharmacy #3] ... accounts for over 50% of the sales in the MI market (1.3M in last 100days)[.] They are positioning themselves as 'the' pharmacy that specializes in pain meds.
> Reported that other stores are conservative in dispensing CIIs (only 25 stores have dispense [sic] ... [the Fentanyl Spray] in last 100 days by my calculations)
> Have working relation with [Practitioner #3] and can ID other pain targets
> Have seen tremendous results with ... [the Fentanyl Spray] and see the clear difference
> Currently ship to patients in the region and have nationwide capability...
>
> ... Looking to establish direct relationship; to include Direct shipment of product
> Use in expanding appropriate writing for product {MDs that are maxing on current opioids' and have yet to try ... [the Fentanyl Spray] }...
> ...
> We can handle the shipment request
> ...
> I am working on contract and will submit to you tomorrow....

159. On February 24, 2017, the Company formerly entered an Authorized Retail Agreement with Pharmacy #3. The Agreement provided that the Company would ship directly to Pharmacy #3 and promised to pay the pharmacy "five percent of [the pharmacy's] monthly Gross Purchases."

160. Between in or about February 2014 and in or about August 2014, the defendants, and other co-conspirators known and unknown to the Grand Jury, directly shipped the Fentanyl Spray to Pharmacy #3, and during such time paid Pharmacy #3 approximately 5% of its monthly gross purchases of the Fentanyl Spray.

Practitioner #4

161. 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 Pharmacy #4, which was located in the same building as his pain management clinic. As early as 2012, **BABICH**, **BURLAKOFF**, and **SIMON**, and co-conspirators known and unknown to the Grand Jury, identified Practitioner #4 as an important priority. **BABICH**, **BURLAKOFF**, and **SIMON** knew that Practitioner #4 wrote schedule II prescriptions and believed he had potential to write even more.

162. As they had with other co-conspirator practitioners, **KAPOOR, BABICH**, **BURLAKOFF**, **SIMON**, and co-conspirators known and unknown to the Grand Jury, sought to use Speaker Program bribes and kickbacks to cause Practitioner #4 to write prescriptions for the Fentanyl Spray, outside the usual course of professional practice and without regard to medical necessity.

163. In or about September 2012 the sales representative assigned to Arkansas sent a weekly territory update to **BABICH**, **SIMON,** and **BURLAKOFF,** in which he mentioned Practitioner #4:

> 9/7 – Spoke to staff and they informed me … [Practitioner #4] would like to be taken off my call list. They would not give reason and I have been unable to reach … [Practitioner #4] or his office manager for at least a month. The pharmacy which is located in the same stand alone building was shut down due to the high percentage of opioids being dispensed. It has recently been opened but is unable to stock opioids. I spoke to … [my sales manager] and we are both under the opinion that they may be under investigation. I will follow up in 3-4 weeks to let things settle down.

164. On a different date the same sales representative told **BABICH** and **SIMON** that Practitioner #4 was,

> [v]ery pleased with ... [the Fentanyl Spray]. Has had difficulty with insurance coverage lately. Pharmacy located within same building cannot order CII Rx from distributors due to ratio of opioids to other Rx. See once every week.

165. **BABICH**, **BURLAKOFF**, and **SIMON** continued to pursue Practitioner #4. On or about October 8, 2012, the sales representative assigned to Practitioner #4 sent **BABICH** and **SIMON** another update:

> 10/5-RSM Rich Simon and I took ... [Practitioner #4] and his office manager to dinner and turned things around 180 degrees. We set out a plan to conduct dinner programs for ... [Practitioner #4] to speak at his request. ... [Practitioner #4] was not able to receive schedule two drugs in his buildings pharmacy which prevented his writing our drug. Rich Simon and I have been speaking to [the] pharmacist, ... [the Company Director of Trade and Distribution] & ... [Practitioner #4] to resolve the issue but have a guarantee from ... [Practitioner #4] to have "more scripts than we can handle" once the pharmacy issue is resolved and begins to speak."

166. Beginning in or about November 2012, despite concerns about a potential investigation, the Company began paying Practitioner #4 for Speaker Program events.

167. While Practitioner #4 began receiving speaker payments from the Company, he did not increase the number of prescriptions he wrote for the Fentanyl Spray. In or about April 2013, the manager for the Arkansas territory had grown frustrated with Practitioner #4. In an email to the assigned sales representative, copied to **BURLAKOFF**, the manager explained that she had canceled scheduled Speaker Programs for Practitioner #4 because the doctor was not giving the Company enough business.

168. In or about July 2013, the manager sent another email to the assigned sales representative, this time copying both **BURLAKOFF** and **SIMON**,

> "[Practitioner #4] never wrote in Q2 and so far he has not written in Q3. I truly don't believe he is worth any more of your time especially since he is in AR. I am perplexed by his prescribing habits."

169. By the end of 2013, Practitioner #4 was writing approximately one prescription for the Fentanyl Spray each week. In December 2013 **BABICH**, **BURLAKOFF**, **SIMON**, and **ROWAN** hired a new sales representative who had a pre-existing relationship with Practitioner #4, and assigned him to the Company's Arkansas territory.

170. In or about December 2013, **BURLAKOFF** transferred responsibility for Practitioner #4 to the newly hired sales representative. When the manager complained, **BURLAKOFF** responded,

> [t]he current rep did not eat what he killed. He did not KILL anything, he merely braised the doctor! ... I need and want the business TODAY. I need to see if ... [the new sales representative] can bring me what the other rep could not. I need ... [the new sales representative] to make his living off this doctor. This is my job.

171. In or about January 2014, Practitioner #4 approached his newly assigned sales rep and, once again, requested that that the Company help him find a wholesaler willing to supply Pharmacy #4 with the Fentanyl Spray. The new SALES REP forwarded his request to his district manager. In response, **BABICH**, **BURLAKOFF**, **SIMON**, and **ROWAN** sought to arrange direct shipment for Pharmacy #4 in the same manner that they had begun directly shipping to Pharmacy #2 and Pharmacy #3.

172. In or about March 2014, the new SALES REP, **BABICH**, **ROWAN**, and the Director of Trade, took Practitioner #4 to dinner at a steakhouse in Little Rock, Arkansas. During dinner Practitioner #4 asked for help finding a way to stock his pharmacy with the Fentanyl Spray. The group discussed the possibility of directly shipping to Pharmacy #4.

173. The Company and the Director of Trade also took multiple steps toward arranging for direct shipment to Pharmacy #4, including evaluating the pharmacy facility,

forwarding necessary paperwork, validating TIRF REMS status of the pharmacy, and projecting the volume of Fentanyl Spray that Pharmacy #4 would require each month.

174. Just weeks later, however, on March 24, 2014, the Company's V.P. of Operations for the Company sent an email to **KAPOOR** and **BABICH**, copied to the Director of Trade. The email, entitled "Direct Sales Update," explained in detail how the strategy that motivated direct shipment to Pharmacy #2 and Pharmacy #3 was flawed:

> Our wholesalers utilize software algorithms to monitor Schedule II ordering patterns against new order patterns (as well as other factors). As we know, if an order is identified as potentially suspicious, our wholesaler freezes the order and alerts the DEA...and does nothing else until the 30 day allowable order/volume window has expired (passed). This "order freeze" ... with no further evaluation to understand and resolve suspicious order activity is why ... [the Company] intervened and instituted an alternative direct order process through the ... [the Company's 3PL] entity where we believed we had the ability to evaluate a "flagged" suspicious order. However, this is not the case. The ... [Company's 3PL] follows the same "flagging, freeze, and reporting" that our wholesalers do. Right now, however, because [the Company's 3PL] ... had no historical order pattern associated with ... [Pharmacy #2 and Pharmacy #3] ... [the Company 3PL] currently monitors for suspicious order activity using the order projections for ... [Pharmacy #2 and Pharmacy #3] that [the Company] supplied to them. ... Going forward, as we can appreciate, a historical pattern will be established (and it currently is being established via actual orders) and should ... [Pharmacy #2 and Pharmacy #3] increase their order activity materially (i.e., beyond the original order projections provided by ...[the Company]), it is very likely that the ...[Company's 3PL] DEA suspicious ordering software will "kick out, freeze, and report" the particular ... [Pharmacy # 2] and/or [Pharmacy #3] order that caused the flag to occur. As such, our redirection of [Pharmacy #2 and Pharmacy #3] order activity through .. [the Company's 3PL] versus our wholesalers has provided an interim stop gap measure until such time order volumes grow materially beyond the existing projection initially provided to ...[the Company's 3PL] or whatever else the DEA software algorithm is designed to flag. ....

175. Despite describing a strategy designed to circumvent DEA suspicious reporting requirements and lamenting the success of that strategy, the V.P. concluded his email by stating:

> Because we have learned there is more to monitoring and reporting suspicious orders than we are currently doing today, we are looking into what actions we can take as an organization to ensure we are properly complying with DEA rules and guidelines....

176. The Company, however, continued directly shipping to both Pharmacy #2 and Pharmacy #3. However, on the same day as the email described in paragraph 174, the Director of Trade sent an email to **ROWAN**, copying the Company's V.P. of Operations. The email, entitled "direct ship," informed **ROWAN**, "[w]e are sorting out some of the direct ship issues related to the DEA and Suspicious Ordering Monitoring and are putting [Pharmacy #4] ... on hold at this time. ... This will not impact [Pharmacy #2]....

177. While efforts to reward Practitioner #4 and Pharmacy #4 with direct shipment were put on hold, **KAPOOR**, **BABICH**, **BURLAKOFF**, and **SIMON** continued to offer bribes and kickbacks to Practitioner #4. Working with his new sales representative and a new district manager, Practitioner #4 wrote large numbers of prescriptions for the Fentanyl Spray in exchange for bribes and kickbacks, which included, but were not limited to, speaker honoraria. Practitioner #4 was paid for eight Speaker Program events during the first quarter of 2014 alone. By in or about the end of March 2014, Practitioner #4 was writing as many as 30 prescriptions for the Fentanyl Spray in one week.

178. By in or about March of 2014, Practitioner #4 had gone from having Speaker Program events canceled for lack of prescriptions, to an increase in the amount of the honoraria paid to him for Speaker Program events. Nevertheless, many of the Speaker Program events led or attended by Practitioner #4 remained mere social gatherings, attended by friends and office staff of Practitioner #4, and involved no presentations regarding the Fentanyl Spray.

179. Between in or about November 2012 and in or about June 2015 insurers and pharmacy benefit managers authorized payment for approximately 1,454 prescriptions for the Fentanyl Spray written by Practitioner #4. During that period, Reimbursement Center employees working in Arizona placed telephone calls on behalf of the defendants and their co-conspirators, known and unknown to the Grand Jury, to obtain money and property by means of materially false pretenses, representations, and promises. For example, in or about March 2014, RC Employee #4 called Insurer #1. During the call, an employee of Insurer #1 asked if she was "speaking with a provider's office." RC Employee #4 answered, "that is correct." During the call, RC Employee #4 requested prior authorization for 120 units of an 800 mcg dose of the Fentanyl Spray for a patient of Practitioner #4 who was insured by Insurer #1. When the employee for Insurer #1 sought to confirm that the Fentanyl Spray had been prescribed for "cancer pain," the RC employee answered, "Correct, that's what the medication's for and it's what we treat." Medical records demonstrate that, at the time of the call, the patient had not been diagnosed with cancer.

180. Between in or about November 2012 and in or about June 2015, the defendants, and co-conspirators known and unknown to the Grand Jury, sent and caused to be sent to Practitioner #4 checks totaling approximately $143,253.89 for Speaker Program bribes and kickbacks.

Practitioner #5

181. Practitioner #5 owned and operated two pain management clinics in Texas, one in Laredo and the other in Corpus Christi. During the 12 weeks between on or about July 27, 2012 and on or about October 5, 2012, Practitioner #5 wrote eight prescriptions for the Fentanyl Spray and was paid for only one Speaker Program event.

182. In or about October 8, 2012, **SIMON**, acting as sales manager, sent his sales team an email entitled "Speakers Not Used," instructing his sales force to schedule as many office or dinner programs "as possible with your top/targeted physicians." The next day, the sales representative for Practitioner #5 requested that the Company schedule a Speaker Program event for the doctor, describing him to **BURLAKOFF** and **SIMON** as a "local speaker for the San Antonio territory, D[ecile]10." **BURLAKOFF** responded, copying **SIMON**, **ROWAN** and **LEE**, "[e]xcellent work! Keep them coming fast and furious..." Before the end of 2012, Practitioner #5 was scheduled to speak at seven more paid Speaker Program events and averaged more than two prescriptions for the Fentanyl Spray each week.

183. **BABICH**, **BURLAKOFF**, and **SIMON**, and co-conspirators known and unknown to the Grand Jury, focused significant financial resources on Practitioner #5 during the first quarter of 2013. On or about March 19, 2013 **BURLAKOFF** sent an email to the entire Company sales force lauding the top selling sales representatives, one of whom was the sales representative for Practitioner #5. **BURLAKOFF** wrote, "[t]he below 5 names mentioned at the top of the company rankings literally have their entire business being driven by basically 1 customer." **BURLAKOFF** concluded the email, "[o]wn your territory, own a doctor, and own your destiny."

184. Speaker Program events were a vehicle by which **BABICH**, **BURLAKOFF**, and **SIMON** sought to pay Practitioner #5 bribes and kickbacks.

185. Most of the Speaker Program events led or attended by Practitioner #5 were sham events that were mere social gatherings also attended by the friends and office staff of Practitioner #5. For example, during the first week of May 2013, **BURLAKOFF** and **SIMON** traveled to Texas to meet with Practitioner #5. One week later, on or about May 9, 2013, while

identifying his planned speakers for the third quarter of 2013, the sales representative for Practitioner #5 informed **SIMON** that to date the doctor had not "influenced any physicians to write." The sales representative noted, however, that Practitioner #5 was "available to speak at dinners Monday-Thursdays." By the end of the third quarter of 2013, Practitioner #5 averaged more than 12 prescriptions for the Fentanyl Spray each week.

186. Between in or about January 2013 and January 2014, insurers and pharmacy benefit managers authorized payment for approximately 527 prescription for the Fentanyl Spray written by Practitioner #5. During that time period, Reimbursement Center employees working in Arizona placed telephone calls on behalf of the defendants and their co-conspirators, known and unknown to the Grand Jury, to obtain money and property by means of materially false pretenses, representations, and promises made to insurers and pharmacy benefit managers. For example, in or about May 2013, RC Employee #5 called Insurer #2. During the call, RC Employee #5 requested prior authorization for a 1600 mcg dose of the Fentanyl Spray for a patient of Practitioner #5 who was insured by Insurer #2. When the employee for Insurer #2 sought to confirm the diagnosis, RC Employee #5 answered, "she has a hard time swallowing." At the time of the call, the patient had not been diagnosed with difficulty swallowing.

187. Between in or about January 2013 and January 2014, the defendants, and co-conspirators known and unknown to the Grand Jury, sent and caused to be sent to Practitioner #5 checks totaling approximately $123,185.10 for Speaker Program bribes and kickbacks.

188. **BABICH**, **BURLAKOFF**, and **SIMON** expected more than just a large volume of prescriptions from co-conspirator practitioners in exchange for their bribes and kickbacks.

189. On or about March 11, 2013, **SIMON** sent an email to the sales representative for Practitioner #5 complaining that "3 out of the 4 scripts he wrote were refills and were still LOW

units." **SIMON** instructed the sales representative to admonish office staff for Practitioner #5, "[d]rill into ...[his] head that every refill has to be 180-240 etc. and that ... [Practitioner #5] agreed to do this."

Practitioner #6

190. In or about 2012, Practitioner #6 practiced at a pain management clinic in Illinois. While Practitioner #6 frequently wrote prescriptions for rapid onset opioids throughout 2012, he did not write any prescriptions for the Fentanyl Spray during its first five months on the market.

191. On or about September 17, 2012, a sales representative in the Chicago area sent an email to **BABICH** to update him on her efforts with specific practitioners located in her territory, including Practitioner #6:

> I call on ...[him] once sometimes twice a week. ...[He] runs a very shady pill mill and only accepts cash. He sees very few insured patients but does write some ... [prescriptions for a competitor product]. He is extremely moody, lazy and inattentive. He basically just shows up to sign his name on the prescription pad, if he shows up at all. I have been working more with his MA ["Medical Assistant"] who is the one that knows what is going on in his office. He has agreed to try and help me out but I know that he is afraid of [the doctor's] ...outbursts and is reluctant to input. I think that being in the office at the right time, when the right patient walks in, on a day [the doctor] ...is in a good mood is the only way I will get him to write. This is the reason I call on him frequently.

192. Despite concerns about his prescribing practices, Practitioner #6 remained a sales target for **BABICH, BURLAKOFF**, and **SIMON**. Less than a month after the sales representative assigned to Practitioner #6 warned **BABICH** that Practitioner #6 was running a "pill mill," **LEE**, who was then the newly appointed sales manager in the Chicago area, asked the sales representative to set up a lunch with Practitioner #6. The sales representative and **LEE** took Practitioner #6 to lunch in or about early October 2012. At the conclusion of the lunch, **LEE** handed her business card to Practitioner #6 and told him to call if he wanted to discuss the Fentanyl Spray "in private."

193. Practitioner #6 arranged for drinks with **LEE** at a popular rooftop bar in downtown Chicago. A few days later, **LEE** called the assigned sales representative and told her that Practitioner #6 was going to start writing prescriptions for the Fentanyl Spray.

194. On or about October 18, 2012, **LEE** sent an email, copying **BURLAKOFF**, nominating a number of practitioners to be speakers, including Practitioner #6, and canceling further Speaker Program events for practitioners who had not written prescriptions or shown "interest" in the Fentanyl Spray. The next day, on or about October 19, 2012, **BURLAKOFF** forwarded **LEE**'s email to **BABICH** and all of the Company's sales managers, noting, "[g]reat example of how we need to pro-actively manage our speaker data base by both adding and soft deleting speakers on an ongoing basis...."

195. Practitioner #6's first Speaker Program event occurred in or about November 2012. By in or about the last week of November 2012, Practitioner #6 was averaging approximately two prescriptions for the Fentanyl Spray per week. By in or about the second week of January 2013, Practitioner #6 averaged 3.6 prescriptions for the Fentanyl Spray each week.

196. In or about December 2012, the Company changed the way it disbursed bribes and kickbacks to co-conspirator practitioners. The change delayed, until early 2013, the payment of Practitioner #6's first "honoraria" from the Company. Practitioner #6 thus received bribes in exchange for his increasing number of prescriptions from in or about February 2013 through in or about July 2015. By May 2014, Practitioner #6 averaged approximately 10.3 prescriptions for the Fentanyl Spray each week.

197. Between in or about February 2013 and July 2015, many of the Speaker Program events led or attended by Practitioner #6 were sham events that were mere social gatherings also attended by friends and office staff of Practitioner #6.

198. Between in or about February 2013 and July 2015, insurers and pharmacy benefit managers authorized payment for approximately 1,601 prescriptions for the Fentanyl Spray written by Practitioner #6.

199. Between in or about February 2013 and July 2015, the defendants and co-conspirators known and unknown to the Grand Jury, sent and caused to be sent to Practitioner #6 checks totaling approximately $70,800.00 for Speaker Program bribes and kickbacks.

Practitioner #7

200. Practitioner #7 practiced as an Advanced Practice Nurse ("APRN") for a pain management practice with offices in Derby and Meriden, Connecticut. In or about August of 2012, after speaking with Practitioner #7 about the Fentanyl Spray, the sales representative sent **BABICH** and the sales manager an email to inform them that Practitioner #7 "expressed interest in becoming a speaker for us and I told her I would let her know as soon as we had another training scheduled."

201. In or about October 2012, Practitioner #7 signed a speaker agreement with the Company. In or about November 2012, **BURLAKOFF** emailed the sales manager for Connecticut, "[t]his clinician is writing, she has experience... She needs to speak ASAP." The manager responded,

> Damn Right [sic]. I know she was all fired up to get trained on the last training session. She definitely wants to speak, ... [the assigned sales representative has] been in there working to get her dates and places lined up, she got wacked by the storm so that put things back. That's why I told him to plan it, TELL her when and where. And done. It's not rocket science.

202. By in or about March of 2013, Practitioner #7 averaged approximately 0.9 prescriptions for the Fentanyl Spray per week. In or about April 2013, in a private meeting, the

sales representative promised Practitioner #7 payment for additional Speaker Program events in exchange for writing more prescriptions for the Fentanyl Spray.

203. On or about April 12, 2013, the sales representative for Practitioner #7 emailed his manager, stating,

> [y]ou and I both know my goals for ... [Practitioner #7] and what she is verbally agreeing to do. ... on Monday I will email you to get the ... [Speaker Program] when she gives me a firm agreement on what we discussed earlier this week.

204. On or about June 5, 2013, the sales manager for Connecticut expressed frustration with Practitioner #7 in an exchange of emails with the assigned sales representative. The manager wrote,

> [w]hat I am concerned about is you and I spoke about 6 weeks ago when we were giving her this extra program and asked if her finding 1 new patient a week was a reasonable expectation and something to be accountable to. You told me she said yes and that you would be able to hold her accountable to that. In looking at 1 new patient in April and just 1 in May it is clear that is not happening.
>
> Keep in mind these emails are for you and me, not her. But our conversation was very clear about what had to happen. I am not sure why from the tone of your reply you now are seeming to hedge off of that commitment?
>
> Very simply when I look at return on investment as she has not motivated any new prescriber as of yet and she is not significantly increasing her own business, I am going to have tremendous difficulty in justifying more programs.

205. By on or about July 19, 2013, Practitioner #7 had increased her prescriptions for the Fentanyl Spray to an average of approximately 2.3 each week. By on or about September 27, 2013, Practitioner #7 averaged approximately three prescriptions for the Fentanyl Spray each week.

206. Between in or about December 2012 and April 2015, many of the Speaker Program events led or attended by Practitioner #7 were sham events that were mere social gatherings also attended by the friends and office staff of Practitioner #7.

207. Between in or about December 2012 and April 2015, insurers and pharmacy benefit managers authorized payment for approximately 556 prescriptions for the Fentanyl Spray written by Practitioner #7. During that time period, Reimbursement Center employees working in Arizona placed telephone calls on behalf of the defendants and their co-conspirators, known and unknown to the Grand Jury, to obtain money and property by means of materially false pretenses, representations, and promises. For example, in or about November 2013, RC Employee #5 called Insurer #1. During the call, an employee of Insurer #1 asked if she was "speaking with the provider's office." RC Employee #5 answered, "yes." During the call, RC Employee #5 requested prior authorization for 120 units of a 400 mcg dose of the Fentanyl Spray for a patient of Practitioner #7 who was insured by Insurer #1. Further, when the employee for Insurer #1 sought to determine whether the Fentanyl Spray had been prescribed for malignant cancer pain, the RC employee answered, "it's for the breakthrough pain episodes for that." Medical records demonstrated that, at the time of the call, the patient had not been diagnosed with cancer.

208. Between in or about December 2012 and April 2015, the defendants and co-conspirators known and unknown to the Grand Jury sent and caused to be sent to Practitioner #7 checks totaling approximately $78,758.25 for Speaker Program bribes and kickbacks.

Practitioner #8

209. Practitioner #8 practiced as a Physician Assistant at a pain management clinic in Somersworth, New Hampshire. In or about late April 2013, a sales representative for the Company catered a lunch at Practitioner #8's pain clinic.

210. On or about July 15, 2013, the sales representative encouraged Practitioner #8 to forward his resume to the Company for consideration as a paid speaker. Practitioner #8 forwarded his resume the same day.

211. Practitioner #8's resume did not reflect that he had ever published a scholarly article regarding TIRF drugs or pain management, nor did it indicate any previous speaking roles related to TIRF drugs and rapid onset opioids.

212. The Fentanyl Spray had been on the market for more than a year when Practitioner #8 wrote his first prescription for the drug on or about June 27, 2013. Just over one month later, on or about August 2, 2013, **BURLAKOFF** emailed the Company employee responsible for scheduling Speaker Program events and endorsed Practitioner #8 as a speaker:

> I noticed that ... [Practitioner #8] out of the Manchester, NH territory has expressed a true passion and enthusiasm for ... [The Fentanyl Spray] that I have not seen or felt in a very long time.
>
> These are the exact type of clinicians we want to put in front of a local audience. Often times we look for the most well-known speakers, however, with this type of product—I believe passion supersedes all!
>
> With this being said, I would like to note my desire to see this clinician have a significant increase in speaking opportunities-ASAP.
>
> In my brief phone conversation with ... [Practitioner #8], I could literally feel this clinician's excitement coming through the phone.
>
> His excitement, made me excited / this is undoubtedly what we need.

213. On or about August 8, 2013, Practitioner #8 signed a Speaker Agreement with the Company. Between in or about August 2013 and the end of the year, Practitioner #8 was paid for speaking at seven Speaker Program events.

214. During the 12 weeks after his nomination as a speaker, Practitioner #8 wrote approximately 124 prescriptions for the Fentanyl Spray. He continued to write a large number of prescriptions for the Fentanyl Spray throughout the remainder of 2013. By in or about the second week of January 2014, Practitioner #8 averaged 11.8 prescriptions for the Fentanyl Spray per week.

215. Between in or about August 2013 and November 2014, many of the Speaker Program events led or attended by Practitioner #8 were sham events that were mere social gatherings also attended by the friends and office staff of Practitioner #8.

216. Between in or about August 2013 and November 2014, insurers and pharmacy benefit managers authorized payment for approximately 672 prescriptions for the Fentanyl Spray written by Practitioner #8. During that time period, Reimbursement Center employees working in Arizona placed telephone calls on behalf of the defendants and their co-conspirators, known and unknown to the Grand Jury, to obtain money and property by means of materially false pretenses, representations, and promises. For example, in or about October 2013, RC Employee #3 called Insurer #1. During the call, an employee of Insurer #1 asked if she was "speaking with the office of [Practitioner #8]." RC Employee #3 answered, "yes." During the call, RC Employee #3 requested prior authorization for 120 units of a 200 mcg dose of the Fentanyl Spray for a patient of Practitioner #8 who was insured by Insurer #1. Further, when the employee for Insurer #1 asked if the drug was prescribed, for malignant cancer pain, the RC employee told

her, "Yes, for the BTP [break through pain]." At the time of the call, the patient had not been diagnosed with cancer.

217. Between in or about August 2013 and November 2014, the defendants, and co-conspirators known and unknown to the Grand Jury, sent and caused to be sent to Practitioner #8 checks totaling approximately $44,000.00 for Speaker Program bribes and kickbacks.

218. The number of prescriptions for the Fentanyl Spray written by Practitioner #8 generated enough demand on his support staff that he requested the sales representative to handle the administrative work associated with obtaining prior authorization from his patient's insurers and pharmacy benefit managers. To accomplish this, Practitioner #8 routinely assembled the medical charts of each patient for whom he prescribed the Fentanyl Spray and gave them to the sales representative, or to the Company employee assisting the sales representative. The sales representative then took the patient charts to her apartment in Boston, in the District of Massachusetts, where she or her assistant filled out the required prior authorization paperwork and faxed it to the RC in Arizona.

Practitioner #9

219. Practitioner #9 owned and managed a pain management practice in southwest Florida. Practitioner #9 wrote a large volume of schedule II prescriptions. By at or about the end of the second quarter of 2012, Practitioner #9 averaged 1.9 prescriptions for the Fentanyl Spray per week.

220. Shortly after joining the Company, **BURLAKOFF** and the sales representative assigned to southwest Florida met with Practitioner #9 at his office. Following the meeting, **BURLAKOFF** told the sales representative that the Speaker Program would help the Company get more prescriptions from practitioners paid as speakers.

221. Practitioner #9 was made a speaker for the Company in or about the end of July 2012. On or about August 1, 2012, **BABICH** sent the sales representative assigned to Practitioner #9 an email stating, "I have listed your top targets below and need a brief weekly email summarizing how, if and when the doctor will write, if he is already and can he be a bigger doctor to you." **BABICH** included Practitioner #9 as a top target.

222. On or about August 20, 2012, the sales representative assigned to Practitioner #9 sent **BABICH** a weekly update email, copying **BURLAKOFF,** stating that prescriptions from Practitioner #9 had:

> dropped off as he has told me some of his patients are preferring ... [a competitor]. ... But he continues to tell me that he will continue to prescribe ... [the Fentanyl Spray] whenever he can. I think using him as a speaker will cause things to pick back up again. I have two programs planned so far.

223. By the end of November of 2012, Practitioner #9 was averaging 1.6 prescriptions for the Fentanyl Spray per week.

224. In or about December of 2012, **BABICH**, **BURLAKOFF**, **SIMON**, and **ROWAN** hired a new sales representative for southwest Florida.

225. By in or about February of 2013, the new sales representative was using the Speaker Program to pay bribes and kickbacks to doctors in his territory in exchange for Fentanyl Spray prescriptions. **BABICH**, **BURLAKOFF**, and **ROWAN,** and other co-conspirators, began investing more financial resources in Practitioner #9.

226. **BABICH**, **BURLAKOFF**, and **ROWAN** knew that during the first quarter of 2013, Practitioner #9 wrote prescriptions for approximately 328 TIRF medicines, 90 of which were for the Fentanyl Spray.

227. On or about March 12, 2013, **BURLAKOFF** sent an email to **ROWAN** and the sales representative for Practitioner #9,

> [w]here is ... [Practitioner #9], we cannot go a single day with out [sic] a prescription from ... [Practitioner #9]. I do not want to hear excuses, we pay good money here (we need 1 a day from ...[Practitioner #9]).

228. By in or about the middle of July 2013, Practitioner #9 averaged approximately 6 prescriptions for the Fentanyl Spray per week.

229. Bribes and kickbacks paid to Practitioner #9 were not limited to Speaker Program honoraria. In or about September 2013, **BABICH**, **BURLAKOFF**, and **ROWAN** hired a woman known to be the girlfriend of Practitioner #9 as an ABL for his practice. By the last week of September 2013, Practitioner #9 was averaging 7.5 prescriptions for the Fentanyl Spray each week.

230. **BURLAKOFF**, however, was not satisfied with the increase in the number of prescriptions for the Fentanyl Spray Practitioner #9 wrote each week through 2013. On or about October 3, 2013, **BURLAKOFF** sent an email to the assigned sales representative explicitly describing what was expected in exchange for bribes and kickbacks paid to Practitioner #9:

> Where is ... [Practitioner #9]?
> Not even close to meeting anyone's expectations thus far, perhaps- We had failed in setting our expectations?
> We were looking to go from 40 percent market share to 90 percent?
> ...I have to sit in the corporate office and answer these questions face to face. It is not fun, and the recent move we made on an ABL appears as if it is potentially not worth it?

231. Between in or about August 2012 and in or about August 2015, insurers and pharmacy benefit managers authorized payment for approximately 1,178 prescriptions for the Fentanyl Spray written by Practitioner #9. During that same time period, Reimbursement Center employees working in Arizona placed telephone calls on behalf of the defendants and

their co-conspirators, known and unknown to the Grand Jury, to obtain money and property by means of materially false pretenses, representations, and promises. For example, RC Employee #6 called Insurer #1. During the call, RC Employee #6 stated that she was calling from the office of Practitioner #9 to appeal a previous decision to deny prior authorization for 120 units of an 800 mcg dose of the Fentanyl Spray for a patient. The employee for Insurer #1 commented that authorization had been previously denied because the patient did not have malignant cancer pain. RC Employee #6 then told the insurer that the patient did in fact have cancer. At the time of the call, however, the patient had not been diagnosed with cancer.

232. Between in or about August 2012 and in or about August 2015, the defendants, and co-conspirators known and unknown to the Grand Jury, sent and caused to be sent to Practitioner #9 checks totaling approximately $275,550.00 for Speaker Program bribes and kickbacks.

Practitioner #10

233. Practitioner #10 operated a pain management practice in south Florida. On his first day working for the Company, **BURLAKOFF** joined the sales representative assigned to the south Florida District. After explaining that Practitioner #10 was first and foremost a business man, **BURLAKOFF** directed the sales representative to use the Speaker Program as a way to pay Practitioner #10 for writing prescriptions for the Fentanyl Spray.

234. At or about the beginning of August 2012, when the Speaker Program was set to begin, Practitioner #10 averaged 0.8 prescriptions for the Fentanyl Spray each week. A month earlier, **BURLAKOFF** had acknowledged to the south Florida sales representative that Practitioner #10 was a good speaker, but that "even the docs he spoke to won't write."

235. Between the first week in August 2012 and the first week in December 2012, **BABICH**, **BURLAKOFF**, and co-conspirators known and unknown to the Grand Jury paid Practitioner #10 approximately $36,000 for 15 Speaker Program events.

236. By in or about early January 2013, Practitioner #10 averaged approximately 3.3 prescriptions for the Fentanyl Spray per week. This was an improvement, but **BABICH**, **BURLAKOFF**, and **ROWAN** believed Practitioner #10 had potential to write many more prescriptions for the Fentanyl Spray.

237. On or about January 18, 2013, **BABICH**, **BURLAKOFF**, and **ROWAN** invited Practitioner #10 to Company headquarters in Arizona. During the trip **BURLAKOFF** and **ROWAN** took Practitioner #10 to a club. The next morning **BURLAKOFF** sent the sales representative a text stating, "went fantastic last night. ... [Practitioner #10] and I got back around 4AM. He had to have had one of the best nights of his life."

238. One week later, the sales representative assigned to Practitioner #10 informed **BURLAKOFF** and **ROWAN** that Practitioner #10 had written 17 prescriptions for the Fentanyl Spray in less than a week. The same day, **ROWAN** texted Practitioner #10, "we appreciate you more than you could believe. Leaving that meeting Alec and I felt very confident and [sic] what was going to happen. And ... you show loyalty to us like no other. You need anything at all, it is done. Thank you for being you."

239. Practitioner #10 continued to receive Speaker Program bribes and kickbacks, and by July of 2013 averaged approximately five Fentanyl Spray prescriptions per week. By January 2014, Practitioner #10 averaged approximately seven prescriptions for the Fentanyl Spray per week.

240. Between in or about August 2012 and November 2015, insurers and pharmacy benefit managers authorized payment for approximately 2,030 prescriptions for the Fentanyl Spray written by Practitioner #10. During that same time period, Reimbursement Center employees working in Arizona placed telephone calls on behalf of the defendants and their co-conspirators, known and unknown to the Grand Jury, to obtain money and property by means of materially false pretenses, representations, and promises made to insurers and pharmacy benefit managers. For example, in or about April 2014, RC Employee #7 called Insurer #1. During the call, RC Employee #7 was asked if she was "speaking with the doctor's office?" RC Employee #7 answered, "yes." RC Employee #7 then requested prior authorization for 120 units of a 200 mcg dose of the Fentanyl Spray for a patient of Practitioner #10 insured by Insurer #1. When the employee for Insurer #1 asked if the patient's diagnosis included breakthrough cancer pain, RC Employee #7 told her, "Yes, for the breakthrough pain." At the time of the call, a cancer diagnosis did not appear on the "opt-in" form.

241. Between in or about August 2012 and November 2015, the defendants, and co-conspirators known and unknown to the Grand Jury, sent and caused to be sent to Practitioner #10 checks totaling approximately $260,050.00 for Speaker Program bribes and kickbacks.

CRIMINAL COUNTS

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

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

242. The allegations contained in paragraphs 1 through 241 are re-alleged and incorporated herein by reference.

243. At all times relevant to the First Superseding Indictment, within the District of Massachusetts and elsewhere, **(1) BABICH, (2) BURLAKOFF, (3) GURRY, (4) SIMON, (5) ROWAN, (6) LEE,** and **(7) KAPOOR**, the co-conspirator practitioners ("co-conspirator practitioners"), the co-conspirator pharmacies ("co-conspirator pharmacies"), and other persons and entities known and unknown to the Grand Jury, collectively constituted an "enterprise," as defined in Title 18, United States Code, Section 1961(4), that is, a group of individuals and entities associated in fact. The enterprise constituted an ongoing organization whose members functioned as a continuing unit for a common purpose of achieving the objectives of the enterprise.

244. The enterprise was engaged in, and its activities affected, interstate commerce. The enterprise operated in the District of Massachusetts and elsewhere.

245. From in or about June 2012 and continuing until in or around December 2015, within the District of Massachusetts and elsewhere, **(1) BABICH, (2) BURLAKOFF, (3) GURRY, (4) SIMON, (5) ROWAN, (6) LEE,** and **(7) KAPOOR**, being persons employed by and associated with the enterprise described in paragraph 243 above, which engaged in, and the activities of which affected, interstate commerce, knowingly conspired with one another and with others known and unknown to the Grand Jury, 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).

246. The pattern of racketeering activity through which **(1) BABICH, (2) BURLAKOFF, (3) GURRY, (4) SIMON, (5) ROWAN, (6) LEE,** and **(7) KAPOOR**, 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 acts indictable under:

(a) Title 18, United States Code, §§ 1341 and 1346 (mail fraud, including honest services mail fraud);

(b) Title 18, United States Code, §§ 1343 and 1346 (wire fraud, including honest services wire fraud); and

(c) Title 18, United States Code, § 1952 (interstate and foreign travel or transportation in aid of racketeering);

(d) multiple offenses involving the distribution of controlled substances, in violation of 21 U.S.C. §§ 841 and 846;

and multiple acts involving bribery in violation of Connecticut General Statutes Annotated (C.G.S.A.) § 53a-160 (commercial bribery); Florida Statutes Annotated (F.S.A.) § 838.16 (commercial bribery); Revised Statutes Annotated of the State of New Hampshire (N.H. Rev. Stat. § 638.7 (commercial bribery); and Vernon's Texas Statutes and Codes Annotated (V.T.C.A.) § 32-43 (commercial bribery).

247. It was part of the conspiracy that each defendant agreed that a conspirator would commit at least two acts of racketeering activity in the conduct of the affairs of the enterprise.

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

COUNT 2

18 U.S.C. § 1349 – Mail Fraud Conspiracy

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

248. The allegations contained in paragraphs 1 through 241 are re-alleged and incorporated herein by reference.

249. From in or about June 2012 until in or about December 2015, within the District of Massachusetts and elsewhere, **(1) BABICH, (2) BURLAKOFF, (3) GURRY, (4) SIMON, (5) ROWAN, (6) LEE,** and **(7) KAPOOR**, along with others known and unknown to the Grand Jury, did knowingly conspire with one another to commit mail fraud in violation of 18 U.S.C. §§ 1341 and 1346, that is, having devised and intending to devise a scheme and artifice to defraud patients of honest services and to obtain money and property by means of materially false and fraudulent pretenses, representations and promises, for the purpose of executing such scheme and artifice to defraud, placed and caused to be placed in any post office and authorized depository for mail matter a matter and thing, to wit, checks and payments, to be sent and delivered by the United States Postal Service, and deposited and caused to be deposited a matter and thing, to wit, checks and payments, to be sent and delivered by a private and commercial interstate carrier.

All in violation of Title 18, United States Code, Section 1349.

COUNT 3

18 U.S.C. § 1349 – Wire Fraud Conspiracy

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

250. The allegations contained in paragraphs 1 through 241 are re-alleged and incorporated herein by reference.

251. From in or about December 2012 and continuing until in or around December 2015, within the District of Massachusetts and elsewhere, **(1) BABICH, (2) BURLAKOFF, (3) GURRY, (4) SIMON, (5) ROWAN, (6) LEE,** and **(7) KAPOOR**, along with others known and unknown to the Grand Jury, did knowingly conspire to commit wire fraud in violation of 18 U.S.C. §§ 1343, and 1346, that is, having devised and intending to devise a scheme and artifice to defraud patients of honest services and to obtain money and property by means of materially false and fraudulent pretenses, representations and promises, for the purpose of executing such scheme and artifice to defraud, transmitted and caused to be transmitted by means of wire communication in interstate commerce, writings, signs, signals, pictures, and sounds, to wit: telephone communications, email, and facsimile communications.

All in violation of Title 18, United States Code, Section 1349.

COUNT 4

18 U.S.C. § 371--Conspiracy to Violate the Anti-Kickback Law

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

252. The allegations contained in paragraphs 1 through 241 are re-alleged and incorporated herein by reference.

253. From in or about June 2012 until in or around December 2015, within the District of Massachusetts and elsewhere, **(1) BABICH, (2) BURLAKOFF, (3) GURRY, (4) SIMON, (5) ROWAN, (6) LEE,** and **(7) KAPOOR**, knowingly conspired with others known and unknown to the Grand Jury, to commit an offense against the United States, that is, to knowingly and willfully offer and pay remuneration, directly and indirectly, overtly and covertly, in cash and in kind, that is, kickbacks and bribes, from the Company, to induce physicians and other health care professionals to purchase, order, and arrange for goods, services and items, that is, prescriptions for the Fentanyl Spray, for which payment may be made in whole and in part by a federal health care program, in violation of Title 42, United States Code, Section 1320a-7b(b)(2).

All in violation of Title 18, United States Code, Section 371.

RACKETEERING FORFEITURE ALLEGATION

(18 U.S.C. § 1963)

THE GRAND JURY FURTHER FINDS THAT:

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

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

(7) KAPOOR,

the defendants herein, shall forfeit to the United States, jointly and severally, 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. forfeiture money judgment equal to the amount of proceeds obtained as a result of the offense alleged in Count One of the First Superseding Indictment;

255. If any of the property described in Paragraph 254, above, as being forfeitable pursuant to Title 18, United States Code, Section 1963, and Title 28, United States Code, Section 2461(c), 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 254.

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

MAIL AND WIRE FRAUD FORFEITURE ALLEGATIONS

(18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c))

256. Upon conviction of one or more of the offenses in violation of Title 18, United States Code, Section 1349, set forth in Counts Two and Three of this First Superseding Indictment,

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

(7) KAPOOR,

the defendants herein, shall forfeit to the United States, pursuant to Title 18, United States Code, Section 981(a)(1)(C), and Title 28, United States Code, Section 2461(c), any property, real or personal, which constitutes or is derived from proceeds traceable to the offense.

257. If any of the property described in Paragraph 256, above, as being forfeitable pursuant to Title 18, United States Code, Section 981(a)(1)(C), and Title 28, United States Code, Section 2461(c), 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 which cannot be divided without difficulty;

it is the intention of the United States, pursuant to Title 28, United States Code, Section 2461(c), incorporating Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of the defendants up to the value of the property described in Paragraph 256 above.

All pursuant to Title 18, United States Code, Section 981(a)(1)(C), and Title 28, United States Code, Section 2461(c).

CONSPIRACY TO VIOLATE THE ANTI-KICKBACK LAW
FORFEITURE ALLEGATIONS

(18 U.S.C. § 982(a)(7))

258. Upon conviction of Conspiracy to Violate the Anti-Kickback Law, in violation of Title 18, United States Code, Section 371, set forth in Count Four of this First Superseding Indictment,

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

(7) KAPOOR,

the defendants herein, shall forfeit to the United States, pursuant to Title 18, United States Code, Section 982(a)(7), any property, real or personal, which constitutes or is derived from proceeds traceable to the offense.

259. If any of the property described in Paragraph 258, above, as being forfeitable pursuant to Title 18, United States Code, Section 982(a)(7), as a result of any act or omission of the defendants –

(f) cannot be located upon the exercise of due diligence;

(g) has been transferred or sold to, or deposited with, a third party;

(h) has been placed beyond the jurisdiction of the Court;

(i) has been substantially diminished in value; or

(j) has been commingled with other property which cannot be divided without difficulty;

it is the intention of the United States, pursuant to Title 18, United States Code, Section 982(b), incorporating Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of the defendants up to the value of the property described in Paragraph 258 above.

All pursuant to Title 18, United States Code, Section 982(a)(7).

A TRUE BILL

[redacted]

Foreperson of the Grand Jury

SUSAN M. POSWISTILO
K. NATHANIEL YEAGER
Assistant United States Attorneys

DISTRICT OF MASSACHUSETTS: October 24, 2017

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

Deputy Clerk

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS
HARALD PUTNAM
10/24/17 @ 3:19 pm